Prior Authorization Criteria

AS OF February 20, 2019

SAN FRANCISCO HEALTH PLAN
Here for you

Prior Authorization Criteria

The following is the listing of SFHP prior authorization criteria that will be used to evaluate prior authorization requests. SFHP's pharmacy prior authorization criteria are based on clinical monographs and National Pharmacy and Therapeutics guidelines (P&T) and have been approved by SFHP Pharmacy and Therapeutics (P&T) Committee. Prior Authorization Criteria will be updated regularly to reflect ongoing changes and is subject to change without notice.

Prior Authorization Requests for Non-Preferred Medications

Non-preferred medications may be authorized when there is clinical justification for doing so. Clinicians can submit a prior authorization (PA) request for a non-preferred medication in one of three different ways:

1. **Download and fax** Prior Authorization Request Form to **1(855) 811-9331** for both standard and urgent requests. Urgent requests should be clearly labeled "URGENT" at the top of the prior authorization request form.
2. **Call our Pharmacy Benefits Manager** (PBM) PerformRx at **(888)989-0091** to submit a verbal request.
3. **Submit Online** using the Online Pharmacy Prior Authorization Request Form.

Prior Authorization Request Form and Online Pharmacy Prior Authorization Request Form can be accessed from our website at http://www.sfhp.org/providers/formulary/prior-authorization-requests/.

Blanket Criteria

EXPERIMENTAL/INVESTIGATIONAL USES
Formulary Status: Formulary, PA or Non-formulary
Coverage Duration: 1 year
Diagnosis Considered for Coverage: • Experimental or investigational use, as defined below
Prescribing Restriction: • Prescriber restriction: provider is a board-certified specialist in the area of requested therapy
Clinical Information Required for Review: • Diagnosis • Previous therapy • Supporting documentation
Coverage Criteria: Per Evidence of Coverage (EOC) document page 64, SFHP does not cover experimental or investigational care, defined as care that: • Is not seen as safe and effective by generally accepted medical standards to treat a condition, or • Has not been approved by the government to treat a condition **I. Initiation of Therapy:** • Requests not meeting criteria below will be denied per the Investigational/Experimental Section of the PBM-SFHP Prior Authorization (PA) First-Level Review Desktop Procedure as an excluded benefit • If ALL of the following are met, a request for experimental or investigational use will be reviewed by the SFHP Medical Director o The requested therapy is for a life-threatening (likely to cause death unless the couse of disease is interrupted) or seriously debilitating (causes major irreversible morbidity) condition ▪ If requested therapy is not for a life-threatening or seriously debilitating condition, utilize “Off-Label Uses” criteria: a. No other formulary medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia AND b. Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR c. Requested use can be supported by at least two published peer reviewed clinical studies o The requested therapy is a therapy approved by the FDA o Documentation is provided meeting any of the following for each standard therapy for the diagnosis: ▪ Trial and failure of standard therapy(ies) ▪ Contraindication to standard therapy(ies) ▪ Documentation that the requested therapy is likely to be more beneficial to the member than standard therapy(ies): a. as evidenced by two documents from medical and scientific evidence (including peer-reviewed medical literature, federal research institutes findings, medical compendia and/or guidelines) OR b. as certified in writing by provider, and the provider is an in-network physician c. If the request is denied following review by SFHP Medical Director due to not meeting criteria (a) and (b) above, SFHP’s decision will be sent for examination via the independent medical review process for investigational/experimental uses **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Refer to “Initiation of Therapy” section

EXPERIMENTAL/INVESTIGATIONAL USES
III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Patient is stable and continuing the medication
References: • California Health and Safety Code 1370.4, Accessed at https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1370.4.&lawCode=HSC.
Last review/revision date: 10/2018

MEDICATIONS FOR TERMINAL ILLNESS

Formulary Status: Formulary, PA or Non-formulary

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Terminal illness, as defined below

Prescribing Restriction:

- Prescriber restriction: provider is a board-certified specialist in the area of requested therapy

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

California Health and Safety Code Section 1368.1 refers to terminal illness as an incurable or irreversible condition that has a high probability of causing death within one year or less.

I. Initiation of Therapy:

- If a request for treatment is for terminal illness as defined above, approve if medication and dose are appropriate based on nature and severity of the terminal illness, and is not considered likely to cause undue harm
  - Criteria above overrides drug-specific criteria and Non-Formulary Medications criteria, when requested for terminal illness
  - If request is for experimental/investigational use in terminal illness, Experimental/Investigational Uses criteria must also be met
- For requests that are denied due to not meeting corresponding criteria above, the following will be provided to the enrollee within five business days of the denial:
  - A statement setting forth the specific medical and scientific reasons for denying coverage
  - A description of alternative treatment, services or supplies covered by the plan, if any

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to “Initiation of Therapy” section

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References:

- California Health and Safety Code 1368.1, Accessed at https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1368.1.&lawCode=HSC.

Last review/revision date: 10/2018

MEDICATIONS WITHOUT SPECIFIC CRITERIA

Formulary Status: Non-formulary or Formulary, PA Criteria Required (without specific criteria)

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.

Prescribing Restriction:

- Quantity Limit* As requested not to exceed FDA approved or off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- Approve if:
  - For IV medications, if request includes a documented reason why the medication cannot be provided via the Medical Benefit (**Medi-Cal only**), then the request must confirm that the medication is administered by a healthcare professional* AND
  - Drug-specific PA criteria does not exist for the requested drug AND
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND

    Off-label criteria:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Appropriate dose of medication based on age (i.e. pediatric and elderly populations) and indication AND
  - In the absence of evidence supporting use of requested medication compared to preferred agents, documented trial and failure or inability to use all (but no more than 3) available preferred medications indicated for the diagnosis OR
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia OR
  - All other formulary medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy

*Note: capitation deduction may be required, alert Pharmacy Director of approval via this criteria

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

MEDICATIONS WITHOUT SPECIFIC CRITERIA
III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Patient is stable and continuing the medication AND • Continuation of therapy is medically necessary
References: N/A
Last review/revision date: 10/2018

STEP THERAPY EXCEPTION

Formulary Status: Formulary, step therapy required
*For drugs without specific criteria

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: As requested not to exceed FDA approved or off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information required for Review

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- Approve if:
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND

    Off-label criteria:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Provider has demonstrated knowledge of step therapy requirements AND
  - Medical justification why required step therapy drug(s) would be ineffective or have the potential to cause harm or deterioration of the member's condition OR
  - Medical justification why the requested drug would be superior to the required prerequisite trail(s) with formulary drug(s)

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria above

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 04/2018

QUANTITY LIMIT EXCEPTION

Formulary Status: Formulary, PA or Non-formulary

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit: N/A

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- Approve if:
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND
    Off-label criteria:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Member has a documented treatment failure with the drug prescribed at the quantity limit OR
  - Member requires a dose within prescribing guidelines that exceeds the quantity limit AND
  - Medical justification why the plan's quantity limit will be inadequate based on the member's condition and treatment history AND
  - Dose requested is supported by Medical Compendia or current treatment guidelines

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification for continuation of therapy

References: N/A

Last review/revision date: 04/2018

SAFETY EDIT EXCEPTION

Formulary Status: Formulary, PA or Non-formulary
*For drugs without specific criteria

Coverage Duration: 1 year*
**One month approval for duplication of therapy when transitioning from one agent to another.*

Diagnosis Considered for Coverage:

- Dosing or use in age populations outside of FDA-approved or accepted off-label indications

Prescribing Restriction: N/A

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose and duration of therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- **For requests exceeding the FDA or compendia max dose, administration frequency or duration of therapy recommendations, approve if:**
  - Patient has documented treatment failure with the drug at the maximum tolerated dose or maximum dose (whichever is the lesser dose), administration frequency or duration of therapy AND
  - Medical justification why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history AND
  - Dose requested is supported by the Medical Compendia or current treatment guidelines
- **For requests for a duplication of therapy**
  - **Transition from one agent to another (**one month only**), approve if:**
    - Provider has outlined a plan to transition member to a similar drug OR
    - Provider has provided a dose titration schedule
  - **Ongoing concurrent therapy with two similar agents, approve if:**
    - Medical justification why treatment with more than one drug in the same class is required based on the patient's condition and treatment history OR
    - Provider has submitted disease state specific standard of care guidelines supporting concurrent therapy
- **For requests exceeding an age restriction, approve if:**
  - Medical justification why the drug is needed outside age limit
  - Indication and dose requested are supported by the Medical Compendia or current treatment guidelines

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification for continuation of therapy

References: N/A

Last review/revision date: 04/2018

BRAND NAME MEDICATION

Formulary Status: all

Coverage Duration:

- Refer to drug-specific PA criteria OR
- Indefinite for chronic medications OR
- 1 year for non-chronic medications

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit* See drug-specific PA criteria OR As requested not to exceed FDA approved or off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation for failure of generic alternatives

Coverage Criteria:

*SFHP has a mandatory generic policy and requires generic substitution when an equivalent generic product is available.

I. Initiation of Therapy:

- Approve if:
  - The requested medication is in one of the following classes: anti-epileptics, immunosuppressants OR
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND
    Off-label criteria:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Trial and failure of at least 2 generic versions of the requested medication by different manufacturers per claims history or documentation from the provider (i.e. dates tried, reason for trial and failure) OR inability to use at least 2 generic versions of the requested medication by different manufacturers (e.g. 2 generic versions are not available) AND
  - Documented trial and failure or inability to use up to three preferred medications (if available) used to treat the documented diagnosis provided there is no evidence supporting use of the requested non-preferred medication compared to preferred medications

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Clear information provided documenting why generic versions cannot be used

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

BRAND NAME MEDICATION
• The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND • Clear information provided documenting why generic versions cannot be used.
References: N/A
Last review/revision date: 10/2018

ORAL AND INTRAVENOUS ONCOLYTICS

Category: Policy
Formulary Status: Formulary, PA

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-Label indications: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Authorized quantity: 30 days supply
- Prescriber restriction: Prescriber must be oncologist or hematologist

Clinical Information Required for Review:

- Diagnosis
- Dose
- Prescriber specialty

Coverage Criteria:

I. Initiation of Therapy:

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) AND
- Documentation provided of results of genetic testing where required per drug package insert AND
- Documentation provided of results of all required laboratory values and patient specific information (e.g. weigh, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert AND
- Requested quantity does not exceed FDA approved or standard off-label dose AND
- For IV medications, if request includes a documented reason why the medication cannot be provided via the Medical Benefit (**Medi-Cal only**), then the request must confirm that the medication is administered by a healthcare professional*

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- For IV medications, if documented reason why it cannot be provided via the Medical Benefit (**Medi-Cal only)**: medication is administered by a healthcare professional*

*Note: capitation deduction may be required, alert Pharmacy Director of approval via this criteria)

References:

- NCCN Guidelines® & Clinical Resources. Development and Update of the NCCN Guidelines® Available at: https://www.nccn.org/professionals/development.aspx. Accessed September 4, 2018.

Last review/revision date: 10/2018

SOLID ORAL SUBSTITUTION

Category: Policy

Formulary Status: Formulary, age limit ≤12 OR non-formulary

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- FDA-approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: FDA approved or standard off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Dose
- Diagnosis

Coverage Criteria:

I. Initiation of Therapy:

- Approve if:
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND *Off-label criteria:*
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Documentation of trial and failure, intolerance, contraindication, or inability (e.g. inability to swallow, etc.) to use **tablet or capsule** formulation

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Continued inability to use **tablet or capsule** formulation of the same medication

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Continued inability to use **tablet or capsule** formulation of the same medication

References: N/A

Last review/revision date: 10/2018

NON-FORMULARY EXTENDED-RELEASE FORMULATION

Formulary Status: Non-formulary

Coverage Duration:
1 year to indefinite depending on drug class (e.g. indefinite for anticonvulsants)

Diagnosis Considered for Coverage:
- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:
- Quantity Limit*: FDA approved or standard off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:
- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:
- Approve if:
  - Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND
    Off-label criteria:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies
  - Documentation of trial and failure, intolerance, contraindication, or inability (e.g. compliance difficulty, etc.) to use **formulary immediate release** formulation if available

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:
- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2018

INTRAVENOUS MEDICATIONS
Category: Policy **(applies to Medi-Cal only)** **Formulary Status:** Formulary, PA
Coverage Duration: up to 6 months
Diagnosis Considered for Coverage: • FDA approved indications • Off-Label indications: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • None
Clinical Information Required for Review: • Diagnosis • Dose
Coverage Criteria: (applies to Medi-Cal only) **I. Initiation of Therapy:** • Approve if: o Medication or product is administered by a healthcare professional AND o Appropriate diagnosis/indication for requested non-formulary medication or meets off-label criteria below AND *Off-label criteria:* ▪ No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND ▪ Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR ▪ Requested use can be supported by at least two published peer reviewed clinical studies o Requested quantity does not exceed FDA approved or standard off-label dose AND o Documented reason why it cannot be provided via the Medical Benefit (**Medi-Cal only**): medication is administered by a healthcare professional* **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Continuation of therapy is clinically appropriate AND • Medication or product is administered by a healthcare professional AND • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Continuation of therapy is clinically appropriate AND • Medication or product is administered by a healthcare professional
References: N/A
Last review/revision date: 10/2018

COMPOUNDED MEDICATIONS

Formulary Status: Non-Formulary/Prior Authorization required

Coverage Duration: Initial: Not to exceed 3 months Reauthorization: 6 months

Diagnosis Considered for Coverage:

- Diagnosis appropriate for medications contained in the compounded product.

Prescriber Restriction:

- Quantity Limit* 30 day supply

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Current therapy
- Other medications that have been used for diagnosis
- Comorbidities

Coverage Criteria:

I. Initiation Criteria

The plan may authorize coverage of compounded prescription medications with an ingredient cost greater than or equal to $75 when ALL of the following criteria are met:

- The indication, therapeutic amount, and route of administration of each of the active ingredients in
- the compound are FDA-approved or CMS-recognized compendia supported, AND
- All of the active ingredients included in the compound are FDA-approved medications (bulk chemicals are not FDA approved), AND
- If there are existing clinical coverage criteria for any of the active ingredients, those criteria must also be met for these ingredients, AND
- And one (1) of the following:
  - o There is a current supply shortage of the commercial product, OR
  - o The member has a medical need for a dosage form or dosage strength that is not commercially available, OR
  - o The member had a trial and intolerance to or contraindication to the commercially available product (e.g. allergen/preservative/dye-free, palatability for pediatrics, adverse effects to binders/fillers/other active ingredients), OR
  - o The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Continuation of therapy is clinically appropriate AND
- Prescriber attests that member has been on this medication continuously before joining SFHP

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Continuation of therapy is clinically appropriate

Note: All of the active ingredients included in the compound need to be included on the request for authorization

References: N/A

Last review/revision date: 10/2018

Drug Specific Criteria
Allergy/Cold/ENT

THERAPEUTIC ALLERGENIC EXTRACTS

Standard/Specific Therapeutic Class: *Allergens, Therapeutic Allergenic Extract*
Formulary Status:

- Non-formulary:
  - Timothy Grass Pollen Extract (Grastek®)
  - Mixed Allergen Extract (Oralair®)
  - Short Ragweed Pollen Extract (Ragwitek®)
  - House Dust Mite Allergen Extract (Odactra™)

Coverage Duration: 3 years

Diagnosis Considered for Coverage:

- Moderate to severe allergic rhinitis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit* #30/30 days
- Prescriber restriction: Prescribed by or in consultation with an allergist, an immunologist, an otolaryngologist, or other physician currently providing subcutaneous immunotherapy to patients in their practice

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Positive skin test
- Dose and duration of therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **moderate or severe allergic rhinitis**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **at least three formulary alternatives** from at leat one of each pharmacologic classes indicated to treate allergic rhinitis:
    - oral antihistamines (e.g. loratadine, cetirizine, fexofenadine)
    - intranasal corticosteroids (e.g. fluticasone, flunisolide)
    - leukotriene-receptor antagonists (e.g montelukast)
  - Documentation of a positive skin test to the relevant perennial aeroallergen:
    - Timothy Grass aeroallergen for GRASTEK use
    - Ragweed aeroallergen for RAGWITEK use
    - Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass aeroallergen for ORALAIR use
    - House dust mites for Odactra™ use
  - Prescribed by or in consultation with an allergist, an immunologist, an otolaryngologist, or other physician currently providing subcutaneous immunotherapy to patients in their practice
  - Documentation that the sublingual immunotherapy will begin at least 12 weeks (for Grastek® or Ragwitek®) or 16 weeks (for Oralair®) before the start of the allergy season.

THERAPEUTIC ALLERGENIC EXTRACTS
o Meets the following age groups: ▪ Grastek® SL tablet: between the age of 5 – 65 years old ▪ Ragwitek® SL tablet: between the age of 18 – 65 years old ▪ Oralair® SL tablet: between the age of 18 – 65 years old ▪ Odactra™ SL tablet: between the age of 18 – 65 years old • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Prescriber attests that member has been on this medication continuously before joining SFHP AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:** • Medical justification provided for continuation of therapy
References: N/A
Last review/revision date: 7/2018

SECOND-GENERATION ANTIHISTAMINES

Standard/Specific Therapeutic Class: *Antihistamines, Second Generation Antihistamines*

Formulary Status:

- Formulary:
  - loratadine 10mg, 10 mg disintegrating tablet, 5mg/5mL oral solution
  - loratadine-pseudoephedrine 5mg-120mg and 10mg-240mg 24HR-ER tabs
  - cetirizine 5mg & 10mg tablet, 1mg/mL solution
  - desloratadine 5 mg tabs
  - fexofenadine 60mg, 180mg tablet, 30mg/5mL oral suspension
  - levocertirizine
- Non-Formulary:
  - desloratadine (Clarinex®) 2.5mg, 5 mg rapid disintegrating tabs
  - desloratadine 2.5mg/5mL syrup
  - fexofenadine 30 mg rapid disintegrating tablet
  - cetirizine 5mg, 10mg chewable/tablet

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Allergic rhinitis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Desloratadine 2.5mg, 5mg rapid disintegrating tabs: #90 per 90 days
  - Desloratadine 2.5mg/5mL syrup, fexofenadine 30mg ODT: sufficient quantity for 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **allergic rhinitis**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use at least three formulary antihistamines (e.g. loratadine, cetirizine, fexofenadine)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" section

References: N/A

Last review/revision date: 10/2018

INTRANASAL STEROIDS

Standard/Specific Therapeutic Class: *Allergy/Cold/ENT: Nasal Sprays, Steroid*
Formulary Status:

- Formulary:
  - budesonide (Rhinocort®) (Rx)
  - Rhinocort® (budesonide) (OTC)
  - flunisolide (Nasarel®)
  - fluticasone (Flonase®)
  - triamcinolone (Nasacort® Allergy 24HR - OTC)
- Non-formulary:
  - beclomethasone (Beconase AQ®)
  - fluticasone (Veramyst®)
  - mometasone (Nasonex®)
  - triamcinolone (Nasacort AQ®)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - budesonide (Rhinocort®) (Rx): #8.6g per 30 days
  - Rhinocort® (budesonide) (OTC): #8.43mL per 30 days
  - flunisolide (Nasarel®): #25g per 30 days
  - fluticasone (Flonase®): #16g per 30 days
  - triamcinolone (Nasacort® Allergy 24HR - OTC): #16.9mL per 30 days
  - beclometasone (Beconase AQ®): #25g per 30 days
  - fluticasone (Veramyst®): #10g per 30 days
  - mometasone (Nasonex®): #17g per 30 days
  - triamcinolone (Nasacort® AQ): #16.5g per 30 days
  - Rhinocort® (budesonide) (OTC): #8.43g per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Previous therapy
- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For FDA-approved indications:
  - For patients ≥ 4 years of age, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use at least **three formulary alternatives**
  - For patients < 4 years of age, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use triamcinolone (Nasacort Allergy 24HR - OTC) nasal spray)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months): • Refer to "Initiation of Therapy" section
References: N/A
Last review/revision date: 10/2018

Analgesics, Misc

RECTIV® (NITROGLYCERIN) 0.4% OINTMENT
Standard/Specific Therapeutic Class: *Miscellaneous, Local Anorectal Nitrate Preperations* **Formulary Status:** Formulary, PA
Coverage Duration: 3 months (one-time approval)
Diagnosis Considered for Coverage: • Moderate to severe pain associated with chronic anal fissure OR • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: #30 per 30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis
Coverage Criteria: **I. Initiation of Therapy:** • For diagnosis of moderate to severe pain associated with chronic anal fissure, approve • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Medical justification provided for continuation of therapy.
References: N/A
Last review/revision date: 7/2018

LYRICA® (PREGABALIN)

Standard/Specific Therapeutic Class: *Anticonvulsants*

Formulary Status: Formulary, Step Therapy

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Any pain disorder, seizure disorders
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Immediate release: #270 per 90 days (max 600 mg/day)
  - Extended release: #90 per 90 days (max 330 mg/day)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For fibromyalgia, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ONE of the following alternatives:
  - SSRI
  - TCA
  - SNRI
- For all other diagnoses of **pain**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **gabapentin**
- For off-label indications, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 10/2018

Analgesics: Migraine

ANTI-MIGRAINE PREPARATIONS
Standard/Specific Therapeutic Class: *Non-narcotic Analgesics, Antimigraine Preparations* **Formulary Status:** • Formulary, PA required: o butalbital/acetaminophen/caffeine (Esgic®) 50-325-40mg tablet • Non-formulary: o acetaminophen/isometheptene/ichloralphenazone (Migragesic IDA, Nodolor) o butalbital/acetaminophen/caffeine 50-325-40 mg caps (Esgic®), and 50-300-40 mg caps and tabs (Fioricet®) o butalbital/aspirin/caffeine 50-325-40 mg capsules and tablets o isometheptene/caffeine/acetaminophen (Prodrin®)
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Diagnosis of migraine • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit* #60 per 30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Previous therapy
Coverage Criteria: **I. Initiation of Therapy:** • For diagnosis of **migraine**, approve if: o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use ALL of the following formulary alternatives: ▪ sumatriptan AND rizatriptan ▪ One NSAID (e.g. naproxen, ibuprofen) ▪ acetaminophen/aspirin/caffeine 250/250/65mg tablet OR acetaminophen/caffeine 500/65mg tablet (Excedrin®) • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider**

ANTI-MIGRAINE PREPARATIONS
attestation on PA request that member is continuing the medication), approve if: ▪ Patient is stable and continuing the medication, AND ▪ Medication is used for appropriate indication and at appropriate dose
References: N/A
Last review/revision date: 10/2018

CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS

Standard/Specific Therapeutic Class: *Non-narcotic analgesics/Antimigraine preparations*

Formulary Status:

- Formulary, PA required:
  - Emgality™ (galcanezumab)
- Non-formulary:
  - Aimovig™ (erenumab)
  - Ajovy™ (fremanezumab)

Coverage Duration:

Initial: 6 months
Renewal: Indefinite

Diagnosis Considered for Coverage:

- Migraine headache (episodic or chronic)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity*:
  - Aimovig™: 2 auto-injectors (140mg) per 30 days
  - Ajovy™: 3 syringes (675mg) per 90 days
  - Emgality™: 1 auto-injector or syringe (120mg) per 30 days
- Prescriber: Prescribed by a neurologist or in consultation with a neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **migraine headache,** approve if:
  - Patient must have at least 4 migraine days per month or one or more severe migraines lasting for greater than 12 hours despite use of abortive therapy (e.g. triptan or NSAIDs) AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least one drug from two categories below for at least 4 weeks EACH, at minimum effective doses, AND:
    - Beta-adrenergic blockers
    - Topiramate or divalproex ER or DR
    - Amitriptyline or venlafaxine
    - Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis)
  - For Aimovig™ or Ajovy™, documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use Emgality™
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS
• Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Documentation supporting re-evaluation of patient and a reduction in number of headache days by at least 1 day per month during the initial authorization period
References: N/A
Last review/revision date: 1/2019

TRIPTANS

Standard/Specific Therapeutic Class: *Non-narcotic Analgesics, Antimigraine Preparations*

Formulary Status:

- Formulary:
  - sumatriptan (Imitrex®) 25mg, 50mg, 100mg tablet: AL minimum 12 yo
  - rizatriptan (Maxalt®) 5mg, 10mg tablet; 5mg, 10mg oral disintegrating tablet (ODT): AL minimum 6 yo
- Formulary, Step therapy:
  - naratriptan (Amerge®) 1, 2.5 mg tablet
- Formulary, PA required:
  - sumatriptan 5mg, 20mg nasal spray
- Non-formulary:
  - almotriptan (Axert®)
  - frovatriptan (Frova®)
  - eletriptan (Relpax®)
  - sumatriptan SQ, Sumatriptan Jet-injector (Sumavel DosePro®)
  - sumatriptan/Naproxen (Treximet®)
  - zolmitriptan nasal spray, tablet, ODT (Zomig®)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Migraines, migraines with nausea and vomiting, cluster headaches
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Tablet/ODT formulations: #36 tablets per 30 days
  - Sumatriptan nasal spray: 1 fill (6 sprays) per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For FDA-approved diagnoses:
  - For **naratriptan**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sumatriptan AND rizatriptan**
  - For **sumatriptan nasal spray**, approve if there is diagnosis of migraine with nausea and vomiting OR diagnosis of cluster headaches
  - For **non-formulary oral triptan**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use:
    - sumatriptan AND rizatriptan as first line formulary alternatives AND
    - naratriptan as second line formulary alternative
  - For **non-formulary non-oral triptan**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability to use **oral tablets** (e.g. migraine with nausea and vomiting) **AND sumatriptan nasal spray**

TRIPTANS
• For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 10/2018

Analgesics: NSAIDs

TOPICAL NSAIDS
Standard/Specific Therapeutic Class: *Antiarthritics, Topical Anti-inflammatory NSAIDs* **Formulary Status:** • Formulary: o diclofenac 1% gel (Voltaren®) • Non-formulary: o diclofenac epolamine 1.3% patch (Flector®) o diclofenac 1.5% drops (Pennsaid®)
Coverage Duration: 1 year
Diagnosis Considered for Coverage: • Mild to moderate musculoskeletal pain • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: o diclofenac 1% gel: #300 per 30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Previous therapy
Coverage Criteria: **I. Initiation of Therapy:** • For musculoskeletal pain, approve if: o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, age >65, on oral anticoagulant, GFR < 30 ml/min, history of GI issues/bleed/ulcer etc.) to use the at **least 2 oral NSAIDs** AND o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, age >65, on oral anticoagulant, GFR < 30 ml/min, history of GI issues/bleed/ulcer etc.) to use the formulary alternative: **diclofenac (Voltaren®) 1% gel** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Refer to "Initiation of Therapy" section **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Patient is stable and continuing the medication
References: N/A
Last review/revision date: 10/2018

Analgesics: Opioids

SHORT-ACTING OPIOIDS

Standard/Specific Therapeutic Class: *Narcotic Analgesics*
Formulary Status:

- Formulary:
  - codeine tablet (age minimum, 12 yo)
  - hydromorphone (Dilaudid®) tablet
  - morphine sulfate (MS-IR®) tablet
  - oxycodone (Roxicodone®) tablet
  - tramadol (Ultram®) 50 mg tablet (age minimum, 18 yo)
  - codeine phosphate/ acetaminophen (Tylenol w/codeine®) tablet (age minimum, 12 yo)
  - hydrocodone/acetaminophen (Vicodin®) 2.5-325, 5-325, 7.5-325, 10-325 mg tablet
  - oxycodone/acetaminophen (Percocet®) 2.5-325, 5-325, 7.5-325, 10-325 mg tablet
  - oxycodone/aspirin (Percodan®) 4.8355-325 mg tablet
  - acetaminophen with codeine (Tylenol-Codeine #3®) 300-30 mg tablet (age minimum, 12 yo)
  - acetaminophen with codeine (Tylenol-Codeine #4®) 300-60 mg tablet (age minimum, 12 yo)
  - acetaminophen with codeine (Capital with codeine®) 300-15 mg tablet (age minimum, 12 yo)
  - tramadol/acetaminophen (Ultracet®) 37.5-325 mg tablet (age minimum, 18 yo)
  - oxymorphone
  - oxycodone/acetaminophen 5-325 mg/5 ml solution
  - morphine sulfate 10, 20, 100 mg/5 ml solution
  - oxycodone 5 mg/5 ml solution
  - oxycodone 20 mg/ml oral concentrate
  - morphine sulfate 5, 20, 20, 30 mg suppository
  - acetaminophen with codeine 120-12 mg/5ml solution (age minimum, 12 yo)
  - acetaminophen with codeine 120-12 mg oral suspension (age minimum, 12 yo)
- Non-formulary:
  - oxycodone/APAP 5/300, 7.5/300, 10/300 mg tab (Primlev®)
  - hydrocodone/acetaminophen (Xodol®) 5-300, 7.5-300, 10-300 mg tablet; oral solution

Coverage Duration:
Initial days supply > 7 days: one-time only
Subsequent quantity > #120 per 30 days: for duration requested up to one year
Non-formulary drug: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain, chronic pain
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days for products listed below:*
    - Codeine tablet (age minimum, 12 yo)
    - Hydromorphone (Dilaudid®) tablet
    - Morphine sulfate (MS-IR®) tablet
    - Oxycodone (Roxicodone®) tablet
    - Tramadol (Ultram®) 50 mg tablet
    - Codeine phosphate/ acetaminophen (Tylenol w/codeine®) tablet

SHORT-ACTING OPIOIDS

- Hydrocodone/acetaminophen (Vicodin®) 2.5-325, 5-325, 7.5-325, 10-325 mg tablet
- Oxycodone/acetaminophen (Percocet®) 2.5-325, 5-325, 7.5-325, 10-325 mg tablet
- Oxycodone/aspirin (Percodan®) 4.8355-325 mg tablet
- Acetaminophen with codeine (Tylenol-Codeine #3®) 300-30 mg tablet
- Acetaminophen with codeine (Tylenol-Codeine #4®) 300-60 mg tablet
- Acetaminophen with codeine (Capital with codeine®) 300-15 mg tablet
- Tramadol/acetaminophen (Ultracet®) 37.5-325 mg tablet

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
- For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
  - Medication is prescribed by a practitioner involved with care of the diagnosis provided AND
  - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met (see A below)
  - If medication is non-formulary, criteria for that drug are met (see B below) AND
  - One of the following:
    - Member has history of opioid use within the last 180 days documented through IPNS or CURES, or documented by requesting physician if member was on opioids out of state OR
    - Indication of cancer pain OR
    - Indication of palliative care OR
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease) OR
    - expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
- (A) For requests for formulary medication over subsequent fill quantity limit, approve if:
  - Use is short-term (i.e. less than 6 months requested) for post-operative or acute injury pain OR
  - Indication of chronic cancer pain OR
  - There is failure with or inability to use long-acting opiates (e.g. morphine sulfate ER tablets) OR
  - Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates
- (B) For non-formulary strength of oxycodone/APAP or hydrocodone/APAP, approve if:
  - Trial or failure or inability to use oxycodone/APAP 5/325 mg or formulary hydrocodone/APAP(e.g. total daily APAP dose exceeded, unable to split tablets, etc.) or inability to use oxycodone and APAP as separate ingredient products
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), refer to "Initiation of Therapy" section

- Refer to "Initiation of Therapy" section but allow up to 2 months to transition to preferred agents

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

SHORT-ACTING OPIOIDS
• Patient is stable and continuing the medication • For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit (A) are met
References: N/A
Last review/revision date: 8/2018

LONG-ACTING OPIOIDS

Therapeutic Class: *Analgesics: Opiates, Long-Acting*
Formulary Status:

- Formulary: morphine sulfate ER tablet (MS Contin®)
- PA required:
  - fentanyl transdermal (Duragesic®) 12, 25, 37.5, 50, 62.5, 75, 87.5, 100 mcg/h patch
  - oxycodone ER (Oxycontin®) tablet
  - morphine sulfate (Kadian®) 10, 20, 30, 40, 50, 60, 80mg 24h ER capsule
  - oxymorphone 12h ER tablet
- Non-formulary:
  - methadone
  - morphine sulfate (Avinza®) 45, 75, 90, 120mg 24h ER capsule
  - hydromorphone (Exalgo®) 24h ER abuse-deterrent tablet
  - MorphaBond® ER (morphine sulfate) 12h ER abuse-deterrent tablet
  - Arymo® ER (morphine sulfate) ER abuse-deterrent tablet
  - Xtampza® ER (oxycodone) 12h ER abuse-deterrent tablet
  - Nucynta® (tapentadol) 12h ER tablet

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Chronic pain
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescriber Restriction:

- Quantity Limit:*
  - fentanyl: #15 patches per 30 days
  - oxycodone ER, oxymorphone ER, Nucynta® ER, Xtampza® ER, MorphaBond® ER, Arymo® ER: #60 per 30 days
  - methadone: #180 per 30 days (up to 60 mg/day)
  - morphine sulfate 24h caps, hydromorphone ER: #30 tablets per 30 days

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
- For **fentanyl patches, morphine sulfate ER caps, oxycodone ER,** approve if:
  - there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **morphine sulfate ER tablets at an adequate (equianalgesic) dose** OR
  - there is documentation of pain caused by active cancer
- For **methadone**, approve if:
  - Diagnosis of pain
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction,

LONG-ACTING OPIOIDS

allergy, adverse reaction, etc.) to use the following alternatives AND
  - short-acting opiates AND
  - morphine sulfate ER tablets AND one other long-acting opioid at an adequate (equianalgesic) dose
- Naloxone has been prescribed for the member

- For **hydromorphone ER, Nucynta ER®**, or **oxymorphone ER**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use ALL of the following alternatives at an adequate (equianalgesic) dose
    - Oxymorphone immediate release AND
    - Morphine sulfate ER tablets or capsules AND
    - Fentanyl patches AND Oxycodone ER
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months):
- Refer to "Initiation of Therapy" section but allow up to 2 months to transition to preferred agents

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if patient is stable and continuing the medication

References:

- CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. Recommendations and Reports / March 18, 2016 / 65(1); 1–49. Accessed at http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
- Whalen, J. FDA Advisory Panel Says Benefits of Painkiller Opana ER No Longer Outweigh Risks. Wall Street Journal. March 14, 2017. Available at https://www.wsj.com/articles/fda-advisory-panel-says-benefits-of-painkiller-opana-er-no-longer-outweigh-risks-1489524063

Last review/revision date: 1/2019

Cardiovascular

RANEXA® (RANOLAZINE)
Standard/Specific Therapeutic Class: *Other Cardiovascular Preps/Non-hemodynamic, Antianginal & Anti-ischemic Agents* **Formulary Status:** Formulary, Step Therapy
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Chronic angina • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: #180 per 90 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Previous therapy
Coverage Criteria: **I. Initiation of Therapy:** • For diagnosis of **chronic angina**, approve if: o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use at least one anti-anginal agent (beta-blocker, amlodipine, nifedipine, isorbide, or long-acting nitroglycerin) • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members (within the last 6 months), approve if:** • Patient is stable and continuing the medication AND • Medication is used for appropriate indication and at appropriate dose
References: N/A
Last review/revision date: 1/2019

HYDERGINE® (ERGOLOID MESYLATES)
Standard/Specific Therapeutic Class: *Vasodilators Peripheral* **Formulary Status:** Non-formulary
Coverage Duration: Initial: 6 months Re-auth: 12 months
Diagnosis Considered for Coverage: • Mental capacity decline • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: up to #90 per 30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Previous therapy • Dose
Coverage Criteria: **I. Initiation of Therapy:** • For diagnosis of mental capacity decline, approve if: o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **first line therapies (e.g. donepezil, memantine)** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 10/2018

SAMSCA® (TOLVAPTAN)

Standard/Specific Therapeutic Class: *Diuretics/Arginine Vasopressin (AVP) Receptor Antagonists*
Formulary Status: Non-formulary

Coverage Duration: up to 30 days of total therapy

Diagnosis Considered for Coverage:

- Hyponatremia
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose including titration schedule

Coverage Criteria:

I. Initiation of Therapy:

- For hyponatremia, approve if:
  - Diagnosis is hyponatremia AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **fluid restriction and other therapies (e.g. IV diuretics)** AND
  - Therapy will be initiated at a hospital to monitor serum sodium levels
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
- Patient has used the medication for less than 30 days (only up to 30 days of total therapy will be approved)

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification for why duration of therapy greater than 30 days is needed

References:

- Yancy, CW et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013; 128: 000–000.
- Yancy CW, et al. 2017 ACC/AHA/HFSA Focused Updated of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: a Report of the American College of of Cardiology Foundation/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017; 136: e137-61.

Last review/revision date: 10/2018

Cardiovascular: Anticoagulants

DIRECT FACTOR XA INHIBITORS

Standard/Specific Therapeutic Class: *Anticoagulants/Direct Factor Xa Inhibitors*
Formulary Status:

- Formulary:
  - Eliquis® (apixaban) 2.5mg, 5mg
  - Xarelto® (rivaroxaban) 15mg-20mg dose pack, 15mg, 20mg
  - warfarin
- Formulary, PA required:
  - Savaysa® (edoxaban) 15mg, 30mg, 60mg
  - Pradaxa® (dabigatran) 75mg, 110mg, 150mg

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Nonvalvular arial fibrillation, deep vein thrombosis (DVT), pulmonary embolism (PE)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Savaysa®: #90/90 days
  - Pradaxa®: #180/90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For **Savaysa®**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: **Eliquis® AND Xarelto®**
  - Indication for one of the following:
    - Nonvalvular atrial fibrillation
    - Treatment of deep vein thrombosis (DVT)
    - Treatment of pulmonary embolism (PE)
- For **Pradaxa®**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: **Eliquis® AND Xarelto®**
  - Indication for one of the following:
    - Nonvalvular atrial fibrillation
    - Treatment and reduction in the risk of recurrent of DVT or PE
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

DIRECT FACTOR XA INHIBITORS
II. Continuation of Therapy for NEW Members (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 10/2018

PLATELET AGGREGATION INHIBITORS

Standard/Specific Therapeutic Class: *Anticoagulants, Platelet-Aggregation Inhibitors*

Formulary Status:

- Formulary:
  - anagrelide (Agrylin®)
  - aspirin and dipyridamole (Aggrenox®) 25 mg-200 mg
  - Brilinta® (ticagrelor) 90 mg
  - cilostazol (Pletal®) 50, 100 mg
  - clopidogrel (Plavix®) 75 mg
  - dipyridamole (Persantine®) 25, 50, 75 mg
- Formulary, Step Therapy:
  - Effient® (prasugrel) 5 mg, 10 mg
- Non-Formulary:
  - Zontivity® (vorapaxar)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- For Zontivity® (vorapaxar): prevention of thrombosis in patients with a history of MI or PAD
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescriber Restriction:

- Quantity Limit:
  - Effient®, Zontivity®: #90/90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy

- For **Effient®**, approve if:
  - There is documented trial and failure, intolerance, contraindications or medical reason for inability to use **clopidogrel** (e.g. due to drug interaction, allergy, adverse reaction, patient is poor CY2C19 metabolizer [e.g. Asian descent])
- For **Zontivity®,** approve if**:**
  - Requested diagnosis is ACS and patient has history of myocardial infarction or established peripheral arterial disease (PAD) AND
  - Trial and failure, intolerance, contraindication or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **clopidogrel** alone as a first line preferred product AND
  - Documentation (confirmed by chart notes or claims history) that patient is concurrently using aspirin and/or clopidogrel
  - Documentation patient has no previous medical history of stroke, TIA, or intracranial hemorrhage
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND

PLATELET AGGREGATION INHIBITORS
o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 10/2018

Cardiovasuclar: Chronic Heart Failure

ENTRESTO® (SACUBITRIL/VALSARTAN)

Standard/Specific Therapeutic Class: *Other Cardiovascular Preps, Angiotensin Receptor-Neprilysin Inhibitor (ARNI)*
Formulary Status: Formulary, Step Therapy

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:
- NYHA class II-IV heart failure
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:
- Quantity Limit*: #180 per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:
- Prior therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:
- There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **ACEIs or ARBs**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months):
- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 1/2019

Cardiovascular: Hypertension

DIBENZYLINE® (PHENOXYBENZAMINE)
Standard/Specific Therapeutic Class: *Other Cardiovascular Preps, Alpha-adrenergic blockers* **Formulary Status:** Formulary, PA required
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Hypertension and sweating with pheochromocytoma • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: #360 per 30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Dose
Coverage Criteria: **I. Initiation of Therapy:** • For diagnosis of **hypertension and sweating with pheochromocytoma**, approve if: o Phenoxybenzamine is being prescribed at an FDA approved dose • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 10/2018

BLOOD PRESSURE MONITORS

Formulary Status:

- Formulary: **(Applies to Medi-Cal and Cal-WRAP only)**
  - Omron 3 Series (NDC 73796-0271-04)
  - Omron 5 Series (NDC 73796-0274-24)
  - Omron 7 Series (NDC 73796-0276-04; 73976-0267-61)
  - Omron 10 Series (NDC 73796-0267-54; 73796-0267-86)
  - Walgreens Automatic Arm (NDC 11917-0144-84)
  - Walgreens Premium Arm (NDC 11917-0144-87)
  - Walgreens Deluxe Arm (NDC 11917-0144-85)
  - CVS Series 100 (NDC 50428-0535-60)
- Non-formulary:
  - All other monitors

Coverage Duration: One time approval

Diagnosis Considered for Coverage:

- Hypertension

Prescribing Restriction:

- Quantity Limit*: 1 per 5 years (entered as 1/30 days)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- n/a

Coverage Criteria: (Applies to Medi-Cal and Cal-WRAP only)

I. Initiation of Therapy:

- For **non-formulary BP monitor,** approve if there is documentation of inability to use formulary BP monitor (e.g. member needs BP monitor with extra-large BP cuff due to upper arm circumference > 17")
- **BP monitors with extra large cuff:**

Name	Circumference	NDC
Life Source Advanced BP Monitor with Accufit Extra Large Cuff (UA-789AC)	16.5-23.6"	93764-0600-62
Zewa UAM-880DC Deluxe Automatic Blood Pressure Monitor with 2 Cuffs	13.4-18.9"	82891-0388-00

References: N/A

Last review/revision date: 4/2018

NON-FORMULARY ACE INHIBITORS AND ACE COMBINATION PRODUCTS

Standard/Specific Therapeutic Class: Antihypertensives, *Angiotensin-Converting Enzyme Inhibitors*

Formulary Status:

- Non-Formulary:
  - moexipril (Univasc®)
  - captopril-HCT (Capozide®)
  - fosinopril-HCT (Monopril-HCT®)
  - moexipril-HCT (Uniretic®)
  - quinapril-HCT (Accuretic®)
  - trandolopril-verapamil (Tarka®)
  - Prestalia® (perindopril-amlodipine)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- FDA-approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction: N/A

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **non-formulary ACE,** approve if:
  - Trial and failure or inability to use ALL formulary agents (benazepril, enalapril, lisinopril, quinapril, captopril, perindopril, fosinopril, ramipril, and trandolopril)
- For **non-formulary ACE+HCTZ,** approve if:
  - Trial and failure or inability to use ALL formulary agents (benazepril/HCTZ, lisinopril/HCTZ, enalapril/HCTZ and benazepril/amlodipine)
- For **non-formulary ACE+CCB,** approve if:
  - Trial and failure or inability to use ALL formulary agents (benazepril/HCTZ, lisinopril/HCTZ, enalapril/HCTZ and benazepril/amlodipine)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last Review/Revision Date: 4/2018

NON-FORMULARY ARBS AND ARB COMBINATION PRODUCTS

Standard/Specific Therapeutic Class: *Angiotensin II Receptor Antagonists*

- Formulary, Step Therapy:
  - candesartan (Atacand®), candesartan-HCTZ (Atacand-HCTZ®)
- Non-Formulary:
  - Edarbi® (azilsartan)
  - eprosartan (Teveten®)
  - Benicar® (olmesartan)
  - Edarbyclor® (azilsartan-chlorthalidone)
  - Benicar-HCT® (olmesartan-hydrochlorothiazide)
  - telmisartan-hydrochlorothiazide (Micardis-HCT®)
  - Azor® (olmesartan-amlodipine)
  - telmisartan-amlodipine (Twynsta®)
  - Tribenzor® (olmesartan-amlodipine-HCTZ)
  - valsartan-amlodipine-HCTZ (Exforge-HCT®)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- FDA-approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction: N/A

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **candesartan,** approve if:
  - Trial and failure or inability to use irbesartan, losartan, telmisartan AND valsartan
- For **candesartan-HCTZ,** approve if:
  - Trial and failure or inability to use irbesartan/HCTZ, losartan/HCTZ, valsartan/HCTZ AND valsartan/amlodipine
- For **non-formulary ARB,** approve if:
  - Trial and failure or inability to use irbesartan, losartan, telmisartan, valsartan AND candesartan
- For **non-formulary ARB-combination,** approve if:
  - Trial and failure or inability to use irbesartan/HCTZ, losartan/HCTZ, valsartan/HCTZ, candesartan/HCTZ, AND valsartan/amlodipine
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND

• The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision Date: 4/2018

COREG CR® (CONTROLLED-RELEASE CARVEDILOL)
Standard/Specific Therapeutic Class: *Other Cardiovascular Preps, Alpha/Beta-Adrenergic Blocking Agents* **Formulary Status:** Non-formulary
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Congestive heart failure (CHF) stage B, C, or D • Left ventricular dysfunction following myocardial infarction (MI) • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: #90 tablets per 90 days • Prescriber Restriction: N/A **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Previous therapy
Coverage Criteria: **I. Initiation of Therapy:** • For diagnosis of **congestive heart failure (CHF) stage B, C, or D** OR **left ventricular dysfunction following myocardial infarction(MI),** approve if: o Documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: carvedilol immediate release • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 4/2018

TEKTURNA® (ALISKIREN), TEKTURNA HCT® (ALISKIREN/HCTZ), TEKAMLO® (ALISKIREN/AMLODIPINE)

Standard/Specific Therapeutic Class: *Other antihypertensives, Renin Inhibitor, Direct*

Formulary Status: Non-Formulary

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Hypertension
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #90 per 90 days

Clinical Information Required for Review:

- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For hypertension, approve if:
  - Trial and failure or inability to use at least 3 agents from the following classes:
    - ACE-Inhibitors (e.g. lisinopril)
    - ARBs (e.g. losartan)
    - calcium channel blockers (e.g. amlodipine, diltiazem)
    - clonidine
    - beta blockers (e.g. metoprolol)
- For off-label indications, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 4/2018

INSPRA® (EPLERENONE)
Standard/Specific Therapeutic Class: *Aldosterone Antagonists, Potassium Sparing Diuretics* **Formulary Status:** Formulary, step therapy
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • FDA-approved indications • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit* #90 per 90 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*.
Clinical Information Required for Review: • Diagnosis • Previous therapy • Age
Coverage Criteria: **I. Initiation of Therapy:** • For FDA-approved indications, approve if: o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **spironolactone** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 4/2018

Cardiovascular: Dyslipidemia

LOVAZA® AND VASCEPA®
Standard/Specific Therapeutic Class: *Lipotropics* **Formulary Status:** • Non-formulary: o omega-3 acid ethyl esters (Lovaza®) o Vascepa® (icosapent ethyl)
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Hypertriglyceridemia • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.
Prescribing Restriction: • Quantity Limit*: #360 per 90 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Previous therapy • Dose
Coverage Criteria: **I. Initiation of Therapy:** • For diagnosis of **hypertriglyceridemia**, approve if: o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **statins** at maximum tolerated dose AND o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use at least two of the following: **fibric acids, OTC omega-3 fatty acids, nicotinic acid** o For **Vascepa®**, of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **Lovaza®** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 1/2019

BILE ACID SEQUESTRANTS

Standard/Specific Therapeutic Class: *Cholesterol Reducers, Bile Salt Sequestrants*

Formulary Status:

- Formulary:
  - cholestyramine (Questran®) 4g powder/packet, cholestyramine light 4g powder/packet
  - colestipol (Colestid®) 1g tab
- Formulary, PA required
  - colesevelam (Welchol®) 3.75g powder packet and 625mg tab
  - colestipol (Colestid®) 5g granules, packets

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - colesevelam granules:#90 packets per90 days
  - colesevelam tablets: #540 tablets per 90 days
  - colestipol granules, packets: #2,700g per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For FDA-approved indications, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use cholestyramine powder/packets or cholestyramine light powder/packets and colestipol tablets
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 1/2019

PCSK-9 INHIBITORS

Standard/Specific Therapeutic Class: *Lipotropics, Antihyperlipidemic – PCSK-9 inhibitors*

Formulary Status:

- Formulary, PA required:
  - Praluent® (alirocumab)
  - Repatha® (evolocumab) preferred NDCs **only**:
    - 140mg/mL syringe: 72511-0750-01
    - 140mg/mL SureClick pen injector: 72511-0760-02
    - 420mg/3.5mL Pushtronex wearable injector: 72511-0770-01

Coverage Duration:

Initial: 6 months

Continuation: Indefinite

Diagnosis Considered for Coverage:

- Heterozygous Familial Hypercholesterolemia (HeFH), primary hyperlipidemia, homozygous familial hypercholesterolemia (HoFH)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Praluent® #2mL per 30 days
  - Repatha® #2mL per 28 days (140 mg mg/ml every 2 weeks)
- Prescriber restriction: Prescriber must be cardiologist or specialist in treatment of lipid disorders

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy, concurrent therapy
- Dose
- Lipid levels

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **familial hypercholesterolemia (FH)**, approve if:
  - 2 fasting lipid panel labs within the past 12 months with abnormal LDL levels ≥190mg/dL for FH in adults or ≥160mg/dL for FH in children AND
  - Documentation submitted indicates the patient is a non-smoker AND
  - Documented claim history or chart notes showing consistent therapy and trial with one high-intensity statin regimen (atorvastatin 40-80mg or rosuvastatin 20-40mg) with inadequate response still requiring additional LDL lowering, or a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing high-dose statin AND
  - If request indicates that the patient is “statin intolerant”, documentation was provided including description of the side effects, duration of therapy, “wash out”, re-trial, and then change of agents. Patient should have documentation of trial and failure of at least two statin therapies AND
  - One of the following applies:
    - LDL > 400mg/dL with documented strong (1st and 2nd degree relatives) family history of high levels of LDL and/or heart attack and relationship to member

PCSK-9 INHIBITORS

  - Documented chart notes of clinical manifestations of FH such as xanthomas or aortic valve disease at <20 years of age
  - Autosomal Dominant Hypercholesterolemia Genetic Testing Reflex Panel (ADHP Panel) with positive genetic testing for LDL raising gene defect or autosomal-recessive FH
  - Premature coronary artery disease
- For diagnosis of **primary hyperlipidemia**, approve if:
  - Two fasting lipid panel labs within the past 12 months demonstrate abnormal LDL levels > 70mg/dL AND
  - Documentation submitted indicates the patient is a non-smoker AND
  - Documented claim history or chart notes showing consistent therapy and trial with one high-intensity statin regimen (atorvastatin 40-80mg or rosuvastatin 20-40mg) with inadequate response still requiring additional LDL lowering, or a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing high-dose statin AND
  - If request indicates that the patient is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents. Patient should have documentation of trial and failure of at least two statin therapies AND
  - If ezetimibe is indicated prior to PCSK9 inhibitor per table below, documentation of trial and failure, intolerance, contraindication, or inability to use ezetimibe
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

Member Age	Co-Morbidities	LDL Level	Treatment Regimen
≥ 21 years old	• Stable Clinical ASCVD • **NO** other co-morbidities	>70-189mg/dL	1. Add EZETIMIBE to current statin therapy first 2. Add PCSK9 inhibitor **OR** replace with PCSK9 inhibitor second
≥ 21 years old	• With or Without ASCVD • **NO** other co-morbidities	≥190mg/dL	1. Add EZETIMIBE **OR** PCSK9 inhibitor
≥ 21 years old	• Clinical ASCVD • **WITH** co-morbidities that increase likelihood of cardiovascular event [Diabetes Mellitus (DM), daily smoker, metabolic syndrome, etc.]	>70-189mg/dL	1. Add EZETIMIBE **OR** PCSK9 inhibitor
40-75 years old	• Diabetes (DM) and without ASCVD • No diabetes with ≥ 7.5% estimated 10 year risk for ASCVD	70-189mg/dL	1. Add EZETIMIBE to current statin therapy* **May also consider bile acid sequestrant* **NO RECOMMENDATION TO USE PCSK9 inhibitors as they do not have an established role for primary prevention of ASCVD**
Any age	• Symptomatic Heart Failure • Pregnancy • Maintenance hemodialysis	N/A	**PCSK9 inhibitors are NOT RECOMMENDED due to lack of safety and efficacy data**

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

PCSK-9 INHIBITORS
• Refer to "Initiation of Therapy" section **III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:** • Documentation submitted indicates that member obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has had at least 40% reduction in LDL AND • The patient's claim history shows consistent therapy (i.e. monthly fills).
References: N/A
Last review/revision date: 1/2019

Cardiovascular: PH

PULMONARY HYPERTENSION
Standard/Specific Therapeutic Class: *Other Antihypertensives, Pulmonary Anti-Hypertension, Endothelin Receptor Antagonists, Prostacyclin-type, Selective C-GMP Phosphodiesterase T5 Inhibitors, Soluble Guanylate Cyclase Stimulators* **Formulary Status:** • Formulary, PA required: o Adcirca® (tadalafil) 20mg oral tablet o Adempas® (riociguat) oral tablet o Letairis® (ambrisentan) oral tablet o Opsumit® (macitentan) oral tablet o Remodulin® (treprostinil) vial for infusion o sildenafil (Revatio®) 20mg oral tablet o Tyvaso® ampule for nebulized inhalation starter and refill kits o Uptravi® (selexipag) oral tablet and initial titration pack o Ventavis® (iloprost) ampule for nebulized inhalation • Non-formulary: o epoprostenol Na glycine (Flolan®) vial for injection [medical benefit] o Orenitram® (treprostinil) ER oral tablet o Revatio® (sildenafil) 10mg/mL oral suspension and 10mg/12.5mL vial for injection o Tracleer® (bosentan) oral tablet o Tyvaso® (treprostinil) 1.74mg/2.9mL amp for nebulizer
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • World Health Organization (WHO) group 1 pulmonary hypertension (PAH) and documented functional class II-IV • WHO group 4 pulmonary hypertension (CTEPH) and documented functional class II-IV (Adempas® only) • Off-label diagnoses, including PH groups 2, 3 and 5: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit* o Adcirca®: #60 tablets per 30 days o Adempas®: #90 tablets per 30 days o Letairis®: #30 tablets per 30 days o Opsumit®: #30 tablets per 30 days o Remodulin® solution for injection: weight-based dosing dependent on previous treatment o sildenafil: #360 tablets per 30 days (up to 80mg TID) o Tyvaso® Inhalation Starter Kit (NDC 66302-0206-01): #81.2 mL per 28 days, 1 fills only o Tyvaso® Inhalation Refill Kit (NDC 66302-0206-02): #81.2 mL per 28 days o Uptravi® titration pack: ▪ 200mg #140 tablets (first pack, NDC 66215-0602-14) for 28 days ▪ 200-800mg #200 tablets (second pack, NDC 66215-0628-20) for 28 days o Uptravi® tablet (all strengths): #60 per 30 days o Ventavis® neb ampule: #270 mL per 30 days

PULMONARY HYPERTENSION

- Non-Formulary:
  - epoprostenol vial for injection: weight-based dosing, no defined maximum [medical benefit]
  - Orenitram® ER: #60 tablets per 30 days
  - Revatio® oral suspension: #180 mL per 30 days
  - Tracleer®: #60 tablets per 30 days
  - Tyvaso® 1.74mg/2.9mL neb ampule: #81.2 mL per 28 days
- Prescriber restriction: Cardiologist, pulmonologist, or credible expert

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For World Health Organization (WHO) **Group 1 pulmonary hypertension, or pulmonary arterial hypertension (PAH)**, approve if:
  - Confirmed diagnosis and documentation of functional class (II-IV) by a cardiologist, pulmonologist, or credible expert AND
  - Request is for initial monotherapy with preferred formulary agent or initial dual therapy with preferred formulary agents of different mechanism of action AND
  - **Other criteria**:
    - If the provider is requesting to switch between formulary agents, then documentation is submitted of intolerance or ineffectiveness of prior/current therapy
    - If the provider is requesting combination therapy with three agents, then documentation is submitted of an adequate trial of dual therapy with two agents of different mechanism, and patient has been compliant with dual therapy
    - If the request is for Tracleer®, documentation is submitted of trial and failure, intolerance of, or contraindication to Letairis® AND Opsumit®
    - If request is for Adcirca®, documentation is submitted of trial and failure, intolerance of, or contraindication to sildenafil oral tablets
    - If the request is for Revatio® oral suspension, documentation submitted as to why patient cannot use sildenafil oral tablets (i.e., difficulty swallowing)
    - If the request is for Orenitram®, the patient must have documented failure or inability to use other formulary prostanoids
- For WHO **Group 4 pulmonary hypertension**, or chronic thromboembolic pulmonary hypertension (CTEPH) approve if:
  - Request is for Adempas® (for other medications, refer to off-label criteria) AND
  - Confirmed diagnosis and documentation of functional class (II-IV) by a cardiologist, pulmonologist, or credible expert AND
  - Recurrent or persistent CTEPH following pulmonary thromboendarterectomy OR inoperable CTEPH
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR

PULMONARY HYPERTENSION
o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND • If dose is being increased, document compliance to prior dose AND • For Uptravi® continuation requests, documentation is submitted of current dosing and titration schedule **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • The mediation is being recommended and prescribed by a pulmonologist or cardiologist at a dose within FDA approved guidelines AND • For dose increases, documentation is submitted of patient compliance with prior dose • For Uptravi® continuation requests, documentation is submitted of current dosing and titration schedule
References: N/A
Last review/revision date: 4/2018

Dermatology

ATOPIC DERMATITIS

Standard Therapeutic Class, Specific Therapeutic Class: *Topical anti-inflammatory, phosphodiesterase-4 inhibitor, topical calcineurin inhibitors, eczema agents, systemic interleukin-4 receptor antagonist monoclonal antibody*
Formulary Status:

- Formulary, Step therapy:
  - tacrolimus (Protopic®) 0.03%, 0.1% ointment
- Non-formulary:
  - Elidel® (pimecrolimus) 1% cream
  - Eucrisa® (crisaborole) 2% ointment
  - Dupixent® (dupilumab) 300 mg/3 ml syringe

Coverage Duration:
Tacrolimus, Elidel®: indefinite
Eucrisa®: 30 days
Dupixent®: Initial: 4 months; Renewal: indefinite

Diagnosis Considered for Coverage:

- Atopic dermatitis (mild, moderate, or severe eczema)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Tacrolimus and Elidel®: #30 grams per 30 days
  - Eucrisa®: #60 grams per 30 days
  - Dupixent®: #2 syringes for initiation and #1 syringe every other week
- Prescriber restriction: pediatrician or dermatologist (Dupixent® and Eucrisa® only)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For tacrolimus, approve if:
  - Diagnosis of moderate to severe atopic dermatitis in non-immunocompromised patient AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 medium to high potency topical corticosteroid
- For **Elidel®**, approve if:
  - Diagnosis of mild to moderate atopic dermatitis in non-immunocompromised patient AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 medium to high potency topical corticosteroid AND
  - Documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction) to use tacrolimus ointment
- For **Eucrisa®,** approve if:
  - Diagnosis of mild to moderate atopic dermatitis AND

ATOPIC DERMATITIS

- Age > 2 years AND
- There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 medium to high potency topical corticosteroid AND topical calcineurin inhibitor

- For **Dupixent®**, approve if:
  - Age > 18 years AND
  - Diagnosis of moderate to severe atopic dermatitis AND
  - Body surface area (BSA) involvement > 10%
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 medium to high potency topical corticosteroid AND topical calcineurin inhibitor
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use Eucrisa®
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- For Eucrisa®, patient has used the medication for less than 30 days (only up to 30 days of total therapy will be approved)
- For Dupixent®, documentation of improvement in BSA involvement from baseline

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing medication
- For Eucrisa®, medical justification for why duration of therapy greater than 30 days is needed
- For Dupixent®, documentation of improvement in BSA involvement from baseline

References: N/A

Last review/revision date: 3/2018

FINACEA®, AZELEX® (AZELAIC ACID)

Standard/Specific Therapeutic Class: *All other dermatologicals/Topical Rosacea agents*

Formulary Status:

- Formulary, PA required:
  - azelaic acid (Azelex® cream, Finacea® foam and gel)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Acne vulgaris, Papulopustular Rosacea
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Azelex®: #30g per 30 days
  - Finacea®: #50g per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **acne vulgaris**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use ALL of the following formulary alternatives: **Differin® OTC 0.1% gel*, benzoyl peroxide, topical clindamycin or erthyromycin, and topical tretinoin***
- For diagnosis of **papulopustular rosacea**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **topical metronidazole**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

*age limit ≤ 30 years, PA required for members > 30 years

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" section

References: N/A

Last review/revision date: 7/2018

METROGEL® (METRONIDAZOLE 1% TOPICAL GEL)
Standard/Specific Therapeutic Class: *All Other Dermatologicals/Rosacea Agents, Topical* **Formulary Status:** Formulary, Step Therapy
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Rosacea • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: 60 grams per 30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Prior therapy • Dose
Coverage Criteria: **I. Initiation of Therapy:** • For rosacea, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **metronidazole 0.75% gel** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months): • Refer to "Initiation of Therapy" section
References: N/A
Last review/revision date: 10/2018

SULFACETAMIDE CLEANSER GEL

Standard/Specific Therapeutic Class: *All Other Dermatologicals, Topical Acne Agents*

Formulary Status:

- Formulary: sulfacetamide/sulfur 10%-5% cleanser
- Formulary, PA required: sulfacetamide 10% topical gel

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Acne vulgaris, Rosacea
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - sulfacetamide/sulfur 10%-5% cleanser: #170mL per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **sulfacetamide/sulfur 10% topical cleanser gel,** approve if:
  - Diagnosis is **rosacea**
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **sulfacetamide/sulf 10/5% cleanser**
  - Diagnosis is **acne vulgaris**
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use ALL of the following formulary alternatives: **topical benzoyl peroxide, topical clindamycin or erythromycin, topical tretinoin** and **sulfacetamide/sulfur 10%-5% cleanser**
  - For off-label indications or dosing, approve if:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" section

References: N/A

Last review/revision date: 7/2018

AMNESTEEM®, CLARAVIS®, MYORISAN®, ZENATANE® (ISOTRETINOIN)

Standard/Specific Therapeutic Class: *All Other Dermatologicals, Systemic Acne agents*

Formulary Status:

- Formulary, PA required: Amnesteem®, Claravis®, Myorisan®, Zenatane®, and generics
- Non-formulary: Absorica®

Coverage Duration: 5 months or max cumulative dose 150mg/kg per course (≥2 months off medication required before retreatment)

Diagnosis Considered for Coverage:

- Acne, rosacea
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #60/30 days; all strengths are approvable to allow for dose titration

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **severe recalcitrant nodular acne vulgaris, severe recalcitrant rosacea**, **severe scarring acne,** approve if:
  - Request is for Amnesteem®, Claravis®, Myorisan®, Zenatane®, or generic
  - If request is for **Absorica®**, there documentation of trial/failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use other isotretinoin formulations
- For diagnosis of **moderate nodular acne vulgaris**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use products in ALL of the following drug categories: **topical retinoids** (e.g., tretinoin), **topical benzoyl peroxide, oral antibiotics** (e.g., minocycline, doxycycline) AND
  - For **Absorica®** requests, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **other isotretinoin formulations**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation

AMNESTEEM®, CLARAVIS®, MYORISAN®, ZENATANE® (ISOTRETINOIN)
on PA request that member is continuing the medication), approve if: • Therapeutic response is documented on the PA request AND • Duration requested does not exceed recommended dosing guidelines (see Coverage Duration above)
References: N/A
Last review/revision date: 7/2018

TOPICAL RETINOIDS

Standard/Specific Therapeutic Class: *All Other Dermatologicals, Vitamin A Derivative*

Formulary Status:

- Formulary (age limit ≤ 30 years):
  - tretinoin 0.01%, 0.025% gel; 0.025%, 0.05%, 0.1% cream
  - Differin® (adapalene) OTC 0.1% gel
- Formulary, Step therapy:
  - adapalene 0.3%gel, gel with pump
- Non-formulary:
  - adapalene 0.1% lotion, cream, and gel (Rx)
  - adapalene/benzoyl peroxide 0.1%-2.5% gel (Epiduo®)
  - tazarotene (Tazorac®) 0.1% cream and Avage® 0.1% cream
  - Tazorac® (tazarotene) 0.05% cream, 0.05% and 0.1% gel
  - Fabior® (tazarotene) 0.1% foam

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Acne
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - adapalene (all forms), Epiduo®: #45g per 30 days
  - tretinoin gel: #15g per 30 days
  - tretinoin cream: #20g per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **acne** and request is for **adapalene 0.3% gel** or **gel/pump**, approve if:
  - There is documentation of trial and failure of **Differin® OTC 0.1% gel** (for Medi-Cal ONLY) AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **formulary tretinoin products** (for all lines of business)
- For diagnosis of **acne** and request is for **adapalene/benzoyl peroxide 0.1-2.5% gel**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use ALL of the following: **benzoyl peroxide, formulary tretinoin/ products,** AND, for Medi-Cal only, **Differin 0.1% gel**
- For diagnosis of **acne** and request is for **tazoretene (Fabior®, Tazorac®)**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use highest strength formulary tretinoin product, if tolerated
- For **formulary tretinoin products** and **Differin® OTC** for member > 30 yo, approve for diagnosis of acne

TOPICAL RETINOIDS
• For **non-formulary tretinoin** or **adapalene products** and member > 30 yo, approve if: o Diagnosis is acne AND o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **formulary tretinoin products** AND, for Medi-Cal only, **Differin® OTC 0.1% gel** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Refer to "Initiation of Therapy" section
References: N/A
Last review/revision date: 7/2018

TOPICAL ANTIBIOTICS AND BENZOYL PEROXIDE

Standard/Specific Therapeutic Class: *All other dermatologicals, Topical acne agents*

Formulary Status:

- Formulary:
  - benzoyl peroxide 5, 10% gel; 4, 5, 6, 10% cleanser; 2.5% cream; 5, 10% lotion
  - clindamycin 1% gel, lotion, solution, topical swab
  - erythromycin with ethanol 2% gel, solution
- Non-formulary:
  - clindamycin-benzoyl peroxide 1%-5% gel, gel pump (Benzaclin®)
  - clindamycin-benzoyl peroxide 1%-5% gel pump (Benzaclin®)
  - clindamycin-benzoyl peroxide 1.2(1)%-5% gel (Duac®, Neuac®)
  - Acanya® (clindamycin-benzoyl peroxide) 1.2%-2.5% gel pump
  - Onexton® (clindamycin-benzoyl peroxide) 1.2%-3.75% gel pump
  - erythromycin-benzoyl peroxide 3%-5% gel (Benzamycin®)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Acne
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - benzoyl peroxide 2.5%, 10% gel: #60g per 30 days
  - clindamycin-benzoyl peroxide #25g per 30 days
  - erythromycin-benzoyl peroxide #23.3g per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For acne:
  - For **clindamycin-benzoyl peroxide**, approve if there is documentation of trial and failure, intolerance, contraindication or inability to use **clindamycin 1% gel and benzoyl peroxide 5% gel as separate ingredients**
  - For **erythromycin-benzoyl peroxide**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability to use **erythromycin 2% gel and benzoyl peroxide 5% gel as separate ingredients**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

TOPICAL ANTIBIOTICS AND BENZOYL PEROXIDE
II. Continuation of Therapy for NEW Members (within the last 6 months), approve if: • Refer to "Initiation of Therapy" section
References: N/A
Last review/revision date: 7/2018

TOPICAL VITAMIN D ANALOGS

Standard/Specific Therapeutic Class: *All Other Dermatologicals, Antipsoriatics Agents*

Formulary Status:

- Formulary:
  - calcipotriene (Dovonex®) 0.005% scalp solution
- Formulary, Step therapy:
  - calcipotriene (Dovonex®) cream, ointment
  - calcitriol (Vectical®) ointment

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Psoriasis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - calcipotriene (Dovonex®): #60 grams or #60 milliliters per 30 days
  - calcitriol ointment (Vectical®): #100 grams per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For psoriasis, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **at least two (2)** medium or high potency steroids
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" section

References: N/A

Last review/revision date: 10/2018

MUPIROCIN (BACTROBAN®)

Standard/Specific Therapeutic Class: *Other Antibiotics, Topical Antibiotics*

Formulary Status:

- Formulary:
  - mupirocin 2% ointment (Bactroban®)
- Non-formulary:
  - mupirocin 2% cream (Bactroban®)
  - Bactroban Nasal® (mupirocin) 2% ointment

Coverage Duration: 1 fill

Diagnosis Considered for Coverage:

- Topical infection
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: Bactroban Nasal® ointment 2% and mupirocin 2% cream: #10 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For topical infection, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use mupirocin 2% ointment
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Medical justification provided for continuation of therapy

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification provided for continuation of therapy

References: N/A

Last review/revision date: 10/2018

DICLOFENAC (SOLARAZE®) 3% GEL

Standard/Specific Therapeutic Class: *Antineoplastics, Topical Antineoplastic Premalignant Lesion Agents*
Formulary Status: Non-formulary

Coverage Duration: 3 months

Diagnosis Considered for Coverage:

- Actinic Keratosis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #100 gm per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **actinic keratosis**, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ALL of the following alternatives: liquid nitrogen cryotherapy, surgical removal or phototherapy AND topical 5-fluorouracil or imiquimod
- For off-label indications or dosing, approve if:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification provided to continuation of therapy

References: N/A

Last review/revision date: 10/2018

ACITRETIN (SORIATANE®)

Standard/Specific Therapeutic Class: *All Other Dermatologicals, Systemic Antipsoriatic Agents*
Formulary Status: Formulary, PA required

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Plaque psoriasis, moderate to severe psoriasis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: # 90 per 90 days
- Prescriber restriction: Prescriber must be a dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose
- Prescriber specialty

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **moderate to severe plaque psoriasis**, approve if:
    - Member is 18 years of age or older AND
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use topical steroids AND calcipotriene, tazarotene, anthralin, or coal tar OR
    - Failure of cyclosporine, methotrexate or UVB or PUVA therapy
- For off-label indications or dosing, approve if:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References:

- Menter, Alan et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Journal of the American Academy of Dermatology. 2008; 58(5): 826–50.

Last review/revision date: 10/2018

TOPICAL STEROIDS

Standard/Specific Therapeutic Class: *Glucocoricoids, Topical Anti-Inflammatory Steroidals*
Formulary Status: See "Topical Steroids Formulary Status" table below

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Psoriasis, dermatitis/dermatoses
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*

See "Topical Steroids Formulary Status" table below **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For psoriasis, dermatitis/dermatoses, approve if there is documentation of trial and failure, intolerance, contraindication, or inability^ (see below) to use at **least 2 different formulary alternatives** (if available) within the same potency group as listed below
  ^example of inability to use cream, lotion, gel or ointment formulations is need for oil, shampoo or solution formulation for scalp conditions
  ^example of inability to use other agents for desoximetasone requests is corticosteroid-induced contact dermatitis (note desoximetasone 0.25% cream preferred)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

Topical Steroids Formulary Status

Generic Name	Formulation	Brand Name	Strength	GCN	GCN/Formulary Status
Super high potency (Group 1)					
Betamethasone dipropionate, augmented	Ointment	Diprolene	0.05%	31910	Formulary #120 per 30 days
	Lotion	Diprolene	0.05%	30980	Formulary #120 per 30 days
	Gel	Diprolene	0.05%	32091	Formulary #120 per 30 days

TOPICAL STEROIDS

Clobetasol propionate	Ointment	Temovate	0.05%	32130	Formulary #120 per 30 days
	Cream	Temovate	0.05%	32140	Formulary #120 per 30 days
	Cream, emollient base	Temovate E	0.05%	34141	Non-formulary
	Gel	Temovate	0.05%	15892	Formulary #120 per 30 days
	Lotion	Clobex	0.05%	34040	Non-formulary
	Foam aerosol	Olux-E	0.05%	97649	Non-formulary
	Foam aerosol (scalp)	Olux	0.05%	89743	Non-formulary
	Shampoo	Clobex	0.05%	21475	Formulary #118 per 30 days
	Solution (scalp)	Temovate, Cormax	0.05%	15891	Formulary #100 per 30 days
	Spray aerosol	Clobex	0.05%	25909	Non-formulary
Clobetasol propionate/cleanser	Shampoo	Clodan	0.05%	36752	Non-formulary
Halobetasol propionate	Ointment	Ultravate	0.05%	31211	Formulary #120 per 30 days
	Cream	Ultravate	0.05%	31251	Formulary #120 per 30 days
	Lotion	Ultravate	0.05%	40975	Non-formulary
Halobetasol/lactic acid	Cream	Ultravate X	0.5%-10%	32631	Non-formulary
	Ointment	Ultravate X	0.5%-10%	32630	Non-formulary
Fluocinonide	Cream	Vanos	0.1%	24306	Non-formulary
Flurandrenolide	Tape (roll)	Cordran	4 mcg/cm2	28721	Non-formulary
Diflorasone diacetate	Ointment (petrolatum)	Psorcon, ApexiCon	0.05%	31480	Non-formulary
High potency (group 2)					
Amcinonide	Ointment	Cyclocort, Amcort	0.1%	31500	Non-formulary
Betamethasone dipropionate	Ointment	Diprosone	0.05%	31070	Formulary #120 per 30 days
	Cream, augmented formulation (AF)	Diprolene AF	0.05%	31890	Formulary #120 per 30 days
Halcinonide	Ointment	Halog	0.1%	31451	Non-formulary
	Cream	Halog	0.1%	31441	Non-formulary
Fluocinonide	Ointment	Lidex	0.05%	31400	Formulary #240 per 30 days
	Gel	Lidex	0.05%	31380	Formulary #240 per 30 days
	Solution	Lidex	0.05%	31401	Formulary #240 per 30 days
	Cream	Dermacin	0.05%	31390	Formulary #240 per 30 days
Diflorasone diacetate	Cream, emollient	ApexiCon E	0.05%	67730	Non-formulary
	Ointment	Florone	0.05%	31480	Non-formulary
	Cream	n/a	0.05%	31470	Non-formulary
Desoximetasone	Ointment	Topicort	0.25%	30800	Non-formulary
	Cream	Topicort	0.25%	31181	Formulary #60 per 30 days
	Gel	Topicort	0.05%	06120	Non-formulary
	Ointment	Topicort	0.05%	11403	Non-formulary
	Spray	Topicort	0.25%	34545	Non-formulary
High potency (group 3)					
Amcinonide	Cream	n/a	0.1%	31490	Non-formulary
	Lotion	n/a	0.1%	31560	Non-formulary
Betamethasone dipropionate	Lotion	Diprosone	0.05%	30980	Non-formulary
	Cream	Diprosone	0.05%	31060	Formulary #240 per 30 days
Betamethasone valerate	Ointment	Valisone	0.1%	31110	Formulary #240 per 30 days
	Foam	Luxiq	0.12%	32052	Non-formulary
Fluticasone propionate	Ointment	Cutivate	0.005%	48641	Non-formulary
Fluocinonide E (emollient)	Cream	Lidex-E	0.05%	54650	Non-formulary
Mometasone furoate	Ointment	Elocon	0.1%	45930	Formulary #240 per 30 days
Desoximetasone	Cream	Topicort LP	0.05%	31180	Non-formulary
Diflorasone diacetate	Cream	Florone	0.05%	31470	Non-formulary
Triamcinolone acetonide	Ointment	Kenalog	0.5%	31241	Formulary #240 per 30 days
	Cream	Triderm, Aristocort HPΔ	0.5%	31233	Formulary #240 per 30 days
Medium potency (group 4)					
Triamcinolone	Cream	Kenalog	0.1%	31232	Formulary #454 per 30 days

TOPICAL STEROIDS

acetonide					
	Ointment	Kenalog	0.1%	31242	Formulary #454 per 30 days
	Ointment	Trianex	0.05%	31243	Non-formulary
	Aerosol spray	Kenalog	0.147 mg/g	98339	Non-formulary
Triamcinolone acetonide, emollient	Cream	Dermasorb TA	0.1%	35653	Non-formulary
Flurandrenolide	Ointment	Cordran	0.05%	28711	Non-formulary
Fluocinolone acetonide	Ointment	Synalar	0.025%	31351	Non-formulary
Fluocinolone acetonide, emollient	Ointment	Synalar	0.025%	33829	Non-formulary
Mometasone furoate	Cream	Elocon	0.1%	45850	Formulary #60 per 30 days
	Solution	Elocon	0.1%	06034	Formulary #240 per 30 days
Hydrocortisone valerate	Ointment	Westcort	0.2%	06040	Non-formulary
Clocortolone pivalate	Cream	Cloderm	0.1%	31190	Non-formulary
Betamethasone dipropionate	Spray	Sernivo	0.05%	40655	Non-formulary
Lower-mid potency (group 5)					
Triamcinolone acetonide	Lotion	Kenalog	0.1%	31261	Formulary #240 per 30 days
	Ointment	Kenalog	0.025%	31241	Formulary #240 per 30 days
Betamethasone dipropionate	Lotion	Diprosone	0.05%	31080	Formulary #240 per 30 days
Betamethasone valerate	Cream	Valisone	0.1%	31101	Formulary #240 per 30 days
Fluocinolone acetonide, emollient	Cream	Synalar	0.025%	31344	Formulary #240 per 30 days
Flurandrenolide	Cream	Cordran	0.05%	28711	Non-formulary
	Lotion	Cordran	0.05%	31310	Non-formulary
Fluticasone propionate	Cream	Cutivate	0.05%	43951	Formulary #60 per 30 days
	Lotion	Cutivate	0.05%	24717	Non-formulary
Prednicarbate	Cream	Dermatop	0.1%	37181	Non-formulary
	Ointment	Dermatop	0.1%	37182	Non-formulary
Desonide	Ointment	DesOwen, TridesilonΔ	0.05%	31430	Non-formulary
	Gel	Desonate	0.05%	97930	Non-formulary
Hydrocortisone valerate	Cream	Westcort	0.2%	30890	Non-formulary
Hydrocortisone butyrate	Ointment	Locoid	0.1%	30885	Non-formulary
	Cream	Locoid, Locoid Lipocream	0.1%	30880	Non-formulary
	Lotion	Locoid	0.1%	62480	Non-formulary
	Solution	Locoid	0.1%	48811	Non-formulary
Hydrocortisone butyrate, emollient	Cream	Locoid Lipocream	0.1%	20706	Non-formulary
Hydrocortisone probutate	Cream	Pandel	0.1%	50550	Non-formulary
Low potency (group 6)					
Alclometasone dipropionate	Ointment	Aclovate	0.05%	33730	Non-formulary
	Cream	Aclovate	0.05%	33710	Non-formulary
Triamcinolone acetonide	Cream	KenalogΔ, AristocortΔ	0.025%	31231	Formulary #240 per 30 days
	Lotion	KenalogΔ	0.025%	31260	Formulary #240 per 30 days
Desonide	Cream	DesOwen, TridesilonΔ	0.05%	31425	Non-formulary
	Lotion	DesOwen, LoKara	0.05%	48971	Non-formulary
	Foam	Verdeso	0.05%	97254	Non-formulary
Betamethasone valerate	Lotion	Beta-Val, Valisone	0.1%	31120	Formulary #240 per 30 days
Fluocinolone acetonide	Cream	Synalar	0.01%	31342	Non-formulary
	Solution	Synalar	0.01%	31360	Formulary #120 per 30 days
	Shampoo	Capex	0.01%	86641	Non-formulary
	Oil (scalp)	Derma-Smoothe/FS	0.01%	24484	Formulary #119 per 30 days

TOPICAL STEROIDS

	Oil (body)	Derma-Smoothe/FS	0.01%	85080	Formulary #119 per 30 days
Least potent (group 7)					
Hydrocortisone (base)	Cream	n/a	2.5%	30943	Formulary #240 per 30 days
	Lotion	n/a	2.5%	30975	Formulary #240 per 30 days
	Ointment	n/a	2.5%	30952	Formulary #240 per 30 days
	Cream/PR applicator	Proctosol-HC	2.5%	28850	Formulary #60 per 30 days
	Solution	Texacort	2.5%	09181	Non-formulary
	Lotion	Scalacort	2%	26603	Non-formulary
	Ointment	Cortaid	1%	30951	Formulary #240 per 30 days
	Cream	Cortaid	1%	30942	Formulary #240 per 30 days
	Cream (OTC)	n/a	1%	30841	Formulary #240 per 30 days
	Lotion	Aquanil HC	1%	30974	Formulary #240 per 30 days
	Cream with aloe	Hydroskin	1%	92421	Formulary #240 per 30 days
	Lotion	Aquinil HC, Sarnol HC, Cortizone-10	1%	29135	Non-formulary
	Spray	Cortaid	1%	30900	Non-formulary
	Solution	Cortaid, Noble, Scalp relief	1%	09180	Non-formulary
	Cream/PR applicator	Procto-Pak	1%	28851	Non-formulary
	Ointment	Cortaid	0.5%	30950	Formulary #240 per 30 days
	Cream	Cortaid	0.5%	30941	Formulary #240 per 30 days

References: N/A

Last review/revision date: 7/2018

Emergency: Toxicity

CHEMET® (SUCCIMER)

Standard/Specific Therapeutic Class: *Antidotes; Metallic Poison, Agents to Treat*
Formulary Status: Formulary, PA required

Coverage Duration: up to 19 days

Diagnosis Considered for Coverage:

- Lead poisoning
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity: not to exceed maximum dose (10 mg/kg/dose (or 350 mg/m2/dose) every 8 hours for 5 days followed by 10 mg/kg/dose (or 350 mg/m2/dose) every 12 hours for 14 days. Maximum: 500 mg/dose

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For lead poisoning, approve if:
  - Treatment plan is provided by or in consultation with a toxicologist or clinician who has experience with chelating agents AND
  - Blood lead level (BLL) > 45 mcg/dL in children and > 50 mcg/dL with significant symptoms or > 100 mcg/dL with or without symptoms in adults
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW or EXISTING members:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Repeat treatment course is required per PA request

References:

- Centers for Disease Control and Prevention. Managing elevated blood lead levels among young children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention. Atlanta, GA, Centers for Disease Control and Prevention, 2002. http://www.cdc.gov/nceh/lead/CaseManagement/caseManage_main.htm
- Lexicomp Online®, Dimercaptosuccinic acid (succimer): Drug information, Hudson, Ohio: Lexi-Comp, Inc.

Last review/revision date: 10/2018

EXJADE®, JADENU® (DEFERASIROX)

Standard/Specific Therapeutic Class: *Miscellaneous, Agents to Treat Metallic Poison*
Formulary Status: Formulary, PA required

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Chronic iron overload due to blood transfusions or non-transfusion dependent thalassemia syndromes
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: FDA approved dose based on weight
- Prescriber restriction: Initially prescribed or being followed by a hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Labs (e.g. serum ferritin level)
- Concurrent therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **chronic iron overload due to blood transfusion**, approve if:
  - Patient is between 2 and 65 years of age AND
  - Patient is transfusion dependent AND
  - Initially prescribed or being followed by a hematologist AND
  - Serum ferritin consistently greater than 1000 mcg/L AND
  - Not being used in combination with other chelator therapies
- For diagnosis of **chronic iron overload in non-transfusion dependent thalassemia syndromes**, approve if:
  - Patient is 10 years of age or older AND
  - Diagnosis of thalassemia syndrome AND
  - Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight AND
  - Serum ferritin level on ≥ 2 measurements one month apart of > 300 mcg/L AND
  - Not being used in combination with other chelator therapies
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Diagnosis of chronic iron overload due to blood transfusion AND
- Serum ferritin is NOT consistently below 500 mcg (if consistently < 500 mcg/L, therapy must be discontinued)

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation

EXJADE®, JADENU® (DEFERASIROX)
on PA request that member is continuing the medication), approve if: • Diagnosis of chronic iron overaload due to blood transfusion AND • Serum ferritin is NOT consistently below 500 mcg (if consistently < 500 mcg/L, therapy must be discontinued)
References: • UCSF Benioff Children's Hospital. Thallasemia Standard-ofCare Practice Guidelines (2012). Accessed at http://thalassemia.com/treatment-guidelines-5.aspx#gsc.tab=0 • Thalassemia Foundation of Canada and Anemia Institute for Research & Education. Guidelines for the Clinical Care of Patients with Thalassemia in Canada. 2009. Accessed at http://www.thalassemia.ca/wp-content/uploads/Thalassemia-Guidelines_LR.pdf. • Thalassaemia International Foundation. Guidelines for the Management of Non Transfusion Dependent Thalassaemia (NTDT). 2013. Accessed at http://thalassemia.com/documents/NTDT-TIF-guidelines.pdf.
Last review/revision date: 10/2018

WILSON DISEASE

Standard/Specific Therapeutic Class: *Antiarthritics, Anti-Arthritic and Chelating Agent; Antidotes, Metallic Poison, Agents to Treat*

Formulary Status: Non-Formulary

- Cuprimine® (penicillamine)
- trienterine (Syprin®)
- Galzin® (zinc acetate)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Wilson Disease
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restrictions:

- Quantity Limit*:
  - Cuprimine®: 6 capsules per day (1500 mg/day divided)
  - trienterine: 8 capsules per day (2 g/day divided)
  - Galzin®:
    - 25mg: up to 6 capsules/day
    - 50 mg: up to 3 capsules/day

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For Wilson disease:
  - For **Cuprimine®** or **trienterine**, approve
  - For **Galzin®**, approve if patient is undergoing **maintenance therapy** (following treatment with a chelator)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References:

- Roberts EA, Scilsky ML. Diagnosis and Treatment of Wilson Disease: An Update. AASLD PRACTICE GUIDELINES. Hepatology June 2008. https://www.aasld.org/sites/default/files/guideline_documents/Wilson%20Disease2009.pdf
- http://www.crlonline.com.ucsf.idm.oclc.org/lco/action/doc/retrieve/docid/sfcomb_f/5385704?hl=Chelating%20Agent#f_preparations

Last review/revision date: 10/2018

Endocrine/Metabolism

TESTOSTERONE REPLACEMENT
Standard/Specific Therapeutic Class: *Endocrine/Metabolism, Androgens* **Formulary Status:** • Formulary: o testosterone cypionate 100 mg/mL, 200 mg/mL intramuscular oil o testosterone enanthate 200 mg/mL intramuscular oil • Formulary, PA required: o testosterone (Androgel®, Vogelxo®, Testim®) 1%: 25mg/2.5g and 50mg/5g packets, 50mg/5g gel tube, 12.5mg/1.25g gel pump o testosterone (Fortesta®) 2% 10mg gel pump o Androderm® (testosterone) transdermal patch • Non-formulary: o Androgel® 1.62%: 20.25mg/1.25g gel packet, pump, 40.5mg/2.5g gel packet o testosterone (Axiron®) 2% 30mg solution pump o Natesto® 5.5mg/0.122g nasal gel pump o Aveed® 750mg/3mL vial – medical benefit
Coverage Duration: • Primary hypogonadism and gender dysphoria (formerly termed gender identity disorder (GID): indefinite • Secondary hypogonadism: o Initial: 6 months o Re-authorization: 1 year
Diagnosis Considered for Coverage: • Primary (testicular) hypogonadism (i.e. Klinefelters syndrome, primary failure due to radiation, 5-alpha reductase deficiency, myotonic dystrophy, cryptorchidism, hemochromatosis, mumps orchitis) • Secondary (hypogonadotropic) hypogonadism (i.e. hx of pituitary tumor, panhypopituitarism, d/t high dose opiate use (hypothalamic dysfunction), obesity, Kallmann syndrome, fertile eunuch syndrome) • Gender dysphoria (previously gender identity disorder, or GID) • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limits*: o testosterone 1% gel: #150g (30 tubes) per 30 days o testosterone 25mg/2.5 gm (1%) gel packet: up to #225 g (90 packets) per 30 days (75 mg/day) o testosterone 50mg/5 gm (1%) gel packet: #300 g (60 packets) per 30 days (100 mg/day) o testosterone 12.5mg/1.25g (1%) pump: #150g (2 pumps) per 30 days o Fortesta® 2% pump: #60g (1 pump) per 30 days o Androderm® 2mg/24hr, 4mg/24h: #30 patches per 30 days o testosterone 20.25mg/1.25g (1.62%) gel packet: #75g (60 packets) per 30 days o testosterone 40.5mg/2.5g (1.62%) gel packet: #75g (30 packets) per 30 days o testosterone 20.25mg/2.5g (1.62%) pump: #75g (1 pump) per 30 days o testosterone 30mg/1.5mL solution: #90mL (1 pump) per 30 days o Natesto® (testosterone) 5.5mg/0.122g nasal gel pump: #21.96g (3 pumps) per 30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

TESTOSTERONE REPLACEMENT

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **hypogonadism** approve if**:**
  - Documentation of low testosterone level on **at least 2 samples before 10 am** (e.g. total testosterone level below lower limit of normal as defined by the laboratory where the test was done OR total testosterone level below 280 ng/dL (9.7 nmol/L) for younger men or below 200 ng/dL (6.9 nmol/L) for symptomatic older men (> 40 y/o) AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (e.g. difficulty with self-injections) to use formulary **injectable testosterone** AND
  - For non-formulary products: there is documentation of trial and failure, intolerance, contraindication, or inability to use the **1% and 2% gel products and patches** (e.g. Androgel 1.62% is requested)
- For diagnosis of **Gender Dysphoria (previously termed GID)**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (e.g. difficulty with self-injections) to use formulary **injectable testosterone** AND
  - For non-formulary products: there is documentation of trial and failure, intolerance, contraindication, or inability to use the **1% and 2% gel products and patches** (e.g. Androgel 1.62% is requested)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- For diagnosis of **primary hypogonadism and gender dysphoria** approve if:
  - Patient is stable and continuing the medication AND
  - Medication is used at appropriate dose
- For diagnosis of **secondary hypogonadism**, approve if:
  - Medication is used at an appropriate dose AND
  - Testosterone level is within therapeutic range as defined by the laboratory where the test was done OR total testosterone level is above 280 ng/dL (9.7 nmol/L) for younger men or above 200 ng/dL (6.9 nmol/L) for symptomatic older men (> 40 y/o)

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication):

- For diagnosis of **primary hypogonadism and gender dysphoria (GID)** approve if:
  - Patient is stable and continuing the medication
- For diagnosis of **secondary hypogonadism**, approve if:
  - Testosterone level is within therapeutic range as defined by the laboratory where the test was done OR total

TESTOSTERONE REPLACEMENT
testosterone level above 280 ng/dL (9.7 nmol/L) for younger men or above 200 ng/dL (6.9 nmol/L) for symptomatic older men (> 40 y/o)
References: N/A
Last review/revision date: 1/2019

OXANDROLONE (OXANDRIN®)

Standard/Specific Therapeutic Class: *Anabolics, Androgenic agents*
Formulary Status: Formulary, PA required

Coverage Duration: 4 weeks

Diagnosis Considered for Coverage:

- Weight loss following extensive surgery, chronic infections, or severe trauma
- To offset protein catabolism with prolonged corticosteroid administration
- Relief of bone pain associated with osteoporosis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: Up to 2.5-20 mg in divided doses 2-4 times daily based on individual response.

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For any of the following diagnoses, approve:
  - Adjunctive therapy to promote weight gain following extensive surgery, chronic infection, or severe trauma OR
  - Therapy to offset protein catabolism associated with long-term use of corticosteroids OR
  - Treatment of bone pain associated with osteoporosis
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- For diagnosis of **extensive surgery, chronic infection, severe trauma**, or bone pain associated with osteoporosis, approve if there is documented therapeutic response and continued medical need per PA request
- For diagnosis of **therapy to offset catabolism associated with long-term use of corticosteroids**, approve if there is documented response to therapy AND patient is still on corticosteroids

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- For diagnosis of **extensive surgery, chronic infection, severe trauma**, or bone pain associated with osteoporosis, approve if there is documented therapeutic response and continued medical need per PA request
- For diagnosis of **therapy to offset catabolism associated with long-term use of corticosteroids**, approve if there is documented response to therapy AND patient is still on corticosteroids

References: N/A

Last review/revision date: 1/2019

HP ACTHAR® (CORTICOTROPIN) 80 UNITS/ML GEL

Standard/Specific Therapeutic Class: *Corticotropins, Adrenocorticotrophic Hormones*
Formulary Status: Formulary, PA required

Coverage Duration:

- Infantile spasms (West syndrome): 4 weeks
- Acute exacerbation of multiple sclerosis: 3 weeks
- Nephrotic syndrome: 4 weeks
- All other FDA approved indications: 4 weeks

Diagnosis Considered for Coverage:

- Infantile Spasms (West Syndrome)
- Acute exacerbation of multiple sclerosis
- Nephrotic syndrome
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Infantile spasm (West syndrome): up to 15 ml per 14 days (three 5 ml vials (~80 units per day))
  - Nephrotic syndrome: up to 10 ml per 30 days (two 5 ml vials; 80 units twice weekly)
  - Acute exacerbation of multiple sclerosis: 80 to 120 units/day for 2 to 3 weeks
- Diagnosis by a nephrologist for Nephrotic Syndrome
- Diagnosis by a neurologist or neonatologist for infantile spasms (West Syndrome)
- Diagnosis by a neurologist for multiple sclerosis

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Infantile Spasms (West Syndrome)**, approve if:
  - Patient is < 2 years of age (Medi-Cal only)
  - Documentation of patient's current weight (in kg) and height/length (in cm) or body surface area (BSA)
  - Dose is not to exceed 150 units/m2/day for 2 weeks, followed by a 2-week taper.
- For diagnosis of Idiopathic or Lupus Erythematosus associated **nephrotic syndrome**, approve if:
  - There is documentation of intolerance/side effects with oral corticosteroids that would not also be expected with ACTH AND
  - There is documentation of trial and failure of or inability to use all other standard therapies AND
  - Dose does not exceed 80 units per day
- For diagnosis of **acute exacerbation of multiple sclerosis**, approve if:
  - Documentation patient is currently receiving maintenance treatment for MS AND
  - Documentation was submitted that patient is having acute attack, with neurologic symptoms and increased disability or impairments in vision, strength or cerebellar function, and has failed therapy with corticosteroids, has intolerable side effect or contraindication to corticosteroids not expected to be seen with HP Achtar, or a medical reason has been submitted why patient is unable to use corticosteroids AND
  - Dose does not exceed 120 units/day for 3 weeks per exacerbation episode.
- For **all other FDA approved indications and conditions**, approve if:
  - There is documentation of intolerable side effect or contraindication to corticosteroids that is not also expected with HP Acthar AND
  - Documentation was provided that ALL other standard therapies have been used to treat the member's

HP ACTHAR® (CORTICOTROPIN) 80 UNITS/ML GEL

condition as described in the medical compendium (Micromedex, AHFS, Drug Points, and package insert) as defined in the Social Security Act and/or per recognized standard of care guidelines OR there is a documented medical reason (i.e. medical intolerance, treatment failure, etc.) for why all other standard therapies could not be used to treat the member's condition AND
    - Prescriber is a specialist in the condition they are treating
- For off-label indications or dosing, approve if:
    - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- For diagnosis of infantile spasms, documented confirmation of diagnosis of infantile spasm via EEG and prescribed dose follows FDA approved dosing guidelines.
- For diagnosis of Idiopathic or Lupus Erythematosus associated Nephrotic Syndrome, provider attestation patient is responding to therapy and prescribed dose follows FDA approved dosing guidelines.
- For diagnosis of acute exacerbation of multiple sclerosis, see initiation of therapy criteria.
- For all other FDA approved indications, provider attestation patient is responding to therapy and prescribed dose follows FDA approved dosing guidelines.

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- For diagnosis of infantile spasms, documented confirmation of diagnosis of infantile spasm via EEG and prescribed dose follows FDA approved dosing guidelines.
- For diagnosis of Idiopathic or Lupus Erythematosus associated Nephrotic Syndrome, provider attestation patient is responding to therapy and prescribed dose follows FDA approved dosing guidelines.
- For diagnosis of acute exacerbation of multiple sclerosis, see initiation of therapy criteria.
- For all other FDA approved indications, provider attestation patient is responding to therapy and prescribed dose follows FDA approved dosing guidelines.
- Patient is stable and continuing the medication

References:

- Gipson DS, Massengil SF, Yao L, Nagaraj S, Smoyer WE, Mahan JD, Wigfall D, Miles P, Powell L, Lin JJ, Trachtman H, Greenbaum LA. Management of childhood onset nephrotic syndrome. Pediatrics. 2009 Aug;124(2):747-57. doi: 10.1542/peds.2008-1559. Epub 2009 Jul 27.
- Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: medical treatment of infantile spasms. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. Neurology. 2012;78(24):1974. PubMed.
- Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. Cochrane Database Syst Rev. 2008; PubMed
- Niaudet P. Etiology, clinical manifestations, and diagnosis of nephrotic syndrome in children. UpToDate. 7 January 2015.

Last review/revision date: 1/2019

DDAVP® (DESMOPRESSIN)

Standard/Specific Therapeutic Class: *Other Hormones, Antidiuretic and Vasopressor Hormones*
Formulary Status:

- Formulary:
  - desmopressin tablets (DDAVP®)
  - desmopressin (DDAVP®) 10 mcg/spray nasal spray
- Formulary, PA required: Stimate® (desmopressin) nasal spray
- Non-formulary:
  - desmopressin 0.01% nasal solution (rhinal tube)
  - desmopressin 4 mcg/ml injection solution; vial and ampule

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Central cranial (neurogenic) diabetes insipidus (desmopressin nasal solution)
- Hemophilia A, mild to moderate classic von Willebrand disease (type 1) (Stimate®)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - desmopressin solution: up to #15 ml per 30 days
  - Stimate®: #2.5 ml per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **desmopressin nasal solution (rhinal tube)**, approve if:
  - There is confirmed diagnosis of central cranial (neurogenic) diabetes insipidus AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (e.g. doses other than multiples of 10 mcg (0.1 ml) are needed) to use **desmopressin 10 mcg/spray nasal spray**
- For **Stimate®** (desmopressin), approve if:
  - There is documented diagnosis of Hemophilia A with Factor VIII coagulant activity levels greater than 5% OR
  - There is documented diagnosis of mild to moderate von Willebrand's disease (Type 1) with Factor VIII coagulant activity levels greater than 5%
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND

The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 10/2018

GONADOTROPIN RELEASING HORMONE (GnRH) AGONISTS- PEDIATRIC

Standard/Specific Therapeutic Class: *LHRH (GnRH) Agonist – Pituitary Suppressant, Other Hormones*
Formulary Status:

- Formulary, PA required:
  - Lupron Depot-PED® (leuprolide acetate) intramuscular injection
  - Synarel® (histrelin) nasal spray
- Non-formulary:
  - Triptodur® (triptorelin) intramuscular injection – medical benefit

Coverage Duration: 12 months

Diagnosis Considered for Coverage:

- Central precocious puberty (CPP)
- Pubertal delay in transgender adolescents
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Age Limit*: up to 11 years of age for females and 12 years of age for males for indication of CPP. There is not an established age limit for pubertal delay in transgender adolescents.
- Quantity Limit**:
  - Lupron Depot-PED®:
    - 7.5, 11.25, 15 mg 1-month kit: #1 per 30 days
    - 11.25, 30 mg 3-month kit: #1 per 3 months
  - Synarel® nasal spray: #27 mL per 30 days

**Requests for drugs above indicated Age Limits will be reviewed on a case by case basis*
***Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose and weight (for 1-month formulations)
- Clinic notes

Coverage Criteria:

I. Initiation of Therapy:

- For Lupron Depot-PED®:
  - For diagnosis of **central precocious puberty (CPP)**, approve if:
    - Patient is female < 8 or male < 9 years of age AND
    - Patient exhibits onset of secondary sex characteristics AND bone age ≥ 1 year of chronological age
    - Diagnosis of CPP is confirmed by the following:
      - elevated luteinizing hormone (LH) levels (basal or GnRH stimulation test) or a random third generation serum LH above 0.26 mIU/mL AND
      - estradiol levels in girls or testosterone levels in boys
  - For diagnosis of **pubertal delay in transgender adolescents**, approve if:
    - Patient is under the care of provider trained in treating transgender adolescents.
- For Synarel®, approve if:
  - Criteria for CPP or pubertal delay in transgender adolescents above are met AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use injectable GnRH agonist
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR

GONADOTROPIN RELEASING HORMONE (GnRH) AGONISTS- PEDIATRIC

- Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- Medication is used for CPP or pubertal delay in transgender adolescents AND
- Medication is used at an appropriate dose AND
- For CCP diagnosis:
  - Patient is less than 11 years of age if female and 12 years of age if male AND
  - There is documentation of therapeutic response (e.g. decrease in growth velocity, cessation of menses in females, arrested pubertal progression, slowing of bone age advancement, decrease in LH or estradiol/testosterone levels) AND
  - Patient is monitored regularly (i.e. every 3-6 months)

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- For CPP, patient is less than 11 years of age if female and 12 years of age if male AND
- There is documentation of therapeutic response (e.g. decrease in growth velocity, cessation of menses in females, arrested pubertal progression, slowing of bone age advancement, decrease in LH or estradiol/testosterone levels) AND
- Patient is monitored regularly (i.e. every 3-6 months)

References:

- Rafferty J, AAP committee on psychosocial aspects of child and family health, AAP committee on adolescence, AAP section on lesbian, gay, bisexual, and transgender health and wellness. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. Pediatrics. 2018; 142(4): e20182162.

Last review/revision date: 1/2019

SENSIPAR® (CINACALCET)

Standard/Specific Therapeutic Class: *Miscellaneous, Calcimimetic, Parathyroid Calcium Enhancer*
Formulary Status: Formulary, PA required

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Secondary hyperparathyroidism (HPT) in post renal transplant patients OR in patients with chronic kidney disease (CKD) on dialysis
- Hypercalcemia in patients with parathyroid carcinoma (PC)
- Severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: up to 120 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Serum calcium and iPTH levels where appropriate

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **secondary hyperparathyroidism**, approve if:
  - Patient has CKD and is on dialysis (hemodialysis or peritoneal dialysis) or has posttransplant secondary hyperparathyroidism AND
  - Current serum calcium ≥ 8.4 mg/dL AND
  - Current iPTH levels ≥ 300 pg/ml AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **phosphate binders (e.g. calcium acetate) AND calcitriol or another Vitamin D analog**
- For diagnosis of **hypercalcemia with parathyroid carcinoma**, approve if serum calcium level ≥ 10.2 mg/dL
- For diagnosis of **hypercalcemia in primary hyperparathyroidism**, approve if:
  - Patient is unable to undergo parathyroidectomy AND
  - There is documentation of severe hypercalcemia and current serum calcium levels >12.5 mg/dL
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Patient has had response to therapy AND
- Patient does not have hypocalcemia (serum calcium less than the lower limit of normal range)

References:

- Moe SM, Chertow GM, Coburn JW, et al. Achieving NKF-K/DOQI bone metabolism and disease treatment goals with cinacalcet HCl. Kidney Int. 2005;67(2):760 PubMed
- Messa P, Macario F, Yaqoob M, et al. The OPTIMA study: assessing a new cinacalcet (Sensipar/Mimpara) treatment algorithm for secondary hyperparathyroidism. Clin J Am Soc Nephrol. 2008;3(1):36. PubMed
- Arenas MD, Alvarez-Ude F, Gil MT, et al. Implementation of 'K/DOQI Clinical Practice Guidelines for Bone Metabolism and

SENSIPAR® (CINACALCET)
Disease in Chronic Kidney Disease' after the introduction of cinacalcet in a population of patients on chronic haemodialysis. Nephrol Dial Transplant. 2007;22(6):1639. PubMed
Last review/revision date: 10/2018

Endocrine: Diabetes

NON-FORMULARY TEST STRIPS
Standard/Specific Therapeutic Class: *Medical Supplies/Diabetic Supplies* **Formulary Status:** • Formulary: o Accu-Chek SmartView, Accu-Chek Aviva Plus, Accu-Chek Guide Test Strips • Formulary, PA required: o FreeStyle Libre reader and sensor • Non-formulary: all other testing supplies
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Diabetes mellitus type 1 or 2, gestational diabetes
Clinical Information Required for Review: • Diagnosis • Previous medications
Prescribing Restriction: • Quantity Limit*: o Test strips: #4 strips per day o FreeStyle Libre: 4 sensors per month, 1 reader per year **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Coverage Criteria: **I. Initiation of Therapy:** • For **Accu-Chek SmartView, Accu-Chek Aviva Plus, or Accu-Chek Guide test strips over formulary quantity limit,** approve if: o Medical need for glucose monitoring more frequent than 4 times daily, or 8 times daily in the case of gestational diabetes. Eg. Frequent hospitalizations, incidents of hypoglycemia, DKA hospitalizations etc. • For **FreeStyle Libre** reader/sensor system, approve if: o Patient has type I or II diabetes and is on insulin therapy o There is documentation of medical need for glucose monitoring more frequent than 4 times daily (e.g., frequent hospitalizations, hypoglycemia, DKA, etc.) OR o There is documented contraindcication/inability to use fingerstick testing (e.g., fear of needles) • For **Contour test strips**, approve if: o Test strips will be used with insulin pump • For **Freestyle Test Strips, Prodigy No Coding Test Strips, Onetouch Ultra Test Strips**, approve if: o Trial and failure or inability use formulary strips: Accu-Chek SmartView, Aviva Plus, or Guide **II**. For **Continuation of Therapy**, approve
References: N/A
Last review/revision date: 7/2018

NON-FORMULARY BLOOD GLUCOSE METERS
Standard/Specific Therapeutic Class: *Medical Supplies/Diabetic Supplies* **Formulary Status:** • Formulary: o Accu-Chek Guide Retail Care Kit • Non-formulary: all other blood glucose meters
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Diabetes mellitus type 1 or 2, gestational diabetes
Prescribing Restriction: • Quantity Limit*: 1 unit per year (365 days) **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Previous therapy
Coverage Criteria: **I. Initiation of Therapy:** • Approve if there is documentation of trial and failure or inability to use a formulary blood glucose meter (e.g. Prodigy Voice Blood Glucose Meter is needed due to visual impairment) • For FreeStyle Libre reader/sensor system, see Non-Formulary Test Strips criteria **II. Continuation of Therapy for NEW Members** (within the last 6 months), refer to "Initiation of Therapy" criteria
References: N/A
Last review/revision date: 7/2018

DPP-4 INHIBITORS

Standard/Specific Therapeutic Class: *Diabetic Therapy, Antihyperglycemic, DPP-4 Inhibitors*

Formulary Status:

- Formulary, Step therapy:
  - Januvia® (sitagliptin), Janumet XR® (sitagliptin/metformin), Janumet® (sitagliptin/metformin)
  - alogliptin (Nesina®), alogliptin/metformin (Kazano®), alogliptin/pioglitazone (Oseni®)
- Non-formulary:
  - Onglyza® (saxagliptin)
  - Kombiglyze® (saxagliptin/metformin)
  - Tradjenta® (linagliptin), Jentadueto® (linagliptin/metformin)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes mellitus type 2
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Onglyza®, Nesina®, Oseni®, Trajenta®: #90/90 days
  - Kombiglyze®, Kazano®, Jentadueto® (linagliptin/metformin): #180/90 days

Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis.

Clinical Information Required for Review:

- Diagnosis
- Previous medications
- A1C level

Coverage Criteria:

I. Initiation of Therapy:

- For diabetes type 2:
  - For **Januvia®, Janumet®, Janumet XR®**, alogliptin, alogliptin/metformin, alogliptin/pioglitazone approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **metformin** OR combination therapy with metformin is required due to initial A1C > 7.5
  - For **Onglyza®** or **Tradjenta®,** approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc) to use **metformin** OR dual therapy with metformin is required due to initial A1C>7.5 AND
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **Januvia®** and **alogliptin**
  - For **Kombiglyze®** or **Jentadueto®**, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc) to use **metformin** OR dual therapy with metformin is required due to initial A1C>7.5 AND
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **Janumet® or Janumet® XR** and **alogliptin/metformin**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced

DPP-4 INHIBITORS
in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 7/2018

GLP-1 AGONISTS

Standard/Specific Therapeutic Class: *Diabetic Therapy, Antihyperglycemic, Incretin Mimetic (GLP-1 Receptor Agonist)*

Formulary Status:

- Formulary, Step therapy:
  - Victoza® (liraglutide)
  - Ozempic® (semaglutide)
- Non Formulary:
  - Byetta®, Bydureon®, Bydureon BCise® (exenatide)
  - Trulicity® (dulaglutide)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes mellitus type 2
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Victoza®: 27 mL/90 days (1.8 mg [0.3 mL] per day)
  - Ozempic®: 9mL per 84 days (1mg per week)
  - Byetta®: 7.2mL per 90 days (10mcg twice daily)
  - Bydureon®: 12 vials or 7.8mL (pen) or 10.2mL (BCise® injector) per 84 days (2mg per week)
  - Trulicity®: 6 mL/84 days (4 pen injectors; 1 pen per week)

Clinical Information Required for Review:

- Diagnosis
- Previous medications

Coverage Criteria:

I. Initiation of Therapy:

- For diabetes type 2:
  - For **Victoza®** or **Ozempic®**, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use metformin OR dual therapy with metformin is required due to initial A1C > 7.5
  - For **Byetta®**, **Bydreon®**, or **Trulicity®** approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use metformin OR dual therapy with metformin is required due to initial A1C > 7.5 AND
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **Victoza®** and **Ozempic®** for at least 3 months each
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

GLP-1 AGONISTS
II. Continuation of Therapy for NEW Members (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 7/2018

SGLT-2 INHIBITORS

Standard/SpecificTherapeutic Class: *Diabetic Therapy, Antihyperglycemic-Sodium/Glucose Cotransporter-2 Inhibitor*

Formulary Status:

Formulary, Step therapy:

- Invokana® (canagliflozin), Invokamet®/Invokamet XR® (canagliflozin/metformin)
- Jardiance® (empagliflozin), Synjardy®/Synjardy® XR (empagliflozin/metformin)

Non-formulary:

- Farxiga® (dapagliflozin)
- Steglatro® (ertugliflozin)
- Xigduo XR® (dapagliflozin/metformin)
- Segluromet® (ertugliflozin/metformin)
- Glyxambi® (empagliflozin/linagliptin)
- Steglujan® (ertugliflozin/sitagliptin)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes mellitus type 2
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Farxiga®, Steglatro®, Glyxambi®, Steglujan®: #90 per 90 days
  - Xigduo XR®:
    - 2.5mg/1000mg, 5mg/500mg, 5mg/1000mg: #180 per 90 days
    - 10mg/500mg, 10mg/1000mg: #90 per 90 days
  - Segluromet:#180 per 90 days

  **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis.*

Clinical Information Required for Review:

- Diagnosis
- Previous medications

Coverage Criteria:

I. Initiation of Therapy:

- For diabetes type 2:
  - For **Invokana®, Invokamet®/XR, Jardiance®** or **Synjardy®/XR**, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use metformin OR dual therapy with metformin is required due to initial A1C > 7.5
  - For **Farxiga®** or **Steglatro®**, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use metformin OR dual therapy with metformin is required due to initial A1C > 7.5 AND
    - Trial and failure or inability to use **Invokana®** or **Jardiance®**
  - For **Xigduo XR®** or **Segluromet®**, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use metformin OR dual therapy with metformin is required due to initial A1C > 7.5 AND

SGLT-2 INHIBITORS

- Trial and failure or inability to use **Invokamet®/XR** or **Synjardy®/XR**

o For **Glyxambi®** or **Steglujan®**, approve if:
- There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use metformin OR dual therapy with metformin is required due to initial A1C > 7.5 AND
- Formulary SGLT2 or DPP-4 inhibitor concurrently or as dual therapy for at least 3 months

- For off-label indications or dosing, approve if:
  - o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - o Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:
- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND

The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 7/2018

SHORT-ACTING AND RAPID-ACTING INSULINS

Standard/Specific Therapeutic Class: *Diabetic Therapy, Short/Rapid Acting Insulins*
Formulary Status:

- Formulary**:**
  - Admelog® (insulin lispro) 100 units/mL vial, Solostar pen
  - Humulin® R (insulin regular) 100u/mL vial, Kwikpen
  - Novolin® R (insulin regular) 100u/mL vial
  - Humulin® R (insulin regular) 500u/mL vial, Kwikpen
  - Humulin® N (insulin NPH) 100u/mL vial, Kwikpen
  - Novolin® N (insulin NPH) 100u/mL vial
  - Humalog® Mix 75/25 (insulin lispro protamine/lispro) 100u/mL vial, Kwikpen
  - Novolog® Mix 70-30 (insulin aspart protamine/aspart) 100u/mL vial, FlexPen
  - Humulin® Mix 70/30 (insulin NPH suspension/regular) 100u/mL vial, Kwikpen
  - Novolin® Mix 70-30 (insulin NPH suspension/regular) 100u/mL vial
  - Humalog® Mix 50-50 (insulin lispro protamine/lispro) 100u/mL vial, Kwikpen

- Non-formulary:
  - Afrezza® (insulin regular inhalation powder)
  - Apidra® (insulin glulisine) 10mL vial, Apidra®SoloStar (Insulin glulisine) 3mL pen
  - Fiasp (insulin aspart niacinamide) 100u/mL vial, FlexTouch pen
  - Brand Humalog® (insulin lispro) 100u/mL vial, Kwikpen
  - Humalog® (insulin lispro) 200 units/mL Kwikpen
  - Novolog® (insulin aspart) 100u/mL vial, FlexPen, cartridge

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes Mellitus Type 1, Diabetes Mellitus Type 2, Gestational Diabetes Mellitus
- Diabetic ketoacidosis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit – Up to 90 days' supply

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose
- Co-morbid conditions (e.g. asthma, COPD)
- Smoking status/history

Coverage Criteria:

I. Initiation of Therapy:

- For **Fiasp®, Apidra®, Humalog®,** or **Novolog® 100u/mL**, approve if:
  - There is documentation of trial and failure of **Admelog® 100u/mL**
- For **Humalog® 200u/mL**, approve if:
  - There is documentation of trial and failure of **Humalog®** or **Admelog® 100u/mL** and concentrated insulin is required

SHORT-ACTING AND RAPID-ACTING INSULINS
• For **Afrezza®** approve if: o Patient is a non-smoker or has quit smoking at least 6 months prior AND o Patient does NOT have a diagnosis of chronic lung disease (e.g. asthma, COPD) o There is documentation of trial and failure, intolerance, contraindication, or inability to use injectable short/rapid-acting insulin (e.g. fear of injections, etc) • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 7/2018

LONG-ACTING (BASAL) INSULINS

Standard/Specific Therapeutic Class: *Diabetic Therapy, Long Acting Insulins*

Formulary Status:

- Formulary: Basaglar KwikPen® (insulin glargine) 100 units/mL
- Formulary, Step therapy:
  - Tresiba® (insulin degludec) 100u/mL, 200u/mL FlexTouch pen
- Non-formulary:
  - Lantus® (insulin glargine) 100u/mL vial, Solostar pen
  - Levemir® (insulin detemir) 100u/mL vial, FlexTouch pen
  - Toujeo® (insulin glargine) 300units/mL Solostar, Solostar Max pen

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- **FDA Uses:**
  - Diabetes Mellitus Type 1
  - Diabetes Mellitus Type 2
  - Gestational Diabetes Mellitus
  - Diabetic ketoacidosis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit – Up to 90 days' supply

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For **Tresiba®**, approve if:
  - There is documentation of trial and failure (longer duration of action required) or intolerance (e.g., hypoglycemia) with Basaglar® or Lantus®
- For **Lantus®** orLevemir®, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability to use **Basaglar®** OR
  - There is documented medical need for basal insulin with vial/syringe administration rather than pen
- For **Toujeo®**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability to use **Basaglar®** (e.g. dose is >50 units per injection, injection site reactions and/or lipodystrophy with Lantus® or Basaglar®, etc.)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

LONG-ACTING (BASAL) INSULINS
• Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 7/2018

METFORMIN

Standard/Specific Therapeutic Class: *Diabetic Therapy, Antihyperglycemic, Biguanide type*

Formulary Status:

Formulary:

- metformin (Glucophage®) 500mg, 850mg, 1000mg
- metformin (Glucophage XR®): 500mg, 750mg

Non-formulary:

- metformin ER 1000mg (Glumetza®)
- Riomet® (metformin) 500mg/5mL solution

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes mellitus type 2
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescriber Restriction:

- Quantity Limit*
  - metformin ER1000mg: #180 per 90 days

Clinical Information Required for Review:

- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diabetes type 2:
  - For metformin ER 1000mg, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: metformin ER 500mg or 750mg
  - For Riomet®, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, inability to swallow, etc.) to use the following formulary alternatives: metformin ER 500mg or 750mg
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*.

References: N/A

Last review/revision date: 7/2018

Endocrine

SOMATROPIN (GROWTH HORMONE)

Standard/Specific Therapeutic Class: *Other Hormones, Growth Hormones*

Formulary Status:

- Formulary, PA required:
  - Norditropin Flexpro®pen injector
  - Nutropin AQ NuSpin®pen injector
  - Zomacton® vial
- Non-formulary:
  - Genotropin® syringe, cartridge
  - Humatrope® vial, cartridge
  - Omnitrope® vial, cartridge
  - Saizen® vial, cartridge
  - Serostim® vial
  - Zorbtive® vial (see "Medications Without Specific Criteria" blanket criteria)

Coverage Duration:

Indication	Initial Therapy	Re-authorization
Pediatric growth hormone deficiency (GHD)	6 months	1 year
Growth Failure due to Chronic Renal Insufficiency	1 year	1 year
Short stature associated with Turner Syndrome, Prader-Willi Syndrome, SHOX deficiency, or Noonan Syndrome	6 months	1 year
Adult growth hormone deficiency	1 year	1 year

Diagnosis Considered for Coverage:

- Pediatric growth hormone deficiency (GHD)
- Growth Failure due to Chronic Renal Insufficiency
- Short stature associated with Turner Syndrome, Prader-Willi Syndrome, Noonan Syndrome or SHOX deficiency
- Adult growth hormone deficiency
- HIV/AIDS-wasting syndrome
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Excluded Diagnoses:

- **Idiopathic Short Stature (i.e. not GH-deficient short stature)**

Prescriber Restriction:

- Endocrinologist or nephrologist for certain indications; see diagnosis specific criteria below

Clinical Information Required for Review:

- Diagnosis
- Relevant labs (height, weight, etc.)

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Pediatric growth hormone deficiency (GHD)** approve if:
  - Medication is being prescribed by an endocrinologist or pediatric endocrinologist AND
  - Documentation of diagnosis confirmed by the following, AND:
    - Severe short stature or growth failure by one of the following, AND

SOMATROPIN (GROWTH HORMONE)

- Height > 3 standard deviations (SD) below the mean OR
- Height > 1.5 SD below the midparental height (average of mother & father's heights) OR
- Height > 2 SD below the mean and height velocity over 1 year > 1 SD below the mean for chronological age, or decrease in height SD > 0.5 over 1 year in children > 2yo OR
- Height velocity > 2 SD below the menan over 1 year or more than 1.5 SD sustained over 2 years

▪ Documented deficiency of pituitary hormone via IGF-1 and IGFBP-3 AND
▪ Subnormal GH response on stimulation (provocative) testing (not required if the following are also met:

- Hypothalamic-pituitary defect such as congenital malformation, intracranial lesion or irradiation AND
- Deficiency of at least one other pituitary hormone

AND

o Patient's epiphysis has NOT closed (as confirmed by radiograph of the wrist and hand) or patient has NOT reached final height AND
o Weight-based dosing within FDA approved range (weight must be provided on PA request) AND
o For non-preferred growth hormones, documented failure/intolerance/contraindication to Zomacton®

- For diagnosis of **Noonan syndrome** [Norditropin®] or **SHOX deficiency** [Humatrope®, Zomacton®], follow criteria above for pediatric GHD for indicated products
- For diagnosis of **Growth Failure due to Chronic Renal Insufficiency** [Nutropin AQ NuSpin®]**,** approve if:
  o Medication is being prescribed by a nephrologist or endocrinologist AND
  o Weight-based dosing within FDA approved range (weight must be provided on PA request) AND
  o Patient's GFR < 75 mL/min/1.73m^2 AND
  o Patient's epiphysis has NOT closed (as confirmed by radiograph of the wrist and hand) AND
  o Significant growth impairment as documented by one of the following:
    ▪ Height velocity standard deviation score (SDS) < -1.88 OR
    ▪ Height velocity < 3rd percentile for age persisting >3 months
- For diagnosis of short stature associated with **Turner Syndrome** or **Prader-Willi Syndrome**, approve if:
  o Medication is being prescribed by an endocrinologist or pediatric endocrinologist AND
  o Weight-based dose within FDA approved range (weight must be provided on PA request) AND
  o Patient has short stature as defined as ONE of the following:
    ▪ For Turner's Syndrome, height is below the 5th percentile of normal growth curve
    ▪ For Prader Willi Syndrome, height standard deviation score (SDS) < 2.00

  AND
  o Patient's epiphysis has NOT closed (as confirmed by radiograph of the wrist and hand) OR the patient has NOT reached final height AND
  o For Turner Syndrome and non-preferred growth hormone formulation, documented failure/intolerance/contraindication to Zomacton®
  o For Prader Willi Syndrome nad non-preferred growth hormone formulation, documented failure/intolerance/contraindication to Norditropin®
- For diagnosis of **Adult Growth Hormone Deficiency** approve if:
  o Medication is being prescribed by an endocrinologist AND
  o Weight-based dose within FDA approved range (weight must be provided on PA request) AND
  o For hypopituitarism due to pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma, diagnosis has been confirmed by at least one subnormal provocative stimulation test (i.e., insulin-induced hypoglycemia, arginine glucagon) OR

SOMATROPIN (GROWTH HORMONE)

- For childhood-onset growth hormone deficiency (GHD), patient has childhood-onset growth hormone deficiency (GHD) due to organic diseases (e.g. craniopharyngioma) AND
- For non-preferred growth hormone formulation, documented failure/intolerance/contraindication to Zomacton®

- For diagnosis of **HIV/AIDS-wasting syndrome** approve if:
  - Patient is on antiviral therapy AND
  - Patient meets at least one of the following:
    - 10% unintentional weight loss over 12 months
    - 7.5% unintentional weight loss over 6 months
    - 5% body cell mass (BCM) loss within 6 months
    - In men: BCM < 35% of total body weight and body mass index (BMI) < 27kg/m2
    - In women: BCM < 23% of total body weight and BMI < 27 kg/m2
    - BMI < 20kg/m2

  AND
  - Patient has had an inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants or anabolic steroids) AND
  - Weight-based dose within FDA approved range (weight must be provided on PA request)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months) or **EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- For **pediatric growth hormone deficiency (GHD), Growth Failure due to Chronic Renal Insufficiency, short stature associated with Turner Syndrome and Prader-Willi Syndrome**, approve if:
  - There is documented response to growth hormone therapy (e.g. IGF-1 level normalization, increase in height velocity defined by >2cm/year compared to that of previous year) AND
  - Weight-based dose within FDA approved range (weight must be provided on the PA request)
-

References: N/A

Last review/revision date: 1/2019

EGRIFTA® (TESAMORELIN INJECTION)

Standard/Specific Therapeutic Class: *Other Hormones, Growth Hormone Releasing Hormone (GNRH) and Analogs*
Formulary Status: Non-formulary

Coverage Duration: 6 months

Diagnosis Considered for Coverage:

- HIV-Associated Visceral Adipose Tissue (VAT) Lipodystrophy
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Prescriber restriction: endocrinologist or HIV specialist
- Quantity Limit: 60 vials of 1mg Egrifta OR 30 vials of 2mg EgriftaTM per 30 day supply

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For the **reduction of excess abdominal fat in patients diagnosed with HIV-associated lipodystrophy**, approve if:
  - Patient is 18 years of age or older AND
  - Documentation of CT scan indicating excess visceral fat accumulation OR waist circumference ≥ 95cm (37.4 in) for men or ≥ 94cm (37.0 in) for women AND a waist-to hip ratio of ≥ 0.94 for men or ≥ 0.88 for women
  - Physician attests patient does not currently have active malignancy and does not have disruption of the hypothalamic-pituitary axis AND
  - Drug is being requested at an FDA approved dose
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Documentation of clinical response based on decrease in waist circumference OR reduction in visceral adipose tissue on CT scan AND
- Patient is adherent to therapy AND

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Documentation of clinical response based on decrease in waist circumference OR reduction in visceral adipose tissue on CT scan AND
- Patient is adherent to therapy AND

EGRIFTA® (TESAMORELIN INJECTION)
• Drug is being requested at an FDA approved dose
References: • Egrifta [package insert]. Rockland, MA: EMD Serono, Inc.; December 2014. • Falutz J, Potvin D, Mamputu JC, et al. Effects of Tesamorelin, a Growth Hormone-Releasing Factor, in HIV-Infected Patients With Abdominal Fat Accumulation: A Randomized Placebo Controlled Trial With a Safety Extension. J Acquir Immune Defic Syndr. 2010; 53(3):311. • Stanley TK, Falutz J, Marsolais C, et al. Reduction in visceral adiposity is associated with an improved metabolic profile in HIV-infected patients receiving tasmorelin. Clinical Infectious Diseases. 2012; 54(11):1642-51.
Last review/revision date: 1/2019

OCTREOTIDE AND SOMAVERT®

Standard/ Specific Therapeutic Class: *Other Hormones, Somatostatic Agents*

Formulary Status:

- Formulary, PA required:
  - octreotide acetate (Sandostatin®) vial, syringe, ampule
  - Somavert® (pegvisomant)
- Non-formulary:
  - Sandostatin® LAR Depot – medical benefit
  - Signifor® (pasireotide pamoate) LAR Depot – medical benefit

Coverage Duration:

- Initial: 6 months
- Re-authorization: Indefinite

Diagnosis Considered for Coverage:

- Acromegaly
- Metastatic carcinoid tumors, management of symptoms associated (diarrhea and flushing)
- Vasoactive intestinal peptide-secreting tumors (VIPomas), treatment of profuse watery diarrhea associated with VIPomas
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit* up to 1,500 mcg daily
- Prescriber restriction: Prescriber is an endocrinologist or oncologist.

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **acromegaly and request is for octreotide**, approve if documentation of baseline IGF-1 is provided with PA request
- For diagnosis of **acromegaly and request is for Somavert®**, approve if,
  - Documentation of failure to respond to surgery or radiation OR patient is not a candidate for surgery or radiation
  - Documentation of trial and failure to respond to or intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use octreotide
- For diagnosis of **metastatic carcinoid tumors and associated symptoms of diarrhea and flushing**, approve
- For diagnosis of **VIPomas and associated profuse watery diarrhea**, approve
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

OCTREOTIDE AND SOMAVERT®
II. Continuation of Therapy for NEW Members (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • For acromegaly, patient is stable, tolerating and responding to medication and IGF-1 level has decreased or normalized from baseline OR • For all other diagnoses, patient is stable, tolerating and responding to medication and there is continued medical justification for continuation of therapy **III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:** • For acromegaly, patient is stable, tolerating, and IGF-1 level has decreased or normalized from baseline • For all other diagnoses, patient is stable, tolerating and responding to medication and there is continued medical justification for continuation of therapy
References: N/A
Last review/revision date: 1/2019

ANTI-OBESITY MEDICATIONS

Standard/Specific Therapeutic Class: *All Other Antiobesity Preps, Anti-obesity, Anorexic Agents, Others*
Formulary Status:

- Formulary, PA required:
  - Alli® (orlistat 60 mg tablet – OTC)
  - Belviq® (lorcaserin)
  - Contrave® (naltrexone/bupropion)
  - phentermine 15, 30 mg capsule; 37.5 mg tablet and capsule
- Non-formulary:
  - benzphetamine
  - diethylpropion
  - phendimetrazine
  - phentermine HCl (Lomaira®) 8 mg tab
  - Qsymia® (phentermine/topiramate)
  - Saxenda® (liraglutide)
  - Xenical® (orlistat 120 mg tablet)

Coverage Duration:
Initial: 6 months
Re-auth: 12 months

Diagnosis Considered for Coverage:

- Obesity
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Phentermine tablet/capsule: #30 per 30 days
  - Qsymia®: #30 per 30 days
  - Phendimetrazine 35mg: #90 per 30 days, ER 105mg: #30 per 30 days
  - Diethylpropion 25mg: #90 per 30 days; 75mg: #30 per 30 days
  - Benzphetamine: #90 per 30 days
  - Belviq®: #60 per 30 days (IR), #30 per 30 days (ER)
  - Alli®/Xenical® (orlistat): #90 per 30 days
  - Contrave® (naltrexone/bupropion): #120 per 30 days
  - Saxenda® (liraglutide): #15 ml (5 pens) per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy
- BMI, comorbidities, description of trial with lifestyle interventions

Coverage Criteria:

I. Initiation of Therapy:

- For obesity:
  - Baseline weight and BMI is provided with PA request AND
  - There is documentation related to trial and failure of lifestyle modifications (e.g. dietary changes AND exercise) and/or behavior therapy OR pharmacologic therapy will be used as an adjunct to lifestyle modifications
  - BMI is 30 kg/m2 or greater (obese) OR 27 kg/m2 or greater (overweight) in the presence of at least one weight related comorbid condition (e.g. hypertension, dyslipidemia, type 2 diabetes) AND
  - For **Qsymia®**: there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **phentermine and topiramate as separate ingredients**
- For off-label indications or dosing, approve if:

ANTI-OBESITY MEDICATIONS
o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND • Patient had response to therapy (≥4% weight loss from baseline for Saxenda® and ≥5% for other meds AND • Medical justification for continuation of therapy has been provided **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Patient had response to therapy (≥4% weight loss from baseline for Saxenda® and ≥5% for other meds AND • Medical justification for continuation of therapy has been provided
References: • Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 100: 342–362, 2015 doi: 10.1210/jc.2014-3415. • American Association of Clinical Endocrinologists And American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocr Pract. 2016 Jul;22 Suppl 3:1-203 • Jensen, MD. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults. Circulation. 2013;01.cir.0000437739.71477.ee
Last review/revision date: 10/2018

FORTEO® (TERIPARATIDE)

Standard/Specific Therapeutic Class: *Miscellaneous, Bone Formation Stimulation Agents, Parathyroid Hormone*
Formulary Status: Non-formulary

Coverage Duration: 2 years

Diagnosis Considered for Coverage:

- Osteoporosis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #2.4 ml per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose
- T-score
- Fracture history

Coverage Criteria:

I. Initiation of Therapy:

- For osteoporosis, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use **at least one bisphosphonate** AND
  - T-score < 2.5 OR T-score -1.0 and -2.5 with high risk of facture or history of fracture
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Total length of therapy does not exceed 2 years

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification provided for continuation of therapy beyond 2 years

References:

- Camacho PM, Petak SM, Binkley N, et al. American association of clinical endocrinologists and American college of endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016. *Endocrine Practice.* 2016;22:Suppl 4;1-42. Available at: https://www.aace.com/publications/guidelines

Last review/revision date: 10/2018

BISPHOSPHONATES

Standard/Specific Therapeutic Class: *Miscellaneous, Bone Resorption Inhibitors*
Formulary Status:

- Formulary:
  - alendronate 5, 10, 35, 70 mg tablets
- Formulary, PA Required
  - ibandronate (Boniva®)
- Non-formulary:
  - alendronate (Binosto®) 70mg effervescent tablet
  - alendronate 40mg tablet
  - alendronate 70mg/75mL oral solution
  - etidronate 200mg, 400mg tab
  - risedronate (Actonel®) 5, 30, 35, 150 mg tablet
  - risedronate (Atelvia®) delayed release tablet
  - Fosamax® Plus D (alendronate/vitamin D3)
  - zoledronic acid (Reclast®) [medical benefit]

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Osteoporosis, Paget's disease
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - ibandronate 150 mg: #3/90 days
  - risedronate 5 mg: #90/90days
  - risedronate 35 mg: #12/84 days
  - risedronate 150 mg: #3/84 days
  - Fosamax® Plus D: #12/84 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **ibandronate (Boniva®) tablet**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc) to use **alendronate (Fosamax®)**
- For **alendronate 40 mg tab and etidronate**, approve if:
  - Diagnosis is Paget's disease AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc) to use **at least one other bisphosphonate** (e.g zoledronic acid, ibandronate, formulary alendronate, etc)
- For **risedronate (Atelvia®) delayed release tablet and alendronate oral solution**, approve if there is documentation of inability to use **regular tablet formulations**
- For **Fosamax® Plus D**, approve if there is documentation of inability to use **alendronate** and **Vitamin D3** as separate products
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR

- Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References:

- Camacho PM, Petak SM, Binkley N, et al. American association of clinical endocrinologists and American college of endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016. *Endocrine Practice.* 2016;22:Suppl 4;1-42. Available at: https://www.aace.com/publications/guidelines

Last review/revision date: 10/2018

PROLIA® AND XGEVA® (DENOSUMAB)

Standard/Specific Therapeutic Class: *Miscellaneous, Bone Resorption Inhibitors*
Formulary Status: Formulary, PA required

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Prolia®: Osteoporosis; bone loss due to medication therapy (e.g. corticosteroids, androgen deprivation medications or aromatase inhibitors)
- Xgeva®: hypercalcemia of malignancy, prevention of skeletal-related events in bone metastases from solid tumors or in multiple myeloma, treatment of giant cell tumor of the bone
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Prolia: #1mL per 180 days (6 months)
  - Xgeva: #1.7mL per 28 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose
- T-score
- Fracture history

Coverage Criteria:

I. Initiation of Therapy:

- For **Prolia®**, approve if:
  - Diagnosis is FDA approved (see "Diagnosis Considered for Coverage" above) AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use **bisphosphonates** AND
  - T-score < 2.5 OR T-score -1.0 and -2.5 with high risk of fracture or history of fracture
- For **Xgeva®**, approve if:
  - Diagnosis is FDA approved indication (see "Diagnosis Considered for Coverage" above)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References:

- Camacho PM, Petak SM, Binkley N, et al. American association of clinical endocrinologists and American college of endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016. *Endocrine Practice.* 2016;22:Suppl 4;1-42. Available at: https://www.aace.com/publications/guidelines

Last review/revision date: 10/2018

ZAVESCA® (MIGLUSTAT) AND CERDELGA® (ELIGLUSTAT TARTRATE)

Standard/Specific Therapeutic Class: *Miscellaneous, Drugs To Tx Gaucher Dx-Type 1, Substrate Reducing*
Formulary Status: Formulary, PA required

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Gaucher disease, type 1
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Prescriber restriction: endocrinologist
- Quantity Limit*:
  - Zavesca®: #90 per 30 days
  - Cerdelga®: #60 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- For Zavesca®: previous therapy
- For Cerdelga®: CYP2D6 genotype

Coverage Criteria:

I. Initiation of Therapy:

- For Gaucher disease type 1, approve if:
  - Therapy is prescribed or recommended by an endocrinologist AND
  - For **Zavesca®**, there is documentation of trial and failure, intolerance, contraindication, or inability (e.g. due to allergy, hypersensitivity, or poor venous access, etc.) to use **enzyme replacement therapy (ERT)** (e.g. Cerezyme®) via the Medical Benefit
  - For **Cerdelga®**, there is documentation of an FDA-cleared test indicating that member is CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizer (PMs)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References:

- ZAVESCA® [package insert]. Actelion Pharmaceuticals US, Inc. South San Francisco, CA, February 2016.
- CERDELGA™ [package insert]. Genzyme Corporation, August 2014.
- Position statement for treatment of Gaucher disease National Gaucher Foundation medical advisory board January 7, 2014. National Gaucher Foundation, Inc. Retrieved from: http://www.gaucherdisease.org/ngf-position-statement.php
- Mistry PK, Lukina E, Ben Turkia H, et al. Effect of oral eliglustat on splenomegaly in patients with Gaucher disease type 1: the

ZAVESCA® (MIGLUSTAT) AND CERDELGA® (ELIGLUSTAT TARTRATE)
ENGAGE randomized clinical trial. JAMA. 2015 Feb; 313(7): 695-706.
Last review/revision date: 10/2018

THYROID HORMONES

Standard/Specific Therapeutic Class: *Thyroid, Thyroid Function Diagnostics, Anti-thyroid, Iodine*

Formulary Status:

- Formulary:
  - levothyroxine (Synthroid®, Levo-T®, Unithroid®, Levoxyl®) tablet
  - liothyronine (Cytomel®) tablet
  - thyroid, porcine (Armour Thyroid®, Nature-Throid®) tablet
- Non-formulary:
  - Thyrolar® (liotrix) tablet
  - Tirosint® (levothyroxine) capsule

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Hypothyroidism
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity*: #90 per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For hypothyroidism, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **levothyroxine tablets** AND **porcine thyroid** (Armour Thyroid® or Nature-Throid®) for at least 6 months if well tolerated AND
  - There is documentation of good adherence AND
  - TSH >5.5 mIU/L
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References:

- Guidelines for the Treatment of Hypothyroidism: Prepared by the American Thyroid Association Task Force on Thyroid Hormone Replacement. Thyroid. 2014;24(12):1670-1751.
- 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of

THYROID HORMONES
Thyrotoxicosis. Thyroid. 2016 Oct;26(10):1343-1421. • A Systematic Review of Clinical Practice Guidelines' Recommendations on Levothyroxine Therapy Alone versus Combination Therapy (LT4 plus LT3) for Hypothyroidism. Clin Invest Med. 2015 Dec 4;38(6):E305-13.
Last review/revision date: 10/2018

EMFLAZA® (DEFLAZACORT)

Standard Therapeutic Class, Specific Therapeutic Class: *Glucocorticoids*
Formulary Status: Formulary, PA required

Coverage Duration: 6 months

Diagnosis Considered for Coverage:

- Duchenne Muscular Dystrophy
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: up to 0.9 mg/kg daily
- Prescriber restriction: Prescriber must a neurologist.

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Duchenne Muscular Dystrophy**, approve if:
  - Patient is 5 years of age or older AND
  - Documented mutation of dystrophin gene and copies of testing were submitted with request AND
  - Patient has onset of weakness before 5 years of age, and serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) at some stage in their illness AND
  - Patient is ambulatory AND
  - Patient has had a baseline eye examination AND
  - Patient has had a baseline behavioral health evaluation AND
  - Patient had a baseline bone mineral density (BMD) screening completed (including date and results) AND
  - Patient is or will be taking adequate calcium and vitamin D supplementation AND
  - If patient has been previously established on deflazacort before available in the U.S., provider has submitted detailed chart notes including dates of therapy and response AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: prednisone or prednisolone for at least 12 months AND
  - Documented medical reason provided why prednisone or prednisolone are not able to be continued, and Emflaza would be medically necessary and not have the same side effect as the preferred agents AND
  - The request is for an FDA approved dose
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- The patient is ambulatory AND
- Physician attests that the patient's muscle strength has stabilized or improved since the starting treatment AND
- Physician attests patient has had repeat eye and BMD screening as appropriate

EMFLAZA® (DEFLAZACORT)
III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • The patient is ambulatory AND • Physician attests that the patient's muscle strength has stabilized or improved since the starting treatment AND • Patient's claim history shows consistent therapy (monthly fills) AND • Physician attests patient has had repeat eye and BMD screening as appropriate AND • The request is for an FDA approved dose
References: • Gloss D, et al. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy. Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86:465-472 • Emflaza® [package insert] Northbrook, IL: Marathon Pharmaceuticals; 2017.
Last review/revision date: 10/2018

Genitourinary

GENITOURINARY ANTI-SPASMODICS AND ANTI-CHOLINERGICS

Standard/Specific Therapeutic Class: *Antispasmodic and Anticholinergic Agents, Urinary Tract Antispasmodic Antiincontinence Agent*

Formulary Status:

- Formulary: oxybutynin (Ditropan®) IR, ER
- Formulary, Step therapy:
  - tolterodine IR (Detrol®), tolterodine LA (Detrol® LA)
  - trospium IR (Sanctura®), trospium ER (Sanctura® XR)
- Formulary, PA required:
  - Gelnique® 10% gel pump , gel packet
- Non-formulary:
  - darifenacin (Enablex®)
  - fesoterodine (Toviaz®)
  - flavoxate (Urispas®)
  - Myrbetriq® (mirabegron)
  - oxybutynin patch (Oxytrol®, Oxytrol for Women®)
  - Vesicare® (solifenacin)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Overactive bladder
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - darifenacin, fesoterodine, Myrbetriq®, tolterodine LA, trospium ER, Vesicare®,: #90/90 days
  - flavoxate: #360/90 days
  - oxybutynin patch: #24 patches/84 days
  - oxybutynin 10% gel: #90 g (3 pumps)/90 days, 10% gel: #90/90 days
  - tolterodine, trospium: #180/90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For overactive bladder, approve if:
  - For **tolterodine IR and LA, trospium IR and ER**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **oxybutynin IR or ER**
  - For **Gelnique®**, there is documentation of inability to use tablets (e.g. inability to swallow)
  - For **tablet/capsule non-formulary medications**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the

GENITOURINARY ANTI-SPASMODICS AND ANTI-CHOLINERGICS
following: **oxybutynin AND tolterodine or trospium** o For **transdermal non-formulary medications**: ▪ There is documentation of inability to use tablets (e.g. inability to swallow) **AND** ▪ For **Oxytrol®**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **over-the-counter Oxytrol® For Women patch** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: • 2012 Update: Guidelines for Adult Urinary Incontinence Collaborative Consensus Document for the Canadian Urological Association. Can Urol Assoc J 2012; 6(5):354-63. Available at 4TUhttp://www.ncbi.nlm.nih.gov/pmc/articles/PMC3478335/pdf/cuaj-5-354.pdfU4T. • Nonsurgical Management of Urinary Incontinence in Women: A Clinical Practice Guideline from the American College of Physicians. Ann Intern Med. 2014; 161:429-440. Available at 4TUhttp://annals.org/article.aspx?articleid=1905131U4T • Gormley, E. Ann, et al. "Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment." The Journal of urology 193.5 (2015): 1572-1580. 4TUhttp://www.auanet.org/common/pdf/education/clinical-guidance/Overactive-Bladder.pdf
Last review/revision date: 10/2018

ALPHA-BLOCKERS FOR BPH

Standard/Specific Therapeutic Class: *Miscellaneous, Benign Prostatic Hypertrophy, Micturition Agents*

Formulary Status:

- Formulary:
  - alfuzosin (Uroxatral®)
  - doxazosin (Cardura®)
  - tamsulosin (Flomax®)
  - terazosin
- Formulary, PA required:
  - Rapaflo® (silodosin)
- Non-formulary:
  - Cardura XL® (doxazosin ER)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Benign Prostatic Hypertrophy (BPH)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Rapaflo®: #90 per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **BPH**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use at least **3 formulary alternatives**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 10/2018

Gastrointenstinal

PROBIOTICS

Standard/Specific Therapeutic Class: *Miscellaneous, Antidiarrheal Microorganisms Agents*

Formulary Status:

- Formulary:
  - Saccharomyces boulardii (Florastor®) 250mg (equivalent to 5 billion CFU) capsule [GCN 05162]
  - Culturelle® (lactobacillus rhamnosus GG [LGG]) Health & Wellness 15 billion CFU capsule sprinkles [GCN 34623] and Culturelle Kids 5 billion CFU powder packet [GCN 36349]
- Formulary, PA:
  - VSL #3® 900 billion CFU packet [GCN 97109]
- Non-formulary:
  - All other probiotic formulations

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Antibiotic-associated diarrhea (S. boulardii, Culturelle®)
- Ullcerative colitis/pouchitis (VSL #3®)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - VSL #3® [GCN 97109]: #60 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For VSL #3®, approve if documented use in ulcerative colitis patients with chronic relapsing pouchitis
- For all non-formulary probiotics, approve if:
  - At least two peer-reviewed published studies of the requested strain with positive results in the requested diagnosis are provided
  - Documented contraindication, trial and failure, or inability to use both formulary probiotics S. boulardii AND Culturelle® Health & Wellness
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND

PROBIOTICS
• The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND • Medical justification provided for continuation of therapy **III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:** • Medical justification provided for continuation of therapy
References: N/A
Last review/revision date: 10/2018

MARINOL® (DRONABINOL)

Standard/Specific Therapeutic Class: *Antiemetic/Antivertigo Agents*
Formulary Status: Formulary, PA required

Coverage Duration:
HIV related anorexia and wasting; HIV or HIV medication associated nausea and vomiting: 2 years
CINV: 6 months or duration of chemotherapy

Diagnosis Considered for Coverage:
- HIV related anorexia and cachexia, chemotherapy induced nausea and vomiting (CINV), HIV or HIV medication associated nausea and vomiting
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:
- Quantity Limit*
  - HIV related anorexia and wasting: 2.5, 5 mg: #3 per day, 10 mg: #2 per day
  - CINV, HIV associated nausea and vomiting: #3 per day

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:
- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:
Pharmacist may enter ICD code B20 – Human immunodeficiency virus [HIV] disease at point of sale to allow paid claim

I. Initiation of Therapy:
- For diagnosis of **HIV related anorexia and cachexia**, approve
- For diagnosis of **chemotherapy induced nausea and vomiting (CINV**), approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use at least 3 of the following formulary alternatives:
    - **Dopamine receptor antagonists (e.g. prochlorpherazine, promethazine, or metoclopramide)**
    - **5HT3 receptor antagonists (e.g. ondansetron 8 mg BID)**
    - **BZDs (e.g. lorazepam 0.5 mg Q 4-6 hrs)**
    - **Antihistamines (e.g. diphenhydramine 20-50 mg Q 4-6 hrs)**
    - **Atypical antipsychotic (e.g. olanzapine 10 mg/day)**
- For diagnosis of **HIV or HIV medication associated nausea and vomiting** (off-label indication), approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use at least 2 **alternatives (e.g. 5-hydroxytryptamine (5HT3, ondansetron, prochlorperazine, promethazine, metoclopramide, lorazepam)**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

MARINOL® (DRONABINOL)
• Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND • For diagnosis of **HIV related anorexia and cachexia**, approve if there is documented therapeutic response and continued medical need per PA requestFor diagnosis of **chemotherapy induced nausea and vomiting (CINV**), approve if there is documented response to therapy AND patient is still on chemotherapy • For diagnosis of **HIV or HIV medication associated nausea and vomiting (off-label indication)**, approve if there is documented therapeutic response and continued medical need per PA request **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • For diagnosis of **HIV related anorexia and cachexia**, approve if there is documented therapeutic response and continued medical need per PA request • For diagnosis of **chemotherapy induced nausea and vomiting (CINV**), approve if there is documented response to therapy AND patient is still on chemotherapy • For diagnosis of **HIV or HIV medication associated nausea and vomiting (off-label indication)**, approve if there is documented therapeutic response and continued medical need per PA request
References: N/A
Last review/revision date: 10/2018

ANTI-EMETIC/ANTI-VERTIGO AGENTS

Standard/Specific Therapeutic Class: *Antinauseants, Antiemetic/Antivertigo Agents*

Formulary Status:

- Formulary, PA required
  - Aprepitant (Emend)
  - Netupitant/palonestron (Akynzeo)

Coverage Duration: 6 months or duration of chemotherapy

Diagnosis Considered for Coverage:

- Chemotherapy induced nausea/vomiting (CINV) prophylaxis (aprepitant and netupitant/palonosetron)
- Postoperative nausea and vomiting (PONV) prophylaxis (aprepitant only)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Akynzeo: #1 per chemotherapy cycle (usually 14 or 21 days), up to 1 month supply
  - Emend: #3 per chemotherapy cycle (usually 14 or 21 days), up to 1 months supply; for PONV 40 mg 13 hours before anesthesia induction

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Chemotherapy cycle

Coverage Criteria:

I. Initiation of Therapy:

- For chemotherapy-induced or post-operative nausea/vomiting, approve if:
  - Patient is on highly emetogenic chemotherapy (e.g. cisplatin) OR
  - Patient is on moderately emetogenic chemotherapy or risk factors for chemotherapy induced nausea and vomiting (e.g. < 50 yo, female, history of anxiety/motion sickness, NV during pregnancy or prior cycle, alcohol abstinence) OR
  - Patient is scheduled for surgery and requires prevention of PONV prior to surgery
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Patient is still on chemotherapy

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider

ANTI-EMETIC/ANTI-VERTIGO AGENTS
attestation on PA request that member is continuing the medication), approve if: • Patient is still on chemotherapy
References: • National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Antiemesis. V.1.2016. Available at: http://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf.
Last review/revision date: 10/2018

DICLEGIS® (DOXYLAMINE SUCCINATE 10 MG AND PYRIDOXINE HYDROCHLORIDE 10 MG)

Standard/Specific Therapeutic Class: Antinauseants, Antiemetic/Antivertigo Agents
Formulary Status: Non-formulary

Coverage Duration: Up to 9 months

Diagnosis Considered for Coverage:

- Nausea and vomiting associated with pregnancy
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction: N/A

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **nausea and vomiting associated with pregnancy**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: doxylamine succinate 25 mg tablet and pyridoxine hydrochloride 25 mg tablet as separate ingredients
  - Medication is being prescribed at an FDA approved dose OR prescribed quantity does not exceed #120 per 30 days
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" section

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Refer to "Initiation of Therapy" section

References:

- American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin Summary No. 153: Nausea and Vomiting of Pregnancy. Obstetrics & Gynecology: September 2015 - Volume 126 - Issue 3 - p 687–688. doi: 10.1097/01.AOG.0000471177.80067.19

Last review/revision date: 10/2018

SCOPOLAMINE (TRANSDERM®) TRANSDERMAL PATCH

Standard/Specific Therapeutic Class: *Antinauseants, Antiemetic/Antivertigo Agents*
Formulary Status: Formulary, PA required

Coverage Duration: 1 fill

Diagnosis Considered for Coverage:

- Motion sickness
- Nausea and vomiting due to surgery
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Pre-operative nausea: #1 per fill
  - Motion sickness: #4 per fill

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For prevention of nausea and vomiting due to surgery or motion sickness, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use promethazine OR metoclopramide AND meclizine, diphenhydramine, OR dimenhydrinate
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Therapeutic response and continued medical need per PA request

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Therapeutic response and continued medical need per PA request

References: N/A

Last review/revision date: 10/2018

5-HT3 RECEPTOR ANTAGONISTS

Standard/Specific Therapeutic Class: *Antinauseants, Antiemetic/Antivertigo Agents*

Formulary Status:

- Formulary: ondansetron ODT (Zofran ODT®), ondansetron tablets (Zofran®)
- Formulary, PA required: ondansetron solution (Zofran®), granisetron tablets (Kytril®)
- Non-formulary: dolasetron tablets (Anzemet®), granisetron patch (Sancuso®)

Coverage Duration: up to 6 months

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - ondansetron solution #10mL/day
  - granisetron: CINV #12/30 days; other indications up to #60/30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For nausea/vomiting, approve if:
  - For **ondansetron solution**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use the **ondansetron oral disintegrating tablet**
  - For **granisetron tablets**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use the **ondansetron**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Documentation of therapeutic response and, for CINV indication, active chemotherapy AND
- For **ondansetron solution**: continued inability to use oral tablets

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider

5-HT3 RECEPTOR ANTAGONISTS
attestation on PA request that member is continuing the medication), approve if: • Therapeutic response and, for CINV indication, active chemotherapy • For ondansetron solution: continued inability to use oral tablets.
References: N/A
Last review/revision date: 10/2018

DIGESTIVE ENZYMES

Standard/Specific Therapeutic Class: *Enzymes, Pancreatic Enzymes*

Formulary Status:

- Formulary, #150/30 days,
  - Lipase, protease, amylase (Creon® DR, Zenpep®)
- Non-formulary
  - Lipase, protease, amylase (Pancreaze®, Pertyzye®, Ultresa®, Viokace®)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Pancreatic insufficiency
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction: N/A

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For Pancrease®, Pertyzye®, Ultresa®, Viokace® for pancreatic insufficiency, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, high pill burden etc.) to use Creon® AND Zenpep®
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" section

References: N/A

Last review/revision date: 10/2018

RECTAL MESALAMINE

Standard/Specific Therapeutic Class: *Miscellaneous, Chronic Inflammatory Colon Disease, 5-amino-saliclate, Rectal Treatment*

Formulary Status:

- Formulary
  - mesalamine 4 gm/60 ml enema (sfRowasa®, GCN 47270) #1800 ml per 30 days
- Non-formulary
  - mesalamine 4 gm/60 ml enema kit (Rowasa®, GCN 99847)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Ulcerative colitis, proctitis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #90 per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For ulcerative colitis or proctitis, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the following formulary mesalamine 4 mg/60 ml enema (sfRowasa®)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" section

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date10/2018

CONSTIPATION AGENTS

Standard/Specific Therapeutic Class: *Laxatives/Laxatives and Cathartics, Antidotes/Mu-opioid Receptor Peripherally Acting*

Formulary Status:

- Formulary:
  - Stool softeners: docusate (Colace®)
  - Fibers: Metamucil®, Natural fiber laxative
  - Osmotic agents: PEG (Miralax®), milk of magnesia
  - Stimulants: senna, bisacodyl suppository, bisacodyl ER tablets
  - Linzess® (linactolide) [for IBS-C]
- Formulary, PA required:
  - Amitiza® (lubiprostone)
  - Movantik® (naloxegol) [for OIC]
  - Symproic® (naldemedine) [for OIC]
- Non-Formulary: Relistor® (methylnaltrexone) tablet, SQ injection

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Amitiza®: chronic idiopathic constipation (CIC) in adults; irritable bowel syndrome-constipation (IBS-C) in women≥ 18 years old; opioid induced constipation (OIC) (off-label)
- Movantik®: opioid induced constipation (OIC)
- Symproic®: opioid induced constipation (OIC)
- Relistor®: opioid induced constipation (OIC) with chronic non-cancer pain, OIC with advanced illness
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Amitiza®: 8 mcg for IBS-C, 24 mcg for CIC, OIC; #180 per 90 days
  - Movantik®: #90 per 90 days
  - Symproic®: #90 per 90 days
  - Relistor®:
    - For OIC with chronic non-cancer pain: #90 tabs per 90 days, 54 ml per 90 days (12 mg/0.6 ml daily)
    - For OIC with advanced illness: #36-54 ml per 90 days (8 mg/0.4 ml or 12 mg/0.6 ml daily)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For FDA-approved indication (see "Diagnosis Considered for Coverage" section above), approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use at least **2 laxatives from different classes** (e.g. fiber supplements, stimulants, osmotic laxatives, etc.) AND

CONSTIPATION AGENTS
o For **Relistor®**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **Movantik®, Symproic® and Amitiza®** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND **III.** The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Patient is stable and continuing the medication
References: N/A
Last review/revision date: 4/2018

LOTRONEX® (ALOSETRON)

Standard/Specific Therapeutic Class: *Miscellaneous, Irritable bowel syndrome agents, 5-HT3 antagonist*
Formulary Status: Formulary, PA required

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Severe diarrhea-predominant irritable bowel syndrome (IBS) in women who have chronic IBS symptoms (generally lasting 6 months or longer), have had anatomic or biochemical abnormalities of the GI tract excluded, and who have not responded adequately to conventional therapy.
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #180 tablets per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For FDA-approved diagnoses (see "Diagnosis Considered for Coverage" section above), approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use at least **one of the following alternatives: antidiarrheals (i.e., loperamide), antidepressants (i.e., desipramine, imipramine) or antispasmodics (i.e., dicyclomine, hyoscyamine).**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND

III. The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References:

- Ford AC et al. American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. Am J Gastroenterology. 2014;109 S2-S26.

Last review/revision date: 10/2018

DONNATAL® (PHENOBARBITAL/ HYOSCYAMINE/ ATROPINE/ SCOPOLAMINE)

Standard/SpecificTherapeutic Class: *Antispasmodic and Anticholinergic Agents, Belladonna Alkaloids*
Formulary Status: Non-formulary

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Irritable bowel syndrome, acute enterocolitis, duodenal ulcer
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Tablet: up to #240 per 30 days
  - Elixir: up to #1200 ml per 30 days
- Prescriber Restriction: None

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For FDA-approved diagnoses, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **at least 2** the following formulary alternatives: hyoscyamine, dicyclomine, diphenoxylate-atropine, chlordiazepoxide-clidinium
  - For elixir, there is documentation of trial and failure, intolerance, contraindication, or inability (e.g. inability to swallow, etc.) to use Donnatal® tablets
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References:

- Ford AC et al. American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. The American Journal of Gastroenterology 109, S2-S26 (August 2014) | doi:10.1038/ajg.2014.187
- Weinberg, David S. et al. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. Gastroenterology, Volume 147 , Issue 5 , 1146 – 1148.
- Sainsbury A, Ford AC. Treatment of irritable bowel syndrome: beyond fiber and antispasmodic agents. Therapeutic Advances in

DONNATAL® (PHENOBARBITAL/ HYOSCYAMINE/ ATROPINE/ SCOPOLAMINE)
Gastroenterology. 2011;4(2):115-127.
Last review/revision date: 10/2018

CARAFATE® (SUCRALAFATE)

Standard/Specific Therapeutic Class: *Anti-ulcer Preps/Gastrointestinal Preps, Anti-ulcer Preparations*

Formulary Status:

- Formulary
  - sucralafate tablet
- Formulary, ≤ 12 yo
  - sucralafate (Carafate®) suspension
- PA required > 12 yo
  - sucralafate (Carafate®) suspension

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Duodenal ulcer
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #3600 ml per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For duodenal ulcer, approve if:
  - Documented inability to use sucralafate tablet (e.g. inability to dissolve tablets and swallow)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" section

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2018

PROTON PUMP INHIBITORS (PPIs)

Standard/Specific Therapeutic Class: *Anti-ulcer Preps/Gastrointestinal Preps, Proton Pump Inhibitor*

Formulary Status:

- Formulary:
  - omeprazole 10, 20, 40 mg caps (Prilosec®)
  - pantoprazole tabs (Protonix®)
  - lansoprazole (Prevacid®) 15, 30 mg DR caps
  - esomeprazole 20 mg DR cap (Nexium 24HR OTC®)
- Formulary, age limit (≤ 12 y/o): lansoprazole dispersible tablet (Prevacid SoluTab®)
- Formulary, Step therapy:
  - rabeprazole (Aciphex®) 20 mg tabs
- Non-formulary:
  - Dexilant® (dexlansoprazole)
  - esomeprazole (Nexium®)
  - omeprazole 20 mg tabs (Prilosec-OTC®), Prilosec® (omeprazole) granules
  - omeprazole/sodium bicarbonate (Zegerid®)
  - Protonix® granules (pantoprazole)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- FDA approved diagnoses
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Prevacid® SoluTab: #90 per 90 days
  - Protonix® granules: #90 per 90 days
  - omeprazole 20 mg tabs (Prilosec OTC®): #90 per 90 days
  - rabeprazole 20mg tabs (Aciphex®) #90 per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For FDA-approved diagnoses, approve if:
  - For **rabeprazole**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use two of the following formulary alternatives: **esomeprazole DR cap (OTC), lansoprazole cap, omeprazole,** or **pantoprazole**
  - For **lansoprazole dispersible tablet**or **Protonix® granules**, there is documented inability to swallow
  - For **omeprazole 20 mg tablet** or **omeprazole/sodium bicarbonate**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: **omeprazole capsule**
  - For **Dexilant®, esomeprazole (Nexium®)** there is documentation of trial and failure, intolerance,

PROTON PUMP INHIBITORS (PPIs)
contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 4 of the following formulary alternatives: **esomeprazole DR cap (OTC), lansoprazole cap, omeprazole,** or **pantoprazole** as first-line; **rabeprazole** as second line • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months): • Refer to "Initiation of Therapy" section
References: N/A
Last review/revision date: 10/2018

CHOLBAM® (CHOLIC ACID)

Standard Therapeutic Class, Specific Therapeutic Class: *Bile therapy, bile salts*
Formulary Status: Formulary, PA required

Coverage Duration:
Initial: 3 months
Re-authorization: 6 months

Diagnosis Considered for Coverage:

- Bile acid synthesis disorder due to single enzyme defect, peroxisomal disorders including Zellweger spectrum disorders in patients that exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: Up to 10 to 15 mg/kg (once daily or in 2 divided doses) or up to 11 to 17 mg/kg (once daily or in 2 divided doses) in patients with concomitant familial hypertriglyceridemia.
- Prescriber restriction: prescriber must be hepatologist or gastroenterologist

*Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis

Clinical Information Required for Review:

- Diagnosis
- Labs

Coverage Criteria:

I. Initiation of Therapy:

- For confirmed diagnosis of **bile acid synthesis disorder due to single enzyme defect (SEDs) or peroxisomal disorders including Zellweger spectrum disorders in patients that exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption**, approve if:
  - Current labs (within 30 days of request) have been submitted for the following:
    - ALT/AST
    - GGT (serum gamma glutamyltransferase)
    - ALP (alkaline phosphatase)
    - Bilirubin
    - INR
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
- Documentation has been submitted indicating clinical benefit/liver function has improved since beginning treatment.*

*TREATMENT SHOULD BE DISCONTINUED IF LIVER FUNCTION DOES NOT IMPROVE WITHIN 3 MONTHS OF

CHOLBAM® (CHOLIC ACID)
STARTING TREATMENT, IF COMPLETE BILIARY OBSTRUCTION DEVELOPS OR CHOLESTASIS OCCURS • Current labs (within 30 days of request) have been submitted for the following: o ALT/AST o GGT (serum gamma glutamyltransferase) o ALP (alkaline phosphatase) o Bilirubin o INR **III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:** • Documentation has been submitted indicating clinical benefit/liver function has improved since beginning treatment.* *TREATMENT SHOULD BE DISCONTINUED IF LIVER FUNCTION DOES NOT IMPROVE WITHIN 3 MONTHS OF STARTING TREATMENT, IF COMPLETE BILIARY OBSTRUCTION DEVELOPS OR CHOLESTASIS OCCURS • Current labs (within 30 days of request) have been submitted for the following: o ALT/AST o GGT (serum gamma glutamyltransferase) o ALP (alkaline phosphatase) o Bilirubin o INR
References: N/A
Last review/revision date: 10/2018

OCALIVA® (OBETICHOLIC ACID)

Standard Therapeutic Class, Specific Therapeutic Class: *Bile therapy, farnesoid X receptor (FXR) agonist, bile acid analog*
Formulary Status: Formulary, PA required

Coverage Duration:
Initial: 3 months
Re-authorization: 6 months

Diagnosis Considered for Coverage:

- Primary biliary cholangitis (PBC)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: Up to 5 mg once daily (initial) and 10 mg once daily for re-authorization
- Prescriber restriction: prescriber must be hepatologist or gastroenterologist

*Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis

Clinical Information Required for Review: *(to be used as a check list for providers for needed information or guidance for verbal PA requests)*

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **primary biliary cholangitis**, approve if:
  - Patient is taking Ocaliva® in addition to usodeoxycholic acid (UDCA) due to inadequate response to UDCA for at least 1 year OR
  - Patient us unable to tolerate UDCA and is taking Ocaliva® as monotherapy
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2018

Hematology

THROMBOCYTOPENIA

Standard/Specific Therapeutic Class: *Hemostatics, Thrombopoietin Receptor Agonists and Miscellaneous, Spleen Tyrosine Kinase Inhibitors*

Formulary Status:

- Formulary, PA required:
  - Promacta® (eltrombopag)
- Non-formulary:
  - Nplate® (romiplostim)
  - Doptelet® (avatrombopag)
  - Mulpleta® (lusutrombopag)
  - Tavalisse® (fostamatinib)

Coverage Duration:

- Indefinite for Promacta®, Nplate®, and Tavalisse®
- 5 days for Doptelet®
- 7 days for Mulpleta®

Diagnosis Considered for Coverage:

- Promacta®: chronic immune (idiopathic) thrombocytopenia (ITP), severe aplastic anemia, thrombocytopenia associated with hepatitis C infection
- Nplate®: chronic immune (idiopathic) thrombocytopenia (ITP)
- Doptelet® and Mulpleta®: thrombocytopenia associated with chronic liver disease in patients requiring elective surgery
- Tavalisse®: Chronic or refractory immune (idiopathic) thrombocytopenia (ITP)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Promacta®: #30 per 30 days
  - Nplate®: dose appropriate based on patient's weight
  - Doptelet®: #15 per 5 days
  - Mulpleta®: #7 per 7 days
  - Tavalisse®: #60 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Prior therapy
- Platelet level

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **chronic immune (idiopathic) thrombocytopenia (ITP)**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use ONE of the following: **glucocorticoids, intravenous immune globulin (IVIG), Rituxan® (if appropriate) or splenectomy** AND
  - Platelet level < 20,000 mm3 OR < 30,000 mm3 with bleeding AND

THROMBOCYTOPENIA

- For **Nplate®** or **Tavalisse®**, approve if there is a documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Promacta®

- For diagnosis of **severe aplastic anemia** (Promacta® only), approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **at least one immunosuppressive agent**
  - Platelet level < 20,000 mm3 OR < 30,000 mm3 with bleeding
- For diagnosis of **thrombocytopenia in patients with Hepatitis C infection** (Promacta® only), approve if:
  - Patient also has diagnosis of chronic hepatitis C AND
  - Documentation of treatment with interferon-based therapy AND patient's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy AND
  - Medical reason for why patient needs to be treated with interferon over new DAA medication AND
  - Platelet level < 50,000/mm3
- For diagnosis of thrombocytopenia associated with chronic liver disease in patients requiring elective surgery (Doptelet® and Mulpleta® only), approve if:
  - Patient has a diagnosis of chronic liver disase and is scheduled to undergo a procedure AND
  - Platelet level < 50,000/mm3 AND
  - For Doptelet®, approve if there is documentation of trial and failure, intolerance, contradindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Mulpleta®
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND

The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 10/2018

WHITE BLOOD CELL STIMULATORS

Standard/Specific Therapeutic Class: *Hematinics & Blood Cell Stimulators, Leukocyte (WBC) Stimulants*

Formulary Status:

- Formulary, PA required:
  - Zarxio® (filgrastim-sndz) – **preferred**
  - Granix® (TBO-filgrastim)
  - Neulasta® (pegfilgrastim) – **preferred**
  - Mozobil® (plerixafor)
- Non-formulary:
  - Neupogen® (filgrastim)
  - Nivestym™ (filgrastim-aafi)
  - Fulphila™ (pegfilgrastim-jmdb)

Coverage Duration: 6 months or duration of chemotherapy

Diagnosis Considered for Coverage:

- Febrile neutropenia treatment or prevention
- Mobilization of stem cells prior to autologous transplant (G-CSF + Mozobil®)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Neupogen®:
    - 300/0.5 ml syringe: up to 7 ml per 28 days (should be billed in increments of 0.5 ml)
    - 300/ml vial: up to 14 ml per 28 days (should be billed in increments of 1 ml)
    - 480/0.8 ml syringe: up to 11.2 ml per 28 days (should be billed in increments of 0.8 ml)
    - 480/1.6 ml vial: up to 22.4 ml per 28 days (should be billed in increments of 1.6 ml)
  - Granix®:
    - 300/0.5 ml syringe: up to 7 ml per 28 days (should be billed in increments of 0.5 ml)
    - 480/0.8 ml syringe: up to 11.2 ml per 28 days (should be billed in increments of 0.8 ml)
  - Zarxio®:
    - 300/0.5 ml syringe: up to 7 ml per 28 days (should be billed in increments of 0.5 ml)
    - 480/0.8 ml syringe: up to 11.2 ml per 28 days (should be billed in increments of 0.8 ml)
  - Neulasta®: 0.6 ml per chemotherapy cycle, #4 vials or syringes per 30 days
- Prescriber restriction: Prescription written or currently being supervised by a hematologist or an oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Prior therapy

Coverage Criteria:

I. Initiation of Therapy:

- For febrile neutropenia treatment or prevention or stem cell mobilization prior to autologous transplant, approve if:
  - Patient is 18 years of age or older AND
  - Prescription written or currently being supervised by a hematologist or oncologist AND
  - Drug is being used for an FDA-approved indication at an FDA-approved dose AND

WHITE BLOOD CELL STIMULATORS

- For **Neupogen®, Granix®**, or **Nivestym™**, patient has documented **treatment failure** (i.e, failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization, infection requiring prolonged anti-infectives) with an adequate trial (including dates, doses of therapy) of **Zarxio®** or has a documented **medical reason** (intolerance, hypersensitivity, dose dense chemotherapy, or stem cell collection, etc.) for not using **Zarxio®**
- For **Fulphila™,** patient has documented **treatment failure** (i.e, failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization, infection requiring prolonged anti-infectives) with an adequate trial (including dates, doses of therapy) of **Neulasta®** or has a documented **medical reason** (intolerance, hypersensitivity, dose dense chemotherapy, or stem cell collection, etc.) for not using **Neulasta®**

- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Patient is 18 years of age or older AND
- Patient is still receiving chemotherapy

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if patient is still receiving chemotherapy

References: N/A

Last review/revision date: 10/2018

ERYTHROPOIETIN STIMULATING AGENTS (ESAs)

Standard/Specific Therapeutic Class: *Hematinics & Blood Cell Stimulators, Erythropoiesis-stimulating Agents*

Formulary Status:

- Formulary, PA required
  - Retacrit™ (epoetin alfa) - **preferred**
  - Epogen®, Procrit® (epoetin alfa)
  - Aranesp® (darbepoetin alfa)
- Non-Formulary:
  - Mircera® (methoxy peg-epoetin beta)

Coverage Duration:

- ESRD: indefinite
- Chemotherapy: Duration of chemotherapy
- Other: 12 months

Diagnosis Considered for Coverage:

- Anemia due to:
  - Chronic kidney disease (CKD)/ end stage renal disease (ESRD): All
  - Cancer / chemotherapy-induced, myelodysplastic syndrome (MDS), hepatitis C treatment: Epogen®/Procrit®, Aranesp®
  - Zidovudine therapy: Epogen®/Procrit® only
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
- **EXCLUDED DIAGNOSES: Mircera® for chemotherapy induced anemia**

Prescribing Restriction:

- Quantity Limit*:
  - Retacrit™: #12 vials per month
  - Epogen®/Procrit®:
    - 2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: #12 vials per month
    - 20,000U/mL, 20,000U/mL vials and 40,000U/mL vials: #4 vials per month
  - Aranesp®: 30 days' supply (weight-based dosing by indication)
  - Mircera®: #2 syringes per 30 days
- Prescriber: Hematologist/Oncologist, Nephrologist, Hepatologist, or Infectious Disease physician

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Hemoglobin level
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **anemia due to CKD/ESRD, MDS, Hepatitis C treatment,** or **zidovudine therapy**, approve if:
  - Hemoglobin < 10 g/dL AND
  - Drug is FDA approved for the requested diagnosis (see "Diagnosis Considered for Coverage" above) AND
  - For Aranesp®, Procrit®, Epogen® or Mircera®, documented trial and failure, intolerance, contraindication or inability to use Retacrit™
- For **cancer/chemotherapy-induced anemia**:

ERYTHROPOIETIN STIMULATING AGENTS (ESAs)

- Requested drug is NOT Mircera® AND
- For Aranesp®, Procrit®, or Epogen®, documented trial and failure, intolerance, contraindication or inability to use Retacrit™ AND
- Hemoglobin < 10 g/dL AND
- Patient is undergoing palliative treatment, OR on myelosuppressive chemotherapy without other identifiable cause of anemia, OR refusing blood transfusions AND
- Patient does **NOT** meet any of the following (ESAs are not indicated):
  - Patient with cancer not receiving chemotherapy
  - Patients on non-myelosuppressive chemotherapy (e.g. NOT breast, non–small cell lung, head and neck, lymphoid, and cervical cancers)
  - Patients receiving myelosuppressive chemotherapy with curative intent

- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Hemoglobin < 12 g/dL AND
- If taking for chemotherapy induced anemia, patient is still receiving chemotherapy

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Hemoglobin < 12 g/dL AND
- If taking for chemotherapy induced anemia, patient is still receiving chemotherapy

References:

- NCCN: Cancer- and Chemotherapy-Induced Anemia. Ver 2.2017 – Nov 6 2016. Accessed Nov 29 2016. Access at: https://www.nccn.org/professionals/physician_gls/pdf/anemia.pdf

Last review/revision date: 10/2018

Immunology

HEREDITARY ANGIOEDEMA

Standard/Specific Therapeutic Class: *Miscellaneous/C1 Esterase Inhibitors*

Formulary Status:

- Formulary:
  - danazol 50mg, 100mg, 200mg oral capsules
- Formulary, PA required:
  -
  - Kalbitor® (ecallantide) 30mg/3mL subcutaneous syringe
  - Takhzyro™ (lanadelumab-flyo) injection: 300 mg/ mL single-dose vial
- Non-formulary:
  - Firazyr® (C1 Esterase Inhibitor Subcutaneous [Human]) 2000 IU, 3000 IU subcutaneous syringe
- Non-formulary, medical benefit:
  - Haegarda® (C1 Esterase Inhibitor Subcutaneous [Human]) 2000 IU, 3000 IU subcutaneous syringe
  - Cinryze® (C1 esterase inhibitor, human) 500 unit IV vial
  - Berinert® (C1 esterase inhibitor, human) 500 unit IV vial
  - Ruconest® (conestat alfa, recombinant) 2100 units IV vial

Coverage Duration:

- Initial: 3 months
- Re-authorization: 1 year

Diagnosis Considered for Coverage:

- Hereditary Angioedema (HAE)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity*:
  - Haegarda®: #16 vials per 28 days
  - Firazyr®: #30 syringes per 30 days
  - Kalbitor®: #30 vials per 30 days
  - Takhzyro™: #4 mL (2 vials) per 28 days
- Prescriber Restriction: restricted to allergy specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Weight
- Quantity

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of hereditary angioedema:
  - For **Takhzyro™**, approve if:
    - Medication is used for **prevention of HAE attacks**
    - Documentation of patient's weight and quantity/dose requested
    - Documentation of at least one HAE attack per month
  - For **Haegarda®**, approve if :

HEREDITARY ANGIOEDEMA
▪ Documentation meets criteria above for Takhzyro™ AND ▪ Documentation of trial and failure, intolerance, contraindication or inability to use Takhzyro™ o For **Kalbitor®**, approve if medication is used for **on-demand treatment of acute HAE attacks** o For **Firazyr®**, approve if: ▪ Medication is used for **on-demand treatment of acute HAE attacks** ▪ Documentation of trial and failure, intolerance, contraindication, or inability to use: **Kalbitor®** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Documented response to therapy AND • Patient is stable and continuing the medication
References: N/A
Last review/revision date: 1/2019

ORFADIN® AND NITYR® (NITISINONE)

Standard/Specific Therapeutic Class: *Drugs to Treat Hereditary Tyrosinemia*

Formulary Status:

- Formulary, PA required:
  - Nityr® (nitisinone)
- Non-formulary:
  - Orfadin® (nitisinone)

Coverage Duration:

Initial: 6 months

Renewal: 1 year

Diagnosis Considered for Coverage:

- Hereditary tyrosinemia type 1 (HT-1)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity*:
  - Up to 2 mg/kg/day
- Prescriber: Specialist in inherited metabolic disorders

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **diagnosis of hereditary tyrosinemia type 1,** approve if:
  - Diagnosis confirmed by one of the following:
    - DNA testing OR
    - Detection of succinylacetone (SA) in urine
  - Documentation provided attesting to diet restricting tyrosine and phenylalanine AND
  - If request is for Orfadin® capsule or suspension, documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use Nityr® tablet
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

ORFADIN® AND NITYR® (NITISINONE)
• Patient is stable or improving and continuing the medication • Medication is used for appropriate indication and at appropriate dose
References: N/A
Last review/revision date: 1/2019

Immunology: Immunosuppressants

IMMUNOSUPPRESSANTS

Standard/Specific Therapeutic Class: *Miscellaneous, Immunosuppressives*

Formulary Status:

- Formulary:
  - cyclosporine modified 25, 100 mg tablet, 100 mg/ml solution (Neoral®)
  - mycophenolate mofetil 250, 100 mg
  - mycophenolate mofetil 180 mg, 360 mg tablet, delayed release tablet (Myfortic®)
  - tacrolimus 0.5 1, 5 mg (Hecoria, Prograf®)
- Formulary, PA required: sirolimus 0.5,1, 2mg tabs (Rapamune®)
- Non-formulary:
  - cyclosporine Modified 50 mg
  - cyclosporine 25, 100 mg caps, 100 mg/ml solution (Sandimmune®)
  - everolimus 0.25, 0.5, 0.75 mg (Zortress®)
  - mycophenolate mofetil 200 mg/ml suspension (CellCept®)
  - sirolimus 1 mg/ml solution (Rapamune®)
  - tacrolimus 5 mg/ml soln (Prograf®)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Prevention of transplant rejection
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: Dose consolidation may be required depending on medication and regimen

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **prevention of transplant rejection**, approve if:
  - Formulary/preferred immunosuppressants are not appropriate for the indication
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

IMMUNOSUPPRESSANTS
References: N/A
Last review/revision date: 10/2018

Infectious Disease: Antifungals

AZOLE ANTIFUNGALS

Standard/Specific Therapeutic Class: *Antifungals, antifungal agents*

Formulary Status:

- Formulary: fluconazole
- Formulary, PA required:
  - Voriconazole (Vfend)
  - Itraconazole 100 mg capsule, 200 mg tablet (Onmel)
  - Isavuconazonium Sulfate (Cresemba)
- Non-formulary: posaconazole (Noxafil)

Coverage Duration:

Drug	Initial	Re-authorization
Itraconazole	3 months	Up to 1 year
Voriconazole	6 months	Up to 1 year
Posaconazole	6 months	Up to 1 year

Diagnosis Considered for Coverage:

- Blastomycosis, histoplasmosis, sporotrichosis
- For onychomychosis: refer to "onychomycosis" criteria
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - itraconazole 100 mg capsule: #180 per 90 days
  - Onmel® (itraconazole) 200 mg tablet: #30 per 30 days
  - voriconazole 50 mg: #360 per 90 days
  - voriconazole 200 mg: #180 per 90 days
  - Nofaxil® (posaconazole) DR tablet: #30 per 30 days
  - Cresemba® (isavuconazonium sulfate) 186mg: #60 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **itraconazole**, approve if:
  - Diagnosis of blastomycosis, histoplasmosis, or sporotrichosis OR
  - For coccidioidal infections: there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **fluconazole** AND
  - For **Onmel® 200 mg tablet**: documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **itraconazole 100 mg capsules**
- For **voriconazole**, approve if:
  - Diagnosis if one of the following OR
    - Fungal infection by Scedosporium apiospermum or Fusarium species

AZOLE ANTIFUNGALS

- Treatment of invasive candidasis in critically ill patients
- Invasive pulmonary aspergillus infections
- Primary prophylaxis for aspergillus infections for special populations such as lung transplant, Acute Myleoid Leukemia, Allo-stem cell transplant with prolonged neutropenia from chemotherapy AND high risk for infection

o For esophageal candidiasis or candidemia in nonneutropenic patients: documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **fluconazole** OR

o For blastomycosis, histoplasmosis or sporotrichosis: documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **itraconazole**

- For **Noxafil®**, approve for:
  - o For prophylaxis of invasive aspergillus or candida in patients at high risk of developing invasive aspergillus or candida due to being severely immunocompromised: trial and failure or inability to use **voriconazole** OR
  - o For orophangeal candidiasis: trial and failure or inability to use **fluconazole**
- For **Cresemba®**, approve for:
  - o Diagnosis of invasive mucormycosis in adults OR
  - o For invasive aspergillosis in adults: trial and failure or inability to use to **voriconazole**
- For off-label indications or dosing, approve if:
  - o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - o Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Documented response to therapy AND
- Additional therapy is medically necessary and clinically appropriate

References: N/A

Last review/revision date: 10/2018

ONYCHOMYCOSIS

Standard/Specific Therapeutic Class: *Antifungals, Topical Antifungals, Antifungal Agents*

Formulary Status:

- Formulary:
  - terbinafine 250 mg tablet #180 per year
  - ciclopirox 8% solution (Penlac®)
- Formulary, PA required:
  - itraconazole 100 mg capsule
  - Onmel® (itraconazole) 200mg tablet
- Non-formulary:
  - Julia® (efinaconazole) 10% solution
  - itraconazole (Sporanox®) oral solution
  - Kerydin® (tavaborole) 5% topical solution

Coverage Duration:

- itraconazole: 12 weeks
- Julia®, Kerydin®: 48 weeks

Diagnosis Considered for Coverage:

- Onychomycosis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - itraconazole 100mg capsule: #60 per 30 days
  - Onmel® 200mg tablet: #30 per 30 days
  - Julia®: #4 per 30 days
  - Kerydin®: #4 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For onychomycosis, approve if:
  - Member has peripheral vascular disease, diabetes, immunosuppression, recurrent cellulitis, decreased function, pain or other reason why treatment is medically necssary
  - For **itraconazole 100 mg capsule**: documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use terbinafine 250 mg once daily for 12 weeks
  - For **Onmel® 200 mg tablet**: documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use terbinafine 250 mg once daily for 12 weeks AND inability to use itraconazole 100 mg capsule
  - For **itraconazole oral solution**: documentation of inability to swallow oral tablets/capsules
  - For **Julia®** and **Kerydin®**: documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use terbinafine 250 mg once daily for 12 weeks AND

ONYCHOMYCOSIS
inability to use itraconazole 100 mg capsule 200 mg once daily for 12 weeks AND ciclopirox 8% solution for 48 weeks • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Refer to "Initiation of Therapy" section **III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:** • Medical justification provided for continuation of therapy beyond the standard course of treatment
References: N/A
Last review/revision date: 10/2018

Infectious Disease: Antiparasitics

DARAPRIM® (PYRIMETHAMINE)
Standard/Specific Therapeutic Class: *Antiparasitics* **Formulary Status:** Formulary, PA required
Coverage Duration: 1 year
Diagnosis Considered for Coverage: • *Toxoplasma gondii* (Toxoplasmosis) • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity: #30 per 30 days* • Prescriber restriction: HIV specialist, infectious disease specialist, internal medicine specialist OR oncologist **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Prescriber
Coverage Criteria: For all members, discuss with prescribing physician the treatment option of a combination compounded product of pyrimethamine plus leucovorin as an alternative to branded Daraprim®. **I. Initiation of Therapy:** • For **treatment of *Toxoplasma gondii* (toxoplasmosis),** approve if: o Diagnosis of toxoplasmosis AND o Documented immunosuppression (i.e. CD4+ count ≤ 200/mm^3) • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND • Medical justification provided for continuation of therapy **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Medical justification provided for continuation of therapy
References: N/A
Last review/revision date: 10/2018

NEBUPENT® (PENTAMIDINE ISETHIONATE)

Standard/Specific Therapeutic Class: *Antiparasitics/Antiprotozoal Drugs, Misc*

Formulary Status:

- Formulary, PA required
  - Nebupent® (pentamidine isethionate) 300 mg vial for nebulization

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- *pneumocystis jirovecii pneumonia* (PCP)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: 1 vial per 28 days
- Prescriber restriction: HIV specialist, infectious disease specialist, internal medicine specialist OR oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Prescriber

Coverage Criteria:

I. Initiation of Therapy:

- For **prevention of *pneumocystis jirovecii pneumonia* (PCP)**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfamethoxazole/trimethoprim AND
  - Diagnosis of HIV AND
  - Documented history of one or more episodes of PCP OR documented CD4+ count ≤ 200/mm^3
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Medical justification provided for continuation of therapy

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification provided for continuation of therapy

References: N/A

Last review/revision date: 10/2018

TOPICAL ANTIPARASITICS
Standard/Specific Therapeutic Class: *Antiparasitics, Topical antiparasitics* **Formulary Status:** • Formulary: o permethrin 1%, 5% (Nix®, Acticin®, Elimite®) o pyrethrin/piperonyl (Rid®, Pronto®) • Formulary, PA required: o malathion (Ovide®) o spinosad (Natroba®) 0.9% suspension • Non-formulary: o ivermection 0.5% lotion (Sklice®), crotamiton 10% lotion (Eurax®), benzyl alchohol 5% lotion (Ulefsia®)
Coverage Duration: 1 fill
Diagnosis Considered for Coverage: • Lice • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies •
Prescribing Restriction: • Quantity Limit* o malathion (Ovide®): #59 ml per fill o ivermectin (Sklice®): #117 grams per fill o spinosad (Natroba®): #120 ml per fill
Clinical Information Required for Review: • Diagnosis • Previous therapy • Dose

Coverage Criteria:

I. Initiation of Therapy:

- For lice:
  - For **malathion or spinosad**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: **permethrin or pyrethrin/piperonyl**
  - For **Sklice®**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use ALL of the following formulary alternatives: **permethrin or pyrethrin/piperonyl as first line AND malathion 0.5% OR spinosad 0.9% lotion as second line**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Medical justification provided for continuation of therapy.

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification provided for continuation of therapy

References: N/A

Last review/revision date: 10/2018

Infectious Disease: Other Antimicrobials

XIFAXAN® (RIFAXIMIN)

Standard/Specific Therapeutic Class: *Other Antibiotics, Rifamycin and Related Derivative Antibiotics*
Formulary Status: Formulary, Step therapy (lactulose)

Coverage Duration:
Traveler's Diarrhea, SIBO:1 fill
Hepatic Encephalopathy: 1 year
IBS-D: 3 fills total over 1 year

Diagnosis Considered for Coverage:

- Traveler's diarrhea, hepatic encephalopathy, small intestinal bacterial overgrowth (SIBO), irritable bowel syndrome-diarrhea predominant (IBS-D)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Rifaximin 200 mg #90 per 30 days
  - Rifaximin 550 mg #60 per 30 days; SIBO: #3 per day, up to 14 days; IBS-D: 550 mg #42 per 14 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose, previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For **traveler's diarrhea**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: **ciprofloxacin or levofloxacin** (if ≥18 y/o) **AND azithromycin**
- For **hepatic encephalopathy**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **lactulose**
- For **small intestinal bacterial overgrowth (SIBO),** approve up to quantity and duration listed above
- For diagnosis of **irritable bowel syndrome-diarrhea predominant (IBS-D)**, approve if:
  - Patient is ≥ 18 years of age AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use at least one other medication (e.g. **loperamide**)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Therapeutic response and continued medical need per PA requested AND
- For IBS-D: clinical need for dosing over FDA approved dosing regimen

XIFAXAN® (RIFAXIMIN)
III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Therapeutic response and continued medical need per PA requested AND • For IBS-D: clinical need for dosing over FDA approved dosing regimen
References: • Ford AC, Moayyedi P, Lacy BE, et al. Amergican College of Gastroenterology monograph on the management of irritable bowel syndrome and chronic idiopathic constipation. Am J Gastroenterol 2014; 109(1):S2-S26. • Weinberg DS. American Gastroenterological Association Institute Guidelineon the Pharmacological Management of Irritable Bowel Syndrome. Gastroenterology 2014;147:1146–1148. Available at http://www.gastro.org/guidelines/2014/09/14/pharmacological-management-of-ibs. • Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guidelines by AASLD and EASL. The American Association for the Study of Liver Diseases. 2014 Practice Guideline. • The Center for Disease Control and Prevention. Yellow Book. Traveler's Diarrhea. • The Practice of Travel Medicine: Guidelines by the Infectious Diseases Society of America. Clinical Infectious Diseases 2006; 43:1499–539.
Last review/revision date: 10/2018

Infectious Disease: Misc

TOPICAL ANTIVIRALS

Standard/Specific Therapeutic Class: *Antivirals, Topical Antivirals*

- **Formulary Status:** Formulary, PA required:
  - Denavir® (penciclovir) 1% cream
  - acyclovir (Zovirax®) 5% ointment
  - Zovirax® (acyclovir) 5% cream

Coverage Duration: 1 fill per year

Diagnosis Considered for Coverage:

- Herpes labialis (cold sore), genital herpes, herpes simplex
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - acyclovir 5% ointment:15 gm per 30 days
  - Denavir® 1% cream: 1.5 gm per 30 days
  - Zovirax® 5% cream: 5 gm per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For **Zovirax® cream** or **Denavir® cream**, approve if:
  - Patient is > 12 years of age AND
  - Diagnosis of herpes labialis (cold sore) AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use ALL of the following: at least **2 oral antivirals** (i.e. acyclovir, valacyclovir, famciclovir) AND docosanol (Abreva) 10% cream
- For **acyclovir ointment**, approve if:
  - Patient is > 18 years of age AND
  - Diagnosis of genital herpes, or herpes simplex infections in an immuno-compromised patient, AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use at least **2 oral antivirals** (i.e., acyclovir, valacyclovir, famciclovir)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" section

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

TOPICAL ANTIVIRALS
• Medical justification provided for continuation of therapy
References: N/A
Last review/revision date: 10/2018

VALGANCICLOVIR (VALCYTE®)

Standard/Specific Therapeutic Class: *Antivirals, Antivirals, General*

Formulary Status: Formulary, PA required

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Treatment of CMV retinitis
- CMV prophylaxis in heart, kidney, or kidney-pancreas transplant
- CMV prophylaxis in liver transplant (off label)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - CMV treatment:4 tablets or 36 mL per day (1800mg/day)
  - CMV prophylaxis: 2 tablets or 18 mL per day (900mg/day)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For CMV treatment or prophylaxis after solid organ transplant, approve AND
- For oral solution, documentation of trial and failure, intolerance, contraindication, or inability (e.g. inability to swallow, etc.) to use tablet or capsule formulation
- For other off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification provided for continuation of therapy beyond 12 months

References: N/A

Last review/revision date: 10/2018

DIFICID® (FIDAXOMICIN)

Standard/Specific Therapeutic Class: *Streptomycins, Vancomycin and Derivatives, Other Antibiotics, Macrolides*
Formulary Status: Formulary, PA required

Coverage Duration: Quantity as requested by provider at no more than 30 day supply

Diagnosis Considered for Coverage:

- Clostridium difficile infection
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - fidaxomicin (Difcid®): #20 per 10 days, 1 fill per year

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **Dificid®** for clostridium difficile, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, pregnancy in first trimester, etc.) to use oral **vancomycin** (capsule, compound or Firvanq®)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Medical justification is provided for continuation of therapy

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Medical justification is provided for continuation of therapy

References:

- McDonald C, Gerding D, Johnson S et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clinical Infectious Disease 2018: 66(7):1-48. Available at: https://academic.oup.com/cid/article/66/7/e1/4855916. Accessed on August 10th, 2018.

Last review/revision date: 10/2018

ORAL FLUOROQUINOLONES

Standard/Specific Therapeutic Class: *Other Antibiotics, Quinolones*

Formulary Status:

- Formulary:
  - ciprofloxacin (Cipro®) 100, 250, 500, 750mg tablet
  - ciprofloxacin (Cipro®) 250mg/5mL, 500mg/5mL oral suspension (age limit 12 years maximum)
  - levofloxacin (Levaquin®) 250, 500, 750mg tablet
  - levofloxacin (Levaquin®) 250mg/10mL oral solution (age limit 12 years maximum)
- Formulary, PA required: moxifloxacin (Avelox®) 400mg tablet
- Non-formulary:
  - ciprofloxacin (Cipro® XR) 500, 1000mg ER tablet
  - ofloxacin 300, 400mg tablet
  - Baxdela® (delafloxacin) 300mg tablet

Coverage Duration:

- moxifloxacin: Up to 12 months for chronic use
- ciprofloxacin suspension, levofloxacin solution: based on indication, up to 14 days

Diagnosis Considered for Coverage:

- FDA approved uses
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Moxifloxacin: #1 per day

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **moxifloxacin**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability to use **levofloxacin** (i.e., drug interaction, allergy, adverse reaction, culture results indicating resistance to levofloxacin or low-level fluoroquinolone resistance, respiratory pneumococcal infection, complicated intra-abdominal infection, adverse effects with levofloxacin, etc.)
- For **non-formulary fluoroquinolone**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction) to use **levofloxacin, ciprofloxacin AND moxifloxacin**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

ORAL FLUOROQUINOLONES
II. Continuation of Therapy for NEW Members (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND • Therapeutic response and continuation of therapy is medically necessary per PA request (e.g. diagnosis of multi-drug resistant TB or another diagnosis warranting long-term therapy) **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Therapeutic response and continuation of therapy is medically necessary per PA request (e.g. diagnosis of multi-drug resistant TB or another diagnosis warranting long-term therapy)
References: N/A
Last review/revision date: 10/2018

Infectious Disease: Hepatitis B

HEPATITIS B

Standard/Specific Therapeutic Class: *Antivirals/Hepatitis B Treatment Agents and Antivirals, HIV Specific, Nucleotide Analog, RTI*

Formulary Status:

- Formulary
  - entecavir (Baraclude®) tablet, Baraclude® (entecavir) solution
  - Viread® (tenofovir disoproxil fumarate)¥
  - lamivudine HBV (Epivir HBV®) tablet, Epivir HBV® (lamivudine) solution¥
- Non-formulary
  - adefovir (Hepsera®)
  - Vemlidy® (tenofovir alafenamide)¥

¥Excluded for Medi-Cal (covered by fee-for-service (FFS) Medi-Cal as a carve-out)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Hepatitis B
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity*:
  - Liquids: 600 mg per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **Hepatitis B,** approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **entecavir AND Viread®** AND
  - For **Vemlidy®**, patient is in Healthy Workers HMO or Healthy Kids HMO line of business (Vemlidy® is excluded from Medi-Cal line of business and is covered by FFS Medi-Cal as a carve-out)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References:

- AASLD Guidelines for Treatment of Chronic Hepatitis B. Hepatology. 2016;63(1):261-283.
- Asia-Pacific Clinical Practice Guidelines on the Management of Hepatitis B: A 2015 Update. Hepatol Int 2016;10:1-98.
- Hepatitis B (Chronic): Diagnosis and Management. National Institute for Health and Care Excellence. 2013.
- EASL Clinical Practice Guidelines: Management of Chronic Hepatitis B. Journal of Hepatology. 2012;57:167-185.

Last review/revision date: 4/2018

Infectious Disease: Hepatitis C

HEPATITIS C

Standard/Therapeutic Class: *Antivirals/Hepatitis C Virus- NS5A Replication Complex Inhibitor; NS3/4A Serine Protease Inhibitor; Nucleotide Analog NS5B Polymerase Inhibitor; NS5B Polymerase and NS5A Inhibitor Combination; NS5A and NS3/4A Inhibitor Combination; NS5B Polymerase and NS5A Inhibitor Combination; NS5A, NS3/4A, Nucleotide NS5B Inhibitor Combination; Hepatitis C Treatment Agents*

Formulary Status:

Formulary: ribavirin 200mg capsules and tablets

Formulary, PA required:

- Zepatier® (elbasvir/grazoprevir)
- ledipasvir/sofosbuvir (Harvoni®)
- Mavyret™ (glecaprevir/pibrentasvir)
- Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir)
- sofosbuvir/velpatasvir (Epclusa®)
- peginterferon Alfa-2a (Pegasys®, Pegasys Proclick®)
- ribavirin 400 mg tab
- ribavirin 600 mg tab
- ribavirin 200-400 mg tab/600-400 mg tab (Ribapak®)

Non-formulary:

- Daklinza® (daclatasvir)
- Olysio® (simeprevir)
- Sovaldi® (sofosbuvir)
- Technivie® (ombitasvir/paritaprevir/ritonavir)
- Viekira Pak® and Viekira XR® ER (ombitasvir/paritaprevir/ritonavir and dasabuvir)

Coverage Duration: Full course of therapy (8, 12, 16, or 24 weeks depending on therapy)

NOTE: DHCS Hepatitis C Treatment Policy states that therapy will not be restarted in cases where it was discontinued due to non-compliance. SFHP will review such requests on a case-by-case basis

Diagnosis Considered for Coverage:

- Hepatitis C Viral Infection (HCV)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit:

	8 weeks	12 weeks	16 weeks	24 weeks
Mavyret™	#42/14 days + 3 refills	#42/14 days + 5 refills	#42/14 days + 5 refills	n/a
Vosevi™	n/a	#14/14 days + 5 refills	n/a	n/a
sofosbuvir/velpatasvir	n/a	#14/14 days + 5 refills	n/a	#14/14 days + 11 refills
Zepatier™	n/a	#14/14 days + 5 refills	#14/14 days + 7 refills	n/a
ledipasvir/sofosbuvir Daklinza® Sovaldi®	n/a	#14/14 days + 5 refills	#14/14 days + 7 refills	#14/14 days + 11 refills
Viekira Pak®	n/a	1 pack (#112)/28 days + 2 refills	n/a	1 pack (#112)/28 days + 5 refills

HEPATITIS C

Technivie®	n/a	1 pack (#56)/28 days + 2 refills	n/a	n/a

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose and duration of therapy
- Genotype
- Stage of liver disease
- Concurrent medications for drug-interaction assessment
- Difficulty managing blister pack (use or storage) or swallowing 3 large pills (if assessed/anticipated)
- Prior treatment status (i.e. naïve vs experienced) and prior therapies
- If cirrhosis, compensated or decompensated

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of HCV, approve if:
  - Patient is ≥ 13 years old AND
  - Documentation submitted does not indicate that the patient has a life expectancy less than12 months AND
  - Regimen and duration of therapy is appropriate per AASLD/IDSA guidelines (or FDA-approved indications until updated guidelines are released) AND
  - Requested medication is SFHP preferred:

Treatment-naïve

Genotype	Preferred Regimens: non-cirrhotic	Preferred Regimens: compensated cirrhosis
1 (a or b), 4, 5, 6	8 weeks Mavyret™ 12 weeks sofosbuvir/velpatasvir	12 weeks Mavyret™ 12 weeks sofosbuvir/velpatasvir
2, 3	8 weeks Mavyret™ 12 weeks sofosbuvir/velpatasvir	12 weeks Mavyret™ 12 weeks sofosbuvir/velpatasvir *

*For genotype 3, only use if no Y93H resistance

Treatment Experienced, with and without compensated cirrhosis

Failure with PEG-IFN, Ribavirin

Prior Treatment	Genotype	Compensated Cirrhosis?	Preferred Regimen
PEG-IFN + RBV	**1 (a or b), 4, 5, 6**	No	8 weeks Mavyret™, OR 12 weeks sofosbuvir/velpatasvir
		Yes	12 weeks Mavyret™, OR 12 weeks sofosbuvir/velpatasvir
	2	No	8 weeks Mavyret™, OR 12 weeks sofosbuvir/velpatasvir
		Yes	12 weeks Mavyret™, OR 12 weeks sofosbuvir/velpatasvir
	3	No	12 weeks sofosbuvir/velpatasvir (if no Y93H resistance)
		All	16 weeks Mavyret™, OR 12 weeks Vosevi™

Failure with DAA

Genotype	Prior Treatment	Preferred Regimen

HEPATITIS C

1	**NS3 only:** Victrelis® (boceprevir) Olysio® (simeprevir) teleprevir (Incivek®, Oncivo®)	12 weeks Mavyret™, OR 12 weeks sofosbuvir/velpatasvir, OR
	Non-NS5A: Olysio® + Sovaldi®	12 weeks Mavyret™, OR 12 weeks sofosbuvir/velpatasvir (GT1b only)
	NS5A without NS3/4: Epclusa® Harvoni® Daklinza® + Sovaldi®	16 weeks Mavyret™
	NS5A + NS3/4: Zepatier® Viekira Pak®, Viekira XR® Technivie®	12 weeks Vosevi™
2	**Sovaldi® + RBV**	12 weeks Mavyret™, OR 12 weeks sofosbuvir/velpatasvir
	NS5A: Daklinza® Epclusa® Harvoni® Mavyret® Zepatier® Viekira Pak®, Viekira XR® Technivie®	12 weeks Vosevi™
3, 4, 5, 6	**NS5A:** Daklinza® Epclusa® Harvoni® Mavyret® Zepatier® Viekira Pak®, Viekira XR® Technivie®	12 weeks Vosevi™ * *For Genotype 3, add RBV if NS5A failure AND compensated cirrhosis)

Unique Populations

Population	Genotype	Preferred Regimen
Decompensated cirrhosis	1, 4, 5, 6	RBV eligible: 12 weeks sofosbuvir/velpatasvir, RBV ineligible: 24 weeks sofosbuvir/velpatasvir Prior SOF failure: 24 weeks sofosbuvir/velpatasvir + RBV Prior NS5A failure: 24 weeks sofosbuvir/velpatasvir + RBV
	2, 3	RBV eligible: 12 weeks sofosbuvir/velpatasvir + RBV RBV ineligible: 24 weeks sofosbuvir/velpatasvir Prior SOF or NS5A failure: 24 weeks sofosbuvir/velpatasvir + RBV
Recurrent HCV post-transplant	1, 4, 5, 6	With or without compensated cirrhosis: 12 weeks Mavyret™ Decompensated cirrhosis: 12 weeks ledipasvir/sofosbuvir + RBV
	2, 3	With or without compensated cirrhosis: 12 weeks Mavyret Decompensated cirrhosis: 12 weeks sofosbuvir/velpatasvir + RBV
ESRD/eGFR <30*	All	8-16 weeks Mavyret™, duration based on presence of cirrhosis and prior Tx experience (see tables above)

HEPATITIS C

Kidney transplant*	All	12 weeks Mavyret™
	1, 4	12 weeks ledipasvir/sofosbuvir
Children (with and without compensated cirrhosis)	1	Treatment-naïve: 12 weeks ledipasvir/sofosbuvir Treatment-experienced: -No cirrhosis: 12 weeks ledipasvir/sofosbuvir -Compensated cirrhosis: 24 weeks ledipasvir/sofosbuvir
	2	12 weeks Sovaldi® + RBV
	3	24 weeks Sovaldi® + RBV
	4-6	12 weeks ledipasvir/sofosbuvir

Non-preferred agents may be considered for patients unable to use preferred agents above due to failure/intolerance/contraindication.

- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:
- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- Requested regimen and duration is appropriate per AASLD/IDSA guidelines

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:
- Extension of therapy is supported by AASLD/IDSA guidelines

References:

- DHCS Treatment Policy for the Management of Chronic Hepatitis C. 07/01/2018. http://www.dhcs.ca.gov/Documents/DHCS_Hep_C_Policy_7_1_18.pdf.
- AASLD-IDSA. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. https://www.hcvguidelines.org/. Updated 5/24/2018. Accessed 12/11/2018.

Last review/revision date: 1/2019

Infectious Disease: HIV

FUZEON® (ENFUVIRTIDE)
Standard/Specific Therapeutic Class: *Antivirals, HIV-Specific, Fusion Inhibitors* **Formulary Status:** Formulary, PA required
Coverage Duration: • **Initial:** 16 weeks • **Re-approval:** 6 months
Diagnosis Considered for Coverage: • Documented HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescriber Restriction: • Infectious disease or HIV specialist
Clinical Information Required for Review: **Initial approval:** • Genotype/phenotype testing • Prior treatment regimens and evidence of failure • Current therapy and documentation of necessity for Fuzeon® • Adherence level on taking anti-retroviral therapy (>80%) • Documentation of pretreatment CD4 count and viral RNA **Re-authorization:** • Current background drug therapy • Viral load after 12 weeks or CD4 count • After initial reauthorization: CD4 count and HIV RNA viral load
Coverage Criteria (for Healthy Kids HMO and Healthy Workers HMO only) **FOR ADULTS** **I. Initiation of Therapy:** • For HIV: o Documented treatment failure of at least one sensitivity-assisted antiretroviral therapy regimen and at least two drug regimens that included two different NRTIs and two or more PIs, OR patient has documented reason for not trying two drug regimens that included two different NRTIs and two or more PIs AND o Genotype and phenotype testing (within 30 days of request) to determine optimal regimen and eliminate ineffective agents AND o If the patient is currently using Stribild® (elvitegravir/cobicistat/emtricitabine/tenofovir), Triumeq® (abacavir/dolutegravir/lamivudine), Complera® (emtricitabine/rilpivirine/tenofovir) or Atripla® (efavirenz/emtricitabine/tenofovir), documentation of medical necessity for utilizing Fuzeon® in combination with these agents AND o Documented adherence level on taking anti-retroviral therapy >80% and any issue that may have caused decreased adherence in the past (e.g. drug, alcohol abuse, difficulty of dosing schedule, etc.) has been addressed AND o Documentation of pretreatment CD4 count and viral RNA • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR

FUZEON® (ENFUVIRTIDE)

- Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Documentation of current background drug therapy (Fuzeon® not recommended as monotherapy or to be used without optimal oral therapy)
- First reauthorization: documentation of viral load decrease of at least a one-log from baseline after 12 weeks or documented clinical improvement (i.e., increased CD4 count)
- After initial reauthorization: documentation of current (within the past 30 days) CD4 count and HIV RNA viral load
- If there is an increase of ≥2 log in viral load or 30% decline in CD4 counts from baseline, current (within last 30 days) phenotype/genotype testing must be submitted to indicate continued susceptibility of HIV to Fuzeon®

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Documentation of current background drug therapy (Fuzeon® not recommended as monotherapy or to be used without optimal oral therapy) AND
- First reauthorization: documentation of viral load decrease of at least a one-log from baseline after 12 weeks or documented clinical improvement (i.e., increased CD4 count) AND
- After initial reauthorization: documentation of current (within the past 30 days) CD4 count and HIV RNA viral load AND
- If there is an increase of ≥2 log in viral load or 30% decline in CD4 counts from baseline, current (within last 30 days) phenotype/genotype testing must be submitted to indicate continued susceptibility of HIV to Fuzeon®

FOR CHILDREN

I. Initiation of Therapy:

- For HIV:
  - Documentation that the patient is pre-pubertal (if post-pubertal, use adult criteria) AND
  - Documented treatment failure to at least one sensitivity-assisted antiretroviral therapy regimen and at least two drug regimens that included two different NRTIs and two or more PIs, OR patient has documented reason for not trying two drug regimens that included two different NRTIs and two or more PIs AND
  - If the patient is currently using Stribild® (elvitegravir/cobicistat/emtricitabine/tenofovir), Triumeq® (abacavir/dolutegravir/lamivudine), Complera® (emtricitabine/rilpivirine/tenofovir) or Atripla® (efavirenz/emtricitabine/tenofovir), documentation of medical necessity for utilizing Fuzeon® in combination with these agents AND
  - Genotype and phenotype testing (within 30 days of request) to determine optimal regimen and eliminate ineffective agents AND
  - Documented adherence level on anti-retroviral therapy >80% and any issue that may have cause decreased adherence in the past (difficulty of dosing schedule, etc.) has been addressed AND
  - Documentation of pretreatment CD4 count and viral RNA
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Documentation of current background drug therapy (Fuzeon® not recommended as monotherapy or to be used without optimal oral therapy) AND
- First reauthorization: documentation of viral load decrease of at least a one-log from baseline after 12 weeks or

FUZEON® (ENFUVIRTIDE)
documented clinical improvement (i.e., increased CD4 count) AND • Documentation of current (within the past 30 days) CD4 count and HIV RNA viral load AND • If there is an increase of ≥2 log in viral load or 30% decline in CD4 counts from baseline, current (within last 30 days) phenotype/genotype testing must be submitted to indicate continued susceptibility of HIV to Fuzeon® **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if**:** • Documentation of current background drug therapy (Fuzeon® not recommended as monotherapy or to be used without optimal oral therapy) AND • First reauthorization: documentation of viral load decrease of at least a one-log from baseline after 12 weeks or documented clinical improvement (i.e., increased CD4 count) AND • Documentation of current (within the past 30 days) CD4 count and HIV RNA viral load AND • If there is an increase of ≥2 log in viral load or 30% decline in CD4 counts from baseline, current (within last 30 days) phenotype/genotype testing must be submitted to indicate continued susceptibility of HIV to Fuzeon®
References: • Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed: February 22, 2018.
Last review/revision date: 4/2018

HIV MEDICATIONS

Standard/Specific Therapeutic Class: *Antivirals*
Formulary Status: **[HEALTHY KIDS HMO only]**

- Formulary:
  - didanosine (Videx® EC) DR capsule and Videx® (didanosine) oral solution
  - lamivudine (Epivir®) oral solution
  - tenofovir disoproxil fumarate (Viread®) 300mg tablet ONLY (see below for remaining strengths)
  - zidovudine (Retrovir®) capsule, tablet and syrup
- Formulary, PA required:
  - abacavir (Ziagen®) tablet and oral solution
  - abacavir/lamivudine (Epzicom®) tablet
  - abacavir/lamivudine/zidovudine (Trizivir®) tablet
  - Aptivus® (tipranavir) capsule and oral solution
  - atazanavir sulfate (Reyataz®) capsule
  - Atripla® (efavirenz/emtricitabine/tenofovir) tablet
  - Complera® (emtricitabine/rilpivirine/tenofovir) tablet
  - Crixivan® (indinavir) capsule
  - Descovy® (emtricitabine/tenofovir AF) tablet
  - Edurant® (rilpivirine) tablet
  - Emtriva® (emtricitabine) capsule and oral solution
  - fosamprenavir calcium (Lexiva®) tablet and oral suspension
  - Genvoya® (elvitegravir/cobicistat/emtricitabine/tenofovir AF) tablet
  - Intelence® (etravirine) tablet
  - Invirase® (saquinavir) tablet and capsule
  - Isentress® (raltegravir) tablet, chewable tablet, and powder pack
  - Kaletra® (lopinavir/ritonavir) tablet and oral solution
  - lamivudine (Epivir®) tablet
  - lamivudine/zidovudine (Combivir®) tablet
  - nevirapine tablet and oral suspension (Viramune) and ER tablet (Viramune XR®)
  - Norvir® (ritonavir) tablet, sofftgel capsule and oral solution
  - Odefsey® (emtricitabine/rilpivirine/tenofovir AF) tablet
  - Prezcobix® (darunavir/cobicistat) tablet
  - Prezista® (darunavir) tablet
  - Rescriptor® (delavirdine) tablet and dispersible tablet
  - Selzentry® (maraviroc) tablet
  - stavudine (Zerit®) capsule and oral solution
  - Stribild® (elvitegravir/cobicistat/emtricitabine/tenofovir DF) tablet
  - Sustiva® (efavirenz) tablet and efavirenz (Sustiva®) capsule
  - Tivicay® (dolutegravir) tablet
  - Triumeq® (abacavir/dolutegravir/lamivudine) tablet
  - Truvada® (emtricitabine/tenofovir DF) tablet
  - Viracept® (nelfinavir) tablet
  - Viread® (tenofovir disoproxil fumarate) 150, 200, 250mg tablet and 40mg/scoop powder
- Non-formulary:
  - Biktarvy® (bictegravir/emtricitabine/tenofovir AF) tablet
  - Evotaz® (atazanavir/cobicistat) tablet
  - Juluca® (dolutegravir/rilpivirine) tablet
  - Prezista® (darunavir) oral suspension

HIV MEDICATIONS

- Reyataz® (atazanavir) powder pack
- Selzentry® (maraviroc) oral solution
- Tybost® (cobicistat) tablet

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- HIV
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Prescriber: Restricted to infectious disease or HIV specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For formulary medications for **HIV,** approve
- For **non-formulary solid oral dosage forms** for HIV, approve if:
  - Documented trial and failure, intolerance, contraindication, or inability to use at least one formulary first line regimen per DHHS guidelines AND
  - Requested regimen is within FDA-approved and/or guideline-recommended dosing
- For **non-formulary non-solid oral dosage forms** for HIV, approve if:
  - Documented trial and failure, intolerance, contraindication, or inability to at least one first line regimen per guidelines AND
  - Requested regimen is within FDA-approved and/or guideline-recommended dosing AND
  - Documented inability to tolerate/comply with solid oral dosage forms
- For Fuzeon® (enfuvirtide), see separate drug-specific criteria
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 4/2018

Infectious Disease: Tuberculosis

SIRTURO® (BEDAQUILINE)
Standard/Specific Therapeutic Class: *TB Preparations, Antitubercular Antibiotics* **Formulary Status:** Formulary, PA required
Coverage Duration: Up to 2 years
Diagnosis Considered for Coverage: • Laboratory-confirmed pulmonary multi-drug resistant (MDR) tuberculosis • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: 100 mg tablet: #56 per 14 days for 1 fill (400 mg once daily for 2 weeks), then #504 per 84 days for 2 years (200 mg three times weekly) **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis confirmed by laboratory results • Previous therapy • Dose
Coverage Criteria: **I. Initiation of Therapy:** • For MDR tuberculosis, approve if: o Diagnosis is laboratory confirmed pulmonary multi-drug resistant (MDR) tuberculosis (TB) with an isolate showing genotypic or phenotypic resistance to both INH and RIF AND o Effective treatment regimen cannot otherwise be provided (e.g. fluoroquinolones, linezolid, capreomycin/amikacin) • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Medical justification provided for continuation of therapy beyond 2 years
References: • Provisional CDC Guidelines for the Use and Safety Monitoring of Bedaquiline Fumarate (Sirturo) for the treatment of Multidrug-Resistant Tuberculosis.
Last review/revision date: 10/2018

Neurology: Multiple Sclerosis

MULTIPLE SCLEROSIS

Standard/Specific Therapeutic Class: *Miscellaneous, Agents to Treat Multiple Sclerosis*

Formulary Status:

- Formulary, PA required:
  - glatiramer acetate (Copaxone®, Glatopa®) – **preferred injectable**
  - Tecfidera® (dimethyl fumarate)
  - Gilenya® (fingolimod)
  - Avonex® (interferon beta-1a)
  - Rebif® (interferon beta-1a)
  - Betaseron® (interferon beta-1b)
  - Extavia® (interferon beta-1b)
- Non-formulary:
  - Plegridy® (peginterferon beta-1a)
  - Aubagio® (teriflunomide)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Multiple Sclerosis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit *
  - glatiramer acetate
    - 20 mg: #30 mL/30 days
    - 40 mg: #12 mL/28 days
  - Tecfidera®: #60 per 30 days
  - Gilenya®: #30 per 30 days
  - Avonex®: #30mcg weekly (IM)
  - Rebif®: #6 mL (12 syringes) per 28 days
  - Betaseron®: #1 kit (14 vials) per 30 days
  - Extavia®: #1 kit (15 syringes) per 30 days
  - Plegridy® syringe, pen: #2 syringes or pens per 30 days
  - Aubagio®: #28 per 28 days
- Prescriber Restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For multiple sclerosis, approve if:
  - Patient has relapsing/remitting MS (RRMS) or secondary progressive MS (SPMS) with a relapsing element AND
  - The medication is being recommended and/or prescribed by a neurologist at an FDA approved dosage AND
  - For ***Rebif®, Betaseron®, Extavia®, Plegridy®, Plegridy Pen®, Avonex®***, the member has:

MULTIPLE SCLEROSIS
▪ Documented treatment failure to 6 months of therapy with **one preferred agent** OR ▪ Medical reason for not taking **glatiramer** for a minimum of 6 months (e.g. intolerance, hypersensitivity, contraindication, etc.) o For ***Aubagio***®, the member has: ▪ Documented treatment failure to 6 months of therapy with **Gilenya**® **OR Tecfidera**® ▪ Medical reason for not taking **Gilenya**® **or Tecfidera**® for a minimum of 6 months (e.g. intolerance, hypersensitivity, contraindication, etc.) • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 1/2019

DALFAMPRIDINE (AMPYRA®)

Standard/Specific Therapeutic Class: *Agents To Treat Neuromuscular Transmission Disorder, Potassium Channel Blocker*
Formulary Status: Formulary, PA required

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Multiple Sclerosis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Prescriber Restriction: Neurologist
- Quantity Limit*: #60 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Current therapy
- Comorbidities

Coverage Criteria:

I. Initiation of Therapy:

- For multiple sclerosis (MS), approve if:
  - Patient is ambulatory (able to walk at least 25 feet) AND
  - Patient has walking impairment
- For diagnosis of relapse-remitting MS only:
  - Documentation was submitted (consistent with pharmacy claims data or chart notes) that patient is currently being treated for MS (e.g. immunomodulator, interferon, immunosuppressive) OR
  - Documentation of a medical reason (intolerance, hypersensitivity) as to why patient is unable to use one of these agents to treat their medical condition
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 1/2019

Neurology: Parkinson Disease

TOLCAPONE (TASMAR®)
Standard/Specific Therapeutic Class: *Antiparkinson, Antiparkinsonism Drug, Other* **Formulary Status:** Formulary, PA required
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Parkinson's Disease • Other Diagnoses: follow off-label criteria
Prescribing Restriction: • Quantity Limit*: #270 per 90 days • Prescriber restriction: neurology follow-up **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Previous therapy • Dose
Coverage Criteria: **I. Initiation of Therapy:** • For diagnosis of **Parkinson's disease**, approve if: o Patient is being followed by a neurologist AND o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: **carbidopa/levodopa/entacapone or entacapone** AND o Carbidopa/levodopa is taken concurrently with tolcapone • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 1/2019

Neurology: Narcolepsy

MODAFINIL (PROVIGIL®) AND ARMODAFINIL (NUVIGIL®)

Standard/Specific Therapeutic Class: *Psychostimulants-antidepressants, Narcolepsy and Sleep Disorder Therapy Agents*
Formulary Status: Formulary, PA required

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Narcolepsy, excessive sleepiness due to obstructive sleep apnea/hypopnea syndrome (OSAHS), shift work sleep disorder (SWSD), fatigue/sleepiness due to multiple sclerosis (MS), depression
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #90 per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **narcolepsy**, approve if:
  - **Sleep study** has been done to confirm diagnosis of narcolepsy
- For diagnosis of **excessive sleepiness due to obstructive sleep apnea/hypopnea syndrome (OSAHS)**, approve if:
  - Documentation of trial and failure or inability to use: **continuous positive airway pressure (CPAP) therapy**
- For diagnosis of **depression** (augmentation), approve if:
  - Patient is currently being treated for depression (**SSRI**, **SNRI**, **TCA**, etc.) with persistent fatigue
- For diagnosis of **shift work sleep disorder (SWSD)** approve
- For diagnosis of **fatigue/sleepiness due to multiple sclerosis (MS)** approve
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 1/2019

SODIUM OXYBATE (XYREM®)

Standard/Specific Therapeutic Class: *Sedative Non-barbituate, Anti-narcolepsy & Anti-cataplexy Sefative Type Agonist*
Formulary Status: Non-formulary

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Narcolepsy, Treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: FDA-approved dosing limits (maximum 9 g per night)
- Prescriber restriction: Prescribed by or in consultation with a neurologist or sleep specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **narcolepsy with excessive daytime sleepiness**, approve if:
  - Patient is ≥ 18 years of age AND
  - Sleep study has been done to confirm diagnosis of narcolepsy AND
  - If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use the formulary alternatives: **at least two formulary stimulants** AND
  - Medication is being prescribed at an FDA approved dose
- For diagnosis of **narcolepsy with cataplexy**, approve if:
  - Patient is ≥ 18 years of age AND
  - Sleep study has been done to confirm diagnosis of narcolepsy AND
  - If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment AND
  - At least two of the following: formulary SSRI, formulary TCA, or venlafaxine AND
  - Medication is being prescribed at an FDA approved dose
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND

SODIUM OXYBATE (XYREM®)
• The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria • Medical justification provided for continuation of therapy **III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication),** approve if: • Documentation has been submitted indicating patient has clinically benefited from treatment (i.e. improvement on Epworth Sleepiness score) AND • Medication is being prescribed at an FDA approved dose AND • For cataplexy, documentation has been provided that there has been a reduction in frequency of cataplexy attacks
References: • FDA approves new treatment of cataplexy and excessive daytime sleepiness in pediatric patients with narcolepsy- Drug Information Update [news release]. Silver Spring, MD; October 26, 2018: FDA Division of Drug Information. • Xyrem (sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; 2018.
Last review/revision date: 1/2019

Neurology: Neuromuscular Disordrers

DRUGS FOR MOVEMENT DISORDERS

Standard/Specific Therapeutic Class: *Miscellaneous, Drugs to Treat Movement Disorders*
Formulary Status:
Formulary, PA required:

- Tetrabenazine (Xenazine®)
- Austedo® (deutetrabenazine)
- Ingrezza™ (valbenazine)

Coverage Duration:
Initial: 3 months; Re-authorization: 1 year

Diagnosis Considered for Coverage:

- Chorea associated with Huntington's disease (tetrabenazine, Austedo®)
- Moderate to severe tardive dyskinesia (Austedo®, Ingrezza™)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - tetrabenazine, Austedo®: #120/30 days
  - Ingrezza™: #30/30 days
- Prescriber restriction: neurologist or psychiatrist (if patient has Hx of depression, documentation of psychiatrist consult)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy
- History of depression, congenital long QT syndrome or cardiac arrhythmias

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **chorea associated with Huntington's disease**:
  - For **tetrabenazine**, approve if
    - Physician attests that patient has had a baseline electrocardiogram (EKG) and is aware of the possible risk of QT prolongation AND
    - Documentation of baseline Total Maximal Chorea (TMC) score ≥ 8, or Total Functional Capacity (TFC) score ≥ 5 from UHDRS has been provided with the request AND
    - Dose is within FDA approved limits
  - For **Austedo®**, approve if:
    - Physician attests that patient has had a baseline electrocardiogram (EKG) and is aware of the possible risk of QT prolongation AND
    - Documentation of baseline Total Maximal Chorea (TMC) score ≥ 8, or Total Functional Capacity (TFC) score ≥ 5.from UHDRS has been provided with the request AND
    - Documentation of trial and failure of, intolerance of, contraindication to, or inability to use tetrabenazine, AND
    - Dose is within FDA approved limits
- For diagnosis of **moderate to severe tardive dyskinesia**:
  - For **Austedo®,** approve if:
    - Documented baseline evaluation with one of the following scoring tools: Abnormal Involuntary

DRUGS FOR MOVEMENT DISORDERS

Movement Scale (AIMS) > 10 OR Extrapyramidal Symptom Rating Scale (ESRS) > 20 AND
    - Dose is within FDA approved limits
  - For **Ingrezza™,** approve if:
    - Documented baseline evaluation with one of the following scoring tools: Abnormal Involuntary Movement Scale (AIMS) > 10 OR Extrapyramidal Symptom Rating Scale (ESRS) > 20 AND
    - Documentation of trial and failure of, intolerance of, contraindication to, or inability to use Austedo® AND
    - Dose is within FDA approved limits
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- For diagnosis of chorea associated with Huntington's disease:
  - Documentation was provided that demonstrates clinical symptom improvement (i.e. reduction of total chorea score from UHDRS) AND
  - Dose is appropriate
- For diagnosis of moderate to severe tardive dyskinesia:
  - Documentation was provided that demonstrates improvement in AIMS or ESRS scores AND
  - Dose is appropriate

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- For diagnosis of chorea associated with Huntington's disease:
  - Documentation was provided that demonstrates clinical symptom improvement (i.e., reduction of total chorea score from UHDRS) AND
  - Dose is appropriate
- For diagnosis of moderate to severe tardive dyskinesia:
  - Documentation was provided that demonstrates improvement in AIMS or ESRS scores AND
  - Dose is appropriate

References: N/A

Last review/revision date: 10/2018

NUEDEXTA® (DEXTROMETHORPHAN/QUINIDINE)
Standard/Specific Therapeutic Class: *NMDA receptor antagonist and sigma-1 agonist/CYP450 2D6 inhibitor* **Formulary Status:** Formulary, PA required
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Pseudobulbar Affect (PBA) secondary to amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity*: o 60 capsules/30 days • Prescriber: Restricted to neurologist **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Dose
Coverage Criteria: **I. Initiation of Therapy:** • For **diagnosis of Pseudobulbar Affect (PBA) due to ALS or MS,** approve • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 4/2018

Nutrition

PHOSPHATE BINDERS

Standard/Specific Therapeutic Class: *Electrolytes & Miscellaneous Nutrients, Electrolyte Depleters*

Formulary Status:

- Formulary: calcium acetate 667 mg caps/tabs, solution (Eliphos®, Calphron®, Phoslyra®)
- Formulary, PA required
  - sevelamer carbonate (Renvela®)
  - lanthanum (Fosrenol®) chewable tablets
  - Auryxia® (ferric citrate) 210mg tablets
  - Velphoro® (sucroferric oxyhydroxide) 500 mg chewable tablet
- Non-formulary: Renagel® (sevelamer chloride) 400, 800 mg tabs

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Hyperphosphatemia with end stage renal disease
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - lanthanum chew tablets: 500 mg #90 per 30 days; 750 mg #90 per 30 days; 1000 #90 per 30 days
  - sevelamer
    - tablets: #540 per 30 days;
    - packets: 0.8 grams: #180 per 30 days; 2.4 grams: #90 per 30 days
  - Renagel®: #270 per 30 days
  - Auryxia®: #360 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose, previous therapy

Coverage Criteria:

I. Initiation of Therapy, approve if:

- For hyperphosphatemia with ESRD, approve if:
  - Patient meets **ONE** of the following AND
    - Phosphate level > 5.5 mg/dl on **calcium acetate** 667 mg 3 tablets TID OR
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **calcium acetate** due to hypercalcemia (calcium > 9.5 mg/dl) OR
    - Corrected calcium level > 9.5 mg/dl or CalPhos product > 55 OR
    - Calcium level is 8.4-9.5 mg/dl WITH adynamic bone disease, low PTH levels or vascular calcification
  - For **Renagel®**: trial and failure or inability to use **Renvela® 800 mg tablet AND Fosrenol®**
  - For **Renvela® packets**: inability to use Renvela® tablets
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR

PHOSPHATE BINDERS
o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND • For **Renvela® 800 mg tablet** and **Fosrenol®**: patient is stable and continuing the medication • For **Renagel®**: patient is unable to use Renvela® • For **Renvela® packets**: inability to use Renvela® tablets
References: • K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. American Journal of Kidney Diseases. Vol 24, No 4, Suppl 3, October 2013. Available at https://www.kidney.org/sites/default/files/docs/boneguidelines.pdf. • KDIGO Clinical Practice Guidelines for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. Kidney Int Suppl. 2009.
Last review/revision date: 10/2018

ENTERAL NUTRITION PRODUCTS

Standard/Specific Therapeutic Class: *Electrolytes & Miscellaneous Nutrients; Miscellaneous Dietary Supplements*
Formulary Status: Formulary, PA required **(Applies to Medi-Cal and Medicare/Medi-Cal only)**

Coverage Duration: 6 months for all indications except indefinite where chronic tube feeding is needed (e.g. short gut syndrome, severe cerebral palsy or other chronic encephalopathy)

Diagnosis Considered for Coverage:

- In adults: weight loss
- In children: failure to thrive

Prescribing Restriction:

- Quantity Limit*
  - Liquid #21,330 mL per 30 days (3 cans of 237mL/can per day)
  - Powder #4,540 grams per 30 days (32oz or 153.6gm per day; 10 cans of 454 gm/can)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Weight documentation (e.g. BMI, recent weight trends, etc)
- Volume

Coverage Criteria: (Applies to Medi-Cal and Medicare/Medi-Cal only)

I. Initiation of Therapy, approve if:

- Documentation is dated within 3 months of the request AND
- For **Standard Products** (e.g. Ensure, Pediasure, Jevity, Osmolite, Duocal, Boost, Compleat, Isosource, Nutren) ONE of the following applies:
  - For members ≥ 21 years of age:
    - There is documented medical condition AND
    - There is inability to meet nutritional needs with dietary adjustment or altered-consistency (soft/pureed) foods (e.g. member has decreased nutritional intake due to cancer diagnosis) AND
    - There are clinical indicators of nutritional risk (see def inition below)

      Nutritional risk is defined as:
      - ***Involuntary weight loss ≥ 10% of usual body weight within 6 months***
      - ***Involuntary weight loss ≥ 7.5% of usual body weight within 3 months***
      - ***Involuntary weight loss ≥ 5% of usual body weight in 1 month***
      - ***BMI < 18.5 kg/m2***
  - OR, for members < 21 years of age:
    - Diagnosis of failure to thrive AND
    - For children 12-24 months:
    - Weight ≤ 3rd percentile OR
    - Weight ≤ 5th percentile AND one of the following:
      - Product is recommended by GI specialist or nutrition specialist OR
      - Patient has a physiological or behavioral disorder responsible for low weight
    - For children and adolescents 2-20 years of age:
    - Weight ≤ 5th percentile
  - OR there is documentation of severe swallowing or chewing difficulty (e.g. due to cancer in the mouth/throat/esophagus, injury/trauma/surgery/radiation therapy in head or neck, chronic neurological disorders, severe craniofacial anomalies) OR
  - There is documented medical diagnosis requiring enteral nutrition products administered via feeding tube OR

ENTERAL NUTRITION PRODUCTS

- Member is transitioning from parenteral or enteral tube feeding to oral diet

- For **Specialized Enteral Products**, approve if:
  - Criteria for Standard Products listed above are met AND
  - For diabetic products (e.g. Glucerna, Boost Glucose Control, Diabetisource Ac, Glytrol): there is documented diagnosis of hyperglycemia or diabetes OR
  - For renal products (e.g. Nepro with Carb Steady, Suplena with Carb Steady, Novasource Renal, Renalcal, Renastart): there is documented diagnosis of chronic renal disease or abnormal renal indicators within 6 months of the request (e.g. blood serum potassium, BUN, urine creatinine, GFR) OR
  - For hepatic products (e.g. Nutrihep): there is documented liver disease or abnormal LFTs within 6 months of the request OR
  - For carbohydrate modular products (e.g. Benecalorie, Duocal, Sol Carb): there is inability to meet caloric nutritional need with current use of an enteral nutrition product OR
  - For lipid(fat) modular products (e.g. MICROLIPID, Duocal, Liquigen, Lipistart): there is documented diagnosis of inability to digest or absorb conventional fats or uncontrolled seizure disorder that cannot be medically managed OR
  - For protein modular products (e.g. Promod, Porteinex, BENEPROTEIN, Pro-Stat): there is documented inability to meet protein requirement with current use of high protein enteral nutrition product
- For **Elemental and Semi-elemental Enteral Products** (e.g. PediaSure Peptide, EleCare Jr, Perative, Pivot, Vital, Impact, Peptamen, Vivonex, Neocate Jr.) approve if there is documentation of one of the following:
  - Intestinal malabsorption diagnosis (ICD-10-CM codes K90.0 – K90.9 and K91.2) OR
  - Chronic medical diagnosis with trial and failure or contraindication to specialized disease-specific enteral nutrition product AND inability to absorb nutrients or tolerate intact protein that cannot be medically managed
- For **Metabolic Products** (e.g. PhenylAde, Lophlex, Milupa, PKU), approve if:
  - Documentation is dated within 6 months of the time of request AND
  - Diagnosis of inborn errors of metabolism (see DHCS Criteria in the reference section for ICD-10 codes)

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- Continuation of therapy is medically necessary (e.g. weight still below goal or therapy is needed to maintain healthy weight)

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Continuation of therapy is medically necessary (e.g. weight still below goal or therapy is needed to maintain healthy weight)

References:

- California Department of Health Care Services 4TUMedical Criteria for Enteral Nutrition Products.

Last review/revision date: 10/2018

SPECIALTY INFANT/TODDLER ENTERAL PRODUCTS

Standard/Specific Therapeutic Class: *Infant Formulas*

Formulary Status: Formulary, PA required

Coverage Duration:

Premature infants:
Initial: up to 6 months of corrected age
Re-auth: up to 1 year of corrected age
Cow milk protein allergy: up to max age of use per product labeling

Diagnosis Considered for Coverage:

- Prematurity
- Cow milk allergy

Prescribing Restriction:

- Quantity Limit*
  - Liquid: up to #42,660 mL per 30 days (180 cans per 30 days (237 ml per can))
  - Powder: up to #9,080 grams per 30 days (64 ounces per day (4.5 grams per ounce of formula; quantity in grams per can differs by product))

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For products for **premature infants** (e.g. EnfaCare, Enfamil Premature, Gerber Good Start Premature, Similac NeoSure, Similac Special Care), approve if:
  - Documentation of gestational age (< 37 weeks) or birth weight less than 2500 grams AND
  - Member is less than one year of corrected age AND
  - For Alimentum, Pregestimil, Nutramigen: cow milk protein allergy (e.g. blood in stool, eczema) AND inability to use non-cow's milk protein-based formula (i.e. soy based formula)
- For products for **cow milk protein allergy** (e.g. Similac Alimentum, Pregestimil, Nutramigen, Gerber Good Start Extensive HA), approve if:
  - Member is appropriate age for the requested product per product labeling AND
  - There is documentation of cow milk protein allergy AND
  - There is documentation of inability to use non-cow's milk protein-based formula (e.g. soy based formula)

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- There is documented justification for why continuation of therapy is medically necessary

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- There is documented justification for why continuation of therapy is medically necessary

References:

- Vandeplas Y. et al. Guidelines for the diagnosis and management of cow's milk protein allergy in infants. Arch Dis Child. 2007 Oct; 92(10): 902–908.
- LaHood A, et al. Outpatient Care of the Premature Infant Am Fam Physician. 2007 Oct 15;76(8):1159-1164.
- California Department of Health Care Services 4TUMedical Criteria for Enteral Nutrition Products. Updated May 2017. Accessed 9/11 2018.

SPECIALTY INFANT/TODDLER ENTERAL PRODUCTS
Last review/revision date: 10/2018

ENDARI™ (L-GLUTAMINE)

Standard/Specific Therapeutic Class: *Protein lysates, Nutritional therapy, medical condition special formulation*
Formulary Status: Formulary, prior authorization required

Coverage Duration: 12 months

Diagnosis Considered for Coverage:

- Sickle cell disease
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity*:
  - Weight < 30 kg: 60 packets per 30 days
  - Weight 30 to 65 kg: 120 packets per 30 days
  - Weight > 65 kg: 180 packets per 30 days
- Prescriber: Restricted to hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **diagnosis of sickle cell disease,** approve if:
  - Documentation provided that patient had 2 or more crises in the last 12 months
  - Documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use hydroxyurea at the maximum tolerated dose with compliance per submitted documentation or refill history within the last 6 months (or medical reason was provided why patient is unable to use hydroxyurea)
  - Request is for an FDA approved dose
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Prescriber attests member had reduction in the number of sickle cell crises

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Prescriber attests member had reduction in the number of sickle cell crises
- Request is for an FDA approved dose

References: N/A

Last review/revision date: 1/2019

OBGYN

ENDOMETRIN® (PROGESTERONE) VAGINAL INSERTS
Standard/Specific Therapeutic Class: *Other Hormones/Pregnancy Facilitating/Maintaining Agent, Hormonal* **Formulary Status:** Formulary, PA
Coverage Duration: Through 36th week of gestation
Diagnosis Considered for Coverage: • Luteal Phase Support (off-label) • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies • **EXCLUDED INDICATION: To support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an Assisted Reproductive Technology (ART) treatment program for infertile women (labeled indication)**
Prescribing Restriction: • Quantity Limit*: 60 inserts per 30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Gestational age or estimated delivery date
Coverage Criteria: **I. Initiation of Therapy:** • For indication of **Luteal Phase Support**, approve if: o Medication is used to prevent preterm birth in patients with a history of previous preterm birth or short cervix (< 15 mm at 22–26 weeks) AND o Therapy will be started after 20 weeks of gestation AND o There is a documented reason for not using other progesterone formulations (e.g. IM injection) • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months): • Refer to "Initiation of Therapy" section
References: • Endometrin® Prescribing Information. • Romero R, Yeo L, Chaemsaithong P, Chaiworapongsa T, Hassan S. Progesterone to prevent spontaneous preterm birth. Seminars in fetal & neonatal medicine. 2014;19(1):15-26. doi:10.1016/j.siny.2013.10.004. PMCID: PMC3934502. • Check JH. Luteal Phase Support in assisted reproductive technology treatment: focus on Endometrin® (progesterone) vaginal insert. Therapeutics and Clinical Risk Management. 2009;5:403-407. PMCID: PMC2695240. • Beltsos AN, Sanchez MD, Doody KJ, Bush MR, Domar AD, Collins MG. Patients' administration preferences: progesterone vaginal insert (Endometrin®) compared to intramuscular progesterone for Luteal phase support. Reproductive Health. 2014;11:78. doi:10.1186/1742-4755-11-78. PMCID: PMC4414383. • Farine D. The Use of Progesterone for Prevention of Preterm Birth. J Obstet Gynaecol Can 2008;30(1):67–71. • Cahill AG, Odibo AO, Caughey AB, et al. Universal cervical length screening and treatment with vaginal progesterone to prevent

ENDOMETRIN® (PROGESTERONE) VAGINAL INSERTS
preterm birth: a decision and economic analysis. Am J Obstet Gynecol. 2010;202:548 e1–548 e8. [PMC free article] [PubMed] • Werner EF, Han CS, Pettker CM, et al. Universal cervical-length screening to prevent preterm birth: a cost-effectiveness analysis. Ultrasound Obstet Gynecol. 2011;38:32–37. [PubMed]
Last review/revision date: 10/2018

MAKENA® (HYDROXYPROGESTERONE CAPROATE)

Therapeutic Class: *Obstetrics/ Gynecology: Labor Suppression/Tocolytics*

Formulary Status: Formulary, PA required

Coverage Duration: Up to 37 weeks of gestation

Diagnosis Considered for Coverage:

- Preterm birth prevention
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Multi-dose vial: #5 mL per 35 days
  - Single-dose vial: #4 single-dose vials per 28 days
  - SC auto-injector: #4 injectors (4.4mL) per 28 days

Clinical Information Required for Review:

- Past medical history of preterm birth
- Time of treatment initiation (i.e. gestation age)

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **preterm birth prevention**, approve if:
  - Patient is 16 years of age or older
  - History of previous spontaneous preterm birth before 37 weeks gestation
  - Treatment to be started between 16 weeks 0 days gestation and 20 weeks 6 days gestation
  - Documented expected delivery date or current gestational age provided with request
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND
- Duration not to exceed 37 weeks of gestation

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Therapy past 37 weeks of gestation is not covered

References:

- González-Quintero VH, Istwan NB, Rhea DJ, Smarkusky L, Hoffman MC, Stanziano GJ. Gestational age at initiation of 17-hydroxyprogesterone caproate (17P) and recurrent preterm delivery. J Matern Fetal Neonatal Med. 2007 Mar;20(3):249-52. PMID:

17437227.
- Makena® [package insert]. AMAG Pharmaceuticals, Inc. Waltham, MA 02451
- How, HY, et al. Prophylaxis with 17 alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age at initiation of treatment matter? American Journal of Obstetrics & Gynecology, September 2007. 260e1.

Last review/revision date: 1/2019

GONADOTROPIN RELEASING HORMONE (GnRH) AGONISTS- OBSTETRIC

Standard/Specific Therapeutic Class: *LHRH (GNRH) Agonist Analogue Pituitary Suppressants, LHRH (GNRH) Agonist Analogue And Progestin Combinations*

Formulary Status:

- Formulary, PA required:
  - Lupron Depot® (leuprolide acetate) 3.75 (1 mo), 11.25 (3 mos) intramuscular injection
  - Synarel® (histrelin) nasal spray
- Non-formulary:
  - Lupaneta® Pack (leuprolide/norethindrone) kit

Coverage Duration: 6 months

Diagnosis Considered for Coverage:

- Endometriosis/uterine fibroids
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

(*for pediatric indications and products, see GONADOTROPIN RELEASING HORMONE (GnRH) AGONISTS- PEDIATRIC Criteria**)***

Prescribing Restriction:

- Quantity Limit:
- Lupron Depot:
  - 3.75mg 1-month kit: #1 per 30 days
  - 11.25mg 3-month kit: #1 per 90 days
- Synarel®: 12mL per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **endometriosis,** approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **combined oral contraceptive or progestin** AND
  - For **Synarel®**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use injectable GnRH agonist
  - For **Lupaneta® Pack**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use Lupron Depot® and norethindrone tablets
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND

GONADOTROPIN RELEASING HORMONE (GnRH) AGONISTS- OBSTETRIC
• Maximum 12 months total duration as indicated for endometriosis (6 months initial and 6 months retreatment) **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • There is documentation of endometriosis symptom recurrence requiring retreatment
References: N/A
Last review/revision date: 1/2019

Ophthalmology

OPHTHALMIC NSAIDS
Standard/Specific Therapeutic Class: *Ophthalmic Preparations, Eye Anti-inflammatory Agents* **Formulary Status:** • Formulary: o diclofenac 0.1% o flurbiprofen 0.03% o ketorolac 0.5%, 0.4% (Acular®, Acular LS®) • Non-formulary: o bromfenac (Xibrom®) 0.9%, Prolensa® (bromfenac) 0.07%, Bromsite® (bromfenac) 0.08% o Acuvail® (ketorolac) PF 0.45% droperette¥ o Nevanac® (nepafenac) 0.1%, Ilevro® (nepafenac) 0.3%
Coverage Duration: 1 fill
Diagnosis Considered for Coverage: • FDA approved diagnoses • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: 1 bottle • Prescriber restriction: see coverage criteria below **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Previous therapy • Concurrent therapy • Dose • Prescriber specialty
Coverage Criteria: **I. Initiation of Therapy:** • For FDA-approved diagnoses, approve if: o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: flurbiprofen, diclofenac or ketorolac eye drops OR o Prescribed by an ER doctor or diagnosis is either accident or acute injury to the eye(s) • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Refer to "Initiation of Therapy" section

OPHTHALMIC NSAIDS
III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Patient is stable and continuing the medication
References: N/A
Last review/revision date: 4/2018

OPHTHALMIC ANTIHISTAMINES

Standard/Specific Therapeutic Class: *Antihistamines, Ophthalmic Antihistamines*

Formulary Status:

- Formulary:
  - ketotifen (Zaditor®) 0.025% drops
  - azelastine 0.05% drops
- Formulary, Step therapy:
  - epinastine (Elestat®) 0.05% drops
  - olopatadine (Patanol®) 0.1% drops
- Non-formulary:
  - Lastacaft® (alcaftadine) 0.25% drops
  - Bepreve® (bepotastine) 1.5% drops
  - Emadine® (emedastine) 0.05% drops
  - olopatadine (Pataday®) 0.2% drops, Pazeo® (olopatadine) 0.7% drops

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - epinastine: 5 mL per 30 days
  - olopatadine (Patanol®): 5 mL per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For FDA-approved inidications:
  - For **epinastine 0.05%, or olopatadine 0.1%**, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **ketotifen 0.25%**
  - For **non-formulary medications**, approve if:
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: **ketotifen 0.25% or azelastine 0.05% first line** AND
    - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: **epinastine 0.05% or olopatadine 0.1% second line**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND

OPHTHALMIC ANTIHISTAMINES
o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:** • Refer to "Initiation of Therapy" section
References: N/A
Last review/revision date: 4/2018

DUREZOL® (DIFLUPREDNATE) 0.05% EYE DROPS
Standard/Specific Therapeutic Class: *Ophthalmic Preparations/Eye Anti-Inflammatory Agents* **Formulary Status:** Formulary, Step Therapy
Coverage Duration: up to 3 months
Diagnosis Considered for Coverage: • Ophthalamic inflammation, uveitis • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity Limit*: 5 ml per 30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Prior therapy • Dose
Coverage Criteria: **I. Initiation of Therapy:** • For ophthalamic inflammation or uveitis, approve if there is documented trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **prednisolone 0.1% drops** • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months): • Refer to "Initiation of Therapy" section
References: • Weiner G. Savvy Steroid use. American Academy of Ophthalmology, EyeNet Magazine. 2013. https://www.aao.org/eyenet/article/savvy-steroid-use.
Last review/revision date: 4/2018

OPHTHALMIC GLAUCOMA AGENTS

Standard/Specific Therapeutic Class: *Ophthalmic Preparations, Miotics, Other Intraocular Pressure Reducers*
Formulary Status:

- Formulary:
  - latanoprost (Xalatan®) 0.01% drop
  - bimatoprost 0.03% drop
  - timolol maleate (Timoptic®) 0.25%, 0.5% drop
  - betaxolol 0.5% drop
  - levobunolol (Betagan®) 0.5% drop
  - brimonidine (Alphagan P®) 0.15% drop, brimonidine 0.2% drop
  - Alphagan P® (brimonidine) 0.1% drop
  - dorzolamide (Trusopt®) 2% drop
  - dorzolamide/timolol (Cosopt®) 2%-0.5% drop
  - Combigan® (brimonidine/timolol) 0.2%-0.5% drop
  - pilocarpine 1%, 2%, 4% drop
- Non-formulary:
  - Lumigan® (bimatoprost) 0.01% drop
  - Travatan Z® (travoprost) 0.004% sol
  - Zioptan® (tafluprost PF) 0.0015% PF drop
  - Vyzulta™ (latanoprostene bunod) 0.024% drop

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Open angle glaucoma, ocular hypertension
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity*:
  - Non-Formulary Agents: Determined by requested product size

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For **non-formulary prostaglandin analogs** for open angle glaucoma or ocular hypertension, approve if:
  - Diagnosis of glaucoma (open angle) or ocular hypertension AND
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives **latanoprost** and **bimatoprost** OR
  - For **Travatan Z®** and **(Zioptan®)**: allergy to benzalkonium chloride
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision

OPHTHALMIC GLAUCOMA AGENTS
support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 4/2018

OPHTHALMIC ANTI-INFLAMMATORY IMMUNOMODULATORS

Standard/Specific Therapeutic Class: *Ophthalmic preparations, Ophthalmic Anti-inflammatory Immunomodulator Type*

Formulary Status:

Formulary, PA required:

- Restasis® 0.05% ophthalmic emulsion (unit-dose)
- Restasis® 0.05% ophthalmic drops (multi-dose)
- Xiidra® 5% droperette

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Keratoconjunctivitis sicca (KCS) or Dry Eye Disease
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Restasis® 0.05% unit dose emulsion: 6 packages (180 vials) per 90 days
  - Restasis® 0.05% ophthalmic drops: 3 bottles (16.5 mL) per 90 days
  - Xiidra® 5% droperette: 3 packages (180 droperettes) per 90 days
- Prescriber restriction: Initially prescribed or being followed by an ophthalmologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of keratoconjunctivitis sicca (KCS) or dry eye disease, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use artificial tears OR
  - Initially prescribed or being followed by an ophthalmologist
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing medication

References: N/A

Last review/revision date: 4/2018

Pulmonology

IDIOPATHIC PULMONARY FIBROSIS
Standard/Specific Therapeutic Class: *Miscellaneous/Pulmonary Fibrosis – Systemic Enzyme Inhibitors, Antifibrotic Therapy – Pyridone Analogs* **Formulary Status:** • Formulary, PA required: Esbriet® (pirfenidone) • Non-formulary: Ofev® (nintedanib)
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • Idiopathic Pulmonary Fibrosis • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction: • Quantity*: o Esbriet®: ▪ 267mg tablet/capsule: #180/30 days ▪ 801mg tablet: #90/30 days o Ofev®: #60/30 days **Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*
Clinical Information Required for Review: • Diagnosis • Dose
Coverage Criteria: **I. Initiation of Therapy:** • For idiopathic pulmonary fibrosis, approve if: o FVC 50% – 80% (mild to moderate impairment in PFTs) AND o Medication is used for appropriate indication and at appropriate dose that is within FDA approved guidelines AND o For **Ofev®**, documentation of trial and failure, intolerance, contraindication, or inability to use Esbriet AND • For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 10/2018

CYSTIC FIBROSIS

Standard/Specific Therapeutic Class: *Mucolytics, Cystic Fibrosis CFTR Potentiators, Aminoglycosides, Betalactams*

Formulary Status:

- Formulary:
  - Mucolytics:
    - acetylcysteine 100 mg/ml, 200 mg/ml vial for nebulization
    - sodium chloride 3%, 7% vial for nebulization
- Formulary, PA required:
  - CFTR agents:
    - Kalydeco® (ivacaftor)
    - Orkambi® (lumacaftor/ivacaftor)
    - Symdeko™ (tezacaftor/ivacaftor)
  - Inhaled antibiotics:
    - Cayston® (aztreonam)
    - Tobramcyin (TOBI®) 300 mg/5 mL solution, 300 mg/5mL solution with nebulizer (Kitabis™ Pak)
  - Mucolytics:
    - Pulmozyme® (dornase alfa)
  - Inhaled antibiotics:
    - tobramycin 300mg/5mL for nebulization
- Non-formulary:
  - Inhaled antibiotics:
    - Bethkis® (tobramycin) 300 mg/4 mL nebulization solution
    - Tobi PodHaler® (tobramycin 28 mg caps)
    - tobramycin (Kitabis® Pak) 300 mg/5 mL ampule for nebulization

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Cystic Fibrosis
- Non-cystic fibrosis bronchiectasis (for tobramycin only; off-label)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit* :
  - Kalydeco®: 56 tablets or granules per 28 days (1 tablet every 12 hours; granules for kids 1-6 yo)
  - Orkambi®: 112 tablets per 28 days (2 tablets every 12 hours; 200/125 mg for adults, 100 mg/125 for pediatrics) or 56 packets per 28 days (1 packet every 12 hours, weight based dosing)
  - Symdeko™: 56 tablets per 28 days (1 tablet tezacaftor/ivacaftor 100mg-150mg qAM, 1 tablet ivacaftor 150mg qPM)
  - TOBI PodHaler®: 224 caps per 56 days (4 caps twice daily; 28 days on, 28 days off therapy)
  - Pulmozyme: 75 mL per 30 days
  - Cayston® (75 mg/mL): 84 ml per 56 days (75 mg/mL TID; 28 days on, 28 days off therapy)
  - BETHKIS®: 224 mL per 56 days (300 mg/4mL twice daily; 28 days on, 28 days off therapy)
  - Tobramycin (TOBI®): 280 mL per 56 days (300 mg/5mL twice daily; 28 days on, 28 days off therapy)
  - Tobramycin Pak (Kitabis™ Pak): 280 mL per 56 days (300 mg/5mL twice daily; 28 days on, 28 days off therapy)

CYSTIC FIBROSIS

- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Mutation
- Prescriber specialty: pulmonologist

Coverage Criteria:

I. Initiation of Therapy:

- For **Kalydeco®**, approve if:
  - The medication is for the treatment of a CF patient who has an FDA approved indication for treatment of the patient's genotype (FDA cleared CF mutation test can be used to determine genotype if unknown) AND
  - Copy of the FDA-cleared CF mutation test has been provided with request AND
  - The patient is **NOT** homozygous for the F508del mutation in the CFTR gene AND
  - The medication is being prescribed at a dose that is within FDA approved guidelines AND
  - For patients 12 months-6 years of age: documentation of weight is required to determine appropriate dosing
- For **Orkambi®**, approve if:
  - The patient is **homozygous** for the F508del mutation in the CFTR gene AND
  - Copy of the FDA-cleared CF mutation test has been provided with request AND
  - The medication is being prescribed at a dose that is within FDA approved guidelines AND
  - For patients 2-5 years of age: documentation of weight is required to determine appropriate dosing
- For **Symdeko™**, approve if:
  - The patient is **homozygous** for the F508del mutation in the CFTR gene OR
  - The patient has a tezacaftor/ivacaftor-responsive mutation in the CFTR gene AND
  - Copy of the FDA-cleared CF mutation test has been provided with request AND
  - The medication is being prescribed at a dose that is within FDA approved guidelines
- For **tobramycin solution for nebulization,** approve if:
  - Diagnosis is cystic fibrosis patient with *P. aeruginosa* or non-cystic fibrosis bronchiectasis AND
  - The medication is being prescribed at a dose that is within FDA approved guidelines AND
  - For non-preferred formulations (TOBI PodHaler®, Bethkis®, or tobramycin pak 300mg/5mL): trial with or inability to use **tobramycin 300 mg/5 mL solution**
- For **Pulmozyme®**, approve if:
  - The patient is 5 years or older AND
  - The medication is not being used as monotherapy AND
  - The medication is being prescribed at a dose that is within FDA approved guidelines
- For **Cayston®**, approve if:
  - The medication is being prescribed for a cystic fibrosis patient colonized with *P. aeruginosa* AND
  - The medication is being prescribed at a dose that is within FDA approved guidelines
- For off-label indications or dosing (any , approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND

CYSTIC FIBROSIS
• Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 1/2019

LONG-ACTING BETA-ADRENERGIC AGENTS (LABA)

Standard Therapeutic Class, Specific Therapeutic Class: *Bronchial Dilators, Orally inhaled, long-acting beta-adrenergic agents*

Formulary Status:

- Formulary:
  - Striverdi® Respimat (olodaterol) MDI
  - Arcapta® Neohaler (indacaterol) DPI
- Formulary, PA required:
  - Serevent® Diskus (salmeterol) DPI
  - Brovana® (arformoterol) 15mcg/2mL solution for nebulizer
- Non-formulary:
  - Perforomist® (formoterol fumarate) 20mcg/2mL solution for nebulizer

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Asthma (Serevent®, Perforomist® only), bronchospasm, COPD
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Striverdi®: #12g per 90 days
  - Arcapta®: #90 inhalations per 90 days
  - Serevent®: #180 inhalations per 90 days
  - Brovana® #360mL per 90 days
  - Perforomist® #360mL per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **asthma/bronchospasm**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: Dulera®, Symbicort® and Advair Diskus® AND
  - LABA therapy is not being used as monotherapy
- For diagnosis of **COPD**, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use the following formulary alternatives: Striverdi® and Arcapta® AND
  - For Perforomist®, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use Brovana®
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND

LONG-ACTING BETA-ADRENERGIC AGENTS (LABA)
o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: • National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm. • Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2018. https://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov_WMS.pdf. Accessed 12/11/2018.
Last review/revision date: 1/2019

DALIRESP® (ROFLUMILAST)

Standard/Specific Therapeutic Class: *Miscellaneous, phosphodiesterase-4 (PDE) inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Severe COPD
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #90 per 90 days
- Prescriber restriction: pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Prescriber specialty
- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For severe COPD, approve if:
  - FEV ≤ 50% predicted with nonreversible obstructive lung disease AND
  - Patient has chronic bronchitis AND
  - Patient has history of COPD exacerbations within the previous 1 year AND
  - Patient has tried at least two of the following classes of medications at maximum tolerated doses for 3 consecutive months: **long-acting beta2-agonist (LABA), long-acting anticholinergic, and/or inhaled corticosteroids** and COPD symptoms and exacerbations are not adequately controlled AND
  - Documentation that Daliresp® is being used as add-on treatment in conjunction with at least one long-acting bronchodilator: long-acting beta2-agonist (LABA) and/or long-acting anticholinergic
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria AND Daliresp® is being used as add-on treatment in conjunction with at least one long-acting bronchodilator: long-acting beta2-agonist (LABA) and/or long-acting anticholinergic.

References:

- Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2018. https://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov_WMS.pdf. Accessed 12/11/2018

Last review/revision date: 1/2019

INHALED BETA-ADRENERGIC AND GLUCOCORTICOID COMBINATIONS (ICS/LABA)

Standard Therapeutic Class, Specific Therapeutic Class: *Bronchial Dilators, Inhaled Beta-adrenergic and Glucocorticoid Combinations*

Formulary Status:

- Formulary:
  - Symbicort® (budesonide/formoterol) DPI
  - Dulera® (mometasone/formoterol) MDI
  - Advair® Diskus (fluticasone/salmeterol) DPI
  - fluticasone/salmeterol (AirDuo® RespiClick) DPI
- Formulary, PA required:
  - Advair® HFA (fluticasone/salmeterol) MDI
  - Breo Ellipta® (fluticasone/vilanterol) DPI

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Asthma, COPD
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - Symbicort®: #30.6g per 90 days
  - Dulera®: #39g per 90 days
  - fluticasone/salmeterol: #3 inhalers per 90 days
  - Advair® Diskus: #180 inhalations per 90 days, Advair® HFA: #36g per 90 days
  - Breo Ellipta®: #180 inhalations per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For asthma or COPD, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use at least 2 preferred alternatives (e.g. Symbicort®, Dulera®, Advair Diskus®, fluticasone/salmeterol)

Advair HFA strength	Preferred medication strength
Advair HFA 45/21 mcg	Symbicort 80/4.5 mcg Advair Diskus 100/50 mcg fluticasone/salmeterol 55/14
Advair HFA 115/21 mcg	Symbicort 160/4.5 mcg Dulera 100/5 mcg Advair Diskus 250/50 mcg fluticasone/salmeterol 113/14
Advair HFA 230/21 mcg	Dulera 200/5 mcg Advair Diskus 500/50 mcg fluticasone/salmeterol 232/14

INHALED BETA-ADRENERGIC AND GLUCOCORTICOID COMBINATIONS (ICS/LABA)
• For off-label indications or dosing, approve if: o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: • UpToDate. Usual doses of combination inhaled glucocorticoids and long-acting beta-agonists for the treatment of asthma in adolescents age 12 and older and adults. Graphic 68143 Version 13.0. 2018 • National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm. • Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2018. https://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov_WMS.pdf. Accessed 12/11/2018.
Last review/revision date: 1/2019

SHORT-ACTING BETA-ADRENERGIC AGONIST (SABA)

Standard/Specific Therapeutic Class: *Bronchial Dilators, Beta-adrenergic Agents*

Formulary Status:

- Formulary:
  - albuterol sulfate tablet, oral syrup
  - albuterol sulfate 1.25mg/3mL, 2.5mg/0.5mL, 2.5mg/0.5mL (0.083%), 5mg/mL (0.5%) nebulizing solution
  - albuterol HFA 90mcg inhaler
  - Proair® RespiClick
- Formulary, age limit ≤ 12 years
  - albuterol sulfate 2mg/5mL syrup
- Formulary, Step therapy required:
  - levalbuterol (Xopenex®, Xopenex HFA®)
- Non-formulary:
  - albuterol sulfate 12h ER tablet
  - brand-name Proair®, Proventil® and Ventolin® HFA

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Asthma, COPD
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Inhaled formulations: #2 inhalers per 30 days
  - Oral formulations:
    - albuterol tablet, oral solution: #360 per 90 days
    - albuterol ER tablet: #180 per 90 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For asthma or COPD, approve if:
  - For Proventil® HFA, Proair® HFA, or Ventolin® HFA, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **generic albuterol HFA 90 mcg inhaler**
  - For levalbuterol (Xopenex®, Xopenex® HFA), there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **albuterol inhaler**
  - For albuterol sulfate ER tablet, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **albuterol IR formulation**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision

SHORT-ACTING BETA-ADRENERGIC AGONIST (SABA)
support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: • National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm. • Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2018. https://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov_WMS.pdf. Accessed 12/11/2018.
Last review/revision date: 1/2019

Psychiatry: ADHD

CNS STIMULANTS FOR ADHD
Therapeutic Category: *Psychiatric, ADHD, Central Nervous System Stimulants* **Formulary Status:** • Formulary, age limit (5-18y): o Short-acting ▪ amphetamine salts tablets (Adderall®) ▪ dexmethylphenidate tablets (Focalin®) ▪ dextroamphetamine 5 mg, 10 mg tablet ▪ methylphenidate HCL 5mg/5mL, 10mg/5mL solution (Methylin®) ▪ methylphenidate tablets (Ritalin®) ▪ methylphenidate SR 20 mg tablet (Ritalin SR®) ▪ methylphenidate ER 10, 20mg (Metadate ER®) o Long-acting ▪ amphetamine salts ER capsules (Adderall XR®) ▪ dexmethylphenidate 24h ER capsules (Focalin XR®) ▪ dextroamphetamine 24h SR capsules (Dexedrine®) ▪ methylphenidate ER osmotic release tablets (Concerta®) ▪ methylphenidate ER capsules (Metadate CD®) ▪ Ritalin LA® (methylphenidate) 24h ER capsules • Non-formulary: o Short-acting: ▪ dextroamphetamine IR 5 mg/5 mL solution (ProCentra®) ▪ methylphenidate chewable tablets (Methylin®) ▪ methamphetamine (Desoxyn®) 5 mg tablet ▪ Zenzedi® (dextroamphetamine sulfate) tablet ▪ amphetamine sulfate tablet (Evekeo®) o Long-acting: ▪ Adzenys XR-ODT® (amphetamine sulfate) ODT ▪ Adzenys® ER (amphetamine sulfate) 1.25mg/mL ER oral suspension ▪ Dyanavel XR® (amphetamine sulfate) 2.5 mg/ml suspension ▪ Vyvanse® (lisdexamfetamine) capsules, chewable tablets ▪ Daytrana™ (methylphenidate) patches ▪ QuilliChew ER® (methylphenidate) chewable ER tablet ▪ Quillivant XR® (methylphenidate) 25 mg/5mL XR oral suspension ▪ Aptensio XR® (methylphenidate) 24h ER capsule ▪ Cotempla XR-ODT® (methylphenidate) ER ODT ▪ methylphenidate 72mg ER tablet (Relexxii®)
Coverage Duration: Indefinite
Diagnosis Considered for Coverage: • ADD/ADHD • Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies
Prescribing Restriction:

CNS STIMULANTS FOR ADHD

- Quantity Limit*:
  - IR tablet/capsule formulations: #90 per 30 days
  - ER tablet/capsule formulations: #60 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For ADD or ADHD:
  - For requests for **formulary medications for members > 18 years of age**, approve
  - For **non-formulary long-acting stimulants (whole dosage forms),** approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **TWO formulary long-acting stimulants**
  - For **non-formulary long-acting stimulants, NON-tablet/capsule formulations,** approve if there is documentation of inability to use **formulary long-acting tablet/capsule formulations** (e.g. inability to swallow)
  - For **non-formulary short-acting stimulants (whole dosage forms)**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **THREE formulary short-acting stimulants**
  - For **non-formulary short-acting stimulants NON-tablet/capsule formulations,** approve if there is documentation of:
    - Inability to use **formulary short-acting tablet/capsule formulations** (e.g. inability to swallow) AND
    - Trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **methylphenidate IR solution**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

References: N/A

Last review/revision date: 1/2019

Psychiatry: Antidepressants

ANTI-DEPRESSANTS

Standard/Specific Therapeutic Class: *Psychostimulants-antidepressants, SSRI & 5HT1A Partial Agonist Antidepressant, SSRI & Serotonin Receptor Modulator Antidepressant*

Formulary Status:

Non-formulary:

- Viibryd® (vilazodone) 10, 20, 40 mg tablet and 10-20 mg dose pack
- Trintellix® (vortioxetine) 5, 10, 20 mg tablet
- desvenlafaxine succinate (Pristiq ER®) 25, 50, 100 mg tablet
- desvenlafaxine ER (Khedezla®) 50, 100 mg tablet
- desvenlafaxine ER 50, 100 mg tablet
- desvenlafaxine fumarate ER 50, 100 mg tablet

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Major depressive disorder (MDD)
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: #90 per 90 days (higher QTY is allowed in the first month for dose titration)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **major depressive disorder (MDD)**, approve if there is documentation of trial and failure at least 2-3 months, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use:
  - At least 2 of the following preferred antidepressants: citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, bupropion SR/XL, mirtazapine, nefazodone, trazodone AND
  - At least 1 SNRI (e.g. venlafaxine, duloxetine)
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

ANTI-DEPRESSANTS
• Patient is stable and continuing the medication
References: N/A
Last review/revision date: 4/2018

Psychiatry: Anxiolytics

ANXIOLYTIC BENZODIAZEPINES

Standard/Specific Therapeutic Class: *Ataractics-Tranquilizers, Anti-anxiety Drugs*

Formulary Status:

- Formulary:
  - chlordiazepoxide capsule
  - clonazepam (Klonopin®) tablet
  - diazepam (Valium®) tablet
  - lorazepam (Ativan®) tablet
  - oxazepam capsule
- Formulary, age limit : clonazepam ODT
- Non-formulary:
  - alprazolam (Xanax®) tablet, ER tablet, ODT (Niravan®), and oral solution (Alprazolam Intensol®)
  - clorazepate (Tranxene-T®) capsule
  - diazepam 5mg/mL oral concentrate and 5mg/mL oral solution
  - lorazepam (Lorazepam Intensol®) 2mg/mL

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Anxiety disorders
- Insomnia: follow "Insomnia Agents" criteria
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*
  - lorazepam 2mg tablet: #150 per 30 days
  - diazepam, oxazepam, chlordiazepoxide: #120 per 30 days
  - clonazepam ODT, alprazolam, buspirone, lorazepam 0.5 and 1mg tablets: #90 per 30 days
  - clonazepam: #60 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For anxiety, approve if:
  - There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **three formulary medications** AND
  - For non-tablet/capsule formulations: there is documentation of inability to use regular tablet/capsule formulations (e.g. difficulty swallowing)
- For insomnia, follow "Insomnia Agents" criteria
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision

ANXIOLYTIC BENZODIAZEPINES
support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if**:** • Patient is stable and continuing the medication
References: N/A
Last review/revision date: 4/2018

Psychiatry: Dependence Disorders

NICOTINE REPLACEMENT THERAPY (NRT)

Standard/Specific Therapeutic Class: *CNS Stimulants, Smoking Deterrant Agents (Ganglionic Stimulant, Others)*

Formulary Status:

- Formulary:
  - nicotine gum
  - nicotine lozenge
  - nicotine patch
- Formulary, PA required:
  - Nicotrol NS® (nicotine nasal solution)
  - Nicotrol® (nicotine inhalation cartridge)

Coverage Duration: 6 months

Indication Considered for Coverage:

- Smoking cessation
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit:
  - nicotine gum: #360 per 30 days
  - nicotine lozenge: #600 per 30 days
  - nicotine patch: #30 per 30 days
  - Nicotrol NS®: #120 mL per 30 days (80 sprays/40 mg per day)
  - Nicotrol® inhaler: up to #504 cartridges per 30 days (max 16 cartridges per day; package size of 168 cartridges)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For smoking cessation, approve if:
  - For **Nicotrol NS®**, **Nicotrol®** inhaler, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use at least 3 of the following formulary alternatives: **nicotine gum, lozenge or patch, bupropion, Chantix®** (examples could include gastritis or esophagitis for nicotine gum and lozenges, rash for nicotine patches)
  - For nicotine lozenge, gum, patch over formulary quantity limit, medical justification is provided for why quantity larger than formulary quantity limit is needed
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND

NICOTINE REPLACEMENT THERAPY (NRT)
• Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if: • Response to therapy and medical justification for why therapy longer than 6 months is needed.
References: N/A
Last review/revision date: 1/2019

NARCOTIC WITHDRAWAL THERAPY AGENTS

Standard/Specific Therapeutic Class: *Miscellaneous, Narcotic Withdrawal Therapy Agents*

Formulary Status:

- Formulary:
  - buprenorphine 2 mg, 8 mg SL tab
  - buprenorphine/naloxone (Suboxone®) 2mg-0.5 mg, 8 mg-2 mg SL tab
- Formulary, PA required:
  - Suboxone® (buprenorphine/naloxone) 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, 12 mg/3 mg SL film
  - Zubsolv® (buprenorphine/naloxone) 1.4 mg/0.36 mg, 2.9 mg/0.71 mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg, 11.4 mg/2.9 mg sublingual tablets
  - Bunavail® (buprenorphine/naloxone) 2.1 mg/0.3 mg, 4.2 mg/0.7 mg, 6.3 mg/1 mg buccal film

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Opioid Dependence or Opioid Addiction **(requests for the diagnosis of pain will be denied)**
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Prescriber restriction: Physician meets all qualifications to prescribe buprenorphine/naloxone (Federal, State, and Local) and has a valid DEA X number
- Quantity limit: #120 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria: (Medi-Cal Carve out: Applies To Healthy Kids HMO And Healthy Workers HMO Only)

I. Initiation of Therapy:

- For opioid dependence or addition, approve if:
  - Physician meets all qualifications to prescribe buprenorphine/naloxone (Federal, State, and Local) and has a valid DEA X number AND
  - Patient is diagnosed with opioid dependence and/or opioid addiction (requests for the diagnosis of pain will be denied) AND
  - For requests for brand medications (i.e. Zubsolv®, Suboxone® film), documentation of trial and failure, intolerance, contraindication, or inability (i.e drug interaction, allergy, adverse reaction, etc.) to use **generic buprenorphine/naloxone sublingual tablets or buprenorphine sublingual tablet**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Refer to "Initiation of Therapy" criteria

References: N/A

Last review/revision date: 1/2019

Psychiatry: Insomnia

INSOMNIA MEDICATIONS

Standard/Specific Therapeutic Class: *Sedative Non-barbituate, Sedative Hypnotics*

Formulary Status:

- Formulary: eszopiclone (Lunesta®), zaleplon (Sonata®), zolpidem (Ambien®), temazepam, trazodone
- Formulary, PA required: ramelteon (Rozerem®), zolpidem CR
- Non-formulary:
  - Non-BZD agents: doxepin (Silenor®), zolpidem (Edluar®) sublingual tablet, sublingual tablet (Intermezzo®), spray pump (Zolpimist®), suvorexant (Belsomra®), tasimelteon (Hetlioz®)
  - BZD agents: estazolam, flurazepam, quazepam, triazolam

Coverage Duration: 6 months

Diagnosis Considered for Coverage:

- Insomnia and other FDA approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: tablet formulations #30 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis, dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For insomnia, approve if::
  - For **zolpidem CR,** there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at **least 2 formulary alternatives including zolpidem IR**
  - For **ramelteon (Rozerem®)**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at **least 3 formulary alternatives** OR there is documented history of substance abuse or current chronic opiate use
  - For **Hetlioz®**, there is documentation that member is blind AND has a diagnosis of sleep-wake disorder
  - For **Belsomra®**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **at least 4 formulary alternatives**
  - For **Silenor®**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **at least 4 formulary alternatives including generic doxepin**
  - For **zolpidem sublingual tablet** or **spray pump (Edluar®, Intermezzo®, Zolipmist®)**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **tablet** formulation
  - For **estazolam, flurazepam, quazepam,** or **triazolam**, there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 formulary alternatives including temazepam**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced

INSOMNIA MEDICATIONS
in the medical compendia AND o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR o Requested use can be supported by at least two published peer reviewed clinical studies **II. Continuation of Therapy for NEW Members** (within the last 6 months): • refer to "Initiation of Therapy" section **III. Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if patient is stable and continuing the medication
References: N/A
Last review/revision date: 4/2018

Psychiatry: Antipsychotics

ORAL TYPICAL AND ATYPICAL ANTIPSYCHOTICS

Standard/Specific Therapeutic Class: *Antipsychotic Agents, Atypical & Typical Antipsychotics*

Formulary Status:

- Non-Formulary
  - Chlorpromazine (Thorazine ®)
  - Fanapt® (Iloperidone) tablets, dose pack
  - Latuda® (Lurasidone) tablets
  - Paliperidone ER (Invega®) extended-release tablets
  - Seroquel XR® (Quetiapine) extended-release tablets
  - Rexulti® (Brexpiprazole) tablets
  - Vraylar® (Cariprazine)
  - Equetro® (Carbamazepine)
  - Risperidone (Risperdal®) 1 mg/ml oral solution, Risperidone M-TAB (Risperdal M-TAB®) ODT
  - Aripiprazole (Abilify Discmelt®), aripiprazole (Abilify®) 1 mg/ml oral solution
  - Olanzapine ODT (Zyprexa Zydis®) 5 mg, 10 mg, 15 mg, 20 mg oral disintegrating tablets
  - Saphris® (Asenapine maleate) 2.5 mg, 5 mg sublingual tablet
  - Clozapine ODT (FazaClo®) 12.5 mg, 25 mg, 100 mg, 150 mg, 200 mg oral disintegrating tablets
  - Versacloz® (Clozapine) 50 mg/ml oral suspension
  - Adasuve® (Loxapine) 10 mg aerosol powder
  - Fluphenazine (Prolixin®) 2.5 mg/5ml , 2.5 mg/ml elixir

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- FDA-approved indications
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*: up to the FDA or compendia accepted maximum and appropriate dosing guidelines.
- Prescriber restriction: Psychiatrist

Clinical Information Required for Review:

- Diagnosis, dose
- Physician specialty

Coverage Criteria (MediCal Carve out: Applies to Healthy Kids HMO and Healthy Workers HMO only)

I. Initiation of Therapy:

- For FDA approved indication, approve if:
  - Prescribing physician is a psychiatrist AND
  - Request is for FDA approved or compendia recommended dose AND
  - For requests for solution, suspension, elixir, ODT formulations: documentation of intolerance, contraindication, or inability (e.g. inability to swallow, etc.) to use **tablet or capsule** formulation
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

ORAL TYPICAL AND ATYPICAL ANTIPSYCHOTICS
II. Continuation of Therapy for NEW Members (within the last 6 months), approve if: • Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: • American Psychiatric Association. Guideline watch (September 2009). Practice guideline for the treatment of patients with schizophrenia http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia-watch.pdf
Last review/revision date: 4/2018

NUPLAZID® (PIMAVANSERIN)

Standard/Specific Therapeutic Class: *Ataractics-Tranquilizers, Selective Serotonin 5-HT2A Inverse Agonists (SSIA)*

Formulary Status: Formulary, PA required

Coverage Duration:

Initial: 3 months

Re-authorization: Indefinite

Diagnosis Considered for Coverage:

- Parkinson's disease psychosis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit* #180 tablets/90 days
- Prescriber restriction: Neurologist or in consultation with neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Prescriber specialty

Coverage Criteria (MediCal Carve out :Applies to Health Kids HMO and Healthy Workers HMO only)

I. Initiation of Therapy:

- For diagnosis of **Parkinson's disease psychosis**, approve if there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **clozapine**
- For off-label indications or dosing, approve if:
  - o No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - o Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - o Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND
- Request is for generic or single source brand AND
- The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria

III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Documentation of therapeutic response per PA request or clinic notes

References:

- Miyasaki JM, Shannon K, Voon V, et al. Practice Parameter: evaluation of treatment of depression, psychosis, and dementia in Parkinson disease (an evidence based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2006;66:996-1002.
- Product information. Nuplazid. Acadia Pharmaceuticals Inc. San Diego, CA, 2016.

Last review/revision date: 4/2018

Rheumatology

DISEASE MODIFYING BIOLOGICS

Therapeutic Category: *Rheumatologic/Derm, Disease Modifying Biologics*
Formulary Status:

- Formulary, PA required
  - Humira® (adalimumab) –**preferred**
  - Enbrel® (etanercept) -**preferred**
  - Actemra® (tocilizumab)
  - Xeljanz®, Xeljanz XR® (tofacitinib)
  - Orencia® (abatacept)
  - Kineret® (anakinra)
  - Otezla® (apremilast)
  - Cimzia® (certolizumab)
  - Simponi® (golimumab)
  - Cosentyx® (secukinumab)
  - Stelara® (ustekinumab)
- Non-formulary
  - Remicade®/Inflectra®/Renflexis® (infliximab/-dyyb/-abda) [medical benefit- to be administered by HCP]
  - Ilaris® (canakinumab) [medical benefit- to be administered by HCP]
  - Taltz® (ixekizumab)
  - Siliq® (brodalumab)
  - Tremfya® (guselkumab)
  - Kevzara® (sarilumab)
  - Olumiant® (baricitinib)

Coverage Duration:
Initial: 1 year (8 weeks for ulcerative colitis)
Re-authorization: Indefinite

Diagnosis Considered for Coverage:

- Rheumatoid arthritis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis, guttate psoriasis
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restrictions:

- Quantity Limit*:

Drug	Indication	Dose
Enbrel®	Rheumatoid arthritis Juvenile Idiopathic Arthritis* Psoriatic arthritis Ankylosing spondylitis	• 25 mg #8 (syringes) or 4.08 ml (8 vials) per 28 days (25 mg 2x/week dosing) OR • 50 mg 3.92 ml per 28 days (1 kit, 4 syringes/pen injectors) (50 mg once weekly dosing) **NOTE: for Juvenile Idiopathic Arthritis, dose should be 0.8 mg/kg once weekly (max 50 mg/dose) or 0.4 mg/kg 2x/week (max 25 mg/dose)*

DISEASE MODIFYING BIOLOGICS		
	Plaque Psoriasis	• Up to 50 mg 7.84 ml per 28 days (2 kits, 8 syringes/pen injectors) for the first 3 months (50 mg 2x/week dosing) • Then 50 mg 3.92 ml per 28 days (1 kit, 4 syringes/pen injectors) (50 mg once weekly dosing)
Humira®	Rheumatoid Arthritis Ankylosing Spondylitis Psoriatic Arthritis	• #2 per 28 days (1 kit or #2 syringes/vials) OR • #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate OR patient will continue methotrexate but requires titration due to ongoing symptoms
	Juvenile Idiopathic Arthritis	#2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
	Plaque Psoriasis	• #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes) • Then #2 per 28 days (#1 kit/#2 syringes/pens)
	Crohn's Disease Ulcerative Colitis	• 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes) • Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
Cimzia®	Ankylosing Spondylitis	Initial: #3 per 28 days (400 mg weeks 0, 2, 4; dosed with starter kit of 3 sets of 2 syringes 200 ml each) Maintenance #1 per 28 days (200 mg every 2 weeks or 400 mg every 4 weeks; dosed with 1 set of 2 vials or 2 syringes 200 mg each)
	Crohn's Disease	Initial: #3 per 28 days (400 mg at weeks, 0, 2 and 4) Maintenance: #2 per 28 days (400 mg every 28 days)
	Psoriatic Arthritis Rheumatoid Arthritis	Initial: #3 per 28 days (400 mg at weeks, 0, 2 and 4) Maintenance: 200 mg (#1) every other week or 400 mg (#2) every 28 days
Actemra®	Rheumatoid Arthritis	< 100 kg: #1.8 ml (2 syringes) per 28 days ≥ 100 kg: #3.6 ml (4 syringes) per 28 days
Xeljanz®	Rheumatoid Arthritis	60 tablets per 30 days
Xeljanz XR®	Rheumatoid Arthritis	30 tablets per 30 days
Olumiant®	Rheumatoid Arthritis	30 tablets per 30 days
Cosentyx®	Ankylosing spondylitis Psoriatic arthritis	#4/28 days x 1 fill, then #1/28 days
Taltz®	Plaque Psoriasis	Initial: #2 (160 mg) once for 14 days, then #1 (80 mg) week 2, 4, 6, 8, 10 and 12 Maintenance #1 per 28 days
Siliq®	Plaque Psoriasis	Initial: 210 mg at week 0, 1, and 2 Maintenance 210 mg be every 2 weeks
Tremfya®	Plaque Psoriasis	Initial: 100 mg (#1) weeks 0 and 4 Maintenance: 100 mg (#1) every 8 weeks
Kevzara®	Rheumatoid Arthritis	Up to 200 mg (#1.140 ml) every 2 weeks
Kineret®	Rheumatoid Arthritis	Up to 8 mg/kg daily
Otezla®	Plaque Psoriasis Psoriatic Arthritis	Initial: 10 mg on day 1, 10 mg twice daily day 2, 10 mg in morning 20 mg in evening day 3, 20 mg twice daily day 4, 20 mg in morning and 30 mg in evening day 5 Maintenance: 30 mg twice daily starting on day 6

DISEASE MODIFYING BIOLOGICS		
Orencia®	Psoriatic Arthritis Rheumatoid Arthritis Juvenile Idiopathic Arthritis	Psoriatic Arthritis and Rheumatoid Arthritis: 125 mg once weekly Juvenile Idiopathic Arthritis: 10 to <25 kg: 50 mg weekly 25 to <50 kg: 87. 5 mg weekly 50 kg or more: 125 mg once weekly
Simponi®	Ankylosing Spondylitis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis	Ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis: 50 mg per 28 days Ulcerative colitis: Initial: 200 mg at week 0, 200 mg at week 2; Maintenance: 100 mg every 28 days
Stelara®	Crohn's Disease Plaque Psoriasis Psoriatic Arthritis	Crohn's disease: Maintenance only, 90 mg every 8 weeks Plaque psoriasis: 100 kg or less: 45 mg at week 0, 4 and then 45 mg every 12 weeks; >100 kg: 90 mg at week 0, 4, and then 90 mg every 12 weeks Psoriatic arthritis: 45 mg at week 0, 4 and then 45 mg every 12 weeks; coexistent plaque psoriasis and >100 kg: 90 mg at week 0, 4, and then 90 mg every 12 weeks

- Prescriber restriction: rheumatologist, dermatologist, or gastroenterologist (see specific diagnosis in Coverage Criteria)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older AND
  - Patient has diagnosis of moderate to severe rheumatoid arthritis AND
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a rheumatologist AND
  - Documented trial and failure with at least **ONE DMARD** (e.g. methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g. boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation) AND
  - For non-preferred medications Actemra®, Orencia®, Xeljanz®, Xeljanz® XR: trial and failure, intolerance, contraindication, or inability (e.g. inability to self-inject for Xeljanz® or Xeljanz® XR requests, drug interaction, allergy, adverse reaction, etc.) to use the following alternatives: **Enbrel® OR Humira®** AND
  - For non-preferred medications Cimzia®, Kineret®, Simponi®, Kevzara®, or Olumiant®: trial and failure intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **ALL** of the following:
    - Enbrel® OR Humira®,
    - Actemra®
    - Orencia® AND
    - Xeljanz®/Xeljanz XR®
- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older AND
  - Patient has diagnosis of ankylosing spondylitis AND
  - Request is for subcutaneous administration (self-administration or by caregiver at home)

DISEASE MODIFYING BIOLOGICS

- Drug has been prescribed by or is currently being supervised by a rheumatologist AND
- Trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID AND
- For non-preferred medications Cimzia®, Simponi®, or Cosentyx®: trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **Enbrel® OR Humira®**

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 17 years of age or younger AND
  - Patient has diagnosis of juvenile idiopathic arthritis AND
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a rheumatologist. AND
  - Documented trial and failure with at least **ONE DMARD** (e.g. methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent. AND
  - For non-preferred medication Orencia®: trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **Enbrel® OR Humira®**
- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 17 years of age or younger AND
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis AND
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a rheumatologist AND
  - For non-preferred medication Orencia®: trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **Enbrel® OR Humira®**
- For diagnosis of **Psoriasis**, approve if:
  - Patient is 18 years of age or older AND
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis AND
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a dermatologist AND
  - Trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives** AND
    - Topical steroids
    - Topical medications [i.e. Dovonex® (calcipotriene), Tazorac® (tazorotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane®)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g. systemic lupus erythematus, cataracts)
    - Prior trial of disease modifying biologic
  - For non-preferred medications Cosentyx®, Otezla®, Stelara®, Taltz®, Siliq®, or Tremfya®: trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **Enbrel® OR Humira®**
- For diagnosis of **guttate psoriasis**, approve if:
  - Patient has moderate to severe guttate psoriasis AND
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Medication is being prescribed by a dermatologist AND

DISEASE MODIFYING BIOLOGICS

- There is documentation of trial and failure, intolerance or inability (e.g. drug interaction, allergy, adverse reaction, etc.) to treatment with ALL of the following alternatives**:** There is documentation of trial and failure, intolerance or inability (e.g. drug interaction, allergy, adverse reaction, etc.) to use at least **2** of the following:
  1. **Medium to high potency steroid or another topical medication (e.g. calcipotriene, tazorotene, anthralin, or a coal tar preparation)**
  2. **Ultraviolet (UV) phototherapy**
  3. **Oral DMARDs (e.g. methotrexate)**
- For non-preferred medications Cosentyx®, Otezla®, or Stelara®: trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **Enbrel® OR Humira®.**

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older AND
  - Diagnosis of psoriatic arthritis AND
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a rheumatologist or dermatologist AND
  - Documented trial and failure, intolerance, contraindication with at least one DMARD (e.g. methotrexate) or inability to use DMARD (e.g. liver toxicity with methotrexate) OR predominantly axial symptoms (i.e. spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of **NSAIDS or steroids** AND
  - For non-preferred medications Cimzia®, Cosentyx®, Simponi®, Otezla®, Stelara®, or Orencia®: trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **Enbrel® OR Humira®**
- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older AND
  - Patient has a diagnosis of moderate to severely active Crohn's Disease AND
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a gastroenterologist or rheumatologist AND
  - Patient has documented trial and failure of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**. AND
  - For non-preferred medications Cimzia® or Stelara®: trial and failure, intolerance, contraindication, or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **Humira®**
- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older AND
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a gastroenterologist AND
  - Trial and failure or inability (i.e. drug interaction, allergy, adverse reaction, GI intolerance, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids** AND
  - For non-preferred medication Simponi®: trial and failure, intolerance, contraindication or inability (i.e. drug interaction, allergy, adverse reaction, etc.) to use **Humira®**
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

DISEASE MODIFYING BIOLOGICS
• Prescriber attests that member has been on this medication continuously before joining SFHP AND • Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria **III. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication),** approve if: • Patient is stable and continuing the medication AND • Medication is used for appropriate indication and at appropriate dose
References: N/A
Last review/revision date: 10/2018

GOUT

Standard/Specific Therapeutic Class: *Antiathritics, Hyperuricemia Treatment Xanthine Oxidase Inhibitor, Uricosuric agent*

Formulary Status:

- Formulary:
  - allopurinol
  - probenecid
- Formulary, PA required: Uloric® (febuxostat)
- Non-formulary: Zurampic® (lenisurad)

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Gout
- Off-label uses: medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies

Prescribing Restriction:

- Quantity Limit*:
  - Uloric®: #90 per 90 days
  - Zurampic®: #30 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case by case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For gout:
  - For Uloric®, approve if:
    - Intolerance or adverse event with allopurinol (e.g. hypersensitivity or rash) OR
    - Inadequate response to allopurinol (failure to achieve serum uric acids levels < 6 mg/dl when using maximum tolerated doses of allopurinol)
  - For Zurampic®, approve if:
    - Intolerance , adverse event, or contraindication to probenecid AND
    - Inadequate response to allopurinol (failure to achieve serum uric acids levels < 6 mg/dl when using maximum tolerated doses of allopurinol) AND
    - Active allopurinol prescription
- For off-label indications or dosing, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND
  - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
  - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for NEW Members (within the last 6 months), approve if:

- Prescriber attests that member has been on this medication continuously before joining SFHP AND

GOUT
• Request is for generic or single source brand AND • The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria
References: N/A
Last review/revision date: 10/2018

If you are hearing impaired, please call the TDD/TYY line at **1(415) 547-7830**, toll-free at **1(888) 883-7347** or through the California Relay Service at 711. You may request this document in alternative formats like Braille, large size print, and audio. To request other formats, or for help with reading this document and other SFHP materials, please call Customer Service at **1(415) 547-7800** or toll-free at **1(800) 288-5555**.