

**Texas Prior Authorization Program
Clinical Criteria**

Leukotriene Modifiers

Clinical Criteria Information Included in this Document

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- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Zafirlukast

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- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
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Zileuton

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- **References:** clinical publications and sources relevant to this clinical criteria

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Revision Notes

- Annual review by staff
- Updated Table 3, pages 6-8
- Updated Table 5, pages 9-10
- Updated Table 7, page 10
- Updated Table 10, page 11
- Added GCN for Zileuton ER 600mg tablets to drug table, page 18
- Updated references, pages 20-21



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Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

| Drugs Requiring Prior Authorization | |
|-------------------------------------|-------|
| Label Name | GCN |
| MONTELUKAST SOD 10MG TABLET | 94444 |
| MONTELUKAST SOD 4MG GRANULES | 18803 |
| MONTELUKAST SOD 4MG TAB CHEW | 42373 |
| MONTELUKAST SOD 5MG TAB CHEW | 94440 |
| SINGULAIR 10MG TABLET | 94444 |
| SINGULAIR 4MG GRANULES | 18803 |
| SINGULAIR 4MG TABLET CHEW | 42373 |
| SINGULAIR 5MG TABLET CHEW | 94440 |



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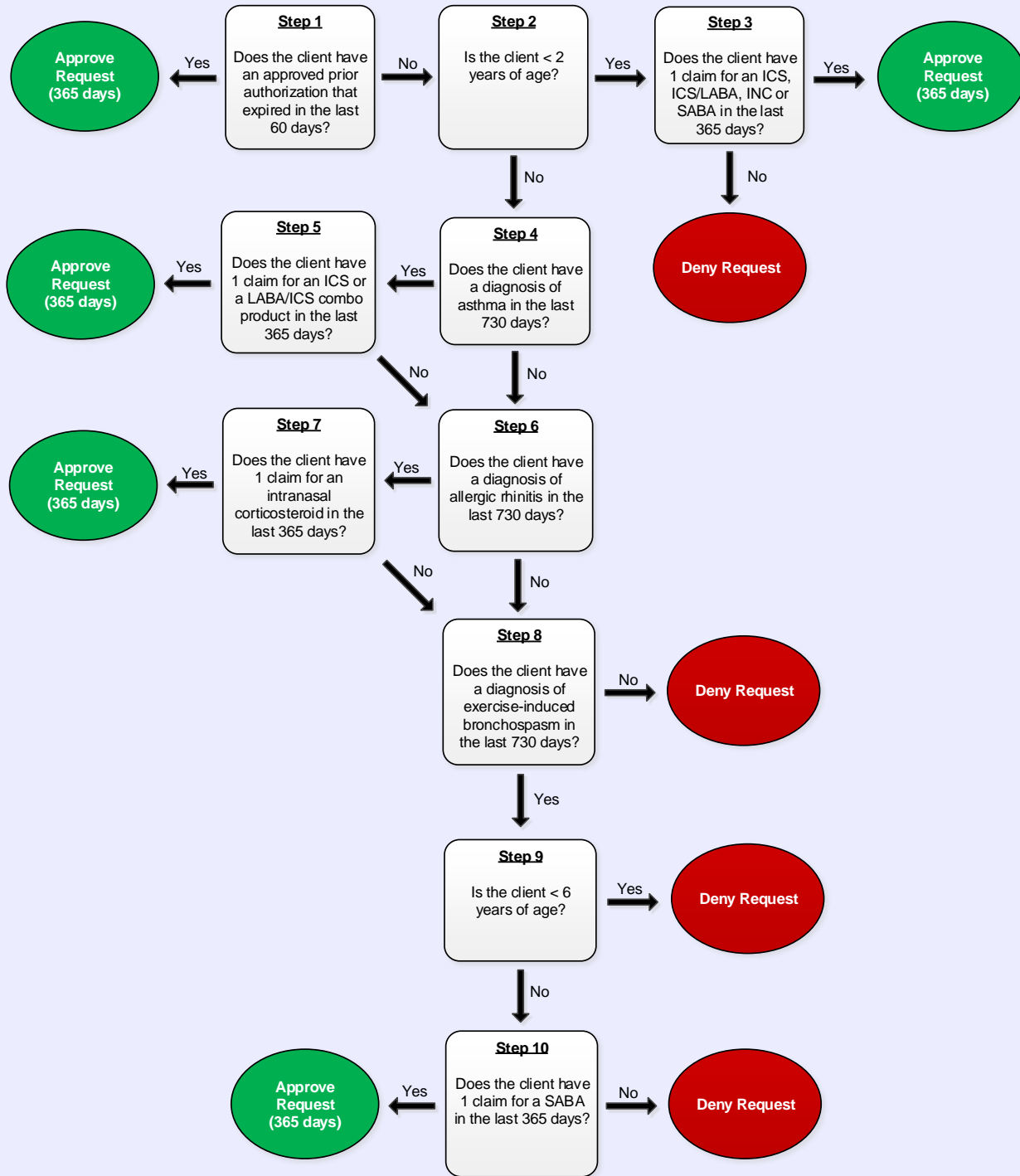
Clinical Criteria Logic

1. Does the client have an approved prior authorization that expired in the last 60 days?
 Yes – Approve (365 days)
 No – Go to #2
2. Is the client less than (<) 2 years of age?
 Yes – Go to #3
 No – Go to #4
3. Does the client have 1 claim for an **inhaled corticosteroid (ICS), long-acting beta agonist (LABA)/ICS combination product, intranasal corticosteroid or a short-acting beta agonist (SABA)** in the last 365 days?
 Yes – Approve (365 days)
 No – Deny
4. Does the client have a **diagnosis of asthma** in the last 730 days?
 Yes – Go to #5
 No – Go to #6
5. Does the client have 1 claim for an **ICS or a LABA/ICS combination product** in the last 365 days?
 Yes – Approve (365 days)
 No – Go to #6
6. Does the client have a **diagnosis of allergic rhinitis** in the last 730 days?
 Yes – Go to #7
 No – Go to #8
7. Does the client have 1 claim for an **intranasal corticosteroid** in the last 365 days?
 Yes – Approve (365 days)
 No – Go to #8
8. Does the client have a diagnosis of **exercise-induced bronchoconstriction** in the last 730 days?
 Yes – Go to #9
 No – Deny
9. Is the client less than (<) 6 years of age?
 Yes – Deny
 No – Go to #10
10. Does the client have 1 claim for a **short-acting beta agonist (SABA)** in the last 365 days?
 Yes – Approve (365 days)
 No – Deny



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Clinical Criteria Logic Diagram





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Clinical Criteria Supporting Tables

| Step 3 (claim for an ICS, ICS/LABA, INC or SABA) | |
|---------------------------------------------------------|------------|
| Required quantity: 1 | |
| Look back timeframe: 365 days | |
| Label Name | GCN |
| ADVAIR 100-50 DISKUS | 50584 |
| ADVAIR 250-50 DISKUS | 50594 |
| ADVAIR 500-50 DISKUS | 50604 |
| ADVAIR HFA 115-21MCG INHALER | 97136 |
| ADVAIR HFA 230-21MCG INHALER | 97137 |
| ADVAIR HFA 45-21MCG INHALER | 97135 |
| ALBUTEROL 2.5MG/0.5ML SOLUTION | 22697 |
| ALBUTEROL 5MG/ML SOLUTION | 41680 |
| ALBUTEROL SUL 0.63MG/3ML SOLUTION | 14633 |
| ALBUTEROL SUL 1.25MG/3ML SOLUTION | 14634 |
| ALBUTEROL SUL 2.5MG/3ML SOLUTION | 41681 |
| ALVESCO 160MCG INHALER | 24152 |
| ALVESCO 80MCG INHALER | 24149 |
| ARMONAIR RESPICLICK 232MCG | 42985 |
| ARMONAIR RESPICLICK 55MCG | 42979 |
| ARNUITY ELLIPTA 100MCG INHALER | 37007 |
| ARNUITY ELLIPTA 200MCG INHALER | 37008 |
| ARNUITY ELLIPTA 50MCG INH | 44783 |
| ASMANEX TWISTHALR 110MCG #30 | 99721 |
| ASMANEX TWISTHALR 220MCG #120 | 18987 |
| ASMANEX TWISTHALR 220MCG #30 | 24928 |
| ASMANEX TWISTHALR 220MCG #60 | 24929 |
| BECONASE AQ 0.042% SPRAY | 47100 |
| BREO ELLIPTA 100-25MCG INHALER | 34647 |
| BREO ELLIPTA 200-25MCG INHALER | 35808 |
| BUDESONIDE 0.25MG/2ML | 17957 |
| BUDESONIDE 0.5MG/2ML | 17958 |
| BUDESONIDE 1MG/2ML INH SUSP | 62980 |
| BUDESONIDE 32MCG NASAL SPRAY | 40708 |

| Step 3 (claim for an ICS, ICS/LABA, INC or SABA) | |
|---------------------------------------------------------|------------|
| Required quantity: 1 | |
| Look back timeframe: 365 days | |
| Label Name | GCN |
| DULERA 100/5MCG INHALER | 28766 |
| DULERA 200/5MCG INHALER | 28767 |
| DYMISTA NASAL SPRAY | 32099 |
| FLOVENT 100MCG DISKUS | 53633 |
| FLOVENT 250MCG DISKUS | 53634 |
| FLOVENT 50MCG DISKUS | 53635 |
| FLOVENT HFA 110MCG INHALER | 53636 |
| FLOVENT HFA 220MCG INHALER | 53639 |
| FLOVENT HFA 44MCG INHALER | 53638 |
| FLUNISOLIDE 0.025% SPRAY | 34280 |
| FLUTICASONE PROP 50MCG SPRAY | 62263 |
| FLUTICASONE PROP 50MCG SPRAY | 37683 |
| FLUTICASONE-SALMETEROL 55-14 | 42956 |
| FLUTICASONE-SALMETEROL 113-14 | 42957 |
| FLUTICASONE-SALMETEROL 232-14 | 42958 |
| LEVALBUTEROL 0.31/3ML SOLUTION | 15665 |
| LEVALBUTEROL 0.63MG/3ML SOLUTION | 24540 |
| LEVALBUTEROL 1.25MG/3ML SOLUTION | 24541 |
| LEVALBUTEROL CONC 1.25MG/0.5ML | 23146 |
| LEVALBUTEROL TAR HFA 45MCG INH | 24422 |
| MOMETASONE FUROATE 50MGCG SPRY | 71431 |
| NASONEX 50MCG NASAL SPRAY | 71431 |
| PROAIR HFA 90MCG INHALER | 22913 |
| PROAIR RESPICLICK INHAL POWDER | 38212 |
| PROVENTIL HFA 90MCG INHALER | 22913 |
| PULMICORT 0.25MG/2ML RESPULE | 17957 |
| PULMICORT 0.5MG/2ML RESPULE | 17958 |
| PULMICORT 180MCG FLEXHALER | 98025 |
| PULMICORT 1MG/2ML RESPULE | 62980 |
| PULMICORT 90MCG FLEXHALER | 98024 |
| QNASL CHILDRENS 40MCG SPRAY | 37654 |
| QNASL 80MCG NASAL SPRAY | 31769 |
| QVAR REDIHALER 40MCG | 43724 |
| QVAR REDIHALER 80MCG | 43725 |
| SYMBICORT 160-4.5MCG INHALER | 98500 |

| Step 3 (claim for an ICS, ICS/LABA, INC or SABA) | |
|---------------------------------------------------------|------------|
| Required quantity: 1 | |
| Look back timeframe: 365 days | |
| Label Name | GCN |
| SYMBICORT 80-45MCG INHALER | 98499 |
| TRIAMCINOLONE 55MCG NASAL SPRAY | 36145 |
| VENTOLIN HFA 90MCG INHALER | 22913 |
| XHANCE 93MCG NASAL SPRAY | 43878 |
| XOPENEX 0.31MG/3ML SOLUTION | 15665 |
| XOPENEX 0.63MG/3ML SOLUTION | 24540 |
| XOPENEX 1.25MG/3ML SOLUTION | 24541 |
| XOPENEX HFA 45MCG INHALER | 24422 |

| Step 4 (diagnosis of asthma) | |
|--------------------------------------|-------------------------------------------------------|
| Required quantity: 1 | |
| Look back timeframe: 730 days | |
| ICD-10 Code | Description |
| J454 | MODERATE PERSISTENT ASTHMA |
| J4540 | MODERATE PERSISTENT ASTHMA, UNCOMPLICATED |
| J4541 | MODERATE PERSISTENT ASTHMA, WITH (ACUTE) EXACERBATION |
| J4542 | MODERATE PERSISTENT ASTHMA, WITH STATUS ASTHMATICUS |
| J455 | SEVERE PERSISTENT ASTHMA |
| J4550 | SEVERE PERSISTENT ASTHMA, UNCOMPLICATED |
| J4551 | SEVERE PERSISTENT ASTHMA, WITH (ACUTE) EXACERBATION |
| J4552 | SEVERE PERSISTENT ASTHMA, WITH STATUS ASTHMATICUS |
| J459 | OTHER AND UNSPECIFIED ASTHMA |
| J4590 | UNSPECIFIED ASTHMA |
| J45901 | UNSPECIFIED ASTHMA, WITH (ACUTE) EXACERBATION |
| J45902 | UNSPECIFIED ASTHMA, WITH STATUS ASTHMATICUS |
| J45909 | UNSPECIFIED ASTHMA, UNCOMPLICATED |
| J4599 | OTHER ASTHMA |
| J45998 | OTHER ASTHMA |

| Step 5 (claim for an ICS or LABA/ICS combination product) | |
|------------------------------------------------------------------|------------|
| Required quantity: 1 | |
| Look back timeframe: 365 days | |
| Label Name | GCN |
| ADVAIR 100-50 DISKUS | 50584 |

| Step 5 (claim for an ICS or LABA/ICS combination product) | |
|------------------------------------------------------------------|------------|
| Required quantity: 1 | |
| Look back timeframe: 365 days | |
| Label Name | GCN |
| ADVAIR 250-50 DISKUS | 50594 |
| ADVAIR 500-50 DISKUS | 50604 |
| ADVAIR HFA 115-21MCG INHALER | 97136 |
| ADVAIR HFA 230-21MCG INHALER | 97137 |
| ADVAIR HFA 45-21MCG INHALER | 97135 |
| ALVESCO 160MCG INHALER | 24152 |
| ALVESCO 80MCG INHALER | 24149 |
| ARMONAIR RESPICLICK 232MCG | 42985 |
| ARMONAIR RESPICLICK 55MCG | 42979 |
| ARNUITY ELLIPTA 100MCG INHALER | 37007 |
| ARNUITY ELLIPTA 200MCG INHALER | 37008 |
| ARNUITY ELLIPTA 50MCG INH | 44783 |
| ASMANEX TWISTHALR 110MCG #30 | 99721 |
| ASMANEX TWISTHALR 220MCG #120 | 18987 |
| ASMANEX TWISTHALR 220MCG #30 | 24928 |
| ASMANEX TWISTHALR 220MCG #60 | 24929 |
| BREO ELLIPTA 100-25 MCG INHALER | 34647 |
| BREO ELLIPTA 200-25MCG INHALER | 35808 |
| BUDESONIDE 0.25MG/2ML | 17957 |
| BUDESONIDE 0.5MG/2ML | 17958 |
| BUDESONIDE 1MG/2ML INH SUSP | 62980 |
| DULERA 100/5MCG INHALER | 28766 |
| DULERA 200/5MCG INHALER | 28767 |
| FLOVENT 100MCG DISKUS | 53633 |
| FLOVENT 250MCG DISKUS | 53634 |
| FLOVENT 50MCG DISKUS | 53635 |
| FLOVENT HFA 110MCG INHALER | 53636 |
| FLOVENT HFA 220MCG INHALER | 53639 |
| FLOVENT HFA 44MCG INHALER | 53638 |
| FLUTICASONE-SALMETEROL 55-14 | 42956 |
| FLUTICASONE-SALMETEROL 113-14 | 42957 |
| FLUTICASONE-SALMETEROL 232-14 | 42958 |
| PULMICORT 0.25MG/2ML RESPULE | 17957 |
| PULMICORT 0.5MG/2ML | 17958 |
| PULMICORT 180MCG FLEXHALER | 98025 |

| Step 5 (claim for an ICS or LABA/ICS combination product) | |
|------------------------------------------------------------------|------------|
| Required quantity: 1 | |
| Look back timeframe: 365 days | |
| Label Name | GCN |
| PULMICORT 1MG/2ML RESPULE | 62980 |
| PULMICORT 90MCG FLEXHALER | 98024 |
| QVAR REDHALER 40MCG | 43724 |
| QVAR REDHALER 80MCG | 43725 |
| SYMBICORT 160-4.5MCG INHALER | 98500 |
| SYMBICORT 80-45MCG INHALER | 98499 |

| Step 6 (diagnosis of allergic rhinitis) | |
|------------------------------------------------|----------------------------------|
| Required quantity: 1 | |
| Look back timeframe: 730 days | |
| ICD-10 Code | Description |
| J301 | ALLERGIC RHINITIS DUE TO POLLEN |
| J302 | OTHER SEASONAL ALLERGIC RHINITIS |
| J308 | OTHER ALLERGIC RHINITIS |
| J3089 | OTHER ALLERGIC RHINITIS |
| J309 | ALLERGIC RHINITIS, UNSPECIFIED |

| Step 7 (claim for an intranasal corticosteroid) | |
|--------------------------------------------------------|------------|
| Required quantity: 1 | |
| Look back timeframe: 365 days | |
| Label Name | GCN |
| BECONASE AQ 0.042% SPRAY | 47100 |
| BUDESONIDE 32MCG NASAL SPRAY | 92231 |
| DYMISTA NASAL SPRAY | 32099 |
| FLUNISOLIDE 0.025% SPRAY | 34280 |
| FLUTICASONE PROP 50MCG SPRAY | 62263 |
| MOMETASONE FUROATE 50MGCG SPRY | 71431 |
| NASONEX 50MCG NASAL SPRAY | 71431 |
| QNASL CHILDRENS 40MCG SPRAY | 37654 |
| QNASL 80MCG NASAL SPRAY | 31769 |
| TRIAMCINOLONE 55MCG NASAL SPRAY | 36145 |
| XHANCE 93MCG NASAL SPRAY | 43878 |

| Step 8 (diagnosis of exercise-induced bronchospasm) | |
|------------------------------------------------------------|-------------------------------|
| Required quantity: 1 | |
| Look back timeframe: 730 days | |
| ICD-10 Code | Description |
| J45990 | EXERCISE INDUCED BRONCHOSPASM |

| Step 10 (claim for a SABA) | |
|--------------------------------------|------------|
| Required quantity: 1 | |
| Look back timeframe: 365 days | |
| Label Name | GCN |
| ALBUTEROL 2.5MG/0.5ML SOLUTION | 22697 |
| ALBUTEROL 5MG/ML SOLUTION | 41680 |
| ALBUTEROL SUL 0.63MG/3ML SOLUTION | 14633 |
| ALBUTEROL SUL 1.25MG/3ML SOLUTION | 14634 |
| ALBUTEROL SUL 2.5MG/3ML SOLUTION | 41681 |
| LEVALBUTEROL 0.31/3ML SOLUTION | 15665 |
| LEVALBUTEROL 0.63MG/3ML SOLUTION | 24540 |
| LEVALBUTEROL 1.25MG/3ML SOLUTION | 24541 |
| LEVALBUTEROL CONC 1.25MG/0.5ML | 23146 |
| LEVALBUTEROL TAR HFA 45MCG INH | 24422 |
| PROAIR HFA 90MCG INHALER | 22913 |
| PROAIR RESPICLICK INHAL POWDER | 38212 |
| PROVENTIL HFA 90MCG INHALER | 22913 |
| VENTOLIN HFA 90MCG INHALER | 22913 |
| XOPENEX 0.31MG/3ML SOLUTION | 15665 |
| XOPENEX 0.63MG/3ML SOLUTION | 24540 |
| XOPENEX 1.25MG/3ML SOLUTION | 24541 |
| XOPENEX HFA 45MCG INHALER | 24422 |



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Drugs Requiring Prior Authorization

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| Drugs Requiring Prior Authorization | |
|-------------------------------------|-------|
| Label Name | GCN |
| ZAFIRLUKAST 10MG TABLET | 52271 |
| ZAFIRLUKAST 20MG TABLET | 18690 |



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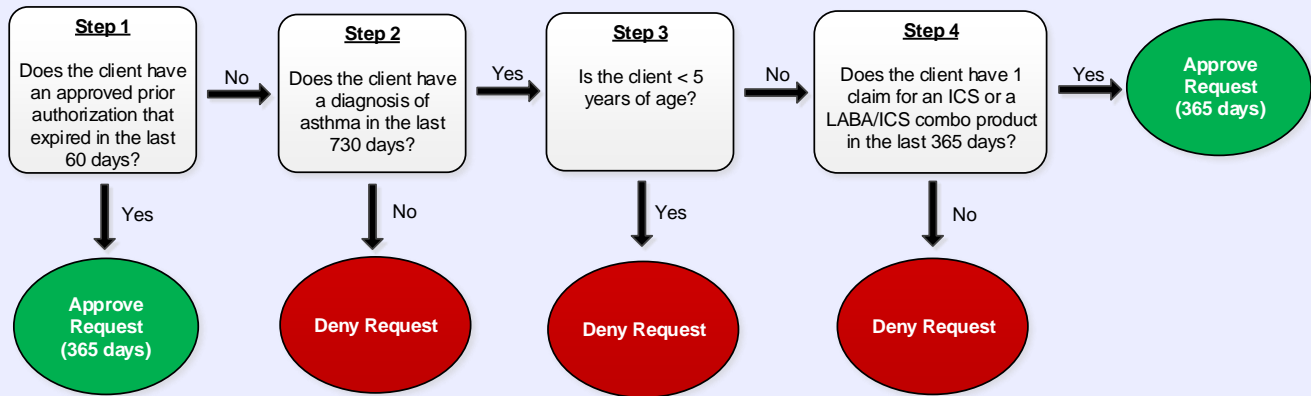
Clinical Criteria Logic

1. Does the client have an approved prior authorization that expired in the last 60 days?
 Yes – Approve (365 days)
 No – Go to #2
2. Does the client have a **diagnosis of asthma** in the last 730 days?
 Yes – Go to #3
 No – Deny
3. Is the client less than (<) 5 years of age?
 Yes – Deny
 No – Go to #4
4. Does the client have 1 claim for an **inhaled corticosteroid (ICS) or a long-acting beta agonist (LABA)/ICS combination product** in the last 365 days?
 Yes – Approve (365 days)
 No – Deny



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Clinical Criteria Logic Diagram





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Clinical Criteria Supporting Tables

Step 1 (diagnosis of asthma)**Required quantity:** 1**Look back timeframe:** 730 days

For the list of asthma diagnosis codes that pertain to this step, see the **Asthma Diagnoses** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 3 (claim for an ICS or LABA/ICS combination product)**Required quantity:** 1**Look back timeframe:** 365 days

For the list of ICS or LABA/ICS combination product GCNs that pertain to this step, see the **ICS or LABA/ICS combination products** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

**Zileuton****Drugs Requiring Prior Authorization**

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| Drugs Requiring Prior Authorization | |
|--------------------------------------------|------------|
| Label Name | GCN |
| ZILEUTON ER 600MG TABLET | 98822 |
| ZYFLO CR 600MG TABLET | 98822 |

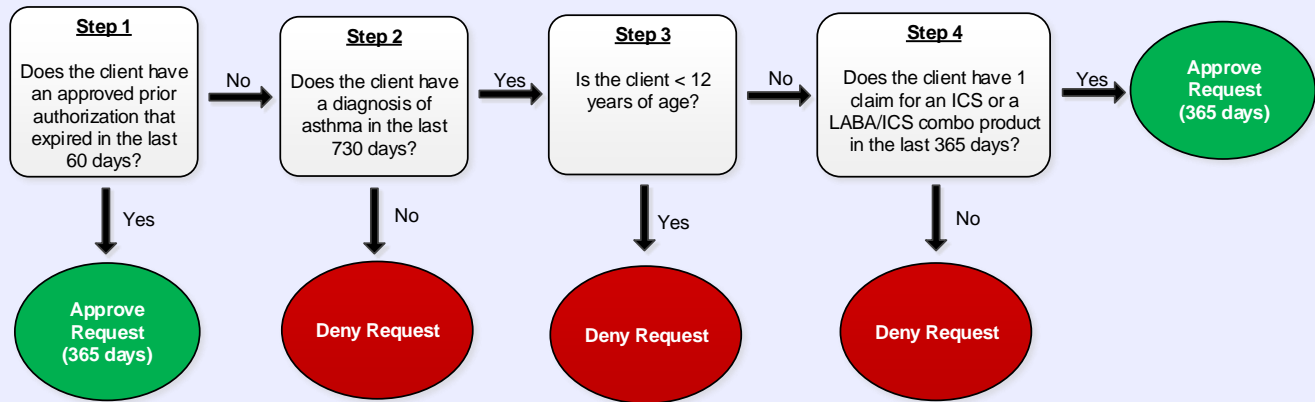
**Zileuton****Clinical Criteria Logic**

1. Does the client have an approved prior authorization that expired in the last 60 days?
 Yes – Approve (365 days)
 No – Go to #2
2. Does the client have a **diagnosis of asthma** in the last 730 days?
 Yes – Go to #3
 No – Deny
3. Is the client less than (<) 12 years of age?
 Yes – Deny
 No – Go to #4
4. Does the client have 1 claim for an **inhaled corticosteroid (ICS) or a long-acting beta agonist (LABA)/ICS combination product** in the last 365 days?
 Yes – Approve (365 days)
 No – Deny



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Clinical Criteria Logic Diagram



**Zileuton****Clinical Criteria Supporting Tables****Step 1 (diagnosis of asthma)****Required quantity: 1****Look back timeframe: 730 days**

For the list of asthma diagnosis codes that pertain to this step, see the **Asthma Diagnoses** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 3 (claim for an ICS or LABA/ICS combination product)**Required quantity: 1****Look back timeframe: 365 days**

For the list of ICS or LABA/ICS combination product GCNs that pertain to this step, see the **ICS or LABA/ICS combination products** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.



Leukotriene Modifiers

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2015. Available at www.clinicalpharmacology.com. Accessed on March 9, 2015.
2. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on March 9, 2015.
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12. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention 2014. Available at: www.ginasthma.org. Accessed March 12, 2015.
13. Seidman MD, Gurgel RK, Lin SY, et al. Clinical Practice Guideline: Allergic Rhinitis. *Otolaryngol Head Neck Surg* 2015;152(IS):S1-S43. Available at: www.otojournal.org. Accessed March 12, 2015.



Leukotriene Modifiers

Publication History

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

| Publication Date | Notes |
|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 04/23/2015 | Presented at DUR Board |
| 05/31/2015 | Initial publication and posting to website |
| 12/15/2015 | Updated GCNs for Advair 230-21mcg inhaler and Omnaris 50mcg nasal spray |
| 02/01/2016 | Updated GCNs for short-acting beta-agonists and intranasal corticosteroids |
| 03/29/2019 | Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search .) on each 'Drug Requiring PA' table |
| 07/15/2019 | Annual review by staff Updated Table 3, pages 6-8 Updated Table 5, pages 9-10 Updated Table 7, page 10 Updated Table 10, page 11 Added GCN for Zileuton ER 600mg tablets to drug table, page 18 Updated references, pages 20-21 |