Utilization Management Policy Name: Somatostatin Analogs – NC Standard

Restricted Product(s):

- Bynfezia Pen™ (octreotide)
- Mycapssa® (octreotide) delayed-release capsules
- Sandostatin® (octreotide)
- Sandostatin LAR® (octreotide)
- Somatuline® Depot (lanreotide)

FDA Approved Use:

- Bynfezia Pen
  - Reduction of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) [somatomedin C] in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
  - Treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in adult patients
  - Treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) in adult patients
- Mycapssa
  - Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide
- Sandostatin
  - Reduction in blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. The goal is to achieve normalization of growth hormone and IGF-I (somatomedin C) levels.
  - Symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease.
  - Treatment of the profuse watery diarrhea associated with VIP-secreting tumors
- Sandostatin LAR

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  - Treatment in patients who have responded to and tolerated Sandostatin subcutaneous injection for acromegaly, severe diarrhea/flushing episodes associated with metastatic carcinoid tumors, and/or profuse watery diarrhea associated with VIP-secreting tumors.
- Somatulatine Depot
  - For the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy
  - For the treatment of adult patients with unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival
  - For the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy

Criteria for INITIAL Approval of Restricted Product(s):

1. The patient has a diagnosis of acromegaly; **AND**
   a. The use of the requested agent is for adjunctive therapy with irradiation to alleviate acromegaly symptoms; **OR**
   b. The patient had an inadequate response to surgery or pituitary irradiation defined by ONE of the following documented parameters:
      i. Growth hormone level > 5 ng/mL; **OR**
      ii. IGF-1 level > 1.9 U/mL for males or > 2.2 U/mL for females; **OR**
   c. Patient is not a candidate for surgical resection; **OR**
2. The patient has a diagnosis of carcinoid tumor, locally advanced/metastatic gastroenteropancreatic neuroendocrine tumor or poorly differentiated (high-grade)/large or small cell neuroendocrine tumor, pancreas islet cell neuroendocrine tumor, or vasoactive intestinal polypeptidoma; **AND**
   a. ONE of the following:
      I. The patient will be using the medication for symptom control for carcinoid syndrome or hormone hypersecretion; **OR**
      II. The patient is not a candidate for surgical resection or radiation therapy**; AND**
3. If the requested agent is Bynfezia Pen (octreotide) or Mycapssa (octreotide DR capsules), the patient has tried and failed or has a contraindication to generic octreotide injection; **AND**
4. If the requested agent is Mycapssa (octreotide DR capsules), the patient has been adequately controlled and tolerated an octreotide or lanreotide injection; **AND**
5. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies (outlined below)*

Duration of Approval: 24 weeks

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Criteria for CONTINUED Approval of Restricted Product(s):

1. The patient has been approved through the initial BCBSNC coverage criteria (above) and is continuing therapy for one of the indications in the initial coverage criteria; **AND**
2. Has objective markers for improvement, exemplified by:
    a. Growth hormone (GH) level < 5 ng/mL; **OR**
    b. IGF-1 level < 1.9 U/mL for a male or < 2.2 U/mL for a female: **OR**
    c. Clinical improvement in conditions related to the approved diagnosis:
        i. Reduction in tumor size; **OR**
        ii. Decreased headaches; **OR**
        iii. Improved cardiovascular symptoms; **OR**
        iv. Improved respiratory symptom.

Duration of Approval: 1095 days (3 years)

***Non-formulary Exception Criteria**

Non-Formulary Exception criteria applies on formularies which exclude requested product(s). Satisfactory completion of criteria points (above) may satisfy some, or all, portions of the Non-Formulary Exception Criteria. This criteria is summarized as:

a) Request must be for an FDA approved indication; **AND**
b) Patient must have a trial and failure of up to **TWO** formulary medications or a clinical contraindication/intolerance to those medications not tried.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®[1]) for Neuroendocrine Tumors V.1.2019. National Comprehensive Cancer Network, Inc. 2019. Accessed August 22, 2019

2. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab 2014; 99:3933.

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Quantity Limitations: quantity limitations apply to brand and associated generic products.

Medication	Quantity per Day (unless specified)
Mycapssa (octreotide) delayed-release 20 mg	4 capsules

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

***Non-formulary Exception Criteria**

Non-Formulary Exception criteria applies on formularies which exclude requested product(s). Satisfactory completion of criteria points (above) may satisfy some, or all, portions of the Non-Formulary Exception Criteria. This criteria is summarized as:

c) Request must be for an FDA approved indication; **AND**
d) Patient must have a trial and failure of up to **TWO** formulary medications or a clinical contraindication/intolerance to those medications not tried.

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information:

July 2020: Original utilization management criteria issued. Combined Bynfezia Pen™ - Sandostatin® & Somatuline® criteria. Retired both.

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BlueCross BlueShield of North Carolina

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LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-888-206-4697 (TTY: 1-800-442-7028).

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