UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Mycapssa

Program	Prior Authorization- Mycapssa
Medication	Mycapssa™ (octreotide)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	12/2020
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

1. Background:

Mycapssa (octreotide) is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. Somatostatin analogs are recommended in patients who are not candidates or who have had an inadequate response to surgery.

2. Coverage Criteria:

A. Acromegaly

1. Initial Authorization

a. Mycapssa will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of acromegaly by **one** of the following:

i. Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis
ii. Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

-AND-

(b) **One** of the following:

i. Inadequate response to **one** of the following:
- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

-OR-

ii. Not a candidate for **any** of the following:
- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

-AND-

(c) Patient has responded to and tolerated treatment with **one** of the following somatostatin analogs:

i. Sandostatin (octreotide) or Sandostatin LAR
ii. Somatuline Depot (lanreotide)**

** Note: This is a medical benefit, should not be included in denial to provider

AND-

(d) The provider has submitted clinical justification why the patient is unable to be maintained on current octreotide or lanreotide therapy

Note: UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity

-OR-

(2) Patient is currently on Mycapssa therapy for acromegaly

Authorization will be issued for 12 months.

2. Reauthorization

a. **Mycapssa** will be approved based on the following criteria:

(1) Documentation of positive clinical response to Mycapssa therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Mycapssa [package insert]. Needham, MA: Chiasma Inc; June 2020.
2. American Association of Clinical Endocrinologist (AACE) medical guidelines for clinical practice for the diagnosis and treatment of acromegaly. Endocrine Practice. 2004; 10(3): 213-225.
3. Melmed S, Barkan A, Molitch M, et al. Guidelines for Acromegaly Management: An Update. J Clin Endocrinol Metab. May 2009, 94 (5):1509-1517.
4. Katznelson L, Atkinson JL, Cook DM, et al.; American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly--2011 update. Endocr Pract. 2011 Jul-Aug;17Suppl 4:1-44.
5. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. Nov 2014;99(11):3933-3951.

Program	Prior Authorization– Mycapssa (octreotide)
Change Control	
Date	Change
12/2020	New program