UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2225-2
Program	Prior Authorization/Medical Necessity
Medication	Mycapssa™ (octreotide)
P&T Approval Date	12/2020, 12/2021
Effective Date	3/1/2022; Oxford only: 3/1/202

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]:

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)

-AND-

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

-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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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/Medical Necessity - Mycapssa® (octreotide)
Change Control	
12/2020	New program
12/2021	Annual review with no change to clinical criteria.