



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2225-4
Program	Prior Authorization/Medical Necessity
Medication	Mycapssa™ (octreotide)
P&T Approval Date	12/2020, 12/2021, 12/2022, 12/2023
Effective Date	3/1/2024

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]. Dublin, Ireland: Amryt Pharmaceuticals, Inc.; March 2022.
2. Cook DM, Ezzat S, Katznelson L, et al. American Association of Clinical Endocrinologist (AACE) medical guidelines for clinical practice for the diagnosis and treatment of acromegaly. *Endocrine Pract.* 2004;10(3):213-225. doi:10.4158/EP.10.3.213
3. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. *J Clin Endocrinol Metab.* 2009;94(5):1509-1517. doi:10.1210/jc.2008-2421
4. Katznelson L, Atkinson JL, Cook DM, et al.; American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly--2011 update. *Endocrine Pract.* 2011;17(4):636-646. <https://doi.org/10.4158/EP.17.4.636>



5. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99(11):3933-3951.
doi:10.1210/jc.2014-2700

Program	Prior Authorization/Medical Necessity - Mycapssa® (octreotide)
Change Control	
12/2020	New program
12/2021	Annual review with no change to clinical criteria.
12/2022	Annual review with no change to clinical criteria. Updated references.
12/2023	Annual review with no change to clinical criteria.