UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2225-6
Program	Prior Authorization/Medical Necessity
Medication	Mycapssa™ (octreotide)*
P&T Approval Date	12/2020, 12/2021, 12/2022, 12/2023, 1/2025, 1/2026
Effective Date	4/1/2026

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.

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 confirmed 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

-OR-

ii. Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the provider's lab) at time of diagnosis

-AND-

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

i. Octreotide (e.g., Sandostatin, Sandostatin LAR) [Note: Coverage of Sandostatin and Sandostatin LAR may be subject to additional benefit and coverage review requirements]
ii. Lanreotide (e.g., Lanreotide Injection, Somatuline Depot) [Note: Coverage of Lanreotide Injection and Somatuline Depot may be subject to additional benefit and coverage review requirements]

-AND-

(c) The provider has submitted clinical justification on why the patient is

unable to be maintained on current octreotide or lanreotide therapy

-AND-

(d) Prescribed by or in consultation with an endocrinologist

-OR-

(2) **Both** of the following:

(a) Patient is currently on Mycapssa therapy for acromegaly

-AND-

(b) Prescribed by or in consultation with an endocrinologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Mycapssa therapy (e.g., age-normalized serum IGF-1 level)

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.

*Mycapssa is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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]. Scotland, UK: MW Encap Ltd.; August 2024.
2. 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.
3. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. 2021;24(1):1-13.

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.
12/2024	Annual review. Updated wording of criteria without change in clinical intent. Updated references.
1/2026	Annual review. For initial authorization, removed requirements for previous surgery, radiation, or bromocriptine, added Lanreotide Injection as an example of lanreotide, added note that injectable somatostatin analogs may be subject to additional benefit and coverage review requirements, and added prescriber requirement. For reauthorization, added example of positive clinical response. Added exclusion footnote. Updated background and references.