Drug Coverage Policy

Effective Date.....5/1/2026
Coverage Policy Number.....IP0491
Policy Title.....Mycapssa

Somatostatin Analogs – Mycapssa

- Mycapssa® (octreotide delayed-release capsules – Amryt)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Mycapssa, a somatostatin analog, is indicated for long-term maintenance treatment in **acromegaly** patients who have responded to and tolerated treatment with octreotide or lanreotide.[1]

GUIDELINES

The 15th Acromegaly Consensus Conference updated recommendations for the treatment of Acromegaly in a 2025 international consensus statement.[5] Somatostatin analogs remain the first-line medical therapy for most patients with persistent or non-surgically managed disease, with treatment goals centered on normalization of insulin-like growth factor -1 (IGF-1), symptom control, and prevention of tumor growth. Octreotide and lanreotide achieve biochemical control in ~40% of patients overall, with dose escalation or increased dosing frequency recommended before switching therapy. Mycapssa is considered non-inferior to injectable somatostatin analogs in patients previously controlled on injectables and may be selected based on patient preference and adherence. Signifor® LAR (pasireotide intramuscular injection), a multi-receptor somatostatin analog, provides greater biochemical efficacy in some patients inadequately controlled on octreotide or lanreotide but is associated with a substantially higher risk of hyperglycemia, warranting careful patient selection and glucose monitoring. The consensus highlights increasing use of combination therapy (somatostatin analogs plus Somavert® [pegvisomant subcutaneous injection]) for partial responders and stresses tailoring somatostatin analog choice using clinical, imaging, and pathological predictors (e.g., tumor granulation pattern, somatostatin receptor expression) to optimize outcomes.

The Endocrine Society Clinical Practice Guidelines for Acromegaly (2014) recommend medical therapy as adjuvant treatment after surgical intervention.[2] Mycapssa is not addressed in the guidelines. Primary medical therapy with somatostatin analogs (no preferred agent) can be recommended for some patients (e.g., surgery is not curative or patient is a poor surgical candidate). Updated recommendations to the 2014 guidelines on therapeutic outcomes for patients with acromegaly were drafted by the Acromegaly Consensus Group (2020).[3] The guidelines recommend lanreotide deep subcutaneous injection and octreotide long acting intramuscular injection as first-line medical therapies in patients with persistent disease after surgery. Mycapssa is recommended for patients who respond to and tolerate treatment with injectable lanreotide or octreotide. Signifor LAR is recommended as a second-line medical therapy due to its potential for hyperglycemic-associated adverse events. The Pituitary Society Update to Acromegaly Management Guidelines (2021) recommend a personalized approach to acromegaly medication management, especially for patients who are not surgical candidates or have residual disease.8 First-line therapies include somatostatin analogs, with Somavert and cabergoline used for resistant or mild cases. Mycapssa offers more convenient options, with treatment tailored to biochemical response, tumor features, and patient preferences.[4]

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for benefit coverage of Mycapssa. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Mycapssa as well as the monitoring required for adverse events and long-term efficacy, approval requires Mycapssa to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Mycapssa is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Acromegaly.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A.** Patient has (or had) a pretreatment (baseline) insulin-like growth factor 1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory; AND

Note: Pretreatment (baseline) refers to the IGF-1 level prior to the initiation of a somatostatin analog (e.g., Mycapssa [octreotide delayed-release capsules], an octreotide acetate injection product [e.g., Bynfezia Pen, Sandostatin {generic}, Sandostatin LAR Depot], Signifor LAR [pasireotide injection], Somatuline Depot [lanreotide injection], dopamine agonist [e.g., cabergoline, bromocriptine], or Somavert [pegvisomant injection]). Reference ranges for IGF-1 vary among laboratories.

B. According to the prescriber, patient has responded to one octreotide acetate injection product or Somatuline Depot (lanreotide injection); AND

C. The medication is prescribed by or in consultation with an endocrinologist; AND

D. Preferred product criteria is met for the product(s) as listed in the below table(s).

Employer Plans:

Product	Criteria
Mycapssa (octreotide delayed-release capsules)	Patient has tried ONE of octreotide ER injectable suspension (Sandostatin LAR Depot, generic), Somatuline Depot or lanreotide subcutaneous injection [may require prior authorization]. Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67

Individual and Family Plans:

Product	Criteria
Mycapssa (octreotide delayed-release capsules)	Patient has tried ONE of octreotide ER injectable suspension (Sandostatin LAR Depot, generic), Somatuline Depot or lanreotide subcutaneous injection [may require prior authorization]. Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67

Conditions Not Covered

Mycapssa for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Mycapssa® capsules [prescribing information]. Scotland, UK: Amryt; July 2024.
2. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
3. Giustina A, Barkhoudarian G, Beckers A, et al. Multidisciplinary management of acromegaly: A consensus. *Rev Endocr Meta Disord.* 2020;21(4):667-678.
4. Fleseriu M, Biller, BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary.* 2021; 24:1-13.
5. Melmed S, di Filippo L, Fleseriu M, et al. Consensus on acromegaly therapeutic outcomes: an update. *Nat Rev Endocrinol*. 2025;21(11):718-737.

Revision Details

Summary of Changes	Review Date	Effective Date
No Criteria Changes	5/15/2025	7/15/2025
Policy Title: **Updated from** "Mycapssa" **to** "Somatostatin Analogs – Mycapssa" **Acromegaly** **Updated from** "Documentation of a pretreatment insulin-like growth factor 1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory" **to** "Patient has (or had) a pretreatment (baseline) insulin-like growth factor 1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory" **Added** Note: Pretreatment (baseline) refers to the IGF-1 level prior to the initiation of a somatostatin analog (e.g., Mycapssa [octreotide delayed-release capsules], an octreotide acetate injection product [e.g., Bynfezia Pen, Sandostatin {generic}, Sandostatin LAR Depot], Signifor LAR [pasireotide injection], Somatuline Depot [lanreotide injection], dopamine agonist [e.g., cabergoline, bromocriptine], or Somavert [pegvisomant injection]). Reference ranges for IGF-1 vary among laboratories. **Updated from** "Documentation that the individual has responded to one octreotide acetate injection product or Somatuline Depot (lanreotide injection)" **to** "According to the prescriber, patient has responded to one octreotide acetate injection product or Somatuline Depot (lanreotide injection)" **Employer Plans and Individual and Family Plans** **Updated** preferred product criteria	10/30/2025	12/15/2025
Preferred Product Table. **Employer Plans** **Updated from** "Patient has tried Somatuline® Depot (lanreotide) injection [may require prior authorization]." **to** "Patient has tried ONE of octreotide ER injectable suspension (Sandostatin LAR Depot, generic), Somatuline Depot or lanreotide subcutaneous injection [may require prior authorization]. Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-0906-67" **Individual and Family Plans.**	2/5/2026	4/1/2026

Updated from "Patient has tried octreotide acetate ER (Sandostatin LAR Depot, generic) or lanreotide (Somatuline® Depot, generic) injection. [may require prior authorization]" **to** "Patient has tried ONE of octreotide ER injectable suspension (Sandostatin LAR Depot, generic), Somatuline Depot or lanreotide subcutaneous injection [may require prior authorization]. Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-0906-67"		
No criteria changes	4/16/2026	5/1/2026

The policy effective date is in force until updated or retired.