Effective Date 1/15/2024
Next Review Date 1/15/2025
Coverage Policy Number IP0491

Mycapssa

Table of Contents

Related Coverage Resources

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. 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

This policy supports medical necessity review for octreotide delayed-release capsules (**Mycapssa**®).

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Octreotide delayed-release capsules (**Mycapssa**) **are considered medically necessary when the following are met:**

Acromegaly. Individual meets **ALL** of the following criteria:

A. 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.

B. Documentation that the individual has responded to one octreotide acetate injection product or Somatuline Depot (lanreotide injection).
C. The medication is prescribed by, or in consultation with, an endocrinologist.
D. Non-Covered Product Criteria is met, refer to below table(s)

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Mycapssa (octreotide delayed-release capsules)	Documentation of **ONE** of the following: 1. Individual has previously started on or is currently receiving Mycapssa capsules. 2. There is documentation the individual is unable to use to Somatuline® Depot (lanreotide) injection [may require prior authorization].

Individual and Family Plan Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Mycapssa (octreotide delayed-release capsules)	Documentation of **ONE** of the following: 1. Individual has previously started on or is currently receiving Mycapssa capsules. 2. There is documentation the individual is unable to use to Somatuline® Depot (lanreotide) injection [may require prior authorization].

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of Mycapssa is considered medically necessary for acromegaly when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.
Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

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] Mycapssa maintained growth hormone and insulin-like growth factor 1 levels in patients with acromegaly.
GUIDELINES

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 created by the Acromegaly Consensus Group (2017).[3] The guidelines recommend Somatuline® Depot (lanreotide deep subcutaneous injection) and Sandostatin® LAR Depot (octreotide intramuscular injection) as first-line medical therapies in patients with persistent disease after surgery. Signifor® LAR (pasireotide intramuscular injection) is recommended as a second-line medical therapy due to its potential for hyperglycemic-associated adverse events. The Pituitary Society Acromegaly Management Guidelines (2020) recommend oral octreotide capsules as suitable for patients who have demonstrated complete or partial biochemical response to injectable octreotide or lanreotide.[4]

References

1. Mycapssa® capsules [prescribing information]. Scotland, UK: Amryt; March 2022.
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. Melmed S, Bronstein M, Chanson P, et al. A consensus statement on acromegaly therapeutic outcomes. *Natural Reviews Endocrinology.* 2018;14(9):552-561.
4. Fleseriu M, Biller, BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary.* 2020; 24:1-13.