PRIOR AUTHORIZATION POLICY

POLICY: Somatostatin Analogs – Mycapssa Prior Authorization Policy
- Mycapssa® (octreotide delayed-release capsules – Chiasma)

REVIEW DATE: 09/14/2022

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 statement recommends 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.

POLICY STATEMENT

Prior Authorization is recommended for prescription 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Mycapssa is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acromegaly.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Mycapssa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Mycapssa® capsules [prescribing information]. Needham, MA: Chiasma; December 2020.
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.