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5.30.069

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	August 7, 2020
Subject:	Mycapssa	**Page:**	1 of 5

Last Review Date: March 6, 2026

Mycapssa

Description

Mycapssa (octreotide) delayed-release capsules

Background
Mycapssa (octreotide acetate) exerts pharmacological actions similar to the natural hormone somatostatin but is a more potent inhibitor of growth hormone (GH), glucagon, and insulin than somatostatin. Like somatostatin, it also suppresses luteinizing hormone (LH) response to gonadotropin-releasing hormone (GnRH), decreases splanchnic blood flow, and inhibits release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, and pancreatic polypeptide (1).

Regulatory Status
FDA-approved indication: Mycapssa is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to or tolerated treatment with octreotide or lanreotide (1).

The maximum recommended dosage of Mycapssa is 80 mg daily. Once the maintenance dosage of Mycapssa is achieved, IGF-1 levels and the patient's signs and symptoms should be monitored monthly or as indicated (1).

Mycapssa therapy should be withdrawn periodically to assess disease activity. If IGF-1 levels increase and signs and symptoms recur, Mycapssa therapy should be resumed (1).

Mycapssa has warnings regarding: cholelithiasis; hyperglycemia and hypoglycemia; thyroid function abnormalities; cardiac function abnormalities; and decreased Vitamin B_{12} levels and abnormal Schilling's Tests (1).

There is a potential for unintended pregnancy with premenopausal women as the therapeutic benefits of a reduction in GH levels and normalization of IGF-1 concentration in acromegalic females treated with octreotide may lead to improved fertility (1).

The safety and effectiveness of Mycapssa in pediatric patients have not been established (1).

Related policies
Sandostatin LAR, Signifor LAR, Somatuline Depot

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Mycapssa may be considered **medically necessary** if the conditions indicated below are met.

Mycapssa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Acromegaly
a. Used as long-term maintenance treatment

AND ALL of the following:
a. Patient has responded to and tolerated prior treatment with octreotide or lanreotide
b. Prescriber agrees to monitor **ALL** of the following:
    i. IGF-1 levels
    ii. Blood glucose

iii. Thyroid function
iv. Electrocardiogram (ECG)
v. Vitamin B_{12} levels
vi. Signs or symptoms of cholelithiasis (gallstones) or associated complications

c. Prescriber agrees to inform premenopausal female patients that treatment with Mycapssa may result in unintended pregnancy
d. Prescriber agrees to periodically withdraw Mycapssa to assess disease activity

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Acromegaly
a. Used as long-term maintenance treatment

AND ALL of the following:
a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor **ALL** of the following:
i. IGF-1 levels
ii. Blood glucose
iii. Thyroid function
iv. Electrocardiogram (ECG)
v. Vitamin B_{12} levels
vi. Signs or symptoms of cholelithiasis (gallstones) or associated complications
b. Prescriber agrees to inform premenopausal female patients that treatment with Mycapssa may result in unintended pregnancy
c. Prescriber agrees to periodically withdraw Mycapssa to assess disease activity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 336 capsules per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Mycapssa (octreotide acetate) exerts pharmacological actions similar to the natural hormone somatostatin but is a more potent inhibitor of growth hormone (GH), glucagon, and insulin than somatostatin. Like somatostatin, it also suppresses luteinizing hormone (LH) response to gonadotropin-releasing hormone (GnRH), decreases splanchnic blood flow, and inhibits release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, and pancreatic polypeptide. The safety and effectiveness of Mycapssa in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Mycapssa while maintaining optimal therapeutic outcomes.

References

1. Mycapssa [package insert]. Scotland, UK: MW Encap Ltd.; August 2024.

Policy History

Date	Action
August 2020	Addition to PA
September 2020	Annual review
December 2020	Annual review
June 2021	Annual review
June 2022	Annual review and reference update

December 2022	Annual review. Changed policy number to 5.30.069
June 2023	Annual review
June 2024	Annual review
September 2024	Annual review
June 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.