Pharmacy Policy Bulletin: J-0286 Mycapssa (octreotide) – Commercial and Healthcare Reform	
Number: J-0286	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit:** **Commercial:** **Prior Authorization (1.)**: **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0286-007	**Original Date:** 08/05/2020
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Mycapssa (octreotide)
FDA-Approved Indication(s):	• Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide

Background:	• Mycapssa is a somatostatin analog that exerts pharmacologic 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) and decreases splanchnic blood flow. It mimics natural somatostatin by inhibiting serotonin release and the secretion of gastrin, vasoactive intestinal peptide, insulin, glucagon, secretin, motilin, and pancreatic polypeptide. Acromegaly is a hormone disorder characterized by excess levels of GH and insulin-like growth factor 1 (IGF-1). Common characteristics of acromegaly are abnormal growth of bones and soft tissue, irregular glucose metabolism, and cardiovascular disease. • The primary endpoint of the efficacy trials for Mycapssa was IGF-1 levels less than or equal to the upper limit of normal at the end of 9 months of treatment. • The 2014 Endocrine Society's treatment guidelines recommend transsphenoidal surgery as the primary therapy in most patients. In patients with persistent disease following surgery, somatostatin analogs or pegvisomant are recommended for significant disease, while dopamine agonists are recommended for mild disease. • Recommended treatment goals of acromegaly are biochemical targets of an age-normalized serum IGF-1 value and a random GH value of < 1.0 µg/L, which both signify control of acromegaly. • Prescribing Considerations: ○ Monitor IGF-1 levels and patient's signs and symptoms every two weeks during dose titration or as indicated. Once maintenance dosage is achieved, monitor IGF-1 levels monthly.

	○ If IGF-1 levels remain above the upper normal limit after treatment with 80 mg daily, consider discontinuing Mycapssa and switching patient to another somatostatin analog. ○ Advise females of reproductive potential of the potential of an unintended pregnancy.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Mycapssa may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of acromegaly (ICD-10: E22.0).

C. The member has high pretreatment insulin-like growth factor (IGF-1) based on laboratory reference range.

D. The member has previously responded to and tolerated treatment with one (1) of the following products **(1. or 2.)**:

1. octreotide

2. lanreotide

II. Reauthorization

When a benefit, reauthorization of Mycapssa may be approved when one (1) of the following criteria is met **(A. or B.)**:

A. Decreased IGF-1 from baseline

B. Normalized IGF-1 from baseline

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Mycapssa [package insert]. Cincinnati, OH: Chiasma, Inc.; March 2022.
2. Giustina A, Barkan A, Beckers A, et al. A Consensus on the Diagnosis and Treatment of Acromegaly Comorbidities: An Update. *J Clin Endocrinol Metab*. 2020;105(4):dgz096.
3. 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.

4. Insulin-Like Growth Factor (IGF-1). Pathology Handbook. Available at: www.pathology.med.umich.edu. Accessed June 17, 2024.