MEDICAL MUTUAL®

Drug Policy

Policy:	Mycapssa (octreotide) delayed-release capsules	Annual Review Date: 04/18/2024 Last Revised Date: 04/18/2024

OVERVIEW

Mycapssa is an oral somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. Treatment is indicated in patients who have responded to and tolerated Sandosatin subcutaneous injection.

POLICY STATEMENT

This policy involves the use of Mycapssa. Prior authorization is recommended for pharmacy benefit coverage of Mycapssa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Mycapssa be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

AUTOMATION:

- Initial users: When available, 1) ICD-10 code E22.0 confirming diagnosis of Acromegally AND 2) patient age of 18 years or older AND 3) history of any octreotide product (Bynfezia Pen, Sandostatin, Sandostatin LAR), lanreotide product (Somatuline Depot), or other somastatin analoq (Signifor, Signifor LAR) within the previous 730 days will be used for automation to allow approval of the requested medication.
- Continuing users: When available, 1) ICD-10 code E22.0 confirming diagnosis of Acromegally AND 2) patient age of 18 years or older AND 3) history of Mycapssa use within the last 130 days will be used for automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. Acromegaly

Criteria. *Patient must meet the following criteria (A, B, C, and D):*

A. The medication is prescribed by or in consultation with an endocrinologist; AND
B. The patient has previously responded to and tolerated treatment with octreotide or lanreotide; AND
C. The patient had a baseline (prior to initiation of any somatostatin analog [Signifor LAR, Somatuline Depot, Mycapssa], dopamine agonist [bromocriptine, cabergoline] or Somavert) IGF-1 level above the upper limit of normal (ULN) for age and gender per the laboratory's standard reference values; AND
D. The patient is at least 18 years of age.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Mycapssa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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