

# Drug Policy

<b>Policy:</b>	<b>Mycapssa (octreotide) delayed-release capsules</b>	<b>Annual Review Date:</b> <b>08/24/2023</b>
		<b>Last Revised Date:</b> <b>08/24/2023</b>

## 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.

## 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.

This document is subject to the disclaimer found at <https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx> and is subject to change. <https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx>

# Drug Policy

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

1. Mycapssa Depot [prescribing information]. Scotland, UK: MW Encap Ltd. June 2020.
2. Giustina A, Chanson P, Kleinberg D, et al. A consensus on the medical treatment of acromegaly. *Nat Rev Endocrinol*. 2014;10(4):243-248.
3. 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.
4. Melmed S. Acromegaly. *N Engl J Med*. 2006;355:2558-2573.
5. Christofides EA. Clinical importance of achieving biochemical control with medical therapy in adult patients with acromegaly. *Patient Pref Adherence*. 2016;10:1217-1225.
6. Oberg K, Lamberts SW. Somatostatin analogues in acromegaly and gastroenteropancreatic neuroendocrine tumours: past, present and future. *Endocr Relat Cancer*. 2016;23(12):R551-566.
7. Manjila S, Wu OC, Khan FR, et al. Pharmacological management of acromegaly: a current perspective. *Neurosurg Focus*. 2010;29(4):E14.
8. Strosberg JR, Halfdanarson TR, Bellizzi AR, et al. The North American Neuroendocrine Tumor Society consensus guidelines for surveillance and medical management of midgut neuroendocrine Tumors. *Pancreas*. 2017;46(6):707-714.
9. VIPoma Summary. Orphanet. Available at: [http://www.orpha.net/consor/cgi-bin/OC\\_Exp.php?Expert=97282](http://www.orpha.net/consor/cgi-bin/OC_Exp.php?Expert=97282). Last reviewed: November 2014. Accessed July 1, 2019.
10. Dimitriadis GK, Weickert MO, Randeva HS, et al. Medical management of secretory syndromes related to gastroenteropancreatic neuroendocrine tumors. *Endocr Relat Cancer*. 2016;23(9):R423-436.
11. Octreotide acetate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 04 August 2020. Accessed on 12 August 2020.