

## PHARMACY POLICY STATEMENT

### Indiana Medicaid

<b>DRUG NAME</b>	<b>Mycapssa (octreotide)</b>
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Mycapssa is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. It is a delayed-release oral capsule formulation of octreotide.

Acromegaly is typically the result of a GH-secreting pituitary adenoma, thus surgical resection is the preferred treatment whenever possible as the best chance for a cure. If disease persists after surgery, a first-generation long-acting somatostatin receptor ligand is recommended as first-line therapy.

Mycapssa (octreotide) will be considered for coverage when the following criteria are met:

#### Acromegaly

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has a confirmed diagnosis of acromegaly; AND
4. Member had an inadequate response to surgery or surgery is not an option (documentation required); AND
5. Member has been stabilized on injectable octreotide or lanreotide for at least 3 months, with insulin-like growth factor (IGF-1) lab results demonstrating response to treatment; AND
6. Member has documented rationale for why it is medically necessary to switch to the oral formulation of octreotide (e.g., injection site reactions, ongoing symptoms despite biochemical control).
7. **Dosage allowed/Quantity limit:** Initiate at 40mg per day, given as 20mg twice daily. Titrate in 20mg increments, based on IGF-1 levels. Max dose of 80mg per day, given as 40mg twice daily. (QL 112 capsules per 28 days)

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes/lab report must show maintained or normalized IGF-1.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Mycapssa (octreotide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
10/19/2020	New policy for Mycapssa created.
04/01/2022	Transferred to new template. Updated references.

References:

1. Mycapssa (octreotide) [package insert]. Amryt Pharmaceuticals, Inc.; 3/2022.
2. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*. 2014;99(11):3933-3951. doi:10.1210/jc.2014-2700
3. Melmed S, Bronstein MD, Chanson P, et al. A Consensus Statement on acromegaly therapeutic outcomes. *Nature Reviews Endocrinology*. 2018;14(9):552-561. doi:10.1038/s41574-018-0058-5
4. Melmed S, Popovic V, Bidlingmaier M, et al. Safety and efficacy of oral octreotide in acromegaly: results of a multicenter phase III trial [published correction appears in J Clin Endocrinol Metab. 2016 Oct;101(10):3863]. *J Clin Endocrinol Metab*. 2015;100(4):1699-1708. doi:10.1210/jc.2014-4113
5. Samson SL, Nachtigall LB, Fleseriu M, et al. Maintenance of Acromegaly Control in Patients Switching From Injectable Somatostatin Receptor Ligands to Oral Octreotide. *J Clin Endocrinol Metab*. 2020;105(10):dgaa526. doi:10.1210/clinem/dgaa526
6. Zahr R, Fleseriu M. Updates in Diagnosis and Treatment of Acromegaly. *Eur Endocrinol*. 2018;14(2):57-61. doi:10.17925/EE.2018.14.2.57
7. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. 2021;24(1):1-13. doi:10.1007/s11102-020-01091-7

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