CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Mycapssa (octreotide)
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.
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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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