CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Mycapssa (octreotide)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 120 capsules per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Mycapssa (octreotide) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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 (preferred) or lanreotide (non-preferred) 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:** 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.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

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

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Mycapssa (octreotide) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/19/2020	New policy for Mycapssa created.
03/11/2021	Annual review, no changes

References:

1. Mycapssa (octreotide) [package insert]. Needham, MA: Chiasma, Inc.; 2020.
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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*. October 2020. doi:10.1007/s11102-020-01091-7

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Revised date: 03/11/2021