Mycapssa (octreotide delayed-release capsule)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Mycapssa is indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. For acromegaly:
   1. For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or radiotherapy or a clinical reason for not having surgery or radiotherapy.
   2. For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy

Criteria for Initial Approval

A. Mycapssa (octreotide delayed-release capsule) may be considered medically necessary for the treatment of acromegaly when all of the following criteria are met:

1. Member is 18 years of age or older
2. Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
3. Member has a confirmed diagnosis of acromegaly
4. Member had an inadequate or partial response to surgery or radiotherapy (i.e., unable to achieve normalization of IGF-I levels or unable to adequately control tumor mass) OR there is a clinical reason why the member has not had surgery or radiotherapy
5. Member has previously responded to and tolerated treatment with octreotide or lanreotide
6. Member has had a documented inadequate response, intolerable adverse effect, or contraindication to BOTH Sandostatin LAR (octreotide) injection AND Somatuline Depot (lanreotide) injection
7. Member has had a documented inadequate response, intolerable adverse effect, or contraindication to self-administered immediate-release octreotide injection (e.g., generic Sandostatin or Bynfezia pen)

Approval will be for **6 months**

Continuation of Therapy

A. Continued treatment with Mycapssa (octreotide delayed-release capsule) may be considered medically necessary for the treatment of acromegaly when the following criteria are met:
   1. The member has experienced a positive clinical response to Mycapssa therapy as demonstrated by all of the following:
      a. No evidence of disease progression
      b. Documented reduction or normalization of IGF-1 level since initiating therapy

Approval will be for **12 months**

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits
Mycapssa 20mg capsules: 4 per day

CLINICAL RATIONALE

Acromegaly is a rare, chronic disease often caused by a benign pituitary tumor and characterized by excess production of growth hormone and insulin-like growth factor 1 (IGF-1). If left untreated, acromegaly can lead to serious and sometimes life-threatening complications. Acromegaly is primarily treated with surgical resection of the tumor; however, some patients will require chronic injections. The first-line pharmacological treatment is somatostatin analogs (SSAs) such as octreotide and lanreotide, which inhibit growth hormone secretion. Chiasma estimates that there are approximately 8,000 patients in the United States that may be utilizing these agents currently. Use of these drugs is frequently associated with injection site reactions, among other side effects.

On June 26, 2020, the U.S. Food and Drug Administration approved Chiasma's Mycapssa (octreotide acetate) capsules for long-term maintenance treatment in patients with acromegaly who have responded to and tolerated treatment with octreotide or lanreotide. Mycapssa is the first oral SSA and uses Chiasma's TPE technology. Oral absorption of large cyclic peptide molecules such as octreotide is often difficult, but the TPE technology will allow the SSA to enter systemic circulation more readily.

Mycapssa was studied in 56 patients with acromegaly in the 9-month, randomized, double-blind, placebo-controlled CHIASMA OPTIMAL trial. Patients were included if they had a history of prior active disease but had now achieved biochemical control with injectable SSAs for at least 6 months. Patients randomized to the Mycapssa arm initiated therapy at 20 mg twice daily and could titrate up to 40 mg twice daily until deemed adequately controlled. The primary endpoint was the proportion of patients who maintained biochemical response at the end of the 9-month treatment phase. The trial found that 58% of patients treated with Mycapssa maintained biochemical response versus 19% in the placebo arm. Adverse reactions reported were similar to those of injectable alternatives.

Although full data from this study are not available at this time, findings from an open-label study published in 2015 found that 46% of patients achieved normalized IGF-1 levels or a return to baseline at the 40-mg daily dose, 23% at the 60-mg daily dose, and 31% at the 80-mg daily dose.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

1. Mycapssa [package insert]. Needham, MA: Chiasma, Inc.; June 2020.
2. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
3. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. Endocr Pract. 2011;17(suppl 4):1-44.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.04.22
Original Effective Date: January 10, 2021
Reviewed: February 2022
Revised: January 2021
Current Effective Date: January 10, 2021