BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 8/20/2020
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MYCAPSSA® (octreotide) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

MYCAPSSA® (octreotide) oral

Criteria:

- **Criteria for initial therapy:** Mycapssa (octreotide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of acromegaly in an individual who had an inadequate response to surgery or radiation or had documentation these are not appropriate

  4. Individual has failure, intolerance, or contraindication to **BOTH** the following:
     a. Sandostatin LAR (octreotide) injection
     b. Somatuline Depot (lanreotide) injection

  5. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Using the same laboratory assay (laboratory reference range must be provided):
        i. Elevated insulin-like growth factor 1 (IGF-1) level for the patient's age and gender
        ii. Elevated Growth hormone (GH) level within 2-hours after 75 g of oral glucose
     b. Blood glucose level

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Mycapssa (octreotide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist

  2. Individual's condition responded while on therapy
     a. Response is defined as:
        i. No evidence of disease progression
        ii. Achieved and maintains
            1. Using the same laboratory assay that was used at baseline measurement (laboratory reference range must be provided):
               a. GH levels are < 1 µg/L within 2-hours after 75 g of oral glucose
               b. IGF-1 levels are less than or equal to the upper limit of normal for the patient's age and gender

  3. Individual has been adherent with the medication

  4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use

MYCAPSSA® (octreotide) oral

a. Significant adverse effect such as:
   i. Cholelithiasis
   ii. Cholecystitis
   iii. Cholangitis
   iv. Pancreatitis

5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Mycapssa (octreotide) is a somatostatin analog indicated for long-term maintenance treatment in acromegaly.

Octreotide exerts pharmacologic actions similar to the natural hormone somatostatin, but is a more potent inhibitor of growth hormone (GH), glucagon, and insulin than somatostatin. Like somatostatin, it suppresses luteinizing hormone (LH) response to gonadotropin-releasing hormone (GnRH), decreases splanchnic blood flow, and inhibits release of serotonin, gastrin, vasoactive intestinal peptide (VIP), secretin, motilin, and pancreatic polypeptide.

Acromegaly is a disease characterized by excessive release of growth hormone (GH). Increased levels of GH stimulate an increase in hepatic production of insulin-like growth factor-1 (IGF-1). Excess IGF-1 causes increased growth of bones and soft-tissues while excess GH can cause other conditions such as diabetes mellitus, hypertension, and an increase in cardiovascular risk. Both serum GH concentrations and IGF-1 concentrations are increased in virtually all patients with acromegaly.

The goals of therapy in patients with acromegaly are to lower the serum IGF-1 concentration to within the normal range for the patient's age and gender and to lower the serum GH concentration to < 1 mcg/L. The Endocrine Society guidelines suggest that an age-normalized serum IGF-1 and a random GH < 1 mcg/L should both be therapeutic goals as they correlate with control of acromegaly.

Resources:

1. Mycapssa (octreotide) product information, revised by manufacturer 06-2020, accessed 07-17-20 at DailyMed

2. Melmed S and Katznelson L. Diagnosis of acromegaly. In: UpToDate, Snyder PJ (Ed), UpToDate, Waltham, MA.: UpToDate Inc. http://uptodate.com (Accessed on July 17, 2020.)

3. Melmed S and Katznelson L. Treatment of acromegaly. In: UpToDate, Snyder PJ (Ed), UpToDate, Waltham, MA.: UpToDate Inc. http://uptodate.com (Accessed on July 17, 2020.)