

Pharmacy Policy Bulletin

Title: Octreotide Products

Policy #: Rx.01.231

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **octreotide acetate (Bynfezia®)**, and **octreotide (Mycapssa®)** as provided under the member's prescription drug benefit.

Description:

Acromegaly is a disease usually caused by a benign tumor on the pituitary gland, causing increased release of growth hormone. Increased release of growth hormone causes an increase in release of insulin-like growth factor I (IGF-I), causing the signs and symptoms of acromegaly.

Cutaneous flushing and diarrhea are commonly associated with carcinoid syndrome. Most flushing episodes primarily involves the face, neck, upper chest, which become red to violaceous or purple, and is associated with a mild burning sensation. Secretory diarrhea is often debilitating where stools may vary from few to more than 30 per day, are typically watery and non-bloody, can be explosive and accompanied by abdominal cramping. Diarrhea is usually unrelated to flushing episodes, though both can be minimized by pretreatment with octreotide.

Vasoactive intestinal peptide tumor (VIPoma) is suspected in patients with unexplained high-volume secretory diarrhea. Treatment of VIPoma starts with replacement of fluid losses and correction of electrolyte abnormalities. Somatostatin analogs inhibit the secretion of vasoactive intestinal polypeptide and are the treatment of choice to control diarrhea in VIPoma.

Octreotide exerts pharmacologic actions similar to the natural hormone somatostatin. It is a potent inhibitor of growth hormone, insulin like growth factor-1 (IGF-I), glucagon, and insulin. It suppresses luteinizing hormone response to gonadotropin releasing hormone. Since it releases growth hormone and IGF-I levels, it is beneficial in patients with acromegaly.

Bynfezia™ (octreotide acetate) pen is indicated for:

- Reduction of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) [somatomedin C] in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.
- Treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in adult patients.
- Treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) in adult patients.

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

Policy:

ACROMEGALY

INITIAL CRITERIA: Octreotide acetate (Bynfezia™) or octreotide (Mycapssa™) is approved when ALL the following criteria are met:

1. Member is 18 years of age or older; and
2. Diagnosis of acromegaly; and
3. Prescribed by or in conjunction with an endocrinologist; and
4. One of the following:
 - a. Inadequate response to surgery or pituitary irradiation; or
 - b. Not a candidate for surgical resection or pituitary irradiation; and
5. Inadequate response or inability to tolerate a dopamine agonist (e.g. bromocriptine or cabergoline) at maximally tolerated doses; and
6. Member has responded to and tolerated treatment with Octreotide or Lanreotide products (e.g. Somatulline Depot, Sandostatin, Sandostatin LAR depot) [**Applies to Mycapssa™ only**]

Initial authorization: 12 months

REAUTHORIZATION CRITERIA: Octreotide acetate (Bynfezia™) or octreotide (Mycapssa™) is approved with documentation of positive clinical response to therapy (e.g. reduction or normalization of IGF-I or Growth Hormone level for same age and sex)

Reauthorization: 2 years

CARCINOID TUMORS, FOR SYMPTOMATIC TREATMENT OF DIARRHEA OR FLUSHING

INITIAL CRITERIA: Octreotide acetate (Bynfezia) is approved when ALL the following are met:

1. Diagnosis of metastatic carcinoid tumor; and
2. Member requires symptomatic treatment of severe diarrhea or flushing episodes; and
3. Member is 18 years of age or older

Initial authorization: 12 months

REAUTHORIZATION CRITERIA: Octreotide acetate (Bynfezia) is approved with documentation of an improvement in the number of clinical diarrhea or flushing episodes.

Reauthorization: 2 years

VASOACTIVE INTESTINAL PEPTIDE TUMORS, FOR SYMPTOMATIC TREATMENT OF DIARRHEA

INITIAL CRITERIA: Octreotide acetate (Bynfezia) is approved when ALL the following are met:

1. Diagnosis of vasoactive intestinal peptide tumor; and
2. Member requires the treatment of profuse watery diarrhea, and
3. Member is 18 years of age or older

Initial authorization: 12 months

REAUTHORIZATION CRITERIA: Octreotide acetate (Bynfezia) is approved with documentation of an improvement in the number of diarrhea episodes.

Reauthorization: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Strosberg, J. Clinical features of carcinoid syndrome. April 2019. UpToDate. Available from: https://www.uptodate.com/contents/clinical-features-of-carcinoid-syndrome?search=carcinoid%20tumor&topicRef=2622&source=see_link#H11. Accessed November 4, 2020.

Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-3951.

Bynfezia™ (octreotide acetate) injection [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; January 2020. Available from: https://bynfeziapen.com/wp-content/uploads/2020/06/Bynfezia_Pen_PI_and_IFU-1.pdf. Accessed October 23, 2020.

Mycapssa® (octreotide) [prescribing information]. Scotland, UK: MW Encap Ltd.; June 2020. Available from: <https://label.mycapssa.com/wp-content/uploads/sites/4/2020/06/prescribinginformation.pdf>. Accessed October 23, 2020.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Bynfezia, Mycapssa	Octreotide

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:	1.0
P&T Approval Date:	10/8/2020
Policy Effective Date:	1/1/2021
Next Required Review Date:	10/8/2021

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

