BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.30.065

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	March 6, 2020
Subject:	Bynfezia	**Page:**	1 of 4

Last Review Date: March 8, 2024

Bynfezia

Description

Bynfezia (octreotide acetate) pen

Background
Bynfezia (octreotide acetate) is a subcutaneous injection for the treatment of acromegaly, diarrhea or flushing episodes that are associated with metastatic carcinoid tumors, and diarrhea that is associated with vasoactive intestinal peptide (VIP)-secreting tumors. Acromegaly is a rare and debilitating endocrine disorder caused by excess production of growth hormone (GH) and insulin-like growth factor-1 (IGF-1). Metastatic carcinoid tumors are found along the gastrointestinal (GI) tract and release too much serotonin into the body, while VIP-secreting tumors cause increased secretions from the intestines. Bynfezia mimics natural somatostatin by inhibiting the secretion of growth hormone, glucagon, insulin, serotonin, gastrin, VIP, secretin, motilin, and pancreatic polypeptide (1).

Regulatory Status
FDA-approved indications: Bynfezia is a somatostatin analogue indicated for: (1)

1. 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
2. Treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in adult patients
3. Treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) in adult patients

Limitations of Use: (1)

- In patients with acromegaly, the effect of Bynfezia on improvement in clinical signs and symptoms, reduction in tumor size and rate of growth, has not been determined.
- In patients with carcinoid syndrome and VIPomas, the effect of Bynfezia on tumor size, rate of growth, and development of metastases has not been determined.

The safety and effectiveness of Bynfezia in pediatric patients less than 18 years of age have not been established (1).

Related policies
Mycapssa, Sandostatin LAR, Signifor LAR, Somatuline Depot

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Bynfezia may be considered **medically necessary** if the conditions indicated below are met.

Bynfezia may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Acromegaly
    a. Inadequate treatment response or patient is **NOT** a candidate for **ALL** of the following:
        i. Surgery resection
        ii. Pituitary irradiation
        iii. A dopamine agonist (e.g., bromocriptine, cabergoline, etc.)
2. Severe diarrhea or flushing episodes associated with metastatic carcinoid tumor(s)
3. Profuse watery diarrhea associated with VIP-secreting tumor(s)

AND the following:

a. Must have documented reason for requiring special injection device such as: lack of dexterity, visual acuity issues

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Acromegaly
2. Severe diarrhea or flushing episodes associated with metastatic carcinoid tumor(s)
3. Profuse watery diarrhea associated with VIP-secreting tumor(s)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Bynfezia (octreotide acetate) is a subcutaneous injection for the treatment of acromegaly, diarrhea or flushing episodes that are associated with metastatic carcinoid tumors, and diarrhea that is associated with vasoactive intestinal peptide (VIP)-secreting tumors. Acromegaly is a rare and debilitating endocrine disorder caused by excess production of growth hormone (GH)

and insulin-like growth factor-1 (IGF-1). Metastatic carcinoid tumors are found along the gastrointestinal (GI) tract and release too much serotonin into the body, while VIP-secreting tumors cause increased secretions from the intestines. Bynfezia mimics natural somatostatin by inhibiting the secretion of growth hormone, glucagon, insulin, serotonin, gastrin, VIP, secretin, motilin, and pancreatic polypeptide. The safety and effectiveness of Bynfezia in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Bynfezia while maintaining optimal therapeutic outcomes.

References

1. Bynfezia [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2020.

Policy History

Date	Action
March 2020	Addition to PA
June 2020	Annual review
September 2020	Annual review
December 2020	Annual review
March 2021	Annual review
March 2022	Annual review and reference update
December 2022	Annual review. Changed policy number to 5.30.065. Per SME, changed initiation requirement for acromegaly from t/f bromocriptine to t/f a dopamine agonist
March 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.