MEDICAL MUTUAL®

Drug Policy

Policy:	Bynfezia Pen (octreotide acetate)	Annual Review Date: 08/20/2020 Last Revised Date: 08/20/2020

OVERVIEW

Bynfezia Pen is a somatostatin analog 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. Bynfezia Pen is also indicated for treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in adult patients and symptomatic treatment of patients with metastatic carcinoid syndrome and diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors and treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) in adult patients.

POLICY STATEMENT

This policy involves the use of Bynfezia Pen. Prior authorization is recommended for pharmacy benefit coverage of Bynfezia Pen. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Bynfezia Pen as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Bynfezia Pen be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Bynfezia Pen is recommended in those who meet the following criteria:

1. <u>Acromegaly</u>

Criteria. *Patient must meet the following criteria (A, B, C, D, <u>and</u> E):*

- **A.** The medication is prescribed by or in consultation with an endocrinologist; AND
- **B.** The patient has had an inadequate response to or is ineligible for surgery, radiation, or bromocriptine OR is experiencing negative effects due to tumor size (e.g. optic nerve compression); AND
- **C.** The patient had a baseline (prior to initiation of any somatostatin analog [Bynfezia Pen, Sandostatin subcutaneous injection/LAR, Signifor LAR, Somatuline Depot,], dopamine agonist [bromocriptine, cabergoline] or Somavert)

IGF-1 level above the upper limit of normal (ULN) for age and gender per the laboratory's standard reference values; AND

D. The patient is at least 18 years of age; AND

E. The patient has tried and failed or has contraindication(s) to the use of generic octreotide subcutaneous injection.

2. Carcinoid Syndrome

Criteria. *Patient must meet the following criteria (A, B, C, and D):*

A. The medication is prescribed by or in consultation with an endocrinologist, oncologist, or gastroenterologist; AND

B. The patient has severe diarrhea/flushing episodes associated with metastatic carcinoid tumors; AND

C. The patient is at least 18 years of age; AND

D. The patient has tried and failed or has contraindication(s) to the use of generic octreotide subcutaneous injection.

3. Vasoactive Intestinal Peptide (VIP)-Secreting Tumors

Criteria. *Patient must meet the following criteria (A, B, C, and D):*

A. The medication is prescribed by or in consultation with an endocrinologist, oncologist, or gastroenterologist; AND

B. The patient has profuse watery diarrhea associated with VIP-secreting tumors; AND

C. The patient is at least 18 years of age; AND

D. The patient has tried and failed or has contraindication(s) to the use of generic octreotide subcutaneous injection.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Bynfezia Pen has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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