UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3150-1
Program	Step Therapy
Medication	Bynfezia Pen™ (octreotide acetate) *Bynfezia Pen is excluded from coverage for the majority of our benefits
P&T Approval Date	11/2020
Effective Date	2/1/2021; Oxford only: N/A

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial of or contraindication to octreotide acetate (Sandostatin®) before providing coverage for Bynfezia Pen™ (octreotide acetate)

Bynfezia Pen and Sandostatin are both octreotide acetate formulations indicated to reduce blood levels of growth hormone and insulin-like growth factor-I (IGF-1) [somatomedin C] in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation and bromocriptine mesylate at maximally tolerated doses. It is also indicated in adult patients for the treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in and for the treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas).

The NCCN (National Comprehensive Cancer Network) recommends the use of octreotide acetate for the treatment of meningiomas. The NCCN also recommends octreotide acetate for the treatment of several types of neuroendocrine and adrenal tumors, including neuroendocrine tumors of the pancreas, neuroendocrine tumors of the gastrointestinal tract, lung, and thymus (carcinoid tumors), pheochromocytoma/ paraganglioma and thymomas and thymic carcinomas. The NCCN Palliative Care Guidelines recommend octreotide for the treatment of malignant bowel obstruction.[3]

Clinical evidence supports the use of octreotide acetate for the treatment of chemotherapy and/or radiation-induced diarrhea,[3-7] for refractory HIV/AIDS-related diarrhea that does not respond to first-line anti-diarrheal therapy,[8-16] and as an adjunct to endoscopic therapy for bleeding gastroesophageal varices associated with liver disease.[17-22]

2. Coverage Criteria[a]:

A. Bynfezia Pen will be approved based on **both** of the following criterion:

1. Diagnosis of **one** of the following**:**

   (a) Acromegaly

(b) Neuroendocrine or adrenal tumors [e.g., carcinoid tumors, islet cell tumors, gastrinomas, glucagonomas, insulinomas, lung tumors, somatostatinomas, tumors of the pancreas, gastrointestinal tract, lung, thymus, adrenal glands, vasoactive intestinal peptide tumors (VIPomas), pheochromocytoma, paraganglioma]
(c) Meningioma
(d) Thymoma or thymic carcinoma
(e) Malignant bowel obstruction
(f) Chemotherapy and/or radiation induced diarrhea
(g) HIV/AIDS-related diarrhea
(h) Bleeding gastroesophageal varices associated with liver disease

-AND-

2. History of failure, contraindication, or intolerance to generic octreotide acetate (e.g. Sandostatin)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity, Notification may be in place.
- *Exclusion: Bynfezia is excluded from coverage for the majority of our benefits

4. References:

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Program	Step Therapy – Bynfezia Pen (octreotide acetate)
Change Control	
11/2020	New program.