



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE	BYNFEZIA		47454	GPI-14 (3017007010D220)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Therapy is prescribed by or in consultation with an endocrinologist
 - The patient had a trial of or contraindication to ONE generic octreotide product (e.g., octreotide acetate)
 - The patient had an inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumor and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient had a trial of or contraindication to ONE generic octreotide product (e.g., octreotide acetate)

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient had a trial of or contraindication to ONE generic octreotide product (e.g., octreotide acetate)

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Acromegaly (a type of hormone disorder)
 - 2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
 - 3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma: a type of cancer that starts from hormone producing cells)
- B. **If you have acromegaly, approval also requires:**
 - 1. You are 18 years of age or older
 - 2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
 - 3. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)
 - 4. You had an inadequate response to or cannot be treated with **ALL** of the following:
 - a. Surgical resection (removal by surgery)
 - b. Pituitary irradiation (radiation therapy directed at the pituitary)
 - c. Bromocriptine mesylate at maximally tolerated doses
- C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumor, approval also requires:**
 - 1. You are 18 years of age or older
 - 2. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)
- D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma), approval also requires:**
 - 1. You are 18 years of age or older
 - 2. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
 - The patient has a reduction, normalization or maintenance of IGF-1 levels based on age and gender
 - The patient has shown an improvement or sustained remission of clinical symptoms of acromegaly

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumor **AND** meet the following criterion?

- The patient has improvement or sustained remission of clinical symptoms

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma) **AND** meet the following criterion?

- The patient has improvement or sustained remission of clinical symptoms

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:

1. Acromegaly (a type of hormone disorder)
2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma: a type of cancer that starts from hormone producing cells)

(Renewal denial text continued on next page)

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - SQ

RENEWAL CRITERIA (CONTINUED)

B. If you have acromegaly, renewal also requires:

1. You have a reduction, normalization or maintenance of insulin-like growth factor (IGF-1: a growth hormone) levels based on age and gender
2. You have shown an improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

C. If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumor OR profuse watery diarrhea associated with vasoactive intestinal peptide tumor, renewal also requires:

1. You have an improvement or sustained remission (symptoms have gone away) of clinical symptoms

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bynfezia.

REFERENCES

- Bynfezia [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc., January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/22

Created: 08/20

Client Approval: 09/22

P&T Approval: 07/22