

OCTREOTIDE - IM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE	SANDOSTATIN	19000		GPI-12	
ACETATE,MI-SPHERES	LAR DEPOT			(301700701064)	

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?
 - Therapy is prescribed by or in consultation with an endocrinologist
 - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks
 - The patient had an inadequate response to surgery or radiotherapy, OR surgery or radiotherapy is not an option for this patient

If yes, approve the requested strength for 3 months by GPID or GPI-14 with the following quantity limit:

- 10 mg: #6 mL per 28 days.
- 20 mg: #12 mL per 28 days.
- 30 mg: #6 mL 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 criterion?
 - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

If yes, approve for 2 months by HICL or GPI-12 with a quantity limit of #6 mL per 28 days. If no, continue to #3.

- 3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumor (VIPoma) and meet **ALL** of the following criterion?
 - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

If yes, approve for 2 months by HICL or GPI-12 with a quantity limit of #6 mL per 28 days. If no, do not approve.

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

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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 - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Acromegaly (a type of hormone disorder)
 - 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 (VIP)-secreting tumor (a type of cancer that starts from hormone producing cells)
- B. You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks
- C. If you have acromegaly, approval also requires:
 - 1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
 - 2. You had an inadequate response (drug did not work) to surgery or radiotherapy (radiation to treat cancer), OR surgery or radiotherapy is not an option for you

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.

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 the requested strength for 12 months by GPID or GPI-14 with the following quantity limit:

- 10 mg: #6 mL per 28 days.
- 20 mg: #12 mL per 28 days.
- 30 mg: #6 mL per 28 days.

If no, continue to #2.

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RENEWAL CRITERIA (CONTINUED)

- 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 HICL or GPI-12 with a quantity limit of #6 mL per 28 days.

If no, continue to #3.

- 3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumor (VIPoma) **AND** meet the following criterion?
 - The patient has improvement or sustained remission of clinical symptoms

If yes, approve for 12 months by HICL or GPI-10 with a quantity limit of #6 mL 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 - IM (Sandostatin LAR Depot)** 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 (VIP)-secreting tumor (a type of cancer that starts from hormone producing cells)
- 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-secreting 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.

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RATIONALE

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

REFERENCES

 Sandostatin LAR Depot [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Created: 08/22

Commercial Effective: 04/01/23 Client Approval: 02/23 P&T Approval: 07/22

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