

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Injectable somatostatin analogs (First generation): Sandostatin (octreotide), Sandostatin LAR (octreotide), Somatuline depot (lanreotide), Bynfezia Pen (octreotide)
BILLING CODE	J2354/ J2353/ J1930/ NDC
BENEFIT TYPE	Medical, except Bynfezia is a pharmacy benefit
SITE OF SERVICE ALLOWED	Office/Outpatient/Home
COVERAGE REQUIREMENTS	Prior Authorization Required QUANTITY LIMIT— See “dosage allowed”
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Somatuline depot (lanreotide) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit; Sandostatin (octreotide) and Sandostatin LAR (octreotide) are **preferred** products and will only be considered for coverage under the **medical** benefit; Bynfezia is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit, when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ACROMEGALY

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has diagnosis of uncontrolled acromegaly confirmed by insulin-like growth factor (IGF-1) elevation above normal level (lab report required); AND
4. Member had an inadequate response to surgery or radiation, or member is ineligible for these treatments (documentation required); AND
5. If IGF-1 elevation is 1.5x upper limit of normal or less, member must have a trial of, or contraindication or intolerance to cabergoline.³
6. For Somatuline Depot only: Must have a trial and failure of Sandostatin LAR.
7. For Bynfezia only:
 - a) Baseline thyroid function testing is required; AND
 - b) Trial and failure of short acting octreotide (generic Sandostatin).
8. **Dosage allowed:**

Octreotide: Initial 50mcg subQ/IV 3 times daily, titrate as indicated, usual maintenance dose 100mcg 3 times daily, max 500mcg 3 times daily. NOTE: Doses in excess of 300mcg per day seldom confer additional benefit.

Sandostatin LAR: Start at 20mg IM every 4 weeks for 3 months, then adjust according to GH and IGF-1 per package insert, no more than 40mg every 4 weeks.

Somatuline depot: Start at 90mg subQ every 4 weeks for 3 months, then adjust according to GH and IGF-1 per package insert, no more than 120mg every 4 weeks.

Bynfezia Pen: Initial 50mcg subQ 3 times daily, titrate as indicated, usual maintenance dose 100mcg 3 times daily, max 500mcg 3 times daily. NOTE: Doses in excess of 300mcg per day seldom confer additional benefit.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes/lab report must show normalized or improved (decreased) IGF-1.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

NOTE to Reviewer: A short-acting product may be used concurrently with a long-acting product.

CARCINOID SYNDROME

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with an oncologist or gastroenterologist; AND
3. Member has a neuroendocrine tumor, including carcinoid tumor or vasoactive intestinal peptide tumor (VIPoma); AND
4. Member is experiencing flushing and/or diarrhea symptoms associated with carcinoid syndrome (or VIPoma syndrome), not attributed to another cause.
5. For Somatuline Depot only: Must have a trial and failure of Sandostatin LAR.
6. For Bynfezia only:
 - a) Baseline thyroid function testing is required; AND
 - b) Trial and failure of short acting octreotide (generic Sandostatin).
7. **Dosage allowed:**
Octreotide: 100mcg-750mcg per day subQ/IV in divided doses.
Sandostatin LAR: 10mg to 30mg IM every 4 weeks.
Somatuline depot: 120mg subQ every 4 weeks.
Bynfezia: 100-750mcg per day subQ in divided doses.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. For short-acting products (octreotide, Bynfezia): Chart notes must document symptomatic improvement of flushing and/or diarrhea episodes.
2. For long-acting products (Sandostatin LAR, Somatuline Depot): Chart notes must document reduced frequency of short-acting somatostatin analog rescue therapy for symptom control.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

NOTE to Reviewer: A short-acting product may be used concurrently with a long-acting product.

GASTROENTEROPANCREATIC NEUROENDOCRINE TUMORS (GEP-NETs)

Any request for **cancer** must be submitted through [NantHealth/Eviti](#) portal.

CareSource considers Sandostatin (octreotide) Sandostatin LAR (octreotide), Somatuline depot (lanreotide), Bynfezia (octreotide) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
11/03/2020	New policy for injectable somatostatin analogs created.

References:

1. Somatuline Depot (lanreotide acetate) [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; 2019.
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4. Zahr R, Fleseriu M. Updates in Diagnosis and Treatment of Acromegaly. *Eur Endocrinol*. 2018;14(2):57-61. doi:10.17925/EE.2018.14.2.57
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6. Vinik AI, Wolin EM, Liyanage N, Gomez-Panzani E, Fisher GA; ELECT Study Group *. EVALUATION OF LANREOTIDE DEPOT/AUTOGEL EFFICACY AND SAFETY AS A CARCINOID SYNDROME TREATMENT (ELECT): A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL. *Endocr Pract*. 2016 Sep;22(9):1068-80. doi: 10.4158/EP151172.OR. Epub 2016 May 23.
7. Pavel M, Öberg K, Falconi M, Krenning EP, Sundin A, Perren A, Berruti A; ESMO Guidelines Committee. Electronic address: clinicalguidelines@esmo.org. Gastroenteropancreatic neuroendocrine neoplasms: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol*. 2020 Jul;31(7):844-860. doi: 10.1016/j.annonc.2020.03.304. Epub 2020 Apr 6.
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9. Cook R, Hendifar AE. Evidence-Based Policy in Practice: Management of Carcinoid Syndrome Diarrhea. *P T*. 2019;44(7):424-427.
10. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors. (Version 2.2020). https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed November 3, 2020.
11. Pandit S, Annamaraju P, Bhusal K. Carcinoid Syndrome. [Updated 2020 Jun 25]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK448096/>

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