

PHARMACY POLICY STATEMENT

Arkansas PASSE

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), Sandostatin (octreotide), and Sandostatin LAR (octreotide) will only be considered for coverage under the medical benefit; Bynfezia 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. Member had an inadequate response to surgery or radiation, or member is ineligible for these treatments (documentation required); AND
3. For Somatuline Depot only: Must have a trial and failure of Sandostatin LAR.
4. For Bynfezia only:
 - a) Baseline thyroid function testing is required; AND
5. 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. Member has a neuroendocrine tumor, including carcinoid tumor or vasoactive intestinal peptide tumor (VIPoma); AND
3. Member is experiencing flushing and/or diarrhea symptoms associated with carcinoid syndrome (or VIPoma syndrome), not attributed to another cause.
4. For Somatuline Depot only: Must have a trial and failure of Sandostatin LAR.
5. For Bynfezia only:
 - a) Baseline thyroid function testing is required; AND
 - b) Trial and failure of short acting octreotide (generic Sandostatin).
6. 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): Improvement of flushing and/or diarrhea episodes.
2. For long-acting products (Sandostatin LAR, Somatuline Depot): 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.
01/05/2022	Removed prescriber specialty requirement and diagnostic requirement. Removed trial and failure of cabergoline and sandostatin.

1. Somatuline Depot (lanreotide acetate) [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; 2019.
2. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*. 2014;99(11):3933-3951. doi:10.1210/jc.2014-2700
3. Melmed S, Bronstein MD, Chanson P, et al. A Consensus Statement on acromegaly therapeutic outcomes. *Nature Reviews Endocrinology*. 2018;14(9):552-561. doi:10.1038/s41574-018-0058-5
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
5. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. October 2020. doi:10.1007/s11102-020-01091-7
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.
8. Strosberg JR, Halfdanarson TR, Bellizzi AM, Chan JA, Dillon JS, Heaney AP, Kunz PL, O'Dorisio TM, Salem R, Segelov E, Howe JR, Pommier RF, Brendtro K, Bashir MA, Singh S, Soulen MC, Tang L, Zacks JS, Yao JC, Bergsland EK. The North American Neuroendocrine Tumor Society Consensus Guidelines for Surveillance and Medical Management of Midgut Neuroendocrine Tumors. *Pancreas*. 2017 Jul;46(6):707-714. doi: 10.1097/MPA.0000000000000850.
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/>

Effective date: 01/01/2022

Revised date: 11/03/2020