CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Injectable somatostatin analogs (First generation): Sandostatin (octreotide), Sandostatin LAR (octreotide), Somatuline depot (lanreotide)
BILLING CODE	J2354/ J2353/ J1930/ NDC
BENEFIT TYPE	Medical
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) and Sandostatin LAR (octreotide) are **non-preferred** products and will only be considered for coverage under the **medical** benefit; Sandostatin (octreotide) is a **preferred** product and will only be considered for coverage under the **medical** benefit

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. **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.

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. **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.

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

For **reauthorization**:

1. For short-acting products (octreotide): 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) 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.
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. PMID: 27214300.

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. PMID: 32272208.
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. PMID: 28609356; PMCID: PMC5642985.
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: 10/1/2021
Revised date: 11/03/2020