HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

OCTREOTIDE (SANDOSTATIN, SANDOSTATIN LAR DEPOT)

Generic	Brand	HICL	GCN	Exception/Other
OCTREOTIDE	SANDOSTATIN	02826		
OCTREOTIDE	SANDOSTATIN LAR DEPOT	19000		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acromegaly?

   If yes, continue to #2.
   If no, continue to #5.

2. Is the request for a renewal?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient meet **ALL** of the following conditions?
   - Clinical evidence of acromegaly (e.g., frontal bossing, coarse facial features, thick lips, protruding jaw with widely spaced teeth, large hands and feet)
   - Documentation of a high pre-treatment IGF-1 level for age and/or gender
   - An inadequate or partial response to surgery or radiotherapy **OR** there is a clinical reason why the patient has not had surgery (as defined by one of the following) or radiotherapy
     - Medically unstable conditions (poor surgical candidate)
     - High risk for complications of anesthesia because of airway difficulties
     - Major systemic manifestations of acromegaly including cardiomyopathy, severe hypertension and uncontrolled diabetes
     - Patient refuses surgery or prefers the medical option over surgery
     - Lack of an available skilled surgeon
     - Tumor cannot be localized

   If yes, **approve for 12 months by HICL for the requested medication with the following quantity limits: [Sandostatin LAR Depot 10mg, 20mg, and 30mg kits are hard-coded with a quantity limit of one kit per 28 days. Please enter an override if the requested dose is for 40mg per 28 days.]**
   - **Sandostatin/Octreotide: up to 1,500mcg/day per day.**
   - **Sandostatin LAR: up to 40mg per 28 days.**

   Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for **[requested drug]** has been approved for a quantity up to **[___mcg per day OR ___mg per 28 days]** for a 12-month period.

   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's Octreotide (Sandostatin, Sandostatin LAR Depot) guideline, this medication is only covered when prescribed for the diagnosis of acromegaly for a patient who meets the following conditions:
   (Denial text continued on next page)

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

- Clinical evidence of acromegaly (e.g., frontal bossing, coarse facial features, thick lips, protruding jaw with widely spaced teeth, large hands and feet)
- A high pre-treatment IGF-1 level for your age and/or gender based on a submitted lab report
- An inadequate or partial response to surgery or radiotherapy **OR** there is a clinical reason why you have not had surgery or radiotherapy

Your provider did not indicate that you **[specify criteria not met]** and therefore your request was not approved.

4. Does the patient meet **EACH** of the following conditions?
   - Clinical evidence of acromegaly (e.g., frontal bossing, coarse facial features, thick lips, protruding jaw with widely spaced teeth, large hands and feet)
   - Documentation submitted of an IGF-1 level that has decreased or normalized since initiation of therapy

   If yes, **approve for 12 months by HICL for the requested medication with the following quantity limits: [Sandostatin LAR Depot 10mg, 20mg, and 30mg kits are hard-coded with a quantity limit of one kit per 28 days. Please enter an override if the requested dose is for 40mg per 28 days.]**
   - **Sandostatin/Octreotide: up to 1,500mcg/day per day.**
   - **Sandostatin LAR: up to 40mg per 28 days.**

   Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for **[requested drug]** has been approved for a quantity up to **[___mcg per day OR ___mg per 28 days]** for a 12-month period.

   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's Octreotide (Sandostatin, Sandostatin LAR Depot) guideline, authorization for renewal for the diagnosis of acromegaly requires each of the following conditions:
   - Clinical evidence of acromegaly
   - Documentation that your IGF-1 level has decreased or normalized since initiation of therapy

   Your provider did not indicate that you **[specify criteria not met]** and therefore your request was not approved.

5. Does the patient have a diagnosis of neuroendocrine tumors (NETs)?

   If yes, continue to #6.
   If no, continue to #7.

CONTINUED ON NEXT PAGE

OCTREOTIDE (SANDOSTATIN, SANDOSTATIN LAR DEPOT)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ONE** of the following conditions?
   - Tumors of the GI tract (carcinoid tumor) with **ONE** of the following:
     - Distant metastases or unresectable disease
     - The primary site of the tumor is gastric, the tumor is 2 centimeters or less in size, and the patient has hypersecretion of gastrin (e.g., Zollinger-Ellison syndrome)
   - Tumors of the thymus (carcinoid tumor) with distant metastases or unresectable disease
   - Tumors of the lung (carcinoid tumor) with the following:
     - The patient has advanced disease with multiple lung nodules, distant metastases or unresectable disease
   - Tumors of the pancreas with **EACH** of the following:
     - The tumor type is one of the following:
       - ACTH-secreting pancreatic NET
       - Cholecystokininoma (CCKoma)
       - Gastrinoma
       - Glucagonoma
       - Insulinoma
       - Non-functioning pancreatic tumor
       - Pancreatic polypeptidoma (PPoma)
       - Parathyroid hormone-related protein (PTHrp)-secreting pancreatic NET
       - Somatostatinoma or VIPoma
     - Somatostatin receptor status is positive or patient experiences symptoms of hormone hypersecretion (e.g., hypoglycemia, peptic ulcers, diarrhea, flushing)
   - Tumors of the adrenal gland with **ALL** of the following:
     - Diagnosis of non-adrenocorticotropic hormone (non-ACTH) dependent Cushing's syndrome
     - The cortisol production is symmetric
     - Tumors are less than 4 centimeters
     - Somatostatin receptor status is positive
   - Poorly differentiated (high-grade)/large or small cell tumors (excluding lung) with **ALL** of the following criteria:
     - Metastatic or unresectable disease
     - Somatostatin receptor status is positive
     - The patient experiences hormone-related symptoms

   If yes, **approve for 12 months by HICL for the requested medication with the following quantity limits: [Sandostatin LAR Depot 10mg, 20mg, and 30mg kits are hard-coded with a quantity limit of one kit per 28 days. Please enter an override if the requested dose is for 40mg per 28 days.]**
   - **Sandostatin/Octreotide: up to 1,500mcg/day per day.**
   - **Sandostatin LAR: up to 40mg per 28 days.**

   Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for **[requested drug]** has been approved for a quantity up to **[___mcg per day OR ___mg per 28 days]** for a 12-month period.

   If no, do not approve. Please use status code #238 and the denial text provided:
   (Denial text on next page)

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Per your health plan's Octreotide (Sandostatin, Sandostatin LAR Depot) guideline, this medication is only covered when prescribed for the diagnosis of Neuroendocrine Tumors (NETS) for a patient who meets the following conditions:

- Tumors of the GI tract with one of the following:
  - Distant metastases or unresectable disease
  - The primary site of the tumor is gastric, the tumor is 2 centimeters or less in size, and you have hypersecretion of gastrin (e.g., Zollinger-Ellison syndrome)
- Tumors of the thymus (carcinoid tumor) as well as distant metastases or unresectable disease
- Tumors of the lung (carcinoid tumor) that is advanced with multiple lung nodules, distant metastases or unresectable disease
- Tumors of the pancreas with all of the following:
  - The tumor type is one of the following:
    - ACTH-secreting pancreatic NET
    - Cholecystokininoma (CCKoma)
    - Gastrinoma
    - Glucagonoma
    - Insulinoma
    - Non-functioning pancreatic tumor
    - Pancreatic polypeptidoma (PPoma)
    - Parathyroid hormone-related protein-secreting pancreatic NET
    - Somatostatinoma
    - VIPoma
  - Your somatostatin receptor status is positive or you experience symptoms of hormone hypersecretion
- Tumors of the adrenal gland with all of the following:
  - Diagnosis is non-adrenocorticotropic hormone (non-ACTH) dependent Cushing's syndrome
  - The cortisol production is symmetric
  - Tumors are less than 4 centimeters
  - Somatostatin receptor status is positive
- Poorly differentiated (high-grade)/large or small cell tumors (excluding lung) with all of the following criteria:
  - You have metastatic or unresectable disease
  - Somatostatin receptor status is positive
  - You experience hormone-related symptoms

Your provider did not indicate that you **[specify criteria not met]** and therefore your request was not approved.

7. Does the patient have a diagnosis of meningioma?

   If yes, continue to #8.
   If no, continue to #9.

CONTINUED ON NEXT PAGE

OCTREOTIDE (SANDOSTATIN, SANDOSTATIN LAR DEPOT)

GUIDELINES FOR USE (CONTINUED)

8. Does the patient meet **ALL** of the following conditions?
   - Disease is recurrent or progressive
   - Disease in unresectable
   - Disease is refractory to radiation therapy
   - Somatostatin receptor status is positive

   If yes, **approve for 12 months by HICL. [Sandostatin LAR Depot 10mg, 20mg, and 30mg kits are hard-coded with a quantity limit of one kit per 28 days.]** Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for **[requested drug]** has been for a quantity up to **[___mcg per day OR ___mg per 28 days]** for a 12-month period.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Octreotide (Sandostatin, Sandostatin LAR Depot) guideline, this medication is only covered when prescribed for the diagnosis of meningioma for a member who meets **ALL** of the following conditions:
   - Disease is recurrent or progressive
   - Disease in unresectable
   - Disease is refractory to radiation therapy
   - Somatostatin receptor status is positive

   Your provider did not indicate that you **[specify criteria not met]** and therefore your request was not approved.

9. Does the patient have a diagnosis of locally advanced, advanced, or recurrent thymomas and thymic carcinomas?

   If yes, continue to #10.
   If no, continue to #11.

CONTINUED ON NEXT PAGE

OCTREOTIDE (SANDOSTATIN, SANDOSTATIN LAR DEPOT)

GUIDELINES FOR USE (CONTINUED)

10. Has the patient's diseases progressed on at least one prior chemotherapy regimen?

    If yes, **approve for 12 months by HICL. [Sandostatin LAR Depot 10mg, 20mg, and 30mg kits are hard-coded with a quantity limit of one kit per 28 days].** Please use status code #056 and the approval text provided.
    APPROVAL TEXT: Your request for **[requested drug]** has been approved for a quantity up to **[___mcg per day OR ___mg per 28 days]** for a 12-month period.

    If no, do not approve. Please use status code #238 and the denial text provided.
    DENIAL TEXT: Per your health plan's Octreotide (Sandostatin, Sandostatin LAR Depot) guideline, this medication is only covered when prescribed for the diagnosis of locally advanced, advanced, or recurrent thymomas and thymic carcinomas for a member whose disease has progressed on at least one prior chemotherapy regimen. Your provider did not indicate that your disease has progressed on at least one prior chemotherapy regimen and therefore your request was not approved.

11. Does the patient have a diagnosis of congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy?

    If yes, continue to #12.
    If no, do not approve. Please use status code #238 and the denial text provided:
    DENIAL TEXT: Per your health plan's Octreotide (Sandostatin, Sandostatin LAR Depot) guideline, this medication is only covered for members with one of the following diagnoses:
    - Acromegaly
    - Neuroendocrine tumors (NETs)
    - Meningioma
    - Locally advanced, advanced or recurrent thymomas and thymic carcinomas
    - Congenital hyperinsulinism/persistent hyperinsulinemic hypoglycemia in infancy [Sandostatin (octreotide) only]

    Your provider did not indicate that you are being treated for one of these conditions and therefore your request was not approved.

CONTINUED ON NEXT PAGE

OCTREOTIDE (SANDOSTATIN, SANDOSTATIN LAR DEPOT)

GUIDELINES FOR USE (CONTINUED)

12. Does the patient meet the following conditions?
    - Patient is an infant
    - The requested medication is Octreotide (Sandostatin)

    If yes, **approve Octreotide (Sandostatin) for 6 months by HICL.** Please use status code #056 and the approval text provided.
    APPROVAL TEXT: Your request for Octreotide (Sandostatin) has been for a 6-month period.

    If no, do not approve. Please use status code #238 and the denial text provided:
    DENIAL TEXT: Per your health plan's Octreotide (Sandostatin, Sandostatin LAR Depot) guideline, this medication is only covered for patients with a diagnosis of congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy if the requested medication is Octreotide (Sandostatin). Your provider did not indicate that you have requested Octreotide (Sandostatin) and therefore your request was not approved.

RATIONALE
Ensure the appropriate use of octreotide, Sandostatin and Sandostatin LAR for FDA-approved and compendial uses.

FDA APPROVED INDICATIONS
Sandostatin is indicated:
- To reduce blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.
- For the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease
- For the treatment of the profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP-secreting) tumors.

Sandostatin LAR Depot is indicated for:
Treatment in patients who have responded to and tolerated Sandostatin Injection subcutaneous injection for:
- Acromegaly
- Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors
- Profuse watery diarrhea associated with VIP-secreting tumors

REFERENCES
- Octreotide [package insert]. Rockford, IL: Mylan Institutional LLC; March 2013.
- Sandostatin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2012.
- Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2014.

CONTINUED ON NEXT PAGE

OCTREOTIDE (SANDOSTATIN, SANDOSTATIN LAR DEPOT)

REFERENCES (CONTINUED)

- National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed February 19, 2016.
- Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed February 19, 2016.
- AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed February 23, 2016.
- Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014; 99(11):3933-51.
- American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. *Endocr Pract*. 2011;17(suppl 4):1-44.
- The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine Tumors (Version 1.2015). © 2015 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 19, 2016.
- Rinke A, Muller H, Schade-Brittinger C, et al. Placebo-controlled, double-blind, prospective, randomized study on the effect of octreotide LAR in the control of tumor growth in patients with metastatic neuroendocrine midgut tumors: a report from the PROMID study group. *J Clin Oncol*. 2009; 27(28):4656-63.
- The NCCN Clinical Practice Guidelines in Oncology® Small Cell Lung Cancer (Version 1.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 23, 2016.
- The NCCN Clinical Practice Guidelines in Oncology® CNS Cancer (Version 1.2015). © 2015 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 23, 2016.
- The NCCN Clinical Practice Guidelines in Oncology® Thymomas and Thymic Carcinomas. (Version 1.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Assessed February 23, 2016.

Created: 06/17
Effective: 10/01/18 Client Approval: 07/18/18 P&T Approval: 09/27/18