Somatostatin Agents

Somatuline Depot (lanreotide acetate) J1930, Lanreotide (Cipla) (lanreotide acetate) J1932, Sandostatin LAR (octreotide depot) J2353 are Non-preferred. The preferred product is: Sandostatin (octreotide non-depot) J2354 (No PA required for preferred product)

Prior Authorization Step Therapy

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Sandostatin LAR**

- ☐ Acromegaly, with ALL of the following
  - ☐ Age 6 years or older
  - ☐ Contraindication to, inability to tolerate, or inadequate response to pituitary surgery
- ☐ Neuroendocrine tumors, as indicated by ALL of the following:
  - ☐ Locally inoperable or metastatic disease
  - ☐ Midgut (eg, jejunum, ileum, proximal colon) tumor, or tumor of unknown origin believed to be from midgut
- ☐ Neuroendocrine tumors, and need for symptom control, as indicated by 1 or more of the following
  - ☐ Carcinoid tumor (metastatic), with flushing or diarrhea (ie, carcinoid syndrome
  - ☐ Glucagonoma, with migratory necrolytic erythema
  - ☐ Vasoactive intestinal peptide-secreting tumor, with watery diarrhea
- ☐ Palliative treatment of inoperable malignant bowel obstruction due to advanced cancer (eg, ovarian or pancreatic cancer)

☐ **Somatuline Depot** ☐ **Lanreotide:**

- ☐ Age 18 years or older
- ☐ Acromegaly and contraindication to, inability to tolerate, or inadequate response to pituitary surgery
- ☐ Carcinoid syndrome (eg, flushing or diarrhea, abdominal pain, right-sided heart failure) and known neuroendocrine tumor
- ☐ Neuroendocrine tumors,[C] as indicated by 1 or more of the following
  - ☐ Carcinoid tumor(41)(44)(56)(57)(58)
  - ☐ Gastrinoma
  - ☐ Glucagonoma
  - ☐ Vasoactive intestinal peptide tumor with watery diarrhea

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

- ☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**
- ☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Somatostatin Analog Agents PA

Drug Name(s):

SANDOSTATIN	**OCTREOTIDE DEPOT**
SANDOSTATIN LAR	**OCTREOTIDE NON-DEPOT**
SOMATULINE DEPOT	**LANREOTIDE ACETATE**
LANREOTIDE	**LANREOTIDE ACETATE**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed **Sandostatin or Sandostatin LAR** OR member has clinical reasoning to bypass preferred products.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 12 months

FDA Indications:

Sandostatin

- Acromegaly, Inadequate response to or ineligible for surgery, radiation, or bromocriptine mesylate
- Acromegaly, Long-term maintenance with response to and tolerance of octreotide or lanreotide
- Carcinoid syndrome, Metastatic; symptomatic treatment
- Vasoactive intestinal peptide-secreting tumor, Associated diarrhea

Lanreotide, Somatuline Depot

- Acromegaly
- Carcinoid syndrome
- Neuroendocrine tumor, Gastroenteropancreatic

Off-Label Uses:

Lanreotide, Somatuline Depot

- Portal Hypertension

Sandostatin

- Acromegaly
- AIDS – Diarrhea
- Bleeding esophageal varices
- Chylothorax
- Cryptosporidiosis.
- Diabetes mellitus.

- Drug-induced hypoglycemia, Sulfonylurea.
- Dumping syndrome.
- Hypothalamic obesity.
- Lymphorrhea.
- Necrotizing pancreatitis, acute; Adjunct.
- Neuroendocrine tumor
- Non-infective diarrhea.
- Pituitary adenoma.
- Polycystic ovary syndrome.
- Polyostotic fibrous dysplasia of bone; Adjunct.
- Zollinger-Ellison syndrome; Adjunct

Age Restrictions:

Chylothorax: Off-label Dosage

- Dosage (less 18 years): Initial mean dose of 4 mcg/kg/hr as a continuous infusion, with a maximum mean dose of 6 mc/kg/hr
- (7 days to 36 months) 4 to 10 mcg/kg/hr as a continuous infusion

Other Clinical Considerations:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/082AA0/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/E2E20C/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Octreotide&UserSearchTerm=Octreotide&SearchFilter=filterNone&navitem=searchGlobal#

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https://careweb.careguidelines.com/ed24/ac/ac04_082.htm