

Somatostatic Agents Step Therapy Somatuline Depot (lanreotide acetate) J1930 is non-preferred. The preferred product is Sandostatin (octreotide) J2353 Prior Authorization Step Therapy Medicare Part B Request 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.

	Date Req	uested							
	Requesto	r	Clinic name: _		Phone		/ Fax		
MEMBER INFORMATION									
*Name:				*ID#:			*DOB:		
				BER INFORMA					
*Nai	me:		□M	\square MD \square FNP \square DO \square NP \square PA			*Phone:		
*Add	dress:			*Fax:					
DISPENSING PROVIDER / ADMINISTRATION INFORMATION									
*Name:						Phone:			
*Add	dress:			Fax:					
PROCEDURE / PRODUCT INFORMATION									
НС	PC Code	Name of Drug	g □ Self-administered	Dose (Wt:	kg Ht:)	Frequency	End Date if known	
□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) □ Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria. 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									
Any prinsur insur	person who kn ance company ance act, whic	by providing mater h is a crime and sub	uired): est for authorization of coverage ially false information or concea jects such person to criminal and TIME OF SERVICE, MEMBER ELIGIE	ls material informat d civil penalties. THIS	ion for the purpos AUTHORIZATION	th the interse of mislea	ading, commits a fr	audulent	



Prior Authorization Group - Somatostatic Agents PA

Drug Name(s):

SOMATULINE DEPOT INJECTION SANDOSTATIN

LANREOTIDE ACETATE OCTREOTIDE

Criteria for approval of Prior Authorization Drug:

- 1. Prescribed for an approved FDA diagnosis (as listed below):
- 2. Member has tried and failed at least ONE of the formulary alternatives: Sandostatin OR
 - There is clinical documentation stating formulary alternatives are contraindicated.
- 3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
- 4. 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:

Approvals will be for 12 months

FDA Indications:

Somatuline Depot

- Acromegaly
- Carcinoid syndrome
- Neuroendocrine tumor, gastroenteropancreatic

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

Off-Label Uses:

Somatuline Depot

- Carcinoid tumor of stomach
- Portal hypertension

Sandostatin

- 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:

- Safety and effectiveness of ocrelizumab have not been established in pediatric patients
- 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/3A4CAB/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/C7E48F/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Lanreotide&UserSearchTerm=Lanreotide&SearchFilter=filterNone&navitem=searchGlobal#

https://careweb.careguidelines.com/ed24/ac/ac04 096.htm

https://www.micromedexsolutions.com/micromedex2/librarian/CS/082AA0/ND PR/evidencexpert/ND P/evidencexpert/DUPLICATIONSHIELDSYN C/E2E20C/ND PG/evidencexpert/ND B/evidencexpert/ND AppProduct/evidencexpert/ND T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Octreotide&UserSearchTerm=Octreotide&SearchFilter=filterNone&navitem=searchGlobal#

https://careweb.careguidelines.com/ed24/ac/ac04 082.htm