This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
4255-D

POLICY Document for ~~SANDOSTATIN LAR~~SOMAVERT

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, ~~lower cost site of care~~ and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product

EXCEPTIONS CRITERIA
ACROMEGALY PRODUCTS

PREFERRED PRODUCTS: SOMATULINE DEPOT, SANDOSTATIN LAR

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the acromegaly products specified in this policy. Coverage for a targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with the targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Acromegaly Products

	Product(s)
Preferred	• **Somatuline Depot** (lanreotide) • **Sandostatin LAR** (octreotide acetate for injectable suspension)
Targeted	• **Signifor LAR** (pasireotide) • **Somavert** (pegvisomant)

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for both of the preferred products.

This policy applies to the following:

										Reference #
	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B	4255-D
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First	
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on	

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the requested targeted product in the past 365 days.
B. Member has a documented inadequate response or intolerable adverse event to any of the preferred products.

~~REFERENCES~~

1. ~~Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; June 2019.~~
2. ~~1. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.~~
3. ~~1. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; April 2019.~~
4. ~~1. Somavert [package insert]. New York, NY: Pharmacia & Upjohn Co; August 2019.~~

Section 2: Clinical Criteria

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STANDARD MEDICARE PART B MANAGEMENT

~~SANDOSTATIN LAR (octreotide acetate for injectable suspension)~~

UNIVERSAL CRITERIA

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POLICY

The Specialty Universal Med B Criteria ensure appropriate utilization of Specialty medications and confirm that selection elements established in the FDA-approved product labeling and relevant compendia are followed. The criteria may be applied in situations where specific criteria are pending development.

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Authorization of 12 months may be granted for a requested medication when clinically appropriate.

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~~POLICY~~

This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
4255-D

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Sandostatin LAR Depot is indicated in patients in whom initial treatment with Sandostatin injection has been shown to be effective and tolerated.

Indicated for long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option.

Indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.

Indicated for long-term treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

Compendial Uses

Neuroendocrine tumors (NETs)

NETs of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors) or unresected primary gastrinoma

NETs of the pancreas

Pheochromocytoma/paraganglioma

Meningiomas

Thymomas and thymic carcinomas

Treatment of diarrhea in acquired immunodeficiency syndrome (AIDS)

Bowel obstruction due to peritoneal carcinomatosis

Postgastrectomy dumping syndrome

Pediatric hypothalamic obesity

Hepatocellular carcinoma

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Reference #
4255-D

Pancreatic pleural effusion

Pituitary adenoma

Graves' ophthalmopathy

von Willebrand disorder

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

CRITERIA FOR INITIAL APPROVAL

Acromegaly

Authorization of 24 months may be granted for the treatment of acromegaly when all of the following criteria are met:

Member has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range.

Member had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason why the member has not had surgery or radiotherapy.

Carcinoid syndrome

Authorization of 12 months may be granted for treatment of carcinoid syndrome.

Vasoactive intestinal peptide tumors (VIPomas)

Authorization of 12 months may be granted for management of symptoms related to hormone hypersecretion of VIPomas.

Neuroendocrine tumors (NETs)

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	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
4255-D

Authorization of 12 months may be granted for treatment of NETs of the gastrointestinal (GI) tract, lung, thymus (carcinoid tumors) or unresected primary gastrinoma.

Authorization of 12 months may be granted for treatment of NETs of the pancreas.

Pheochromocytoma and paraganglioma

Authorization of 12 months may be granted for treatment of pheochromocytoma/paraganglioma.

Meningiomas

Authorization of 12 months may be granted to members for treatment of unresectable meningioma.

Thymomas and thymic carcinomas

Authorization of 12 months may be granted for treatment of thymoma and thymic carcinoma.

Bowel obstruction due to peritoneal carcinomatosis

Authorization of 12 months may be granted for treatment of bowel obstruction due to peritoneal carcinomatosis.

Postgastrectomy dumping syndrome

Authorization of 12 months may be granted for treatment of postgastrectomy dumping syndrome.

Hepatocellular carcinoma

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma.

Pituitary adenoma

Authorization of 12 months may be granted for treatment of pituitary adenoma.

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	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
4255-D

Diarrhea in acquired immunodeficiency syndrome (AIDS)

Authorization of 12 months may be granted for treatment of diarrhea in a member with acquired immunodeficiency syndrome (AIDS).

Pediatric hypothalamic obesity

Authorization of 12 months may be granted for treatment of hypothalamic obesity in a pediatric member.

Pancreatic pleural effusion

Authorization of 12 months may be granted for treatment of pancreatic pleural effusion.

Graves' ophthalmopathy

Authorization of 12 months may be granted for treatment of Graves' ophthalmopathy.

von Willebrand disorder

Authorization of 12 months may be granted for treatment of von Willebrand disorder.

CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

The member is currently receiving therapy with Sandostatin LAR.

Sandostatin LAR is being used to treat an indication enumerated in Section II.

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	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
4255-D

The member is receiving benefit from therapy.

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Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99:3933-3951.

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