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 #
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POLICY Document for SOMATULINE DEPOT

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:

	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

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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. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; April 2019.

Somavert [package insert]. New York, NY: Pharmacia & Upjohn Co; August 2019.

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Section 2: Clinical Criteria

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STANDARD MEDICARE PART B MANAGEMENT

SOMATULINE DEPOT (lanreotide)

POLICY

I. INDICATIONS

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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.

A. FDA-Approved Indications

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1. Long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option.

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2. Treatment of patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

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

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3. Treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

B. Compendial Uses
1. Neuroendocrine tumors (NETs):
   a. NETs of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors) or unresected primary gastrinoma
   b. NETs of the pancreas
2. Pheochromocytoma/paraganglioma
3. Hepatocellular carcinoma
4. Thyroid carcinoma
5. Pituitary adenoma
6. Uterine leiomyoma

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.

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II. CRITERIA FOR INITIAL APPROVAL

A. Acromegaly
Authorization of 24 months may be granted for the treatment of acromegaly when all of the following criteria are met:
1. Member has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range.
2. 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.

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

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

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

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E. Hepatocellular carcinoma

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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

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

F. Thyroid carcinoma
Authorization of 12 months may be granted for treatment of thyroid carcinoma.

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

H. Uterine leiomyoma
Authorization of 12 months may be granted for treatment of uterine leiomyoma.

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III. 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:

1. The member is currently receiving therapy with Somatuline Depot.
2. Somatuline Depot is being used to treat an indication enumerated in Section II.
3. The member is receiving benefit from therapy.

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Reviewed: CDPR/SD 10/2018, ABM 02/2019; MMF 01/2020

External Review: 11/2018, 03/2019, 03/2020

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SECTION 1

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; June 2019.
2. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; April 2019.

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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**

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4. Somavert [package insert]. New York, NY: Pharmacia & Upjohn Co; August 2019.

SECTION 2

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2. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Updated periodically. https://www.micromedexsolutions.com [available with subscription]. Accessed January 13, 2020.
3. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 13, 2020.
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5. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
6. 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.