

This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	✓	Medical Benefit	Medicare Part B
Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)		Medical: Advanced Biosimilars First	Medicare Part B: Biosimilars First
Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)		Medical Benefit: Managed Medicaid	Medicare Part B: Advanced Biosimilars First
Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)		Medical Benefit: Add-on	
Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

Reference #
4256-D

## EXCEPTIONS CRITERIA ACROMEGALY PRODUCTS

### PREFERRED PRODUCTS: SANDOSTATIN LAR, SOMATULINE DEPOT

#### 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 all members requesting treatment with a targeted product.

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

**Table. Acromegaly Products**

	Product(s)
<b>Preferred*</b>	<ul style="list-style-type: none"> <li><b>Sandostatin LAR</b> (octreotide acetate for injectable suspension)</li> <li><b>Somatuline Depot</b> (lanreotide)</li> </ul>
<b>Targeted</b>	<ul style="list-style-type: none"> <li><b>lanreotide injection</b></li> <li><b>Signifor LAR</b> (pasireotide injectable suspension)</li> <li><b>Somavert</b> (pegvisomant)</li> </ul>

\*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

#### II. EXCEPTION CRITERIA

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

##### A. lanreotide injection

Coverage for the targeted product is provided when all of the following criteria are met:

- The member has had a documented intolerable adverse event to Somatuline Depot, and the adverse event was not an unexpected adverse event attributed to the active ingredient as described in the prescribing information.
- The member has a documented inadequate response or intolerable adverse event to Sandostatin LAR.

##### B. Signifor LAR, Somavert

Coverage for a targeted product is provided when the member has had a documented inadequate response or intolerable adverse event to any of the preferred products.

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Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)		Medical Benefit: Managed Medicaid	Medicare Part B: Advanced Biosimilars First
Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)		Medical Benefit: Add-on	
Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

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## REFERENCES

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; February 2023.
2. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; June 2020.
4. Somavert [package insert]. New York, NY: Pharmacia & Upjohn Co; July 2023.
5. Lanreotide injection [package insert]. Warren, NJ: Cipla USA, Inc.; December 2021.