This policy applies to the following:

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

Reference #
4255-D

EXCEPTIONS CRITERIA
ACROMEGALY PRODUCTS

PREFERRED PRODUCTS: SANDOSTATIN LAR, LANREOTIDE INJECTION

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*	• **Sandostatin LAR Depot** (octreotide acetate for injectable suspension) • **Lanreotide Injection** (lanreotide acetate)
Targeted	• **Signifor LAR** (pasireotide) • **Somatuline Depot** (lanreotide acetate)

*: 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 the preferred products.

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

A. Member has received treatment with the requested targeted product in the past 365 days.
B. The request is for Signifor LAR and member has a documented inadequate response or intolerable adverse event to any of the preferred products.
C. The request is for Somatuline Depot and both of the following criteria are met:
   1. The member has a documented intolerable adverse event to lanreotide injection, and the adverse event was not an unexpected adverse event attributed to the active ingredient as described in the prescribing information.
   2. The member has a documented inadequate response or intolerable adverse event to Sandostatin LAR Depot.

REFERENCES

This policy applies to the following:

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

Reference #
4255-D

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2019.
2. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2021.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; September 2021.
4. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; December 2021.