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

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4255-D

EXCEPTIONS CRITERIA

ACROMEGALY LONG ACTING PRODUCTS

PREFERRED PRODUCT: 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 long acting 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 acetate)
Targeted	• **Lanreotide Injection** (lanreotide acetate) • **Sandostatin LAR Depot** (octreotide acetate for injectable suspension) • **Signifor LAR** (pasireotide)

*: 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.

A. Lanreotide Injection

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

1. Member has received treatment with the requested targeted product in the past 365 days.
2. The member has had a documented intolerable adverse event to Somatuline Depot, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

B. Sandostatin LAR Depot, Signifor LAR

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

1. Member has received treatment with the requested targeted product in the past 365 days.

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

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2. Member has a documented inadequate response or intolerable adverse event with the preferred product.

REFERENCES

1. Somatuline Depot [package insert]. Cambridge, 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; August 2023.
4. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; September 2023.