Reference number(s)
4255-D

This document applies to the following:

Product	Applies
Medicare Part B	☑
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Acromegaly Long Acting Products

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the acromegaly long acting products specified in this document. Coverage for a non-preferred 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 non-preferred product for the first time.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Acromegaly Products

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

	Products
Preferred	• Somatuline Depot (lanreotide acetate)
Non-preferred	• Lanreotide Injection (lanreotide acetate) • Sandostatin LAR Depot (octreotide acetate for injectable suspension) • Signifor LAR (pasireotide)

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Step Therapy Criteria

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

Lanreotide Injection

Coverage for the non-preferred product is provided when either of the following criteria is met:

- Member has received treatment with the requested non-preferred product in the past 365 days.
- 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.

Sandostatin LAR Depot, Signifor LAR

Coverage for a non-preferred product is provided when either of the following criteria is met:

- Member has received treatment with the requested non-preferred product in the past 365 days.
- 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.; July 2024.
2. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; July 2024.
4. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; May 2024.