Drug Coverage Policy

Effective Date.....6/15/2026
Coverage Policy Number.....PSM030
Policy Title..... Growth Disorders – Growth Hormone Long-Acting Products Preferred Specialty Management Policy for Value/Advantage and Total Savings Prescription Drug List Plans

Growth Disorders - Growth Hormone Long-Acting Products Preferred Specialty Management Policy for Value/Advantage and Total Savings Prescription Drug List Plans

- Ngenla® (somatrogon-ghla subcutaneous injection – Pfizer)
- Skytrofa® (lonapegsomatropin subcutaneous injection – Ascendis)
- Sogroya® (somapacitan-beco subcutaneous injection – Novo Nordisk)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most

appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Ngenla, Skytrofa, and Sogroya are the available long-acting (weekly) growth hormone (GH) products.[1-3] All of these agents are indicated for the treatment of growth failure due to inadequate secretion of endogenous GH in pediatric patients. Ngenla is indicated in pediatric patients ≥ 3 years of age, Skytrofa is indicated in pediatric patients ≥ 1 year of age (and ≥ 11.5 kg), and Sogroya is indicated in pediatric patients ≥ 2.5 years of age. Sogroya is the only weekly growth hormone product indicated for pediatric patients (≥ 2.5 years of age) for idiopathic short stature, Noonan syndrome, and born small for gestation age.[3] Skytrofa and Sogroya have an additional indication for the replacement of endogenous GH in adults with GH deficiency.[2,3]

Coverage Policy

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product(s) prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the durations noted in the respective standard *Prior Authorization Policy* criteria. If the patient meets the standard *Prior Authorization Policy* criteria but has not tried the Preferred Products, approval for the Preferred Product(s) will be authorized. All reviews will be directed to a clinician (i.e., pharmacist or nurse) for verification of criteria.

Documentation: Documentation is required for use of somatropin as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. For patient cases in which documentation is required, if this documentation has been previously received upon a prior coverage review, the documentation requirement is considered to be met. All documentation must include patient-specific identifying information.

Advantage/Value/Total Savings Prescription Drug List Plans
Preferred Product with Step: Skytrofa
Non-Preferred Products: Ngenla, Sogroya

Growth Disorders - Growth Hormone Long-Acting non-preferred products are considered medically necessary when the following non-preferred product exception criteria are met. Any other exception is considered not medically necessary.

PREFERRED PRODUCT WITH STEP AND NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Product	Exception Criteria

Ngenla	**A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Ngenla Prior Authorization Policy* criteria; AND **ii.** Patient has tried Skytrofa for 6 months OR experienced an intolerance with Skytrofa **[documentation required]** **B)** If the patient has met criterion Ai (the standard *Growth Disorders – Ngenla Prior Authorization Policy* criteria), but criterion Aii is not met: a request for a Preferred Product (Skytrofa) may be reviewed using the respective standard *Growth Disorders – Skytrofa Prior Authorization Policy* criteria.
Skytrofa	**A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Skytrofa Prior Authorization Policy* criteria; AND **ii.** Patient meets one of the following (a or b): **a.** Patients ≥ 2.5 years of age to < 18 years of age and meets ONE of the following (i or ii): **i.** Patient has been able to adhere to somatropin product(s) administered daily AND has experienced inadequate efficacy (i.e., patient has tried for 12 months and has a growth rate of less than 2 cm per year) **[documentation required]** with ONE product from the following list: Genotropin or Omnitrope; OR **ii.** Patient meets BOTH of the following (1 and 2): **1.** Patient has tried ONE of the following products: Genotropin and Omnitrope **[documentation required]**; AND **2.** Patient cannot continue to use Genotropin OR Omnitrope due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. Note: Meeting the criteria above with a trial of any daily growth hormone product(s) would count toward meeting the requirements regardless of formulary status **b.** Patients ≥ 18 years of age and meets BOTH of the following (i and ii): **i.** Patient has tried ONE of the following products: Genotropin and Omnitrope **[documentation required]**; AND **ii.** Patient cannot continue to use Genotropin OR Omnitrope due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. Note: Meeting the criteria above with a trial of any daily growth hormone product(s) would count toward meeting the requirements regardless of formulary status.

	B) If the patient has met criterion Ai (the standard *Growth Disorders – Skytrofa Prior Authorization Policy* criteria), but criterion Aii is not met: a request for a Preferred Product (Genotropin, Omnitrope) may be reviewed using the respective standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria.
Sogroya	**Idiopathic Short Stature, Noonan Syndrome, Born Small for Gestational Age:** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Sogroya Prior Authorization Policy* criteria; AND **ii.** Patient meets ONE of the following (a or b): **a.** Patient has been able to adhere to somatropin product(s) administered daily AND has experienced inadequate efficacy (i.e., patient has tried for 12 months and has a growth rate of less than 2 cm per year) **[documentation required]** with ONE product from the following list: Genotropin or Omnitrope; OR **b.** Patient meets BOTH of the following (i and ii): **i.** Patient has tried BOTH of the following products: Genotropin and Omnitrope **[documentation required]**; AND **ii.** Patient cannot continue to use BOTH Genotropin AND Omnitrope due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. Note: Meeting the criteria above with a trial of any daily growth hormone product(s) would count toward meeting the requirements regardless of formulary status **B)** If the patient has met criterion Ai (the standard *Growth Disorders – Sogroya Prior Authorization Policy* criteria), but criterion Aii is not met: a request for a Preferred Product (Genotropin, Omnitrope) may be reviewed using the respective standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria. **Other Conditions:** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Sogroya Prior Authorization Policy* criteria; AND **ii.** Patient is 2.5 years of age or older AND has tried Skytrofa for 6 months OR experienced an intolerance with Skytrofa **[documentation required]** **B)** If the patient has met criterion Ai (the standard *Growth Disorders – Sogroya Prior Authorization Policy* criteria), but criterion Aii is not met: a request for a Preferred Product (Skytrofa) may be reviewed using the respective standard *Growth Disorders – Skytrofa Prior Authorization Policy* criteria.

References

1. Ngenla™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; July 2025
2. Skytrofa® subcutaneous injection [prescribing information]. Princeton, NJ: Ascendis Pharma; September 2025.
3. Sogroya® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; February 2026.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	5/7/2026	6/15/2026

The policy effective date is in force until updated or retired.

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