PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Growth Disorders – Growth Hormone Long-Acting Products Preferred Specialty Management Policy
- Ngenla® (somatrogon-ghla subcutaneous injection – Pfizer)
- Skytrofa® (lonapegsomatropin subcutaneous injection – Ascendis)
- Sogroya® (somapacitan-beco subcutaneous injection – Novo Nordisk)

REVIEW DATE: 11/01/2023

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. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 patients ≥ 3 years of age, Skytrofa is indicated in patient ≥ 1 year of age (and ≥ 11.5 kg), and Sogroya is indicated in patients ≥ 2.5 years of age. Sogroya has an additional indication for the replacement of endogenous GH in adults with GH deficiency.[3]

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. 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 for 6 months, or have an intolerance, prior to the approval of a Non-Preferred Products. 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 met the applicable criteria for the Preferred Product, approval for the Preferred Product will be authorized. All reviews will be directed to a clinician (i.e., pharmacist) for verification of criteria.

National Preferred Formulary
Preferred Products: Ngenla
Non-Preferred Products: Skytrofa, Sogroya

Growth Disorders – Growth Hormone Long-Acting non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Skytrofa	**1. National Preferred Formulary.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Growth Disorders – Skytrofa Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient is < 3 years of age; OR **ii.** Patient meets ONE of the following (a or b): **a.** Patient has tried Ngenla for 6 months; OR **b.** Patient has experienced an intolerance with Ngenla. **C)** If the patient has met the respective standard Prior Authorization criteria (1A), but has not met exception criteria (1B), approve Ngenla.

Non-Preferred Product	Exception Criteria
Sogroya	**1. National Preferred Formulary.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Growth Disorders – Sogroya Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i, ii, or iii): **i.** Patient is < 3 years of age; OR **ii.** Patient is ≥ 18 years of age; OR **iii.** Patient meets ONE of the following (a or b): **a.** Patient has tried Ngenla for 6 months; OR **b.** Patient has experienced an intolerance with Ngenla. **C)** If the patient has met the respective standard Prior Authorization criteria (1A), but has not met exception criteria (1B), approve Ngenla.

REFERENCES

1. Ngenla™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; June 2023
2. Skytrofa® subcutaneous injection [prescribing information]. Princeton, NJ: Ascendis Pharma; October 2022.
3. Sogroya® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; April 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/01/2023