PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Growth Disorders – Growth Hormone Short-Acting Products Preferred Specialty Management Policy

- Genotropin® (somatropin injection – Pfizer)
- Humatrope® (somatropin injection – Lilly)
- Norditropin® (somatropin injection – Novo Nordisk)
- Nutropin AQ® Nuspin (somatropin injection – Genentech)
- Omnitrope® (somatropin injection – Sandoz)
- Saizen® (somatropin injection – EMD Serono)
- Zomacton™ (somatropin injection – Ferring)

REVIEW DATE: 09/25/2024; effective 1/1/2025

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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

Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, and Zomacton are growth hormone (somatropin) products.[1-8] Somatropin is an exact reproduction of endogenous hGH; all of the products are clinically equivalent with differences related to delivery device, dose increments, and product storage.

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) 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.

National Preferred Formulary

Preferred Products:	Genotropin, Omnitrope
Non-Preferred Products:	Humatrope, Norditropin, Nutropin AQ, Saizen, Zomacton

Basic Formulary

Preferred Products:	Genotropin, Omnitrope
Non-Preferred Products:	Humatrope, Nutropin AQ, Norditropin, Saizen, Zomacton

High Performance Formulary

Preferred Products:	Omnitrope
Non-Preferred Products:	Genotropin, Humatrope, Norditropin, Nutropin AQ, Saizen, Zomacton

Growth Disorders - Growth Hormone Short-Acting Products Preferred Specialty Management Policy 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
Genotropin	**1. National Preferred Formulary.** Approve if the patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria.

	2. Basic Formulary. Approve if the patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria. **3. High Performance Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried Omnitrope **[documentation required]**; AND **b.** Patient cannot continue to use 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (3Ai), but has not met criterion 3Aii, approve Omnitrope.
Humatrope	**1. National Preferred Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin, and Omnitrope **[documentation required]**; AND **b.** 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (1Ai), but the patient has not met criterion 1Aii, approve Genotropin and Ommitrope. **2. Basic Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii):

	i. Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin and Omnitrope **[documentation required]**; AND **b.** 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (2Ai), but the patient has not met criterion 2Aii, approve Genotropin and Omnitrope. **3. High Performance Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried Omnitrope **[documentation required]**; AND **b.** Patient cannot continue to use 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (3Ai), but the patient has not met criterion 3Aii, approve Omnitrope.
Norditropin	**1. National Preferred Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin and Omnitrope **[documentation required]**; AND

	b. 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria (1Ai), but the patient has not met criterion 1Aii, approve Genotropin and Omnitrope. **2. Basic Formulary.** **A)** Approve if the patient meets BOTH of the following (I and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin and Omnitrope **[documentation required]**; AND **b.** 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria (2Ai), but the patient has not met criterion 2Aii, approve Genotropin and Omnitrope. **3. High Performance Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried Omnitrope **[documentation required]**; AND **b.** Patient cannot continue to use 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]**.

	B) If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (3Ai), but the patient has not met criterion 3Aii, approve Omnitrope.
Nutropin AQ	**1. National Preferred Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin or Omnitrope **[documentation required]**; AND **b.** 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].** **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (1Ai), but the patient has not met criterion 1Aii, approve Genotropin and Omnitrope. **2. Basic Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin and Omnitrope **[documentation required]**; AND **b.** 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria (2Ai), but the patient has not met criterion 2Aii, approve Genotropin and Omnitrope. **3. High Performance Formulary.**

	A) Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried Omnitrope **[documentation required]**; AND **b.** Patient cannot continue to use 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (3Ai), but the patient has not met criterion 3Aii, approve Omnitrope.
Omnitrope	**1. National Preferred Formulary.** Approve if the patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria. **2. Basic Formulary.** Approve if the patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria. **3. High Performance Formulary.** Approve if the patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria.
Saizen	**1. National Preferred Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin and Omnitrope **[documentation required]**; AND **b.** 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (1Ai),

	but the patient has not met criterion 1Aii, approve Genotropin and Omnitrope. **2. Basic Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin and Omnitrope **[documentation required]**; AND **b.** 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (2Ai), but the patient has not met criterion 2Aii, approve Genotropin and Omnitrope. **3. High Performance Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried Omnitrope **[documentation required]**; AND **b.** Patient cannot continue to use 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (2Ai), but the patient has not met criterion 3Aii, approve Omnitrope.
Zomacton	**1. National Preferred Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii):

	i. Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin and Omnitrope **[documentation required]**; AND **b.** 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (1Ai), but the patient has not met criterion 1Aii, approve Genotropin and Omnitrope. **2. Basic Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND **ii.** Patient meets BOTH of the following (a and b): **a.** Patient has tried BOTH of the following products: Genotropin and Omnitrope **[documentation required]**; AND **b.** 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (2Ai), but the patient has not met criterion 2Aii, approve Genotropin and Omnitrope. **3. High Performance Formulary.** **A)** Approve if the patient meets BOTH of the following (i and ii): i. Patient meets the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* criteria; AND ii. Patient meets BOTH of the following (a and b): **a.** Patient has tried Omnitrope **[documentation required]**; AND

	b. Patient cannot continue to use 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]**. **B)** If the patient has met the standard *Growth Disorders – Growth Hormone Prior Authorization Policy* Criteria (2Ai), but the patient has not met criterion 3Aii, approve Omnitrope.

REFERENCES

1. Genotropin® subcutaneous injection [prescribing information]. New York, NY: Pfizer; August 2024.
2. Humatrope® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; December 2023.
3. Norditropin® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; March 2020.
4. Nutropin AQ® Nuspin subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; December 2016.
5. Omnitrope® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2024.
6. Saizen® subcutaneous injection [prescribing information]. Rockland, MA: EMD Serono; February 2020.
7. Zomacton™ subcutaneous injection [prescribing information]. Parsippany, NJ: Ferring; April 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Changes effective for 1/1/2024: Added Basic Formulary criteria. Preferred products for the Basic formulary are Genotropin and Norditropin. For National Preferred Formulary criteria: Norditropin was removed as a Preferred product. For National Preferred, Basic, and High Performance Formulary: Documentation was added for a trial of the preferred agents. The following criterion was also added: Patient cannot continue to use the preferred products due to a formulation differenced in the inactive ingredients which, according to the prescriber, would result in a significant allergy or serious adverse reaction [documentation required].	11/01/2023
Early Annual Revision	Changes effective for 1/1/2025: For Basic Formulary, Omnitrope was moved from a non-preferred agent to a preferred agent and Norditropin was moved from a preferred agent to a non-preferred agent.	09/25/2024