

PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Growth Disorders – Growth Hormone (Daily) 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: 11/30/2022; selected revision 01/04/2023

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.

Automation: None.

National Preferred Formulary

Preferred Products: Genotropin, Norditropin, Omnitrope

Non-Preferred Products: Humatrope, Nutropin AQ, Saizen, Zomacton

High Performance Formulary

Preferred Products: Omnitrope

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

RECOMMENDED EXCEPTION CRITERIA

| Non-Preferred Product | Exception Criteria |
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| Genotropin | <p>1. National Preferred Formulary. Approve if the patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria.</p> <p>2. High Performance Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <p>i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND</p> <p>ii. Patient has tried Omnitrope.</p> <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (2Ai), but has <u>not</u> tried the Preferred Product, approve Omnitrope.</p> |
| Humatrope | <p>1. National Preferred Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <p>i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND</p> <p>ii. Patient has tried two of the following products: Genotropin, Norditropin, or Omnitrope.</p> <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (1Ai), but the patient has <u>not</u> tried two of the Preferred Products, approve Genotropin, Norditropin, and Omnitrope.</p> <p>2. High Performance Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <p>i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND</p> <p>ii. Patient has tried Omnitrope.</p> <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (2Ai), but the patient has <u>not</u> tried the Preferred Product, approve Omnitrope.</p> |
| Norditropin | <p>1. National Preferred Formulary. Approve if the patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria.</p> <p>2. High Performance Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <p>i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND</p> <p>ii. Patient has tried Omnitrope.</p> <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (2Ai), but the patient has <u>not</u> tried the Preferred Product, approve Omnitrope.</p> |
| Nutropin AQ | <p>1. National Preferred Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <p>i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND</p> <p>ii. Patient has tried two of the following products: Genotropin, Norditropin, or Omnitrope.</p> <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (1Ai), but the patient has <u>not</u> tried two</p> |

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| | <p>of the Preferred Products, approve Genotropin, Norditropin, and Omnitrope.</p> <p>2. High Performance Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <ul style="list-style-type: none"> i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND ii. Patient has tried Omnitrope. <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (2Ai), but the patient has <u>not</u> tried the Preferred Product, approve Omnitrope.</p> |
| Omnitrope | <p>1. National Preferred Formulary. Approve if the patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria.</p> <p>2. High Performance Formulary. Approve if the patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria.</p> |
| Saizen | <p>1. National Preferred Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <ul style="list-style-type: none"> i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND ii. Patient has tried two of the following products: Genotropin, Norditropin, or Omnitrope. <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (1Ai), but the patient has <u>not</u> tried two of the Preferred Products, approve Genotropin, Norditropin, and Omnitrope.</p> <p>2. High Performance Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <ul style="list-style-type: none"> i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND ii. Patient has tried Omnitrope. <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (2Ai), but the patient has <u>not</u> tried the Preferred Product, approve Omnitrope.</p> |
| Zomacton | <p>1. National Preferred Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <ul style="list-style-type: none"> i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND ii. Patient has tried two of the following products: Genotropin, Norditropin, or Omnitrope. <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (1Ai), but the patient has <u>not</u> tried two of the Preferred Products, approve Genotropin, Norditropin, and Omnitrope.</p> <p>2. High Performance Formulary.</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <ul style="list-style-type: none"> i. Patient meets the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> criteria; AND ii. Patient has tried Omnitrope. <p>B) If the patient has met the standard <i>Growth Disorders – Growth Hormone Prior Authorization Policy</i> Criteria (2Ai), but the patient has <u>not</u> tried the Preferred Product, approve Omnitrope.</p> |

REFERENCES

1. Genotropin® injection [prescribing information]. New York, NY: Pfizer; April 2019.
2. Humatrope® injection [prescribing information]. Indianapolis, IN: Eli Lilly; October 2019.
3. Norditropin® injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; March 2020.
4. Nutropin AQ® Nuspin injection [prescribing information]. South San Francisco, CA: Genentech; December 2016.
5. Omnitrope® injection [prescribing information]. Princeton, NJ: Sandoz; June 2019.
6. Saizen® injection [prescribing information]. Rockland, MA: EMD Serono; February 2020.
7. Zomacton™ injection [prescribing information]. Parsippany, NJ: Ferring; July 2018.