**Endocrine Agents Growth Hormone**

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| Criteria 1 | Non-Preferred Agents- Humatrope, Nutropin, Omnitrope, Saizen, Serostim, Skytrofa, Zomacton |
| Criteria 2 | Preferred Agents- Genotropin (PA), Norditropin (PA) |

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| **Criteria Title** | Endocrine Agents: Growth Hormone | | |
| **Criteria Subtitle** | Non-Preferred Products | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**     |  |  | | --- | --- | | Preferred |  | | Non-Preferred | X | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| HUMATROPE | 028713 | GCNSeqNo |
| HUMATROPE | 029176 | GCNSeqNo |
| HUMATROPE | 029177 | GCNSeqNo |
| NUTROPIN | 065821 | GCNSeqNo |
| NUTROPIN | 074867 | GCNSeqNo |
| NUTROPIN | 074870 | GCNSeqNo |
| OMNITROPE | 037909 | GCNSeqNo |
| OMNITROPE | 044344 | GCNSeqNo |
| OMNITROPE | 044346 | GCNSeqNo |
| SAIZEN | 043027 | GCNSeqNo |
| SAIZEN | 44087108801 | NDC |
| SAIZEN | 058287 | GCNSeqNo |
| SEROSTIM | 018100 | GCNSeqNo |
| SEROSTIM | 022655 | GCNSeqNo |
| SEROSTIM | 043027 | GCNSeqNo |
| SKYTROFA | 082607 | GCNSeqNo |
| SKYTROFA | 082608 | GCNSeqNo |
| SKYTROFA | 082609 | GCNSeqNo |
| SKYTROFA | 082610 | GCNSeqNo |
| SKYTROFA | 082611 | GCNSeqNo |
| SKYTROFA | 082612 | GCNSeqNo |
| SKYTROFA | 082613 | GCNSeqNo |
| SKYTROFA | 082614 | GCNSeqNo |
| SKYTROFA | 082615 | GCNSeqNo |
| ZOMACTON | 021444 | GCNSeqNo |
| ZOMACTON | 043027 | GCNSeqNo |

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| **Sequence Number** | **Question ID** | **Default Next Question ID** | **Question Type** | **Question Text** | **Choice Text** | **Next Question ID** |
| 1 | 0997 |  | Select | What is the patient’s age? | Pediatric (under 18 years of age) | 0998 |
| Adult (18 years of age or older) | 2000 |
| 2 | 0998 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request) | 0999 |
| Continuation (re-authorization request) | 1233 |
| 3 | 0999 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 1000 |
| N | 1235 |
| 4 | 1000 |  | Select | Is the patient being treated and followed by a pediatric endocrinologist, nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (as appropriate for diagnosis)? | Y | 1001 |
| N | 1235 |
| 5 | 1001 |  | Select and Free Text | Has the provider submitted documentation to justify criteria being met, including height, weight, bone age (children), date and results of most current x-ray, stimulus test results, IGF-1 levels and a growth chart (children)? | Y | 1002 |
| N | 1235 |
| 6 | 1002 |  | Select | Does the provider attest that the requested drug is not being used in combination with another somatropin agent? | Y | 1003 |
| N | 1235 |
| 7 | 1003 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 90 days with at least one preferred drug?  If yes, please submit the medication trials and dates. | Y | 1005 |
| N | 1004 |
| 8 | 1004 |  | Select and Free Text | Has the provider submitted documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances)?  If yes, please submit the medication name and reason for inability to use. | Y | 1005 |
| N | 1236 |
| 9 | 1005 |  | Select | Is the request for any of the following:  1) a nonsolid oral dosage formulation  2) a non-preferred extended release formulation  3) a non-preferred brand name that has a preferred generic product | Y | 1006 |
| N | END (Pending Manual Review) |
| 10 | 1006 |  | Select and Free Text | Has the provider submitted documentation of medical necessity for the requested product (i.e. medical reasons for why the patient cannot be changed to a solid oral dosage formulation, inadequate clinical response with a product’s immediate release formulation, or inadequate clinical response or allergy of two or more generic labelers)? | Y | END (Pending Manual Review) |
| N | 1235 |
| 11 | 2000 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request) | 2001 |
| Continuation (re-authorization request) | 1234 |
| 12 | 2001 |  | Select | Is the patient being treated and followed by an endocrinologist? | Y | 2002 |
| N | 1235 |
| 13 | 2002 |  | Select and Free Text | Has the provider submitted documentation of growth hormone deficiency by means of a negative response to an appropriate stimulation test (clonidine test is not acceptable for adults)? | Y | 2003 |
| N | 1235 |
| 14 | 2003 |  | Select and Free Text | Has the provider submitted documentation of baseline evaluation of the following clinical indicators: (1) insulin-like growth factor (IGF-1); (2) fasting lipid profile; (3) BUN; (4) fasting glucose; (5) electrolyte levels; (6) evaluation of any new osteoarthritis and joint pain; (7) bone density test? | Y | 2004 |
| N | 1235 |
| 15 | 2004 |  | Select | Does the provider attest that other hormonal deficiencies are addressed with adequate replacement therapy? | Y | 2005 |
| N | 1235 |
| 16 | 2005 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 90 days with at least one preferred drug?  If yes, please submit the medication trials and dates. | Y | 2007 |
| N | 2006 |
| 17 | 2006 |  | Select and Free Text | Has the provider submitted documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances)?  If yes, please submit the medication name and reason for inability to use. | Y | 2007 |
| N | 1236 |
| 18 | 2007 |  | Select | Is the request for any of the following:  1) a nonsolid oral dosage formulation  2) a non-preferred extended release formulation  3) a non-preferred brand name that has a preferred generic product | Y | 2008 |
| N | END (Pending Manual Review) |
| 19 | 2008 |  | Select and Free Text | Has the provider submitted documentation of medical necessity for the requested product (i.e. medical reasons for why the patient cannot be changed to a solid oral dosage formulation, inadequate clinical response with a product’s immediate release formulation, or inadequate clinical response or allergy of two or more generic labelers)? | Y | END (Pending Manual Review) |
| N | 1235 |
| 20 | 1233 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring (i.e., height, weight gain, improved body composition)? | Y | END (Pending Manual Review) |
| N | 1235 |
| 21 | 1234 |  | Select and Free Text | Has the provider submitted documentation by an endocrinologist that discontinuing the requested agent would have a detrimental effect on body composition or other metabolic parameters? | Y | END (Pending Manual Review) |
| N | 1235 |
| 22 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |
| 23 | 1236 |  | Free Text | Please explain the reason(s) why the patient is unable to use medications not requiring prior approval. | END (Pending Manual Review) | |

LENGTH OF AUTHORIZATIONS: Initial approvals- 180 days; Reauthorizations- 365 days

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| **Last Approved** | 4/13/2023 |
| **Other** |  |

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| **Criteria Title** | Endocrine Agents: Growth Hormone | | |
| **Criteria Subtitle** | Preferred Products | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**     |  |  | | --- | --- | | Preferred | X | | Non-Preferred |  | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| GENOTROPIN | 024494 | GCNSeqNo |
| GENOTROPIN | 040471 | GCNSeqNo |
| GENOTROPIN | 043434 | GCNSeqNo |
| GENOTROPIN | 043435 | GCNSeqNo |
| GENOTROPIN | 043436 | GCNSeqNo |
| GENOTROPIN | 043437 | GCNSeqNo |
| GENOTROPIN | 043438 | GCNSeqNo |
| GENOTROPIN | 045274 | GCNSeqNo |
| GENOTROPIN | 045275 | GCNSeqNo |
| GENOTROPIN | 045276 | GCNSeqNo |
| GENOTROPIN | 045277 | GCNSeqNo |
| GENOTROPIN | 045278 | GCNSeqNo |
| NORDITROPIN | 058667 | GCNSeqNo |
| NORDITROPIN | 058668 | GCNSeqNo |
| NORDITROPIN | 058669 | GCNSeqNo |
| NORDITROPIN | 065287 | GCNSeqNo |

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| 3 | 0999 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 1000 |
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| N | 1235 |
| 6 | 1002 |  | Select | Does the provider attest that the requested drug is not being used in combination with another somatropin agent? | Y | END (Pending Manual Review) |
| N | 1235 |
| 7 | 2000 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request) | 2001 |
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| N | 1235 |
| 11 | 2004 |  | Select | Does the provider attest that other hormonal deficiencies are addressed with adequate replacement therapy? | Y | END (Pending Manual Review) |
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| 12 | 1233 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring (i.e., height, weight gain, improved body composition)? | Y | END (Pending Manual Review) |
| N | 1235 |
| 13 | 1234 |  | Select and Free Text | Has the provider submitted documentation by an endocrinologist that discontinuing the requested agent would have a detrimental effect on body composition or other metabolic parameters? | Y | END (Pending Manual Review) |
| N | 1235 |
| 14 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |

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| **Last Approved** | 4/13/2023 |
| **Other** |  |