HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

GROWTH HORMONES

Generic	Brand	HICL	GCN	Exception/Other
SOMATROPIN	HUMATROPE GENOTROPIN NORDITROPIN NORDITROPIN FLEXPRO NORDITROPIN NORDIFLEX NUTROPIN NUTROPIN AQ OMNITROPE SAIZEN ZOMACTON TEV-TROPIN	02824		BRAND ≠ ZORBTIVE BRAND ≠ SEROSTIM

NOTE: The Omnitrope Pen device is available in the Starter Kit which is available through the manufacturer program OmniSource, https://www.omnitrope.com/patient-support/omnisource.shtml.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

GUIDELINES FOR USE

1. Is the diagnosis Idiopathic Short Stature (ISS)?

   If yes, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Growth Hormone guideline, this medication is not covered for short stature unless it is related to a deficiency of growth hormone. Your provider indicated that you have a diagnosis of short stature without a growth hormone deficiency and therefore your request was not approved.
   If no, continue to #2.

2. Is the patient less than 18 years old?

   If yes, continue to #3.
   If no, continue to #7.

3. Is the patient diagnosed with one of the following conditions?
   - Turner Syndrome
   - Chronic renal failure (CRF)
   - Prader-Willi Syndrome

   If yes, continue to #10.
   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Is the patient diagnosed with one of the following conditions?
   - intrauterine growth retardation (IUGR)
   - Small for gestational age (SGA)

   If yes, continue to #6.
   If no, continue to #5.

5. Is the patient diagnosed with one of the following conditions?
   - Growth hormone deficiency due to lack of endogenous secretion
   - Idiopathic Growth Hormone Deficiency

   If yes, continue to #8.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Growth Hormone guideline, human growth hormone is only covered when prescribed for growth hormone deficiency, Turner Syndrome, chronic renal failure (CRF), or Prader-Willi syndrome. Your provider did not indicate that you are being treated for any of these conditions and therefore your request was not approved.

6. Is the patient's birth weight or length more than 2 standard deviations below the mean (or below the 3rd percentile) for gestational age and has failed to catch up by age 2?

   If yes, continue to #10.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Growth Hormone guideline, growth hormone therapy is covered when prescribed for intrauterine growth retardation (IUGR), or children small for gestational age (SGA) who fail to catch up by age two. Your provider did not indicate that you are being treated for either of these conditions and therefore your request was not approved.

7. Is the patient diagnosed with one of the following conditions?
   - Childhood onset growth hormone deficiency
   - Acquired growth hormone deficiency resulting from hypothalamic-pituitary disease, craniopharyngioma, head trauma, radiation, or surgery.

   If yes, continue to #8.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Growth Hormone guideline, human growth hormone is only covered when prescribed for childhood onset growth hormone deficiency or acquired growth hormone deficiency resulting from hypothalamic-pituitary disease, craniopharyngioma, head trauma, radiation, or surgery. Your provider did not indicate that you are being treated for any of these conditions and therefore your request was not approved.

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INITIAL CRITERIA (CONTINUED)

8. Has the patient's pituitary gland been removed?

   If yes, continue to #10.
   If no, continue to #9.

9. Has the patient failed to respond to one standard growth hormone stimulation test (such as with insulin, levodopa, arginine, propranolol, clonidine, glucagon, or macrilen); (Failure is defined as a peak measured growth hormone level of less than 5ng/ml after stimulation in adult patients and less than 10ng/mL in pediatric patients after stimulation); (**NOTE:** If the member is new to the plan, lab data obtained at initial diagnosis of growth hormone deficiency will be accepted.)?

   If yes, continue to #10.
   If no, do not approve. Please use status code #238 and the provide denial text.
   DENIAL TEXT: Per your health plan's Growth Hormone guideline, your plan requires confirmation of a failed response to standard growth hormone stimulation testing prior to approving coverage for human growth hormone. Your provider did not submit confirmation of a failed response to standard growth hormone stimulation testing and therefore your request was not approved.

10. Is the request for Omnitrope?

    If yes, **approve for 12 months by HICL up to 13 fills.** Please use status code #057 and the approval text provided.
    APPROVAL TEXT: Your request for Omnitrope has been approved for your condition for a 12 month period.
    If no, continue to #11.

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INITIAL CRITERIA (CONTINUED)

11. Does the patient have a documented inadequate clinical response (i.e., failure to grow) after being on at least 2 months therapy with Omnitrope?

    If yes, **approve for 12 months by HICL.** Please use status code #057 and the approval text provided.
    APPROVAL TEXT: Your request for _____ has been approved for your condition for a 12 month period and at the highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

    If no, **do not approve. Please enter a proactive prior authorization for Omnitrope for 12 months by HICL up to 13 fills.**
    Please use status code #238 and the denial text provided.
    DENIAL TEXT: Per your health plan's Growth Hormone guideline, this medication is only covered after an inadequate clinical response following a two-month trial of Omnitrope (somatropin) growth hormone. Your provider did not indicate that you have tried and had an inadequate clinical response to Omnitrope therapy and therefore your request was not approved. Omnitrope has been approved for your condition for 12 months.

    IMPORTANT NOTE: If you are approving Omnitrope, please enter a 'Y' in the PA restriction field. If you are approving a different growth hormone, please enter an 'F' in the PA restriction field.

RENEWAL CRITERIA

1. Is the request for a patient less than 18 years of age diagnosed with one of the following conditions?
   - Growth hormone deficiency due to lack of endogenous secretions
   - Idiopathic Growth Hormone Deficiency
   - Prader-Willi Syndrome
   - Turner Syndrome
   - Chronic renal failure (and has not received a kidney transplant)
   - Small for gestational age (SGA)
   - Intrauterine growth retardation (IUGR)

   If yes, continue to #2.
   If no, continue to #4.

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RENEWAL CRITERIA (CONTINUED)

2. Are the patient's epiphyses closed (as confirmed by radiograph of the wrist and hand)?

   If yes, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Growth Hormone guideline, continuation of human growth hormone therapy is only covered when there is evidence that bones are still able to grow (referred to as open epiphyses). Your provider indicated that you epiphyses are not open and therefore your request was not approved.
   If no, continue to #3.

3. Is there evidence of an insufficient response to therapy, defined as growth velocity of less than 2cm compared with that observed during the previous year?

   If yes, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Growth Hormone guideline, continuation of human growth hormone therapy is only covered when there is evidence that treatment with growth hormone has been effective. An effective response to growth hormone therapy is defined as a gain of growth by greater than or equal to 2cm compared to that observed during the previous year. Your provider indicated that you have not achieved a sufficient gain of growth and therefore your request was not approved.
   If no, continue to #5.

4. Has the patient been diagnosed with **ONE** of the following conditions?
   - Childhood onset growth hormone deficiency
   - Acquired growth hormone deficiency resulting from hypothalamic-pituitary disease, craniopharyngioma, head trauma, radiation, or surgery

   If yes, continue to #5.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT (patients 18 years of age or older): Per your health plan's Growth Hormone guideline, continuation of human growth hormone is only covered for adults when prescribed for childhood onset growth hormone deficiency or acquired growth hormone deficiency resulting from hypothalamic-pituitary disease, craniopharyngioma, head trauma, radiation, or surgery. Your provider did not indicate that you are being treated for any of these conditions and therefore your request was not approve.

   DENIAL TEXT (patients less than 18 years of age): Per your health plan's Growth Hormone guideline, continuation of human growth hormone is only covered for patients less than 18 years of age when prescribed for conditions, such as growth hormone deficiency, Turner Syndrome, chronic renal failure (CRF), or Prader-Willi syndrome. Your provider did not indicate that you are being treated for any of these conditions and therefore your request was not approved.

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RENEWAL CRITERIA (CONTINUED)

5. **Approve the requested growth hormone for 12 months by HICL up to 13 fills.** Please use status code #057 and use the approval text provided.

   Requests for Omnitrope,
   APPROVAL TEXT: Your request for Omnitrope has been approved for a 12 month period.

   Requests for products not on formulary,
   APPROVAL TEXT: Your request for **[requested medication]** has been approved for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

   IMPORTANT NOTE: If you are approving Omnitrope, please enter a 'Y' in the PA restriction field. If you are approving a different growth hormone, please enter an 'F' in the PA restriction field.

RATIONALE

To ensure that growth hormone replacement therapy is used only when medically necessary. Growth hormone will be provided as a plan benefit for patients who have a documented growth hormone deficiency as evidenced by failed response to standard growth hormone stimulation testing.

FDA APPROVED INDICATIONS

PEDIATRIC: Growth failure due to an inadequate secretion of normal endogenous growth hormone due to hypothalamic-pituitary disease, cranial irradiation or surgery, Turner Syndrome, Chronic Renal Failure, Intrauterine Growth Retardation (IUGR), Small for Gestational Age (SGA), Prader-Willi Syndrome. Additionally, Norditropin is indicated for short stature associated with Noonan syndrome and Humatrope is indicated for SHOX syndrome.

ADULT: Growth hormone deficiency resulting from childhood onset growth hormone deficiency, or adult onset growth hormone deficiency due to hypothalamic-pituitary disease, craniopharyngioma, head trauma, irradiation, or surgery.

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REFERENCES

- Humatrope Product Information. Lilly. September 2016.
- Genotropin Product Information. Pharmacia. September 2016.
- Norditropin Product Information. Novo Nordisk. August 2015.
- Nutropin Product Information. Genentech. June 2014
- Omnitrope Product Information. Sandoz. October 2014
- Saizen Product Information. Serono. December 2016
- Zomacton Product Information Ferring Pharmaceuticals.September 2016.
- AACE Growth Hormone Task Force. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Adults and Children - 2003 update. Endocrine Practice Vol 9 No.1; 2003
- AACE Growth Hormone Task Force. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone Deficient Adults and Transition Patients- 2009 Update. Endocrine Practice Vol 15 (Supplement 2); 2009.

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