CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Somatropin Agents (Genotropin, Humatrope, Norditropin, Nutropin/Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive)
BILLING CODE	Must use valid NDC
STATUS	Prior Authorization Required

Somatropin Agents will be considered for coverage when the following criteria are met:

Pediatric Members (less than 18 years of age)

For **initial** authorization:

1. Diagnosis of one of the following:
   a) One of the following diagnoses (documentation of biochemical evidence or testing supporting the diagnosis is required):
      i) Growth-hormone deficiency
      ii) Noonan syndrome (Norditropin only)
      iii) Prader-Willi syndrome
      iv) Renal function impairment associated with growth failure (Nutropin or Nutropin AQ only)
      v) Short stature homeobox-containing gene (SHOX) deficiency (Humatrope or Zomacton only)
      vi) Small for gestational age (SGA)
      vii) Turner syndrome
   b) Diagnosis of Idiopathic short stature AND both of the following (confirmatory growth chart documentation is required for both):
      i) Height measurement of more than 2.0 standard deviations below population mean for given age
      ii) Growth rate of 5 cm/year or less prior to starting growth hormone therapy
2. Both of the following:
   a) Radiology report documenting a bone age of 14-15 or less in females, 16-17 or less in males
   b) Radiology report documenting open epiphyses (Note: documented evidence of open epiphyses is needed only if member is nearing or at puberty (estimated age range 10-17 years of age))
3. Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors prior to initiating growth hormone therapy

Note: Humatrope and Zomactan are non-preferred unless member has a diagnosis of SHOX deficiency; Nutropin and Nutropin AQ are non-preferred unless patient has a diagnosis of growth failure associated with chronic renal insufficiency; Norditropin is non-preferred unless member has a diagnosis of Noonan syndrome. If a request for a non-preferred agent is medically necessary or required for a particular member, a brief summary for use of the non-preferred agent over a preferred alternative must be provided by the prescriber.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. History of the growth hormone therapy in the past 90 days
2. Both of the following:
   a) Radiology report documenting a bone age of 14-15 or less in females, 16-17 or less in males
   b) Radiology report documenting open epiphyses (Note: documented evidence of open epiphyses is needed only if member is nearing or at puberty (estimated age range 10-17 years of age))
3. Prescriber attestation that they are continuing to monitor the member for intracranial tumor recurrence, progression of underlying disease, or malignant transformation of skin lesions, if appropriate
4. Growth rate of 2 to 2.5 cm/year or more with growth hormone therapy OR provider has submitted valid medical rationale for continued use (for idiopathic short stature only)

If all the above requirements are met, the medication will be approved for an additional 12 months.

Adult Members (18 years of age or older) or Members with Closed Epiphyses

For **initial** authorization:
1. Must meet one of the following:
   a) Member is transitioning from pediatric growth hormone therapy and all of the following:
      i) Member has reached adult height
      ii) Member stopped growth hormone therapy for at least 1-month before re-evaluation of the need for continued therapy
      iii) Prescriber has determined that member will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy
   b) Diagnosis of adult growth-hormone deficiency and the following:
      i) Biochemical evidence or testing supporting the diagnosis
   c) Diagnosis of HIV wasting or cachexia (Serostim only) and all of the following:
      i) Must have failed one other therapy for HIV wasting or cachexia (e.g., dronabinol, megestrol, or anabolic steroids)
      ii) Must be on AIDS anti-retroviral therapy
      iii) Must have involuntary weight loss of > 10% of baseline total body weight or body cell mass of < 30% for initial approval
      iv) Must have quantitative measurement of lean body mass using dual energy X-ray absorptiometry (DEXA) or bioelectric impedance analysis (BIA) prior to initiation of therapy
   d) Diagnosis of Short Bowel syndrome (Zorbtive only) and both of the following:
      i) Documentation supporting diagnosis of Short Bowel Syndrome
      ii) Documentation indicating member is receiving specialized nutritional support

Note: Humatrope and Zomactan are non-preferred unless member has a diagnosis of SHOX deficiency; Nutropin and Nutropin AQ are non-preferred unless patient has a diagnosis of growth failure associated with chronic renal insufficiency; Norditropin is non-preferred unless member has a diagnosis of Noonan syndrome. If a request for a non-preferred agent is medically necessary or required for a particular member, a brief summary for use of the non-preferred agent over a preferred alternative must be provided by the prescriber.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Must meet one of the following:
   a) Member has previously been transitioned from pediatric growth hormone therapy and has a history of growth hormone therapy in the past 90 days
   b) Diagnosis of adult growth hormone deficiency and history of the growth hormone therapy in the past 90 days
   c) Diagnosis of HIV wasting or cachexia (Serostim only) and all of the following:
      i) History of the growth hormone therapy in the past 90 days

ii) Documentation stating member is continuing to utilize AIDS antiretroviral therapy
iii) Documentation of member's current total body weight or lean body mass (total body weight or lean body mass must increase from treatment baseline during treatment period in order to obtain subsequent approval)

d) Diagnosis of short bowel syndrome (Zorbtive only) and both of the following:
i) History of the growth hormone therapy in the past 90 days
ii) Documentation stating member is continuing to receive specialized nutritional support

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Somatropin Agents not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/01/2023	Created to align with IN FFS criteria: https://prdgov-rxadmin.optum.com/rxadmin/INM/20230101_Public_Facing_Growth_Hormone_PA_Criteria%20.pdf

Effective date: 04/01/2023
Revised date: 01/01/2023