

Louisiana Fee-for-Service Medicaid Growth Hormones

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical pre-authorization for growth hormone agents.

| ADULTS AND CHILDREN | | |
|---|--|--|
| Medications Somatotropin Brand Examples | Required ICD-10 Codes | Diagnosis Description |
| Genotropin [®] , Humatrope [®] , Norditropin [®] , Nutropin AQ [®] , Omnitrope [®] , Saizen [®] , Zomacton [™] | E23.0 E23.1 E89.3 | Growth Hormone Deficiency (GHD) - Adult, Children <ul style="list-style-type: none"> ○ Iatrogenic Hypopituitarism ○ Drug-induced Hypopituitarism ○ Post Procedural Hypopituitarism |
| Nutropin AQ [®] | N25.0 | Growth failure in children associated with renal insufficiency or chronic kidney disease; until the time of renal transplantation |
| Genotropin [®] , Humatrope [®] , Norditropin [®] , Nutropin AQ [®] , Omnitrope [®] , Zomacton [™] | Q96* | Turner Syndrome |
| Genotropin [®] , Norditropin [®] , Omnitrope [®] | Q87.1 | Prader-Willi Syndrome |
| Norditropin [®] | Q87.1 | Noonan Syndrome |
| Genotropin [®] , Humatrope [®] , Norditropin [®] , Omnitrope [®] , Saizen [®] , Zomacton [™] | P05.1* | Small for gestational age at birth (fetal growth retardation) who fail to manifest catch-up growth or with no catch-up growth by age 2 to 4. |
| Genotropin [®] , Humatrope [®] , Zomacton [™] , Norditropin [®] , Nutropin AQ [®] , Omnitrope [®] | R62.52 | Short stature in children associated with Idiopathic Small Stature SHOX gene mutation/deficiency |
| ADULTS ONLY | | |
| Serostim [®] | R64 | HIV-associated cachexia or wasting |
| Zorbtive [®] | K90.2, K91.2 | Blind Loop Syndrome, Post-Surgical Malabsorption NEC (Alternative name: Short Bowel Syndrome) |

*Any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10-CM diagnosis code

General Approval Criteria for ALL Growth Hormone agents: (ALL criteria must be met)

Initial Approval Criteria:

- The recipient must have a diagnosis appropriate for the growth hormone agent requested (see table above); **AND**
- The growth hormone agent must be prescribed by or in consultation with an endocrinologist, gastroenterologist or nephrologist (as applicable); **AND**
- Requests for non-preferred agents require clinical justification as to why a preferred agent cannot be used. Justification may include but is not limited to any of the following:
 - Recipient must have had a *treatment failure* with an adequate trial (3 months) of at least one preferred product; **OR**
 - Recipient must have had an *intolerable side effect* to at least one preferred product; **OR**
 - Recipient must have *documented contraindication(s)* to the preferred products that are appropriate for the condition being treated; **OR**
 - There is *no preferred product appropriate to use for the condition being treated*; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no inappropriate concomitant drug therapies or disease states; **AND**
 - There is confirmation of open growth plates in recipients older than 12 years of age (if applicable).

Reauthorization Approval Criteria:

- All initial criteria continue to be met; **AND**
- There is evidence of a positive response to therapy as indicated by improvement in signs, symptoms, and lab results compared to baseline.

Duration of initial and reauthorization approval:

- For a diagnosis of blind loop syndrome or post-surgical malabsorption: **4 weeks**
- For HIV-associated cachexia or wasting: **12 weeks**
- For all other diagnoses (NOT blind loop syndrome, post-surgical malabsorption or HIV-associated cachexia or wasting): **12 months**

References

Genotropin (Somatropin) [package insert]. New York, NY: Pfizer Inc; 2016. Retrieved at <http://labeling.pfizer.com/ShowLabeling.aspx?id=577>

Humatrope (Somatropin) [package insert]. Indianapolis, IN: Eli Lilly and Company; 2016. Retrieved at <http://pi.lilly.com/us/humatrope-pi.pdf>

Norditropin (Somatropin) [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2018. Retrieved at <https://www.novo-pi.com/norditropin.pdf>

Nutropin AQ (Somatropin) [package insert]. South San Francisco, CA: Genentech Inc; 2016. Retrieved at https://www.gene.com/download/pdf/nutropin_aq_prescribing.pdf

Omnitrope (Somatropin) [package insert]. Princeton, NJ: Sandoz Inc; 2016. Retrieved at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=58d84ffa-4056-4e36-ad67-7bd4aef444a5&type=display>

Saizen (Somatropin) [package insert]. Rockland, MA: EMD Serono Inc; 2018. Retrieved at <https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/pi/saizen-ce-pi.pdf>

Serostim (Somatropin) [package insert]. Rockland, MA: EMD Serono Inc; 2018. Retrieved at <https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/pi/serostim-pi.pdf>

Zomacton (Somatropin) [package insert]. Parsippany, NJ: Ferring Pharmaceuticals; 2018. Retrieved at <http://www.ferringusa.com/wp-content/uploads/2018/07/ZOMACTON-PI-7-18.pdf>

Zorbtive (Somatropin) [package insert]. Rockland, MA: EMD Serono Inc; 2017. Retrieved at https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20604s026_zorbtive_lbl.pdf