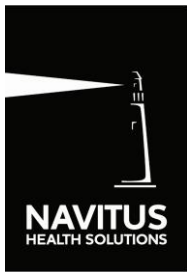




TEXAS MEDICAID
Clinical Edit Prior Authorization
Growth Hormones:
HUMATROPE, NUTROPIN AQ, OMNITROPE, SAIZEN

STEP 1: CLEARLY PRINT AND COMPLETE TO EXPEDITE PROCESSING	
Date:	Prescriber First & Last Name:
Patient First & Last Name:	Prescriber NPI:
Patient Address:	Prescriber Address:
Patient ID:	Prescriber Phone:
Patient Date of Birth:	Prescriber Fax:
STEP 2: MEDICATION INFORMATION	
Medication Requested (Name):	Quantity Requested:
Dose Requested:	Dosing Instructions:
Patient's Primary Diagnosis: _____ ICD 10 Code: _____	
Please indicate ONE (1) of the following: <input type="checkbox"/> STAR / STAR KIDS client (Go to Step 3 - PDL PA Criteria Applies) OR <input type="checkbox"/> CHIP / PERINATE client (Go to Step 4)	
STEP 3: PDL PRIOR AUTHORIZATION CRITERIA FOR NON-PREFERRED PRODUCT	
1. Has the client been stable on one (1) non-preferred agent for 30-days in the last 180 days? <input type="checkbox"/> Yes (Go to Step 4 Question 1) <input type="checkbox"/> No (Go to #2)	
2. Has the client failed a 30-day treatment trial with at least one (1) preferred agent in the last 180 days? <input type="checkbox"/> Yes (Go to Step 4 Question 1) <input type="checkbox"/> No (Go to #3)	
3. Is there a documented allergy or contraindication to preferred agents in this class? <input type="checkbox"/> Yes (Go to Step 4 Question 1) <input type="checkbox"/> No (Go to #4)	



4. Is the drug necessary for treatment of stage-4 advanced metastatic cancer and associated conditions?

- Yes (Go to Step 4 Question 1) No (Deny)

STEP 4: CLINICAL PRIOR AUTHORIZATION CRITERIA

1. Is the client 0 to 16 (greater than (>) 0 and less than or equal to (\leq) 16) years of age?

- Yes (Go to # 2) No (Go to # 9)

2. Does the client have a diagnosis of growth hormone deficiency (GHD) or idiopathic short stature (ISS) in the last 3 years?

- Yes (Go to # 8) No (Go to # 3)

3. Does the client have a diagnosis of panhypopituitarism in the last 3 years?

- Yes (Go to # 4) No (Go to # 5)

4. Has the client had at least 2 claims for the requested medication in the last 90 days (stable therapy)?

- Yes (Go to # 13) No (Go to # 8)

5. Does the client have a diagnosis of ONE (1) of the following in the last 3 years?

- Short Stature Homeobox-Containing Gene (SHOX) Deficiency
- Turner Syndrome
- Noonan Syndrome
- Prader-Willi Syndrome

- Yes (Go to # 13) No (Go to # 6)

6. Does the client have a diagnosis of chronic kidney disease (CKD) in the last 3 years?

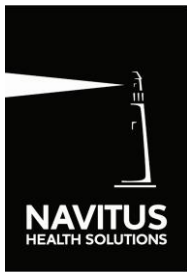
- Yes (Go to # 7) No (Deny)

7. Does the client have a history of a renal transplant (CPT) in the last 3 years?

- Yes (Deny) No (Go to #8)

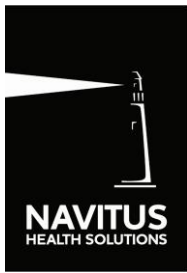
8. Does the submitted documentation support the requested diagnosis? [Manual Step - NOTE: For initial requests, documentation must be from within the past 12 months. For renewal requests, documentation must be from within the past 6 months].

- Yes (Go to # 13) No (Deny)



<p>9. Does the client have a diagnosis of panhypopituitarism in the last 3 years?</p> <p><input type="checkbox"/> Yes (Go to # 11) <input type="checkbox"/> No (Go to # 10)</p>
<p>10. Does the client have a diagnosis of growth hormone deficiency (GHD) or idiopathic short stature (ISS) in the last 3 years?</p> <p><input type="checkbox"/> Yes (Go to # 12) <input type="checkbox"/> No (Deny)</p>
<p>11. Has the client had at least 2 claims for the requested medication in the last 90 days (stable therapy)?</p> <p><input type="checkbox"/> Yes (Go to # 13) <input type="checkbox"/> No (Go to # 12)</p>
<p>12. Does the submitted documentation support the requested diagnosis? [Manual Step - NOTE: For initial requests, documentation must be from within the past 12 months. For renewal requests, documentation must be from within the past 6 months].</p> <p><input type="checkbox"/> Yes (Go to # 13) <input type="checkbox"/> No (Deny)</p>
<p>13. Does the client have a diagnosis of active malignancy in the last 180 days?</p> <p><input type="checkbox"/> Yes (Deny) <input type="checkbox"/> No (Go to # 14)</p>
<p>14. Does the client have a history of chemotherapy/radiation (CPTs) in the last 180 days?</p> <p><input type="checkbox"/> Yes (Deny) <input type="checkbox"/> No (Go to # 15)</p>
<p>15. Does the client have a diagnosis of active proliferative or severe non-proliferative diabetic retinopathy in the last 365 days?</p> <p><input type="checkbox"/> Yes (Deny) <input type="checkbox"/> No (Approve – 365 days)</p>
<p>STEP 5: SIGN AND FAX TO: NAVITUS PRIOR AUTHORIZATION AT: 855-668-8553</p>
<p>Prescriber Signature: _____ Date: _____</p>

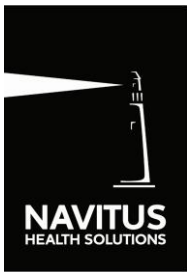
If criteria not met, submit chart documentation with form citing complex medical circumstances. For questions, please call Navitus Customer Care at 1-877-908-6023.



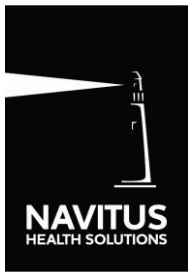
GROWTH HORMONE QUICK REFERENCE GUIDE

Testing Requirements for Clients ≤ 16 Years of Age

Growth Hormone (Excluding Serostim and Zorbtive) Growth Hormone Deficiency, Idiopathic Short Stature, Panhypopituitarism, Chronic Kidney Disease, SHOX Deficiency, Turner Syndrome, Noonan Syndrome and Prader-Willi Syndrome in Children	
Diagnosis	Testing Requirements: For initial requests, documentation must be from within the past 12 months. For renewal requests, documentation must be from within the past 6 months
Panhypopituitarism	<p><u>Initiation of GH Therapy:</u></p> <ul style="list-style-type: none"> • IGF-1 level < 160 ng/mL, AND • Failure to respond (response ≤ 5 ng/mL) to one growth hormone stimulation test (Note: children < 12 months of age are excluded from provocative testing) <p><u>Renewal of GH Therapy:</u></p> <ul style="list-style-type: none"> • No additional testing is required
Growth Hormone Deficiency (GHD)	<p><u>Initiation of GH Therapy:</u></p> <ul style="list-style-type: none"> • Failure to respond (response < 10 ng/mL) to at least 2 growth hormone stimulation tests (Note: children < 12 months of age are excluded from provocative testing), AND • Patient's height > 2.25 SD below the mean for age OR patient's height > 2 SD below the midparental height percentile, AND • Growth velocity < 25th percentile for bone age <p><u>Renewal of GH Therapy:</u></p> <ul style="list-style-type: none"> • Patient's growth should exceed 2 cm/year, AND • Epiphyses are open
Idiopathic Short Stature (ISS)	<p><u>Initiation of GH Therapy:</u></p> <ul style="list-style-type: none"> • Height > 2.25 SD below the mean for age, AND • Predicted adult height < 63 inches for males and < 59 inches for females <p><u>Renewal of GH Therapy:</u></p> <ul style="list-style-type: none"> • Patient's growth should exceed 2 cm/year, OR show an increase in height velocity of 50%, OR an increase of at least 2.5 cm/year above the baseline height velocity, AND • Epiphyses are open



<p>Chronic Kidney Disease</p>	<p><u>Initiation of GH Therapy:</u></p> <ul style="list-style-type: none"> • GFR \leq 75mL/min/1.73m², AND • Patient's height > 2.25 SD below the mean for age OR patient's height > 2 SD below the midparental height percentile OR patient's Z score < -1.88, AND • Pre-transplant <p><u>Renewal of GH Therapy:</u></p> <ul style="list-style-type: none"> • Patient's growth should exceed 2 cm/year, AND • Pre-transplant, AND • Epiphyses are open
<p>SHOX Deficiency, Turner Syndrome, Noonan Syndrome and Prader-Willi Syndrome</p>	<ul style="list-style-type: none"> • Diagnosis only is required, no additional testing is requested



Testing Requirements for Clients > 16 Years of Age

Growth Hormone (Excluding Serostim and Zorbtive) Panhypopituitarism, Growth Hormone Deficiency or Idiopathic Short Stature in patients > 16 years of age	
Diagnosis	Testing Requirements: For initial requests, documentation must be from within the past 12 months. For renewal requests, documentation must be from within the past 6 months
Panhypopituitarism	<u>Initiation of GH Therapy:</u> <ul style="list-style-type: none"> IGF-1 level < 160 ng/mL, AND Failure to respond to one growth hormone stimulation test (response \leq 5ng/mL) <u>Renewal of GH Therapy:</u> <ul style="list-style-type: none"> No additional testing is required
Idiopathic Short Stature (ISS)	<u>Renewal of GH Therapy:</u> <ul style="list-style-type: none"> If patient has been treated as a pediatric patient (\leq 16 years of age) and is requesting a refill, patient's growth should exceed 2 cm/year, AND Bone age < 16 years, AND Epiphyses are open
Growth Hormone Deficiency (GHD) with no other pituitary deficiency	<u>Initiation of GH Therapy:</u> <ul style="list-style-type: none"> IGF-1 level < 160 ng/mL, AND Failure to respond to two growth hormone stimulation tests (response \leq 5ng/mL) <u>Renewal of GH Therapy:</u> <ul style="list-style-type: none"> No additional testing is required