TEXAS MEDICAID
Clinical Edit Prior Authorization
Growth Hormones:
Other Products

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: _____

Indicate the drug's formulary status: *(Formulary available at www.txvendordrug.com)

☐ Non-Preferred Drug **(NPD or NAP Status, Go to Step 3 - PDL PA Criteria Applies)**

OR ☐ Preferred Drug **(Go to Step 4)**

OR ☐ No Status, Drug is not in a Market Basket **(Go to Step 4)**

OR ☐ N/A as this request is for a 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?

   ☐ Yes (Go to Step 4, Question 1) ☐ 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?

   ☐ Yes (Go to Step 4, Question 1) ☐ No (Go to #3)

TEXAS MEDICAID
Clinical Edit Prior Authorization
Growth Hormones:
Other Products

3. Is there a documented allergy or contraindication to preferred agents in this class?

☐ Yes (Go to Step 4, Question 1) ☐ 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 (≤) 16) years of age?

☐ Yes (And the request is for an agent other than Skytrofa – go to # 3)

☐ Yes (And the request is for Skytrofa – go to # 2)

☐ No (Go to # 14)

2. Is the client greater than or equal to (≥) 1 year of age and weigh greater than or equal to (≥) 11.5kg? [Manual Step]

☐ Yes (Go to # 3) ☐ No (Deny)

3. Does the client have a diagnosis of growth hormone deficiency (GHD) in the last 3 years?

☐ Yes (Go to # 13) ☐ No (Go to # 4)

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

☐ Yes (Go to # 5)

☐ No (And the request is for an agent other than Skytrofa - go to # 6)

☐ No (And the request is for Skytrofa - deny)

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

☐ Yes (Go to # 18) ☐ No (Go to # 13)

6. Does the client have a diagnosis of idiopathic short stature (ISS) in the last 3 years?

☐ Yes (Go to # 13) ☐ No (Go to # 7)

7. 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

☐ Yes (Go to # 18) ☐ No (Go to # 8)

TEXAS MEDICAID
Clinical Edit Prior Authorization
Growth Hormones:
Other Products

8. Does the client have a diagnosis of Prader-Willi syndrome in the last 3 years?

☐ Yes (Go to # 9) ☐ No (Go to # 11)

9. Does the client have a diagnosis of obstructive sleep apnea in the last 365 days?

☐ Yes (Go to # 10) ☐ No (Go to #18)

10. Does the client have a history of continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) in the last 730 days?

☐ Yes (Go to # 18) ☐ No (Deny)

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

☐ Yes (Go to # 12) ☐ No (Deny)

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

☐ Yes (Deny) ☐ No (Go to #13)

13. 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 # 18) ☐ No (Deny)

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

☐ Yes (Go to # 16) ☐ No (Go to # 15)

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

☐ Yes (Go to # 17) ☐ No (Deny)

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

☐ Yes (Go to # 18) ☐ No (Go to # 17)

17. 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 # 18) ☐ No (Deny)

TEXAS MEDICAID
Clinical Edit Prior Authorization
Growth Hormones:
Other Products

18. Does the client have a diagnosis of active malignancy in the last 180 days?

☐ Yes (Deny) ☐ No (Go to # 19)

19. Does the client have a history of chemotherapy/radiation (CPTs) in the last 180 days?

☐ Yes (Deny) ☐ No (Go to # 20)

20. Does the client have a diagnosis of active proliferative or severe non-proliferative diabetic retinopathy in the last 365 days?

☐ Yes (Deny) ☐ No (Go to # 21)

21. Does the client have a diagnosis of papilledema in the last 180 days?

☐ Yes (Deny) ☐ No (Approve – 365 days)

STEP 5: SIGN AND FAX TO: NAVITUS PRIOR AUTHORIZATION AT: **855-668-8553**

Prescriber Signature: _____ **Date:** _____

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.

TEXAS MEDICAID
Clinical Edit Prior Authorization
Growth Hormones:
Other Products

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	Initiation of GH Therapy: • 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) Renewal of GH Therapy: • No additional testing is required
Growth Hormone Deficiency (GHD)	Initiation of GH Therapy: • 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 Renewal of GH Therapy: • Patient's growth should exceed 2 cm/year, **AND** • Epiphyses are open

TEXAS MEDICAID
Clinical Edit Prior Authorization
Growth Hormones:
Other Products

Idiopathic Short Stature (ISS)	<u>Initiation of GH Therapy</u>: • Height > 2.25 SD below the mean for age, **AND** • Predicted adult height < 63 inches for males and < 59 inches for females <u>Renewal of GH Therapy</u>: • 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
Chronic Kidney Disease	<u>Initiation of GH Therapy</u>: • GFR ≤ 75mL/min/1.73m^2, **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 <u>Renewal of GH Therapy</u>: • Patient's growth should exceed 2 cm/year, **AND** • Pre-transplant, **AND** • Epiphyses are open
SHOX Deficiency, Turner Syndrome, Noonan Syndrome and Prader-Willi Syndrome	• Diagnosis only is required, no additional testing is requested

TEXAS MEDICAID
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Growth Hormones:
Other Products

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	Initiation of GH Therapy: • IGF-1 level < 160 ng/mL, **AND** • Failure to respond to one growth hormone stimulation test (response ≤ 5ng/mL) Renewal of GH Therapy: • No additional testing is required
Idiopathic Short Stature (ISS)	Renewal of GH Therapy: • If patient has been treated as a pediatric patient (≤ 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	Initiation of GH Therapy: • IGF-1 level < 160 ng/mL, **AND** • Failure to respond to two growth hormone stimulation tests (response ≤ 5ng/mL) Renewal of GH Therapy: • No additional testing is required