Skytrofa (lonapegsomatropin-tcgd) Prior Authorization Request Form

Caterpillar Prescription Drug Benefit
Phone: 877-228-7909 Fax: 800-424-7640

Instructions: Please fill out all applicable sections completely and legibly. Attach any additional documentation that is important for the review (e.g., chart notes or lab data, to support the authorization request). Information contained in this form is Protected Health Information under HIPAA.

☐ **URGENT**

MEMBER INFORMATION	
LAST NAME:	**FIRST NAME:**
PHONE NUMBER:	**DATE OF BIRTH:**
STREET ADDRESS:	
CITY:	**STATE:** **ZIP CODE:**
PATIENT INSURANCE ID NUMBER:	

☐ **MALE** ☐ **FEMALE** **HEIGHT (IN/CM):** _____ **WEIGHT (LB/KG):** _____ **ALLERGIES:** _____

IF YOU ARE NOT THE PATIENT OR THE PRESCRIBER, YOU WILL NEED TO SUBMIT A PHI DISCLOSURE AUTHORIZATION FORM WITH THIS REQUEST WHICH CAN BE FOUND AT THE FOLLOWING LINK: HTTPS://MAGELLANRX.COM/MEMBER/EXTERNAL/COMMERCIAL/COMMON/DOC/EN-US/PHI_DISCLOSURE_AUTHORIZATION.PDF

PATIENT'S AUTHORIZED REPRESENTATIVE (IF APPLICABLE): _____

AUTHORIZED REPRESENTATIVE'S PHONE NUMBER: _____

PRESCRIBER INFORMATION	
LAST NAME:	**FIRST NAME:**
PRESCRIBER SPECIALTY:	**EMAIL ADDRESS:**
NPI NUMBER:	**DEA NUMBER:**
PHONE NUMBER:	**FAX NUMBER:**
STREET ADDRESS:	
CITY:	**STATE:** **ZIP CODE:**
REQUESTOR (if different than prescriber)**:**	**OFFICE CONTACT PERSON:**

MEDICATION OR MEDICAL DISPENSING INFORMATION			
MEDICATION NAME:			
DOSE/STRENGTH:	**FREQUENCY:**	**LENGTH OF THERAPY/REFILLS:**	**QUANTITY:**
☐ **NEW THERAPY** ☐ **RENEWAL** **IF RENEWAL:** DATE THERAPY INITIATED: DURATION OF THERAPY (SPECIFIC DATES):			

Continued on next page.

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MEMBER'S LAST NAME: _____ **MEMBER'S FIRST NAME:** _____

1. HAS THE PATIENT TRIED ANY OTHER MEDICATIONS FOR THIS CONDITION? ☐ YES (if yes, complete below) ☐ NO		
MEDICATION/THERAPY (SPECIFY DRUG NAME AND DOSAGE)**:**	**DURATION OF THERAPY** (SPECIFY DATES)**:**	**RESPONSE/REASON FOR FAILURE/ALLERGY:**

2. LIST DIAGNOSES:	**ICD-10:**
□ Growth hormone deficiencies WITHOUT organic pituatiry disease □ Grwoth hormone deficiences WITH organic pituitary disease □ Idiopathic Short Stature (ISS) □ Small for gestation age (SGA) □ Turner's Syndrome □ Prader-Willi Syndrome □ Noonan Syndrome □ Short Stature Homeobox (SHOX) Syndrome □ Other diagnosis: _____ICD-10_____	

3. REQUIRED CLINICAL INFORMATION: PLEASE PROVIDE ALL RELEVANT CLINICAL INFORMATION TO SUPPORT A PRIOR AUTHORIZATION.

Is this drug being used as part of a clinical trial? □ Yes □ No

PEDIATRIAC PATIENTS <18 YEARS OF AGE:

Is the provider a pediatric endocrinologist or in the case of chronic kidney disease, pediatric nephrologist? □ Yes □ No

Does patient have growth failure secondary to Growth Hormone Deficiency? □ Yes □ No
Chart note documentation required

Have other causes of growth failure been ruled out? □ Yes □ No
Chart note documentation required

Does patient have a current acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure? □ Yes □ No

Has the patient tried and had an intolerance to Norditropin (somatotropin) and all other short-acting growth hormone products? □ Yes □ No
Please provide detailed rationale of why treatment cannot be continued (such as allergic rash or difficulty breathing)

If patient has had an intolerance to the preferred product Norditropin and all other formulary short-acting growth hormone products has the U.S. FDA MedWatch Voluntary Reporting Form for adverse drug reactions (FDA Form 3500) been filed with the FDA? □ Yes □ No ***Please provide chart note documentation of MedWatch form.***

Does patient have an absolute contraindication to trial of the preferred product Norditropin and all other formulary short-acting growth hormone products (such as a documented patient allergy to a known dye or binder or additive in the product)? □ Yes □ No
Please provide documentation.

Has patient failed to achieve adequate height velocity with complete compliance while trying at least 3 - months on the preferred product Norditropin and all short-acting growth hormone products? □ Yes □ No *Please provide documentation.*

<u>For New Starts who have not been previously on a short-acting growth hormone product:</u>
<u>PEDIATRIAC PATIENTS <18 YEARS OF AGE:</u>
Is the provider a pediatric endocrinologist or in the case of chronic kidney disease, pediatric nephrologist? □ Yes □ No

<u>For GHD WITHOUT organic pituitary disease:</u>
Does the patient have growth failure caused by inadequate secretion of endogenous growth hormone in the absence of organic pituitary disease? □ Yes □ No

Has growth hormone deficiency been confirmed by ONE of the following:
□ TWO provocative test with results below 10 ng/ml (i.e. i.e., L-Dopa, insulin-induced hypoglycemia, arginine, glucagon, or clonidine)
□ ONE provocative stimulation test less than 15 ng/mL AND a low insulin-like growth factor-1 (IGF-1) level for the patients age, gender, and pubertal status AND a low IGFBP (insulin-like growth factor binding protein-3)
Documentation must be submitted

Is the patient's height below the third percentile for their age and gender related height? □ Yes □ No
Documentation must be submitted

Does the patient have a decreased growth velocity of ≥ 2 standard deviations (SD) below the age-related mean measured over 1 year? □ Yes □ No
Documentation must be submitted

Does the patient have delayed skeletal maturation of ≥ 2 SD below the age/gender related mean? □ Yes □ No
Documentation must be submitted

In patient's ≥ 10 years of age, are the epiphyses confirmed as open? □ Yes □ No
Documentation must be submitted

<u>For GHD WITH organic pituitary disease:</u>
Does the patient have a diagnosis of GHD caused by an inadequate secretion of endogenous growth hormone in the presence of organic pituitary disease (e.g., head trauma, cranial irradiation, stroke, hypopituitarism, panhypopituitarism, known mutations, irreversible and/or post-surgery hypothalamic-pituitary lesions, embryopathic / congenital defects of the pituitary, septo-optic dysplasia)? □ Yes □ No

Is the serum IGF-1 level lower than the age-specific lower limit of normal? □ Yes □ No
Documentation must be submitted

Does the MRI or CT of head show pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, and/or ectopic posterior pituitary "bright spot"? □ Yes □ No *Documentation must be submitted*

<u>For idiopathic short stature (ISS):</u>
Does the patient have a diagnosis of non growth hormone deficient short stature? □ Yes □ No

Is the patient's height standard deviation score (SDS) of 2.25 or below the mean chronological age and sex?
□ **Yes** □ **No** ***Documentation must be submitted***

Have other causes such as genetic, metabolic, or organ system dysfunction been ruled out and documented?
□ **Yes** □ **No** ***Documentation must be submitted***

For chronic kidney disease:
Has the patient received a renal transplant? □ **Yes** □ **No**

Is the patient's height below the 3rd percentile for their age and gender related height? □ **Yes** □ **No**
Documentation must be submitted

Small for Gestational Age (SAG):
Was the patient born small for gestational age (SGA), defined as birth weight and/or birth length two or more SDs below the mean for gestational age? □ **Yes** □ **No**
Documentation must be submitted

Has the patient failed to catch up in growth by 2-4 years of age, defined as two or more SDs below the mean in birth weight and/or birth height for age and sex? □ **Yes** □ **No**
Documentation must be submitted

Does the patient have another clinically defined syndrome known to cause short stature due to primary growth failure(per ICPED), including Down Syndrome (Trisomy 21) and Silver-Russell syndrome? □ **Yes** □ **No**
Documentation must be submitted

Does the patient have congenital bone dysplasia, including achondroplasia and hypochondroplasia? □ **Yes** □ **No**
Documentation must be submitted

For Turner's syndrome:
Was the patient's diagnosis confirmed by chromosome analysis? □ **Yes** □ **No**
Documentation must be submitted

Does the patient's height fall below the 5th percentile for chronological age and sex? □ **Yes** □ **No**
Documentation must be submitted.

Has the patient's growth velocity, prior to age 14 years, decreased to less than 2 cm /year prior to bone growth cessation? □ **Yes** □ **No**
Documentation must be submitted.

Does the growth chart confirm the child's height for age is less than or equal to 50% of that predicted based on the mean parental height for females ?(mean predicted height in centimeters = mean parental height in cm minus 6.5 cm). □ **Yes** □ **No** ***Documentation must be submitted.***

For Prader-Willi Syndrome: Was the diagnosis confirmed by genetic testing (loss of gene function associated with chromosome 15 such as translocation or maternal uniparental disomy)? □ **Yes** □ **No**
Documentation must be submitted

Has an assessment of underlying airway obstruction including sleep studies been completed? □ Yes □ No
Documentation must be submitted

Does the patient have any of the following:
□ severe obesity
□ history of upper airway obstruction
□ respiratory compromise
□ severe sleep apnea

<u>For Short Stature Homeobox (SHOX) deficiencies</u>: Was the diagnosis confirmed via chromosomes analysis?
□ Yes □ No

<u>For ADULT patients ≥ 18 years of age</u>:
Does the patient have adult onset GHD alone or with multiple hormone deficiencies (such as hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma? □ Yes □ No

Is the patient's serum IGF-1 concentration lower than the age-specific lower limit of normal in a ptient who has organic pituitary disease? □ Yes □ No
Documentation must be submitted.

Does that patient have a subnormal GH response to insulin-induced hypoglycemia (<5.1 ng/mL) or arginine-GHRH (<4.1ng/mL)? □ Yes □ No
Documentation must be submitted.

<u>For Adults with childhood-onset GHD</u>:
Does the patient have childhood-onset GHD as a result of congenital, acquired, or idiopathic causes? □ Yes □ No

Has the patient been retested at least 1 month after GH therapy has been discontinued and final height has been achieved and subnormal responses to at least one standard GH stimulation test confirm need for GH therapy?
□ Yes □ No

<u>For GHD with organic pituitary disease</u>:
Does the patient have organic pituitary disease (e.i. head trauma, cranial irradiation, stroke, hypopituitarism, panhypopituitarism, known mutations, irreversible and/or post-surgery hypothalamic-pituitary lesions, embryopathic / congenital defects of the pituitary, septo-optic dysplasia)? □ Yes □ No
Documentation must be submitted

Does the patient have past OR current IGF-1 levels that are below the age- and sex-appropriate reference range without GH therapy? □ Yes □ No
Documentation must be submitted

Has the patient had a subnormal GH response to insulin-induced hypoglycemia hypoglycemia (<5.1ng/ml) or arginine-GHRH (<4.1ng/ml)? □ Yes □ No

<u>For renewal, please answer the following</u>:
<u>Pediatric patients < 18 years of age</u>:
Does the patient have one of the following diagnosis:

□ growth hormone deficiency
□ small for gestational age (SGA)
□ idiopathic short stature (ISS)
□ growth failure due to Turner's syndrome
□ Noonan Syndrome
□ Short stature homeobox (SHOX) deficiency
□ chronic kidney disease

Are the patient's epiphyses open? □ Yes □ No

If the patient is male with a bone age of up to 16 years of age, is the patient's growth response at least 4.5 cm/year (prepubertal growth rate) or at least 2.5 cm/yr (post-puberty growth rate)? □ Yes □ No

If the patient if female with ab one age of up to 14 years, is the patient's growth response at least 4.5 cm/yr (prepubertal growth rate) or at least 2.5 cm/yr (post-puberty growth rate)? □ Yes □ No

For a diagnosis of Prader-Willi syndrome:
Has the patient experienced an increase in lean body mass, decrease in fat, or maintenance of benefit? □ Yes □ No

Adults (≥ 18 years of age): Has the patient experienced clinical benefit while on therap (ie increase in total lean body mass, increase IGF-1 and IGFBP3 levels, or increase in exercise capacity)? □ Yes □ No

REAUTHORIZATION
Pediatric patients < 18 years of age:
Does the patient have one of the following diagnosis:
□ growth hormone deficiency
□ small for gestational age (SGA)
□ idiopathic short stature (ISS)
□ growth failure due to Turner's syndrome
□ Noonan Syndrome
□ Short stature homeobox (SHOX) deficiency
□ chronic kidney disease

Are the patient's epiphyses open? □ Yes □ No

If the patient is male with a bone age of up to 16 years of age, is the patient's growth response at least 4.5 cm/year (prepubertal growth rate) or at least 2.5 cm/yr (post-puberty growth rate)? □ Yes □ No

If the patient if female with ab one age of up to 14 years, is the patient's growth response at least 4.5 cm/yr (prepubertal growth rate) or at least 2.5 cm/yr (post-puberty growth rate)? □ Yes □ No

For a diagnosis of Prader-Willi syndrome:
Has the patient experienced an increase in lean body mass, decrease in fat, or maintenance of benefit? □ Yes □ No

Adults (≥ 18 years of age): Has the patient experienced clinical benefit while on therap (ie increase in total lean body mass, increase IGF-1 and IGFBP3 levels, or increase in exercise capacity)? □ Yes □ No

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

Please note: Not all drugs/diagnosis are covered on all plans. This request may be denied unless all required information is received.

ATTESTATION: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature or Electronic I.D. Verification: _____ Date: _____

FAX THIS FORM TO: 800-424-7640
MAIL REQUESTS TO: Magellan Rx Management Prior Authorization Program
Attn: CP – 4201
P.O. Box 64811
St. Paul, MN 55164-0811