Member Name: {{MEMFIRST}} {{MEMLAST}} DOB: {{MEMBERDOB}} PA Number: {{PANUMBER}}

### {{PANUMCODE}}

{{DISPLAY\_PAGNAME}} {{PACDESCRIPTION}}

This fax machine is located in a secure location as required by HIPAA regulations. Fax complete signed and dated forms to {{COMPANY\_NAME}} at {{CLIENT\_PAG\_FAX}}. Please contact {{COMPANY\_NAME}} at {{CLIENT\_PAG\_PHONE}} with questions regarding the prior authorization process. When conditions are met, we will authorize the coverage of {{DRUGNAME}}.

Patient's Name: {{MEMFIRST}} {{MEMLAST}} **Date**: {{TODAY}} Patient's ID: {{MEMBERID}} **Patient's Date of Birth:** {{MEMBERDOB}} **Physician's Name:** {{PHYFIRST}} {{PHYLAST}} Patient Phone: <<MEMPHONE>> Specialty: NPI#: Physician Office Telephone: {{PHYSICIANPHONE}} Physician Office Fax: {{PHYSICIANFAX}} Physician Office Address: <<PHYADDRESS1>> <<PHYADDRESS2>> <<PHYCITY>>, <<PHYSTATE>> <<PHYZIP>> **Drug Name:** {{DRUGNAME}} Quantity: Strength: \_\_\_\_\_ Frequency: Expected Length of Therapy: \_\_\_\_\_ Route of Administration: Diagnosis: <<DIAGNOSIS>> ICD Code: <<ICD9>>

1.	What drug is being prescribed Genotropin ( <i>preferred</i> ) Norditropin ( <i>preferred</i> )	Nutropin AQ		□ Saizen □ Other		
2.	<ul> <li>What is the diagnosis?</li> <li>Small for gestational age (SGA)</li> <li>Growth failure associated with cerebral palsy</li> <li>Growth failure associated with cystic fibrosis</li> <li>HIV-associated wasting/cachexia</li> <li>Growth failure associated with chronic kidney disease (CKD)</li> <li>Pediatric growth hormone deficiency (GH) (including panhypopituitarism</li> <li>Growth failure associated with congenital adrenal hyperplasia</li> <li>Growth failure associated with Russell-Silver syndrome</li> <li>Short stature homeobox-containing gene (SHOX) deficiency</li> <li>Other</li> </ul>			( ( ( opituitarism cuitarism)		
3.	What is the ICD-10 code?					
4.	Is this request for continuation of therapy? $\Box$ Yes $\Box$ No If No, skip to diagnosis section.					
5.	Is the patient currently receiv program? If Yes or Unknown				-	
6.	Please indicate/attach the foll <i>medical records</i>	owing information	n provided by the	prescriber.	ACTION REQUIRED: Attach	

- A) Total duration of treatment (approximate duration is acceptable):
- B) Date of the last dose administered:
- C) Approving health plan/pharmacy benefit manager:
- D) Date of the prior authorization/approval:
- E) Attach authorization approval letter

# Complete the following section based on patient's diagnosis, if applicable.

# Section A: Short Bowel Syndrome

1 Is the patient dependent on intravenous parenteral nutrition (e.g. TPN) for nutritional support?  $\Box$  Yes  $\Box$  No

**Member Name:** {{MEMFIRST}} {{MEMLAST}} **DOB:** {{MEMBERDOB}} **PA Number:** {{PANUMBER}}

- Will the requested product be used in conjunction with optimal management of short bowel syndrome (SBS)? 2. □ Yes □ No
- 3. How many weeks of growth hormone (GH) therapy has the patient received in their lifetime? weeks

Section B: Pediatric Disorders *Please complete the following sub-section, if applicable.* 

- 1. Please indicate the date GH deficiency was diagnosed and the date GH therapy was initiated (if applicable). Date of diagnosis: Date GH therapy was initiated:
- 2. Indicate patient's **pretreatment** height and age (two measurements taken 6-18 months apart): ACTION REQUIRED: Attach a growth chart showing pretreatment heights and growth velocity. months Data

a) Height:	cm	Age:	years,	months	Date:
b) Height:	cm	Age:	years,	months	Date:

3. Has patient had any pretreatment pharmacologic provocative tests? ACTION REOUIRED: If Yes, attach laboratory report or medical record of pre-treatment provocative test results. □ Yes, *How many*? \_\_\_\_\_ □ No Peak Level: \_\_\_\_\_ ng/mL Date: Agent:

<b>_</b>			
Agent:	Peak Level:	ng/mL	Date:

- 4. What is the pretreatment 1-year height velocity? ACTION REQUIRED: Attach a growth chart showing growth velocity. cm/year
- 5. Does the patient have a pretreatment slow growth velocity? ACTION REQUIRED: Attach a growth chart *showing growth velocity.* **□** Yes **□** No
- 6. If the patient's pre-treatment age is less than 2.5 years of age, does the patient have a pretreatment height of greater than 2 standard deviations (SD) below the mean for age and gender AND a slow growth velocity? ACTION REQUIRED: If Yes, attach a growth chart showing pretreatment heights and growth velocity and *no further questions.* Q Yes No N/A - pretreatment age is greater than or equal to 2.5 years of age
- 7. Does the patient have a pretreatment 1-year height velocity of greater than 2 standard deviations (SD) below the mean for age and gender? ACTION REOUIRED: If Yes, attach a growth chart showing pretreatment *height velocity*.  $\Box$  Yes  $\Box$  No
- 8. Are the epiphyses still open?  $\Box$  Yes, confirmed by X-ray  $\Box$  Yes, but X-ray is not available  $\Box$  No
- 9. Indicate patient's current: Height: \_\_\_\_\_ cm Age: \_\_\_\_\_ years, \_\_\_\_\_ months
- 10. If currently on therapy, is the patient growing at a rate of more than 2 cm/year? ACTION REOUIRED: If *Yes, collect current growth chart showing growth velocity.* **U** Yes **U** No Indicate therapy start date:
- 11. What is the clinical reason for the lack of efficacy? On treatment less than 1 year - Indicate treatment duration: □ Nearing final adult height/in later stages of puberty Other
- *I. Pediatric GHD (includes panhypopituitarism)*
- 1. Is the patient a neonate or was the patient diagnosed with growth hormone (GH) deficiency as a neonate?  $\Box$  Yes  $\Box$  No If No, skip to #3
- 2. Are medical records available to support the diagnosis of neonatal growth hormone (GH) deficiency such as hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiencies, magnetic resonance imaging (MRI) results, or chart notes? ACTION REQUIRED: If Yes, attach medical records. □ Yes □ No
- 3. What is the pituitary or central nervous system (CNS) disorder? List continues on next page.
- GH secretagogue receptor gene defect
   Optic nerve hypoplasia/septo-optic dysplasia
   Agenesis of corpus callosum
   GH gene defect
   Surgery of the pituitary or hypothalamus
   Empty sella syndrome

Agenesis of corpus callosum

Empty sella syndrome

**Member Name:** {{MEMFIRST}} {{MEMLAST}} **DOB:** {{MEMBERDOB}} **PA Number:** {{PANUMBER}}

- Ectopic posterior pituitary
- □ Pituitary stalk defect
- Encephalocele
- □ Anencephaly or prosencephaly
- □ Vascular malformation
- □ Radiation
- □ CNS infection
- □ Inflammatory process (e.g., autoimmune hypophysitis)

□ Surgery

□ Pituitary aplasia/hypoplasia

□ Holoprosencephaly

- □ Chemotherapy
- □ CNS infarction

□ Hydrocephalus

Arachnoid cyst

□ Head trauma/traumatic brain injury □ Perinatal or postnatal trauma

- □ Aneurysmal subarachnoid hemorrhage
- □ Infiltrative process (e.g., sarcoidosis, histiocytosis, hemochromatosis)
- □ Transcription factor defect (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
- Growth hormone releasing hormone (GHRH) receptor gene defect
- Other mid-line facial defects (e.g., single central incisor, cleft lip/palate)
- CNS tumor/neoplasm (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma)
- Cysts (Rathke cleft cyst or arachnoid cleft cyst)
- □ Other:
- □ No None of the above
- 4. Does the patient have a pretreatment insulin-like growth factor-1 (IGF-1) level greater than 2 standard deviations (SD) below the mean based on the laboratory reference range? ACTION REQUIRED: If Yes, attach laboratory report or medical record of pretreatment IGF-1 level.  $\Box$  Yes  $\Box$  No Indicate patient's pretreatment IGF-1 level: \_\_\_\_\_ Range: \_\_\_\_\_

## II. Turner Syndrome (TS)

- 1. Was the diagnosis of Turner syndrome confirmed by karyotyping? ACTION REQUIRED: If Yes, attach *karvotype study result.*  $\Box$  Yes  $\Box$  No
- 2. Does the patient have a pretreatment height less than the 5th percentile for age? ACTION REQUIRED: If Yes, attach a growth chart showing pretreatment height.  $\Box$  Yes  $\Box$  No

### *III. SHOX Deficiency*

1. Has the diagnosis of SHOX deficiency been confirmed by molecular or genetic analyses? ACTION REQUIRED: If Yes, attach molecular/genetic test results. Yes No

# IV. Prader-Willi Syndrome (PWS)

- 1. Was the diagnosis of Prader-Willi syndrome confirmed by genetic testing demonstrating any of the following: A) Deletion in the chromosomal 15q11.2-q13 region, B) Maternal uniparental disomy in chromosome 15, or C) Imprinting defects, translocations, or inversions involving chromosome 15? ACTION REOUIRED: If *Yes, attach genetic test result.*  $\Box$  Yes  $\Box$  No
- 2. If currently on therapy, have body composition and psychomotor function improved or stabilized in response to growth hormone (GH) therapy?  $\Box$  Yes  $\Box$  No  $\Box$  N/A, not currently on therapy

- 1. What was the patient's gestational age at birth? weeks days
- grams AND <u>Birth</u> Length? \_\_\_\_\_ cm 2. What was the patient's: Birth Weight? ACTION REQUIRED: Attach growth charts showing birth weight and length.
- 3. Was the birth weight or length greater than or equal to 2 standard deviations (SD) below the mean for gestational age? ACTION REQUIRED: If Yes, attach growth charts showing birth weight and length.  $\Box$  Yes  $\Box$  No
- 4. Was the birth weight or length less than the 3rd percentile for gestational age? ACTION REOUIRED: If *Yes, attach growth charts showing birth weight and length.* **Q** Yes **Q** No
- 5. Did the patient fail to manifest catch-up growth by age two as demonstrated by pretreatment height greater than 2 standard deviations (SD) below the mean for age and gender? ACTION REQUIRED: If Yes, collect growth chart showing pretreatment height.  $\Box$  Yes  $\Box$  No

V. Small for Gestational Age (SGA)

VI. Idiopathic Short Stature (ISS)

- 1. Does the patient have the following adult height prediction: A) Boys: Less than 5 feet, 3 inches, B) Girls: Less than 4 feet, 11 inches?  $\Box$  Yes  $\Box$  No
- 2. Has pediatric GH deficiency been ruled out with a provocative growth hormone test with a peak of greater than or equal to 10 ng/mL? *ACTION REQUIRED: If Yes, attach laboratory report or medical record of pretreatment provocative test result.* □ Yes □ No

Section C: Adult Growth Hormone Disorder

- Does the patient have a low pre-treatment insulin-like growth factor-1 (IGF-1) (between 0 to 2 standard deviations below the mean for age and gender based on the laboratory reference range)?
   ACTION REQUIRED: If Yes, attach laboratory report or medical record of pretreatment IGF-1 level.
   Yes I No
- Has the patient had at least 2 pre-treatment pharmacologic provocative growth hormone (GH) tests?
   ACTION REQUIRED: If Yes, attach laboratory report or medical record of pre-treatment provocative test results. □ Yes □ No
- 3. Has patient had any **pretreatment** pharmacologic provocative tests or a pretreatment test with the agent Macrilen? *ACTION REQUIRED: If Yes, attach laboratory report or medical record of pre-treatment provocative test results.*

□ Yes, indicate number(s) and list of pre-treatment provocative test					
□ Agent:	Peak Level:	ng/mL	Date:		
□ Agent:	Peak Level:	ng/mL	Date:		
□ Agent:	Peak Level:	ng/mL	Date:		

- 4. What is the patient's body mass index (BMI)? Height: \_\_\_\_\_ cm Weight: \_\_\_\_\_ lbs / kg Body mass index (BMI): \_\_\_\_\_ kg/m<sup>2</sup>
- 5. Does the patient have a high pretest probability (e.g., acquired structural abnormalities) of growth hormone deficiency? □ Yes □ No
- 6 Does the patient have organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation)? □ Yes □ No If No, skip to #9
- Does the patient have documented deficiencies in at least three of the following pituitary hormones?
   □ Yes □ No If No, skip to #9
- 8. Does the patient have deficiencies of three or more pituitary hormones? Indicate ALL that apply.
  Growth hormone
  Antidiuretic hormone (ADH)
  Luteinizing hormone (LH)
  Prolactin
  No deficiencies of pituitary hormones
- 9. Does the patient have a genetic or structural hypothalamic-pituitary defect (transcription factor defects [PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2], GHRH receptor-gene defects, GH-gene defects associated with brain structural defects, single central incisor, cleft lip/palate) or an acquired cause (perinatal insults)?
  □ Yes □ No
- 11. Does the patient have a congenital abnormality of the central nervous system (CNS), hypothalamus, or pituitary gland? IYes No
- 12. If patient is requesting for a continuation of therapy, is the patient's current IGF-1 elevated for age and gender? ACTION REQUIRED: If No, collect laboratory report or medical record of current IGF-1 level.
  □ Yes □ No □ NA, request is NOT for a continuation of therapy

#### Section D: HIV-Related Wasting

- 1. Is the patient on anti-retroviral therapy? Yes No
- 2. Indicate the following: 

   Pretreatment :
   Height:
   cm
   Weight:
   lbs / kg
   Body mass index (BMI):
   kg/m²

   Current:
   Height:
   cm
   Weight:
   lbs / kg
   Body mass index (BMI):
   kg/m²
- 3. If new to growth hormone (GH) therapy, has the patient tried and had a suboptimal response to alternative therapies (e.g., dronabinol, megestrol acetate, cyproheptadine, or testosterone if hypogonadal)? If Yes, no further questions.  $\Box$  Yes  $\Box$  No  $\Box$  N/A – patient is currently on growth hormone (GH) therapy
- 4. Does the patient have a contraindication or intolerance to alternative therapies (i.e., dronabinol, megestrol acetate, cyproheptadine, or testosterone if hypogonadal)? UYes Ves

### \*\*Please attach the most recent clinical notes or supporting documentation\*\*

Please complete the following contact information in case additional information is needed.

Office Contact Person: \_\_\_\_\_ Contact Phone: \_\_\_\_\_ Ext #: \_\_\_\_

I attest that the medication requested is medically necessary for this patient. I further attest that the information provided is accurate and true, and that the documentation supporting this information is available for review if requested by the claims processor, the health plan sponsor, or, if applicable a state or federal regulatory agency.

Prescriber (Or Authorized) Signature and Date