

GROWTH HORMONE PRIOR AUTHORIZATION REQUEST PRESCRIBER FAX FORM

Only the prescriber may complete this form. This form is for prospective, concurrent, and retrospective reviews.

Incomplete forms will be returned for additional information. The following documentation is required for preauthorization consideration. For formulary information please visit www.myprime.com.

What is the priority level of this request?

- Standard
 Date of service (if applicable): _____
 Urgent (NOTE: Urgent is defined as when the prescriber believes that waiting for a standard review could seriously harm the patient's life, health, or ability to regain maximum function.)

PATIENT AND INSURANCE INFORMATION

Today's Date: _____

Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
Patient Address:		City, State, Zip:	Patient Telephone:
Member ID Number:		Group Number:	

PRESCRIBER/CLINIC INFORMATION

Prescriber Name:	Prescriber NPI#:	Specialty:	Contact Name:
Clinic Name:		Clinic Address:	
City, State, Zip:		Phone #:	Secure Fax #:

RENDERING/SERVICING PRESCRIBER INFORMATION (IF APPLICABLE)

Prescriber Name:	Prescriber NPI#:	Specialty:	Contact Name:
Clinic Name:		Clinic Address:	
City, State, Zip:		Phone #:	Secure Fax #:

PLEASE ATTACH ANY ADDITIONAL INFORMATION THAT SHOULD BE CONSIDERED WITH THIS REQUEST

Patient's diagnosis: <input type="checkbox"/> AIDS wasting/cachexia <input type="checkbox"/> Prader-Willi syndrome <input type="checkbox"/> Small for gestational age (SGA) <input type="checkbox"/> Chronic renal insufficiency <input type="checkbox"/> Short bowel syndrome (SBS) <input type="checkbox"/> Turner syndrome <input type="checkbox"/> Idiopathic short stature (ISS) <input type="checkbox"/> Short stature <input type="checkbox"/> Noonan syndrome <input type="checkbox"/> SHOX gene deficiency <input type="checkbox"/> Growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone <input type="checkbox"/> Panhypopituitarism or deficiencies in 3 or more pituitary axes <input type="checkbox"/> Other (ICD code and description): _____	
Medication requested:	Strength:
Dosing schedule:	Quantity per month:

For all requests:

- Is the patient currently treated with the requested agent? Yes No
- What is the patient's weight? _____(kg)
- Is the patient a child or an adult? Select one: Child Adult
- Is the patient's age within FDA labeling for the requested indication for the requested agent? Yes No
 If no, is there information to support use with the requested agent for the patient's age for the requested indication? Yes No
 If yes, please provide supporting information: _____
- Does the patient have any FDA labeled contraindications to therapy with the requested agent? Yes No
 If yes, please specify FDA labeled contraindications: _____

Please continue to the next page.

Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
-----------------------	-------	----	-------------------

6. Is the prescriber a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis? Yes No
7. Please list all reasons for selecting the requested medication, strength, dosing schedule, and quantity over alternatives (e.g., contraindications, allergies, history of adverse drug reactions to alternatives, lower dose has been tried, information supporting dose over FDA max). _____

8. Please list all medications the patient has previously tried and failed for treatment of this diagnosis. (Please specify if the patient has tried brand-name products, generic products or over-the-counter products.)
 _____ Date(s): _____ Date(s): _____
 _____ Date(s): _____ Date(s): _____
 _____ Date(s): _____ Date(s): _____

For Long-acting growth hormone products (Ngenia, Skytrofa, or Sogroya) requests:

9. Does the patient have an intolerance, hypersensitivity, or FDA labeled contraindication to a preferred short-acting GH agent (Omnitrope, Genotropin, Genotropin MiniQuick) that is not expected to occur with the requested agent? **Please note, medical records are required.** Yes No
If yes, please submit medical records.
10. Has the patient received at least 12 months of therapy with a preferred short-acting GH agent (Omnitrope, Genotropin, Genotropin MiniQuick)? Yes No
11. Is the requested agent Skytrofa? Yes No
 If no, is Skytrofa FDA approved for the requested indication? Yes No
 If yes, has the patient received at least 12 months of therapy with Skytrofa? Yes No
 If no, does the patient have an intolerance, hypersensitivity, or FDA labeled contraindication to Skytrofa that is not expected to occur with the requested agent? **Please note, medical records are required.** Yes No
If yes, please submit medical records.

For Short-acting growth hormone products requests:

12. Does the patient have an intolerance, hypersensitivity, or FDA labeled contraindication to a preferred agent, (Omnitrope, Genotropin, and Genotropin MiniQuick), that is not expected to occur with the requested nonpreferred agent? **Please note, medical records are required.** Yes No
If yes, please submit medical records.
 If no, is there information to support the efficacy of the requested nonpreferred agent over a preferred agent, (Omnitrope, Genotropin, and Genotropin MiniQuick), for the intended diagnosis? **Please note, medical records are required.** Yes No
If yes, please submit medical records.

For children:

13. Is the patient a newborn (4 months of age or less)? Yes No
 If yes, does the patient have hypoglycemia? Yes No
 If yes, does the patient have a serum growth hormone (GH) concentration less than or equal to 5 mcg/L? Yes No
 If yes, does the patient have congenital pituitary abnormality (e.g., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk)? Yes No
 If no, does the patient have deficiency of at least one additional pituitary hormone? Yes No
 If yes, does the patient have a growth hormone (GH) concentration less than 20 mcg/L? Yes No
 If yes, does the patient have a known metabolic disorder? Yes No
 If yes, does the patient have a reduced IGFBP-3 level (e.g., less than -2.0 SD)? Yes No
14. Does the patient have extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD) and delayed bone age? Yes No

Please continue to the next page.

Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
-----------------------	-------	----	-------------------

15. Does the patient have any of the following? Select all that apply.

- Height more than 2 standard deviations (SD) below the mean for age and sex
- Height more than 1.5 SD below the midparental height
- Decrease in height of more than 0.5 SD over one year
- Height velocity (HV) more than 2 SD below the mean over one year
- Height velocity (HV) more than 1.5 SD below the mean sustained over two years
- Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile)
- Height velocity (HV) less than 5.5 cm/year (less than 2.2 inches/year)
- Height velocity (HV) less than 5 cm/year (less than 2 inches/year)

16. For age 6 years to puberty:

Patient's sex is female: Is the patient's height velocity (HV) less than 4.5 cm/year (less than 1.8 inches/year)?.. Yes No

Patient's sex is male: Is the patient's height velocity (HV) less than 4 cm/year (less than 1.6 inches/year)?..... Yes No

17. How many growth hormone (GH) stimulation tests has the patient failed (peak GH value of less than 10 mcg after stimulation or otherwise considered abnormal as determined by testing lab)?

Please select one: None 1 2 Other: _____

18. Does the patient have any of the following? Select all that apply.

- A pathology of the central nervous system
- History of irradiation
- A genetic defect
- A pituitary abnormality and a known deficit of at least one pituitary hormone other than growth hormone
- Other pituitary hormone defect (e.g., multiple pituitary hormone deficiency [MPHD])

For short bowel syndrome (SBS):

19. Is the patient receiving specialized nutritional support?..... Yes No

For panhypopituitarism or deficiencies in 3 or more pituitary axes:

20. Is the patient's serum IGF-I level low (below the age- and sex-appropriate reference range) when off growth hormone therapy?..... Yes No

For chronic renal insufficiency:

21. Is the patient's height velocity (HV) for age less than -1.88 standard deviations (SD) OR HV for age is less than the third percentile?..... Yes No

22. Have all other etiologies for growth impairment been addressed?..... Yes No

For patients small for gestational age (SGA):

23. Does the patient have a documented birth weight and/or birth length that is 2 or more standard deviations below the mean for gestational age?..... Yes No

24. At 24 months of age, did the patient fail to manifest catch-up growth evidenced by a height that remains 2 or more standard deviations below the mean for age and sex?..... Yes No

For idiopathic short stature (ISS):

25. Is the patient's height less than or equal to -2.25 SD below the corresponding mean for age and sex?..... Yes No

26. Does the patient have open epiphyses?..... Yes No

27. Does the patient have a predicted adult height that is below the normal range?..... Yes No

If yes, is the patient's sex male and predicted adult height is less than 63, OR 2) the patient's sex is female and predicted adult height is less than 59 inches?..... Yes No

If no, is the patient more than 2 SD below their mid-parental target height?..... Yes No

28. Has the patient been evaluated for constitutional delay of growth and puberty (CDGP)?..... Yes No

If yes, does the patient have a diagnosis of CDGP?..... Yes No

For adults:

For AIDS wasting/cachexia:

29. Is the patient currently treated with antiretroviral therapy and will continue antiretroviral therapy in combination with the requested agent?..... Yes No

30. Please provide the patient's percent body cell mass (BCM) of total body weight and body mass index (BMI):

BCM: _____ % BMI: _____ kg/m²

Please continue to the next page.

Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
-----------------------	-------	----	-------------------

31. Are the patient's BCM and BMI values medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex? Yes No
 If yes, please explain: _____

32. Has the patient experienced any of the following:
- 10% unintentional weight loss over 12 months
 - 7.5% unintentional weight loss over 6 months
 - A BCM loss greater than or equal to 5% within 6 months

33. Have all other causes of weight loss been ruled out? Yes No

For short bowel syndrome (SBS):

34. Is the patient receiving specialized nutritional support? Yes No

For growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone:

35. Has the patient had a diagnosis of childhood-onset growth hormone deficiency? Yes No

36. How many growth hormone stimulation tests has the patient failed as an adult? Please select one:

- None
- 1
- 2
- Other: _____

37. Does the patient have a low insulin-like growth factor-1 (IGF-1) level? Yes No

38. Does the patient have any of the following? Select all that apply.

- Organic hypothalamic-pituitary disease
- A pituitary structural lesion or trauma
- An established causal genetic mutation OR hypothalamic-pituitary structural defect other than ectopic posterior pituitary
- Panhypopituitarism or multiple (3 or more) pituitary hormone deficiency

For renewal requests:

39. Is the patient being monitored for adverse effects of growth hormone? Yes No

40. Has the patient had clinical benefit with the requested agent? Yes No

For children:

41. Does the patient have closed epiphyses? Yes No

42. Has the patient's height increased greater than or equal to 2 cm over the previous year with GH therapy? Yes No

For idiopathic short stature (ISS):

43. Is the patient's bone age less than 16 years old in patients with a sex of male and 15 years in patients with a sex of female AND the patient has open epiphyses? Yes No

For adults:

For growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone:

44. Has the patient had clinical benefits with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life)? Yes No

45. Has the patient's IGF-I level been evaluated to confirm the appropriateness of the current dose? Yes No

For AIDS wasting/cachexia:

46. Is the patient currently treated with antiretroviral therapy and will continue antiretroviral therapy in combination with the requested agent? Yes No

47. Has the patient had clinical benefit with the requested agent (weight increase or weight stabilization)? Yes No

Please continue to the next page.

Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
-----------------------	-------	----	-------------------

For Capital Health Plan (CHP) members:

48. Has the patient been previously approved to receive the requested agent through the completion of a step-therapy protocol by a separate health coverage plan? **Documentation originating from a previous health coverage plan must be provided.**..... Yes No

If yes, has the health coverage plan paid for the drug on the insured's behalf during the 90 days immediately before the request? **Documentation originating from a previous health coverage plan must be provided.**..... Yes No

Please fax or mail this form to:

Prime Therapeutics LLC
 Clinical Review Department
 2900 Ames Crossing Road Suite 200
 Eagan, MN 55121

TOLL FREE

Phone: 888.274.5158 Fax: 855.212.8110
BCBSFL: 888.271.3183 Fax: 855.212.8110
BCBSNJ: 888.214.1784 Fax: 855.212.8110
BCBSRI: 855.457.0759 Fax: 855.212.8110
CHP: 855.457.0754 Fax: 855.212.8110

CONFIDENTIALITY NOTICE: This communication is intended only for the use of the individual entity to which it is addressed and may contain information that is privileged or confidential. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please return the original message to Prime Therapeutics via U.S. Mail. Thank you for your cooperation.