

| Prior | Auth | oriza | ation |
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## JOHNS HOPKINS HEALTH PLANS (MEDICAID) Growth Hormone - Priority Partners MCO

This fax machine is located in a secure location as required by HIPAA regulations. Complete/review information, sign and date. Fax signed forms to Johns Hopkins Health Plans at **1-410-424-4607**. Please contact Johns Hopkins Health Plans at **1-888-819-1043** with questions regarding the Prior Authorization process.

When conditions are met, we will authorize the coverage of Growth Hormone - Priority Partners MCO.

| Drug Name<br>(specify drug)   |  |          |
|---|--|----------|
| Quantity  | Frequency  | Strength |
| Route of Administration   | Expected Length of Therapy   |          |
| Patient Information<br>Patient Name:<br>Patient ID:<br>Patient Group No.:<br>Patient DOB:<br>Patient Phone:   |  |          |
| Prescribing Physician<br>Physician Name:<br>Physician Phone:<br>Physician Fax:<br>Physician Address:<br>City, State, Zip:   |  | <br><br> |
| Diagnosis:  | ICD Code:  |          |
| Comments:   |  |          |
| Please circle the appropriate   | answer for each question.  |          |
|   | ized this medication in the past for this<br>s authorization is on file under this | Y N      |
| NOTE: The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit.<br>All pertinent criteria must be met in order to be eligible for benefit coverage. |  |          |
| [If no, skip to ques  | stion 11.]   |          |
| 2. Is the patient a child   | !?   | Y N      |

|  | [If no, skip to question 8.]   |  |  |
|--|--|--|--|
| 3.   | Is there documentation that the child is less than 18 years Y N<br>of age?   |  |  |
|  | NOTE: Supporting documentation must be submitted.  |  |  |
|  | [If no, no further questions.]   |  |  |
| 4.   | 4. Is there documentation of all the following criteria: A) Y N<br>Growth hormone has not been effective thus far, B) Child's<br>height is still below 5th percentile, C) Current bone age is<br>less than 15 years for males and 14 years for females?  |  |  |
|  | NOTE: Supporting documentation must be submitted.  |  |  |
|  | [If no, no further questions.]   |  |  |
| 5.   | Does the patient meet any of the following discontinuation Y N<br>criteria: A) Increase in height velocity is less than two<br>centimeters total growth in one year of therapy, B)<br>Expected final adult height has been reached, C) there is a<br>poor response to treatment, generally defined as increase<br>in growth velocity of less than 50 percent from baseline in<br>the first year of therapy, D) There are persistent and<br>uncorrectable problems with adherence to treatment? |  |  |
|  | [If yes, no further questions.]  |  |  |
| 6.   | Does the patient have Prader-Willi syndrome? Y N   |  |  |
|  | [If no, no further questions.]   |  |  |
| 7.   | Has the evaluation of response to therapy taken into<br>account whether body composition (i.e. ratio of lean to fat<br>mass) has significantly improved?   |  |  |
|  | [No further questions.]  |  |  |
| 8.   | Is the patient an adult? Y N   |  |  |
|  | [If no, no further questions.]   |  |  |
| 9.   | Is there documentation of follow-up monitoring for Y N<br>treatment efficacy with insulin-like growth factor (IGF)-1<br>testing being completed at least twice a year?   |  |  |
|  | NOTE: Supporting documentation must be submitted.  |  |  |
|  | [If no, no further questions.]   |  |  |
| 10.  | . Is this request for a transition patient?  |  |  |
| NOTE: Transition patients are defined as patients who complete growth hormone<br>(GH) therapy for childhood onset GH deficiency and are being considered for adult<br>GH replacement therapy. These patients must undergo retesting to determine<br>whether the growth hormone deficiency persists. A stimulation test should be<br>performed prior to reinstitution of growth hormone unless the member has persistent<br>complete hypopituitarism. |  |  |  |
| [If yes, skip to question 38.]   |  |  |  |
|  | [If no, no further questions.]   |  |  |
| 11.  | . Is the patient a child? Y N  |  |  |
|  | [If no, skip to question 38.]  |  |  |

| 12. Does the patient have a documented diagnosis of growth Y N hormone deficiency (GHD)?   |  |  |
|--|--|--|
| NOTE: Supporting documentation must be submitted.  |  |  |
| [If no, skip to question 19.]  |  |  |
| 13. Does the patient have a diminished growth hormone Y N<br>response (peak growth hormone concentration level less<br>than 10 nanograms per milliliter) to at least two different<br>stimulation tests?   |  |  |
| NOTE: Supporting documentation must be submitted. Acceptable tests include: insulin, glucagon, clonidine, arginine, and L-dopa.  |  |  |
| [If yes, no further questions.]  |  |  |
| 14. Does the patient have low insulin-like growth factor (IGF)-1 Y N<br>for age, sex, and pubertal status?   |  |  |
| NOTE: Supporting documentation must be submitted.  |  |  |
| [If no, no further questions.]   |  |  |
| 15. Is the patient 6 years of age or older?  |  |  |
| [If no, no further questions.]   |  |  |
| 16. Does the patient have a chronic disease such as<br>malnutrition, hepatic disease, renal insufficiency, diabetes,<br>or hypothyroidism?   |  |  |
| [If yes, no further questions.]  |  |  |
| 17. Does the patient have a height velocity (HV) less than 25th Y N percentile (in 6-12 months prior to growth hormone (GH) therapy?   |  |  |
| [If no, no further questions.]   |  |  |
| 18. Does the patient meet at least two of the following criteria: Y N <ol> <li>Growth velocity less than 7 centimeters (cm) per year</li> <li>before 3 years old, or less than 4-5 cm per year if between</li> <li>years old and puberty onset (Severe short stature is</li> <li>defined as a height more than 2 standard deviations (SD)</li> <li>below the population mean), 2) Delayed bone age greater</li> <li>than 2 SD below mean for chronological age, generally</li> <li>greater than 2 years delayed in patients with radiographic</li> <li>evidence of epiphyses not closed, 3) Documentation of a</li> <li>known risk factor for growth hormone deficiency (GHD),</li> <li>such as craniofacial anomalies, central nervous system</li> <li>structural abnormalities, congenital hypopituitarism,</li> <li>panhypopituitarism, or syndromes associated with</li> <li>hypopituitarism, history of hypophysectomy (surgical</li> <li>removal of pituitary gland), or history of central nervous</li> </ol> |  |  |
| NOTE: Supporting documentation must be submitted.  |  |  |
| [No further questions.]  |  |  |
| 19. Does the patient have a documented diagnosis of Turner Y N<br>Syndrome with confirmation by karyotyping?   |  |  |
| NOTE: Supporting documentation must be submitted.  |  |  |

| [If yes, no further questions.]   |
|---|
| 20. Does the patient have a documented diagnosis of short<br>stature with renal insufficiency (chronic kidney disease)?   |
| NOTE: Supporting documentation must be submitted.   |
| [If no, skip to question 23.]   |
| 21. Is the patient's height less than the 3rd percentile for Y N chronological age?   |
| NOTE: Supporting documentation must be submitted.   |
| [If no, no further questions.]  |
| 22. Does the patient have renal insufficiency defined as serum Y N<br>creatinine of greater than 3.0 milligrams per deciliter, or a<br>creatinine clearance between 5 and 75 milliliters per<br>minute per 1.73 meters squared before renal transplant? |
| NOTE: Supporting documentation must be submitted. Post-transplant usage is not approvable.  |
| [No further questions.]   |
| 23. Does the patient have a documented diagnosis of Prader- Y N<br>Willi Syndrome with short stature or growth failure?   |
| NOTE: Supporting documentation must be submitted.   |
| [If no, skip to question 25.]   |
| 24. Does the patient have severe respiratory impairment or Y N severe obesity?  |
| [No further questions.]   |
| 25. Does the patient have a documented diagnosis of Noonan Y N<br>Syndrome with short stature?  |
| NOTE: Supporting documentation must be submitted.   |
| [If no, skip to question 27.]   |
| 26. Is the patient's height greater than 2 standard deviations Y N below the mean for gender and age?   |
| NOTE: Supporting documentation must be submitted.   |
| [No further questions.]   |
| 27. Does the patient have a documented diagnosis of short Y N<br>stature homeobox-containing gene (SHOX) deficiency with<br>supporting chromosome analysis?   |
| NOTE: Supporting documentation must be submitted.   |
| [If yes, no further questions.]   |
| 28. Does the patient have a documented diagnosis of Y N<br>intrauterine growth retardation (including those with<br>Russell-Silver syndrome) or small for gestational age<br>(SGA)?   |
| NOTE: Supporting documentation must be submitted.   |
| [If no, skip to question 34.]   |

| 29. Has evaluation by a pediatric endocrinologist been completed?  | Y N |  |
|--|-----|--|
| [If no, no further questions.]   |     |  |
| 30. Is there evidence that the patient was born small for Y N<br>gestational age (SGA)? SGA is defined as birth weight of<br>less than 2500 grams at a gestational age of more than 37<br>weeks or length below the 3rd percentile for gestational<br>age or birth weight and/or length at least 2 standard<br>deviations below the mean for gestational age and gender. |     |  |
| NOTE: Supporting documentation must be submitted.  |     |  |
| [If no, no further questions.]   |     |  |
| 31. Is therapy being initiated between the ages of 2 and 8 years?  | Y N |  |
| [If yes, no further questions.]  |     |  |
| 32. Is the patient greater than 8 years of age?  | Y N |  |
| [If no, no further questions.]   |     |  |
| 33. Does the patient meet both of the following: 1) Child is<br>prepubertal, 2) Therapy will be discontinued when growth<br>velocity is less than 5 centimeters per year or there is<br>evidence of epiphyseal fusion is present?  | Y N |  |
| [No further questions.]  |     |  |
| 34. Does the patient have a documented diagnosis of acquired immunodeficiency syndrome (AIDS) wasting or human immunodeficiency virus (HIV) associated failure to thrive?  | Y N |  |
| NOTE: Supporting documentation must be submitted.  |     |  |
| [If no, no further questions.]   |     |  |
| 35. Does the patient have chronic diarrhea defined as at least 2 loose stools per day for at least 30 days?  | Y N |  |
| NOTE: Supporting documentation must be submitted.  |     |  |
| [If yes, no further questions.]  |     |  |
| 36. Does the patient have chronic weakness that cannot be explained by a concurrent illness other than human immunodeficiency virus (HIV) infection?   | Y N |  |
| NOTE: Supporting documentation must be submitted.  |     |  |
| [If no, no further questions.]   |     |  |
| 37. Is the patient being simultaneously treated with antiviral agents?   | Y N |  |
| [No further questions.]  |     |  |
| 38. Does the patient have a documented diagnosis of growth hormone deficiency (GHD)?   | Y N |  |
| NOTE: Supporting documentation must be submitted.  |     |  |
| [If no, skip to question 43.]  |     |  |

| 39. Is there confirmation of growth hormone deficiency (GHD) Y N<br>with one of the following: 1) An insulin tolerance test (ITT)<br>of less than 5 nanograms per milliliter, 2) Documentation<br>of 3 or more pituitary hormone deficiencies?   |  |  |
|--|--|--|
| NOTE: Supporting documentation must be submitted. ITT is contraindicated in patients with the following characteristics, so an alternative combination of arginine and growth hormone releasing hormone (GHRH) is recommended for patients 65 years of age and older, history of seizure disorders, history of ischemic heart disease or cerebrovascular disease, or abnormal electrocardiogram (EKG).         |  |  |
| [If yes, no further questions.]  |  |  |
| 40. Does the patient have diminished growth hormone Y N<br>response (peak growth hormone concentration level less<br>than 5 nanograms per milliliter) to at least two different<br>stimulation tests?  |  |  |
| NOTE: Supporting documentation must be submitted. Acceptable tests included: insulin, glucagon, clonidine, arginine, and L-dopa.   |  |  |
| [If no, no further questions.]   |  |  |
| 41. Does the patient exhibit clinical symptoms such as<br>increased weight and body fat mass with decreased lean<br>body mass, decreased exercise capacity, decreased<br>muscle mass and strength, reduced cardiac performance,<br>reduced bone density and increased fracture rate, poor<br>sleep, impaired sense of well-being, lack of motivation?  |  |  |
| NOTE: Supporting documentation must be submitted.  |  |  |
| [If no, no further questions.]   |  |  |
| 42. Does the patient meet any of the following: A) Adult onset Y N<br>due to hypothalamic disease, pituitary disease or surgery,<br>or radiation therapy involving the pituitary gland, B) History<br>of growth hormone deficiency (GHD) in childhood, C)<br>Sheehan's syndrome (pituitary infarction), D) Autoimmune<br>hypophysitis, E) Other hypophysitis related inflammatory<br>conditions (sarcoidosis)? |  |  |
| NOTE: Supporting documentation must be submitted.  |  |  |
| [No further questions.]  |  |  |
| 43. Does the patient have a documented diagnosis of<br>acquired immunodeficiency syndrome (AIDS) wasting or<br>human immunodeficiency virus (HIV) associated failure to<br>thrive?   |  |  |
| NOTE: Supporting documentation must be submitted.  |  |  |
| [If no, no further questions.]   |  |  |
| 44. Does the patient have chronic diarrhea defined as at least Y N<br>2 loose stools per day for at least 30 days?   |  |  |
| NOTE: Supporting documentation must be submitted.  |  |  |
| [If yes, no further questions.]  |  |  |

| 45. Does the patient have chronic weakness that cannot be explained by a concurrent illness other than human immunodeficiency virus (HIV) infection? | Y N |
|--|-----|
| NOTE: Supporting documentation must be submitted.  |     |
| [If no, no further questions.]   |     |
| 46. Is the patient being simultaneously treated with antiviral agents?   | Y N |

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 |  |
|---|--|
|   |  |