

Member Name: _____ Member ID: _____ Member DOB: _____
 Drug Name: _____ Strength: _____ Directions: _____
 Physician Name: _____ Physician Phone #: _____ Specialty: _____
 Physician Fax #: _____ Pharmacy Name: _____ Pharmacy Phone: _____

Horizon NJ Health
Growth Hormone (GH) Therapy – Medical Necessity Request

****Please complete pages 1 and 2 for New/Initial requests****

General Information

Current Height*: _____ in or _____ cm Date: _____
 Current Weight: _____ lbs or _____ kg Date: _____

* For Pediatric Patients, please provide most recent growth chart.

Height Standard Deviation: _____

GH Stimulation Test(s):

Stimulated with: _____ Date: _____

Stimulated with: _____ Date: _____

Stimulated with: _____ Date: _____

IGF-1: Below normal? **Yes or No** Percentile: _____

IGFBP3: Below normal? **Yes or No** Percentile: _____

Please provide documentation for all lab/test values

GH Stimulation Test not required for members who have an anatomical absence of the pituitary

Is the member being managed by an Endocrinologist? **Yes or No**

Will the member be receiving any other Somatropin? **Yes or No**

Contraindication Information

Does member have any of the following:

- Active malignancy?
Yes or No
- Active Proliferative or severe non-proliferative diabetic retinopathy?
Yes or No
- Closed epiphyses or epiphyseal fusion?
Yes or No
- Acute critical illness due to complications following open heart surgery, abdominal surgery, multiple accidental trauma or acute respiratory failure? **Yes or No**
- Prader-Willi Syndrome AND are severely obese, history of upper airway obstruction or sleep apnea or severe respiratory impairment in children?
Yes or No

Diagnosis Information (please select diagnosis and provide requested information below the diagnosis):

Pediatric GH deficiency, Isolated GH Deficiency, Pituitary Dwarfism, Hypopituitarism or Panhypopituitarism

1. Does the member have an anatomical absence of the pituitary? **Yes or No**
2. Does the member have signs of multiple pituitary hormone deficiencies (MPHD)? **Yes or No**
3. Does the member have evidence of another pituitary hormone deficiency? **Yes or No**
4. Has the member has received treatment known to cause growth hormone deficiency (e.g., cranial irradiation)? **Yes or No**
5. Does the member have hypothalamic-pituitary defect? **Yes or No**

*If all of the above were answered No, please answer the following questions:

1. Is the member's height more than 2 standard deviations (SD) below the population mean? **Yes or No**
2. Is the projected height > 1.5 SD below the mean midparental height (average of mother's and father's heights)? **Yes or No**
3. Does the member have a 1 year height velocity of > 2 SD below the mean? **Yes or No**
4. Does the member have a 2-year height velocity of > 1.5 SD below the mean? **Yes or No**

6. Has the member failed 2 growth hormone stimulation tests (i.e., Insulin Tolerance Test (ITT), Growth Hormone-Releasing Hormone (GHRH)+ arginine (ARG), glucagon, arginine (ARG) tests, clonidine, levodopa) with growth hormone levels less than 10 ng/mL?
Yes or No

7. Has the member failed at least 1 growth hormone stimulation test with a growth hormone level less than 10 ng/mL (e.g., ITT, GHRH+ARG, glucagon or ARG tests, clonidine, levodopa) AND IGF-I and IGFBP3 levels are below normal? **Yes or No**

Turner syndrome

- Has the member completed puberty? **Yes or No**
- Has diagnosis been confirmed by appropriate genetic testing? **Yes or No** **Please submit documentation*
- Does the member have any of the following: Growth Failure Is Short Has a strong likelihood of short stature (e.g. short parents and short predicted adult height or pubertal at the time of diagnosis).

Chronic renal insufficiency ** Please submit documentation for all of the following questions*

- Is the member less than 20 years old? **Yes or No**
- What is the member's Glomerular Filtration Rate (GFR)? _____
- Is the member on dialysis? **Yes or No**
- Does the member have short stature (defined by height more than 1.88 standard deviations (SD) below the population mean OR height for age is less than the 3rd percentile)? **Yes or No**. ** Growth charts with height from the past 60 days must be received.*
- Does the member have normal metabolic and nutritional status?
 - Yes**
 - No** – Are all growth-inhibiting metabolic derangements (e.g., acidosis, secondary hyperparathyroidism, undernutrition) being managed? **Yes or No**
- Has member undergone renal transplantation?
 - No** **Yes** - Is the transplant failing? **Yes or No**

Physician office's signature* _____ Print Name _____

***Form must be completed and signed by physician or licensed representative from the physician's office.**

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Prader-Willi syndrome

- Has diagnosis been confirmed by appropriate genetic testing? **Yes or No** *Please submit documentation

Noonan Syndrome

- Has diagnosis been confirmed by appropriate genetic testing? **Yes or No** *Please submit documentation

- Is the member less than 20 years old? **Yes or No**

SHOX (short stature homeobox-containing) deficiency

- Has diagnosis been confirmed by appropriate genetic testing? **Yes or No** *Please submit documentation

- Has the member experienced puberty? **Yes or No**

Small for gestational age (including Russell-Silver variant of intrauterine growth retardation)

- Birth Weight: _____

- Gestational Age: _____

- Was birth weight or length 2 standard deviations (SD) or more below mean? **Yes or No**

- Was the birth weight or length below the 3rd percentile? **Yes or No**

- Has the member failed to catch-up on height by age 2 as defined by height less than 2.5 standard deviations (SD) below the mean?

Yes or No

****Please submit documentation of growth charts plotted. ****

Adult GH deficiency – Please specify type of onset and answer associated questions.

Adult Onset *Please submit documentation for all of the following questions and for the growth hormone stimulation tests

- How many deficient pituitary hormones does the member have? _____

- Does the member have a history of hypothalamic-pituitary tumors, surgery, cranial irradiation, empty sella, pituitary apoplexy, traumatic brain injury, subarachnoid hemorrhage, autoimmune hypophysitis, or Rathke's cleft cyst? **Yes or No**

- Does the member have Organic Growth Hormone Deficiency? **Yes or No**

- Does the member have low IGF-1? **Yes or No** *Please submit documentation

- If yes, what is the Standard Deviation Score (SDS)? _____

Childhood Onset *Please submit documentation for the growth hormone stimulation tests

- Was the member diagnosed with growth hormone deficiency as a child? **Yes or No**

- How many deficient pituitary hormones does the member have? _____

- Does the member have congenital defects or genetic defects? **Yes or No**

- Does the member have Organic Growth Hormone Deficiency? **Yes or No**

- Does the member have low IGF-1? **Yes or No** *Please submit documentation

- If yes, what is the Standard Deviation Score (SDS)? _____

- Does the member have idiopathic isolated Growth Hormone deficiency or suspected Hypothalamic Growth Hormone Deficiency? **Yes or No**

- Does the member have congenital defects or genetic defects or organic disease? **Yes or No**

- If No:

- Has longitudinal growth been completed? **Yes or No**

- Was Growth Hormone therapy discontinued for at least 1 month? **Yes or No**

HIV/AIDS wasting syndrome

- Does member have a confirmed diagnosis of HIV or AIDS Wasting Syndrome or cachexia? **Yes or No**

- Is member currently receiving and will continue to receive antiretroviral therapy? **Yes or No**

- Baseline pre-morbid weight: _____ lbs or _____ kg. Date Measured: _____

- Has member tried and failed at least 2 non-invasive forms of nutritional therapy (e.g., nutritional supplements, megestrol acetate, dronabinol) and is otherwise candidates for assisted enteral/total parenteral nutrition?

Yes - Please provide the names of the therapies: _____

No

- How many weeks supply is being requested? _____

- How many weeks of previous therapy has the member received? _____

- Is the member being managed by an Infectious Disease or HIV/AIDS specialist? **Yes or No**

Idiopathic short stature

- Is growth rate unlikely to permit attainment of adult height in the normal range? **Yes or No**

- Does the member have a height at least 2.25 standard deviations below the mean? **Yes or No**

- Have other causes of short stature, including growth hormone deficiency, and familial short stature been excluded? **Yes or No**

- Is the member less than 20 years old? **Yes or No**

Short bowel syndrome

- Is member managed by a Gastroenterologist and/or Endocrinologist? **Yes or No**

- Is the member receiving specialized nutritional support? **Yes or No**

- How many week of therapy has the member previously received? _____

Other (please specify): _____

Physician office's signature* _____ Print Name _____

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****Complete pages 3 and 4 ONLY for Subsequent (Renewal) requests or for dosage changes****

General Information

Current Height: _____ in or cm Date Taken: _____ Previous Dose: _____
 Current Weight: _____ lbs or kg Date Taken: _____ New Dose: _____
 Will the member be receiving any other Somatropin? **Yes or No** Requested Quantity: _____
 Is the member being managed by an Endocrinologist? **Yes or No**

Diagnosis Information (please select diagnosis and provide requested information below the diagnosis):

- Pediatric GH deficiency, Isolated GH Deficiency, Pituitary Dwarfism, Hypopituitarism or Panhypopituitarism**
 - Has epiphyseal closure/fusion occurred? **Yes or No**
 - Is the member's growth velocity greater than 2cm per year? **Yes or No**
 * Documentation (e.g., office notes, growth charts) showing change in height during the past year must be received
- Chronic renal insufficiency**
 - Has member undergone renal transplantation?
 - Yes** - Is the transplant failing? **Yes or No**
 - No**
 - Has epiphyseal closure/fusion occurred? **Yes or No**
 - Is the member less than 20 years old? **Yes or No**
- Turner's syndrome**
 - Is member's bone age less than 14 years old? **Yes or No**
 - Does member have a growth velocity of 1cm or greater per year? **Yes or No** * Documentation (e.g., office notes, growth charts) showing change in height during the past year must be received.
 - Has epiphyseal closure/fusion occurred? **Yes or No**
 - Has the member completed puberty? **Yes or No**
- Noonan Syndrome**
 - Has epiphyseal closure/fusion occurred? **Yes or No**
 - Is the member less than 20 years old? **Yes or No**
- SHOX (short stature homeobox-containing) deficiency**
 - Has epiphyseal closure/fusion occurred? **Yes or No**
 - Has the member experienced puberty? **Yes or No**
- Prader-Willi syndrome**
 - Has epiphyseal closure/fusion occurred? **Yes or No**
- Short for gestational age**
 - Has epiphyseal closure/fusion occurred? **Yes or No**
 - Is the growth velocity greater than 2 cm/year? **Yes or No** (If yes, please provide documentation showing change in height during the past year)
- Adult GH deficiency** *Please provide documentation of any of the below answered Yes
 - Are IGF-1 levels below or within the normal range? **Yes or No**
 - Has there been an improvement in any of the following:
 - blood lipid levels? **Yes or No**
 - waist-to-hip ratio? **Yes or No**
 - body composition? **Yes or No**
 - quality of life? **Yes or No**
 - Has there been a reduction of cardiovascular risk factors? **Yes or No**
- Idiopathic short stature**
 - Has epiphyseal closure/fusion occurred? **Yes or No**
 - Has the member had an adequate height gain over the past year? **Yes or No**
 - Is the member less than 20 years old? **Yes or No**

Physician office's signature* _____ Print Name _____

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Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions: _____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

HIV/AIDS wasting syndrome

- Is member currently receiving and will continue to receive antiretroviral therapy? **Yes or No**
- How many weeks of therapy are being requested? _____

Other (please specify): _____