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**.

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

Drug Name: _____ Strength: _____ Directions: _____

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

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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? _____
- Please provide the dates the member has received therapy. _____
- 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_____**

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

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

Drug Name: _____ Strength: _____ Directions: _____

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

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

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

**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**

**<u>Diagnosis Information</u>** <u>(please select diagnosis and provide requested information below the diagnosis)</u>:

□ **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**

□ **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**
- 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**

□ **Adult GH deficiency**
- 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_____**
***Form must be completed and signed by physician or licensed representative from the physician's office**.

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? **_____**
- Please provide the dates the member received therapy. **_____**

□ **Other (please specify):** _____