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Please note: All information below is required to process this request.

Mon-Fri: 5am to 10pm Pacific / Sat: 6am to 3pm Pacific

## Omnitrope<sup>®</sup> Prior Authorization Request Form (Page 1 of 4)

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Member Information (required)			Provider Information (required)		
Member Name:			Provider Name:		
Insurance ID#:			NPI#:	Specialty:	
Date of Birth:			Office Phone:		
Street Address:			Office Fax:		
City:	State:	Zip:	Office Street Address:		
Phone:			City:	State:	Zip:
Medication Information (required)					
Medication Name:			Strength:		Dosage Form:
<input type="checkbox"/> Check if requesting <b>brand</b>			Directions for Use:		
<input type="checkbox"/> Check if request is for <b>continuation of therapy</b>					
Clinical Information (required)					
<b>Select the diagnosis below:</b>					
<input type="checkbox"/> Pediatric growth hormone deficiency					
<input type="checkbox"/> Growth hormone deficiency in adults					
<input type="checkbox"/> Growth hormone deficiency in transition phase adolescents					
<input type="checkbox"/> Isolated growth hormone deficiency in adults					
<input type="checkbox"/> Pediatric growth failure associated with chronic renal insufficiency					
<input type="checkbox"/> Prader-Willi Syndrome					
<input type="checkbox"/> Short-stature homeobox (SHOX) gene deficiency					
<input type="checkbox"/> Small for gestational age (SGA)					
<input type="checkbox"/> Turner syndrome or Noonan syndrome					
<input type="checkbox"/> Other diagnosis: _____ ICD-10 Code(s): _____					
<b>Prescriber's Specialty:</b>					
Select if the requested medication is prescribed by or in consultation with one of the following specialists:					
<input type="checkbox"/> Endocrinologist <input type="checkbox"/> Nephrologist					
<b>For pediatric growth hormone deficiency, also answer the following:</b>					
Is the patient an infant < 4 months of age? <input type="checkbox"/> Yes <input type="checkbox"/> No					
Does the infant have growth deficiency? <input type="checkbox"/> Yes <input type="checkbox"/> No					
Does the patient have history of neonatal hypoglycemia associated with pituitary disease? <input type="checkbox"/> Yes <input type="checkbox"/> No					
Does the patient have panhypopituitarism? <input type="checkbox"/> Yes <input type="checkbox"/> No					
Select if the diagnosis of pediatric GH deficiency is confirmed by the patient's height as documented by the following (utilizing age and gender growth charts related to height):					
<input type="checkbox"/> Height > 2.0 standard deviations [SD] below mid-parental height					
<input type="checkbox"/> Height > 2.25 SD below population mean (below the 1.2 percentile for age and gender)					
Is the patient's growth velocity > 2 SD below mean for age and gender? <input type="checkbox"/> Yes <input type="checkbox"/> No					
Does the patient have delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared w ith chronological age)? <input type="checkbox"/> Yes <input type="checkbox"/> No					
Is there documentation the patient's bone age is < 16 years for males or < 14 years for females? <input type="checkbox"/> Yes <input type="checkbox"/> No					
<b>&lt;continued on the next page&gt;</b>					

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## Omnitrope® Prior Authorization Request Form (Page 2 of 4)

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### <continuation of pediatric growth hormone deficiency>

Select if the patient has undergone provocative GH stimulation tests with the following: **(Document the GH response)**

- |                                                           |                        |
|-----------------------------------------------------------|------------------------|
| <input type="checkbox"/> Arginine                         | Peak value: _____mcg/L |
| <input type="checkbox"/> Clonidine                        | Peak value: _____mcg/L |
| <input type="checkbox"/> Glucagon                         | Peak value: _____mcg/L |
| <input type="checkbox"/> Insulin                          | Peak value: _____mcg/L |
| <input type="checkbox"/> Levodopa                         | Peak value: _____mcg/L |
| <input type="checkbox"/> Growth hormone releasing hormone | Peak value: _____mcg/L |

For patients less than 1 year of age, select if the following is below the age and gender adjusted normal range as provided by the physician's lab: **(Document the specified lab value and reference range)**

- |                                                                             |                                  |                        |
|-----------------------------------------------------------------------------|----------------------------------|------------------------|
| <input type="checkbox"/> Insulin-like growth factor 1 (IGF-1/Somatomedin-C) | IGF-1/Somatomedin-C level: _____ | Reference range: _____ |
| <input type="checkbox"/> Insulin growth factor binding protein-3 (IGFBP-3)  | IGFBP-3 level: _____             | Reference range: _____ |

#### Reauthorization:

Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

Previous height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Current height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Has the expected adult height been reached?  Yes  No

Document the expected adult height goal: \_\_\_\_\_

#### For growth hormone (GH) deficiency in adults, also answer the following:

Are there clinical records supporting a diagnosis of childhood-onset GH deficiency?  Yes  No

Does the patient have adult-onset GH deficiency?  Yes  No

Are there clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)?  Yes  No

Select if the patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency and the peak GH value is as follows:

- Insulin tolerance test (ITT)  $\leq 5$  mcg/L
- Arginine & GH-releasing hormone (GHRH+ARG)  $\leq 11$  mcg/L if body mass index (BMI) is  $< 25$  kg/m<sup>2</sup>;  $\leq 8$  mcg/L if BMI is  $\geq 25$  and  $< 30$  kg/m<sup>2</sup>;  $\leq 4$  mcg/L if BMI is  $\geq 30$  kg/m<sup>2</sup>
- Glucagon  $\leq 3$  mcg/L
- Arginine (ARG)  $\leq 0.4$  mcg/L

Select if there is documentation the patient has deficiency of the following anterior pituitary hormones:

- |                                                                                    |                                                            |
|------------------------------------------------------------------------------------|------------------------------------------------------------|
| <input type="checkbox"/> Adrenocorticotrophic hormone (ACTH)                       | <input type="checkbox"/> Prolactin                         |
| <input type="checkbox"/> Follicle-stimulating hormone/luteinizing hormone (FSH/LH) | <input type="checkbox"/> Thyroid stimulating hormone (TSH) |

Does the patient have an IGF-1/Somatomedin-C level below the age and gender adjusted normal range as provided by the physician's lab?  Yes  No

#### Reauthorization:

Is there evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin-C level?  Yes  No

#### For isolated growth hormone deficiency in adults, also answer the following:

Is there documentation the patient has deficiency of GH defined by a failure to produce a peak serum GH level of  $> 5$  mcg/L after provocative pharmacologic stimulation by two of the following tests: Insulin, L-arginine, and/or glucagon?  Yes  No

#### Reauthorization:

Is there evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin-C level?  Yes  No

## Omnitrope® Prior Authorization Request Form (Page 3 of 4)

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### For growth hormone (GH) deficiency in transition phase adolescents, also answer the following:

Has the expected adult height been reached?  Yes  No

Are the patient's epiphyses closed on bone radiograph?  Yes  No

Select if there is documentation the patient has high risk of GH deficiency due to GH deficiency in childhood from one of the following:

- Embryopathic/congenital defects
- Irreversible structural hypothalamic-pituitary disease
- Genetic mutations
- Panhypopituitarism
- Deficiency of three or more of the following anterior pituitary hormones: ACTH, TSH, Prolactin, FSH/LH

Does the patient have a low IGF-1/Somatomedin-C level below the age and gender adjusted normal range as provided by the physician's lab?  Yes  No

Is the patient at low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic deficiency)?  Yes  No

Has GH therapy been discontinued for at least 1 month?  Yes  No

Select if the patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month and the peak GH value is as follows:

- Insulin tolerance test (ITT)  $\leq 5$  mcg/L
- Arginine & GH-releasing hormone (GHRH+ARG)  $\leq 11$  mcg/L if body mass index (BMI) is  $< 25$  kg/m<sup>2</sup>;  $\leq 8$  mcg/L if BMI is  $\geq 25$  and  $< 30$  kg/m<sup>2</sup>;  $\leq 4$  mcg/L if BMI is  $\geq 30$  kg/m<sup>2</sup>
- Glucagon  $\leq 3$  mcg/L
- Arginine (ARG)  $\leq 0.4$  mcg/L

#### Reauthorization:

Is there evidence the patient has had a positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)?  Yes  No

### For pediatric growth failure associated with chronic renal insufficiency, also answer the following:

Is there documentation the patient's bone age is  $< 16$  years for males or  $< 14$  years for females?  Yes  No

#### Reauthorization:

Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

Previous height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Current height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Has the expected adult height been reached?  Yes  No

Document the expected adult height goal: \_\_\_\_\_

### For Prader-Willi syndrome, also answer the following:

#### Reauthorization:

Is there evidence the patient has had a positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)?  Yes  No

Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

Previous height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Current height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Has the expected adult height been reached?  Yes  No

Document the expected adult height goal: \_\_\_\_\_

### For short-stature homeobox (SHOX) gene deficiency, also answer the following:

Does the patient have a diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing?  Yes  No

Is there documentation the patient's bone age is  $< 16$  years for males or  $< 14$  years for females?  Yes  No

#### Reauthorization:

Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

Previous height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Current height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Has the expected adult height been reached?  Yes  No

Document the expected adult height goal: \_\_\_\_\_



## Omnitrope<sup>®</sup> Prior Authorization Request Form (Page 4 of 4)

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### For small for gestational age (SGA), also answer the following:

Select if the diagnosis of SGA is based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by one of the following:

- Patient's **birth weight** was below the 3<sup>rd</sup> percentile for gestational age (> 2 SD below population mean)
- Patient's **birth length** was below the 3<sup>rd</sup> percentile for gestational age (> 2 SD below population mean)

Does patient's height remain  $\leq$  the 3<sup>rd</sup> percentile (> 2 SD below population mean)?  Yes  No

### Reauthorization:

Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

Previous height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Current height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Has the expected adult height been reached?  Yes  No

Document the expected adult height goal: \_\_\_\_\_

### For Turner syndrome (gonadal dysgenesis) or Noonan syndrome, also answer the following:

Is there documentation the patient's bone age is < 16 years for males or < 14 years for females?  Yes  No

Is the patient's height below the 5<sup>th</sup> percentile on growth charts for age and gender?  Yes  No

### Reauthorization:

Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

Previous height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Current height: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Has the expected adult height been reached?  Yes  No

Document the expected adult height goal: \_\_\_\_\_

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

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Please note:

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