

10
YEARS

Omnitrope[®] 
(somatotropin [rDNA origin] for injection)

Statement of Medical Necessity

See inside cover for a list of documentation
to accompany the Omnitrope Statement
of Medical Necessity (SMN).

SANDOZ A Novartis
Division

Documentation to Accompany the SMN

The chart below lists general evaluations by indication that are typically required. Please remember to include all pertinent paperwork along with the SMN.

Adult Patients

Recommended Evaluations	Growth hormone deficiency (GHD) ¹
History and physical exam	✓
Genetic testing	
Relevant clinical notes	✓
Stimulation test	✓
Thyroid function test	✓
IGF-1 test	✓
IGFBP-3 test	✓
Growth chart	
Height velocity	
Bone age x-ray	
MRI scan	✓
History of head trauma	✓
Lipid profile	✓
DEXA scan	✓
Insulin tolerance test	✓
Assessment of pituitary gland	✓

Pediatric Patients

Recommended Evaluations	Growth hormone deficiency (GHD) ²	Prader-Willi Syndrome ³	Small for Gestational Age ⁴	Turner Syndrome ⁵	Idiopathic Short Stature ^{6,7}
History and physical exam	✓	✓	✓	✓	✓
Genetic testing		✓		✓	
Relevant clinical notes	✓	✓	✓	✓	✓
Stimulation test	✓				✓
Thyroid function test	✓	✓		✓	✓
IGF-1 test	✓	✓			✓
IGFBP-3 test	✓				✓
Growth chart	✓	✓	✓	✓	✓
Height velocity	✓		✓	✓	✓
Bone age x-ray	✓	✓			✓
Imaging tests		✓		✓	
Cardiac evaluation				✓	
Lipid profile				✓	

Please see Important Safety Information on the last page and accompanying full Prescribing Information at the back of the tearpad.

References: **1.** Cook DM, Yuen KJ, Biller BMK, Kemp SF, Vance ML. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients – 2009 update. American Association of Clinical Endocrinologists. <https://www.aace.com/files/growth-hormone-guidelines.pdf>. Accessed November 8, 2016. **2.** Grimberg A, Divall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-I treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. *Horm Res Paediatr.* 2016. **3.** Deal CL, Tony M, Höybye C, et al. Growth hormone research society workshop summary: consensus guidelines for recombinant human growth hormone therapy in Prader-Willi syndrome. *J Clin Endocrinol Metab.* 2013;98(6):E1072-E1087. **4.** Clayton PE, Cianfarani S, Czernichow P, Johannsson G, Rapaport R, Rogol A. Consensus statement: management of the child born small for gestational age through to adulthood: a consensus statement of the International Societies of Pediatric Endocrinology and the Growth Hormone Research Society. *J Clin Endocrinol Metab.* 2007; 92:804-810. **5.** Bondy CA. Clinical practice guideline care of girls and women with Turner syndrome: a guideline of the Turner Syndrome Study Group. *J Clin Endocrinol Metab.* 2007;92(1):10-25. **6.** Cohen P, Rogol AD, Deal CL, et al. Consensus statement on the diagnosis and treatment of children with Idiopathic Short Stature: a summary of the Growth Hormone Research Society, the Lawson Wilkins Pediatric Endocrine Society, and the European Society for Paediatric Endocrinology Workshop. *J Clin Endocrinol Metab.* 2008;93(11):4210-4217. **7.** Lee MM. Idiopathic Short Stature. *N Engl J Med.* 2006;354:2576-2582.

Statement of Medical Necessity

Please fill out form completely and fax to: 877.828.1052

Call 877.456.6794 Mon-Fri, 8am-8pm ET



Patient is: (choose one) New to Omnitrope Therapy Continuing Omnitrope Therapy Switching from Other Brand of GH

PATIENT INFORMATION

Patient Name (First and Last): _____ DOB: _____ Patient SSN: _____
Address: _____ City: _____ State: _____ Zip: _____
Primary Phone: _____ Alternate Phone: _____ Email: _____
Gender: M F Primary Language: _____
Parent or Guardian Name: _____ Relationship to Patient: _____
Only patient name is required for this section if a patient demographic sheet is submitted.

INSURANCE

Primary/Medical Insurance: _____ Pharmacy Benefit/Rx Insurance: _____
Phone: _____ Phone: _____
Subscriber Name: _____ Member ID: _____
Subscriber ID #: _____ Group ID #: _____
Policy/Group #: _____ Secondary Insurance: _____
Subscriber ID #: _____
Attach copies of BOTH sides of patient's Insurance Card(s) or patient demographic sheet, including Medical and Pharmacy Rx Cards.

DIAGNOSIS

Please check the ICD-10 diagnosis code that applies. (ICD-9 codes are in parentheses.)
GHD (Pediatric and Adult):
 E23.0 Panhypopituitarism (253.2) R62.52 Idiopathic R62.52 Short Stature/Growth Failure (783.43), plus Q87.1 Prader-Willi Syndrome (759.81)
 E23.1 Iatrogenic Hypopituitarism (253.7) **Short Stature** P05.00 Small for Dates (764.00) or Q96.9 Turner Syndrome (758.6)
 E23.0 Growth Hormone Deficiency (253.3) - 2.25 SDS (783.43) P05.9 Intrauterine Growth Retardation, Unspecified (764.90) ICD-10 Code: _____

MEDICAL ASSESSMENT

Attach applicable medical records:
 Growth chart History and physical MRI results
 Growth Hormone Stimulation Test Date: _____
Agent 1: _____ Peak: _____ ng/mL
Agent 2: _____ Peak: _____ ng/mL
 IGF-1 Test Date: _____ IGF-1 Test Results: _____
 Other Test Results: Test: _____ Result: _____
Test: _____ Result: _____
Current Height: _____ cm _____ %
Birth Mother's Height: _____ cm Birth Father's Height: _____ cm
Predicted Adult Height: _____ cm
Current Weight: _____ Birth Weight: _____
Growth Velocity: _____ cm/yr
Chronological Age: _____ Y _____ M Date _____
Bone Age: _____ Y _____ M Date _____
 Open Epiphyses Closed Epiphyses

PRESCRIPTION

Additional Omnitrope drug information available on reverse side.
Drug:
 Omnitrope® 5 mg (NDC 0781-3001-07)
 Omnitrope® 10 mg (NDC 0781-3004-07)
 Omnitrope® 5.8 mg Vial (NDC 0781-4004-36)
Device:
 Omnitrope® Pen 5
 Omnitrope® Pen 10
For Vial:
 3cc Syringe with 18G 1" needle (for mixing)
 1cc Syringe (mL syringe required for dosing)
 Needle: _____
Please remember to indicate the quantity and type of needles that should be shipped to the patient. (Needles are sold separately and may require a separate prescription in some states.)
Needles:
 BD Pen Needle 29 gauge (12.7mm)
 BD Pen Needle 31 gauge (5mm)
 BD Pen Needle 31 gauge (8mm)
 Other: _____
 Ancillary supplies: _____ days' supply _____
Services (check all that apply):
 Benefits Investigation/PA Request
 Interim drug (SOS)
(This must be requested by the Prescriber)
 Patient Starter Kit
 Injection Training
 Co-Pay
See eligibility* requirements on reverse page.

Device Dose: _____ mg/day _____ days/week Dispense: _____ month(s) supply Refills: _____
Vial Dose (Vial dose must be in mL): _____ mL/day _____ days/week Dispense: _____ month(s) supply Refills: _____
Preferred Pharmacy (optional): _____

PHYSICIAN CERTIFICATION




I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. By my signature I also acknowledge that I have obtained the patient's authorization to release the above information and such other information as may be required by Sandoz, its employees, and Sandoz' contractors to assist in obtaining coverage for Omnitrope human growth hormone and to assist in initiating or continuing Omnitrope therapy. I appoint OmniSource, on my behalf, to convey this prescription to the dispensing pharmacy. I further certify that (a) any service provided through OmniSource on behalf of any patient is not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use Omnitrope or any other Sandoz product or service for anyone, and (b) my decision to prescribe Omnitrope was based solely on my determination of medical necessity as set forth herein, and that (c) I will not seek reimbursement for any medication or service provided by or through OmniSource from any government program or third-party insurer.

Print Name: _____ Practice: _____ Date: _____ DEA Number: _____
Address: _____ City: _____ State: _____ Zip: _____
Office Contact: _____ Phone: _____ Fax: _____
Physician Provider / Tax ID Number: _____ Physician Provider / NPI Number: _____
If NP or PA, under direction of Dr.: _____ Dispense as written: _____

Signature†: _____ Date: _____
†This form cannot be processed without prescribing physician's full and usual signature. Actual signature and date are required - no stamps.

Confidentiality Notice: This facsimile is intended for the sole use of the individual and entity to which it is addressed, and may contain information that is proprietary, confidential, privileged and prohibited from being disclosed under applicable law. If you are not the intended addressee, nor authorized to receive for the intended addressee, you are hereby notified that you may not use, copy, disclose or distribute to anyone the facsimile or any information contained in the facsimile. If you received this by mistake, please contact OmniSource at 877.456.6794.

PRESCRIPTION: The following devices are available for Omnitrope® (somatropin [rDNA origin] injection).

Device	Dosing Increments	Max Dose	NDC
Omnitrope® Pen 5 	0.05 mg	2.7 mg	NDC 0781-3001-07
Omnitrope® Pen 10 	0.1 mg	5.4 mg	NDC 0781-3004-07
Omnitrope® 5.8 mg Vial 	0.02 mL	5 mg/mL	NDC 0781-4004-36

Before faxing this form, be sure the following items are properly completed on the front of the SMN:

- Scan or copy **front and back** of the patient's Insurance Card(s), including Medical and Pharmacy/Rx cards, and attach them to this form.
- Make sure that the **correct diagnosis** is checked in the Diagnosis section. **Please note:** Providers should contact each insurer to determine the appropriate diagnosis codes. Sandoz Inc. does not guarantee that use of any code(s) will ensure coverage or payment at any level. The information presented is for informational purposes only and is not intended to provide reimbursement or legal advice.
- Indicate the prescription and be sure to **check the appropriate delivery system** (Pen 5 or Pen 10 or Vial/Syringe) located in the Prescription section. Indicate dosage, number of days' supply and number of refills in the Prescription section.
- To get access to OmniSource services (SOS - Interim Drug Delivery, Patient Starter Kit, Injection Training, etc.), please indicate by checking the appropriate boxes in the Prescription section.
- For Prior Authorization approval, the following items may be required. If necessary, please attach them to this form before faxing:
 - Stim Test results (<10ng/ML; Qty: 2) PGHD
 - Lab Test results
 - Stim Test results (<5ng/ML; Qty: 1) AGHD
 - IGF-1 (IGF-BP3)
 - Growth Chart
 - MRI (if done)
 - Bone Age results
 - Genetic tests when applicable

Please see accompanying full Prescribing Information and Important Safety Information on the last page.

***Omnitrope Co-Pay Savings Program Eligibility**

The Omnitrope Co-Pay Savings Program provides up to \$5,000 in annual Co-Pay support for Omnitrope prescriptions. With the Omnitrope Co-Pay Savings Program, eligible patients may pay \$0 for their Co-Pay. Eligible patients who are commercially insured may receive Co-Pay support in the amount of up to \$5,000 annually and patients who are uninsured may receive Co-Pay support in the amount of up to \$417 monthly, with an annual cap of \$5,000. Prescription must be for an approved indication. This program is not health insurance. Patients are not eligible if prescriptions are paid, in whole or in part, by any state or federally funded programs, including but not limited to Medicare (including Part D, even in the coverage gap) or Medicaid, Medigap, VA, DOD, or TriCare, or private indemnity, or HMO insurance plans that reimburse you for the entire cost of your prescription drugs, or where prohibited by law. Patients can participate for a maximum of 12 months. Eligible patients must have a first use of the program by December 31 of the current year. Omnitrope Co-Pay Savings Program may not be combined with any other rebate, coupon, or offer. Sandoz reserves the right to rescind, revoke, or amend this offer without further notice.

Omnitrope® (somatropin [rDNA origin] for injection) Indications and Important Safety Information

Indications

Omnitrope is a recombinant human growth hormone indicated for:

- **Pediatric:** Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner Syndrome, and Idiopathic Short Stature
- **Adult:** Treatment of adults with either adult onset or childhood onset GHD

Important Safety Information

Contraindications

- **Acute Critical Illness:** Somatropin should not be used to treat patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure. A significant increase in mortality has been reported in such cases
- **Prader-Willi Syndrome in Children:** Somatropin should not be used in pediatric patients with Prader-Willi Syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment. There have been reports of sudden death when somatropin was used in such patients
- **Active Malignancy:** Somatropin is contraindicated in patients with any evidence of active malignancy. Growth hormone deficiency may be an early sign of a pituitary tumor or other intracranial tumor; the presence of such a tumor should be excluded before initiation of somatropin treatment
- **Diabetic Retinopathy:** Somatropin is contraindicated in patients with active proliferative or severe non-proliferative diabetic retinopathy
- **Closed Epiphyses:** Somatropin should not be used for growth promotion in pediatric patients with closed epiphyses
- **Hypersensitivity:** Omnitrope® is contraindicated in patients with a known hypersensitivity to somatropin or any of its excipients. Localized reactions are the most common hypersensitivity reactions

Warnings and Precautions

- **Acute Critical Illness:** Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic doses of somatropin
- **Prader-Willi Syndrome in Children:** There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi Syndrome who had one or more of the following risk factors: severe obesity, history

of upper airway obstruction or sleep apnea, or unidentified respiratory infection. Male patients with one or more of these factors may be at greater risk than females. Patients with Prader-Willi Syndrome should be evaluated for signs of upper airway obstruction and sleep apnea before initiation of treatment with somatropin. If, during treatment with somatropin, patients show signs of upper airway obstruction (including onset of or increased snoring) and/or new onset sleep apnea, treatment should be interrupted

- **Neoplasms:** An increased risk of a second neoplasm has been reported for childhood cancer survivors treated with somatropin for GH deficiency that developed following radiation to the brain/head. Intracranial tumors, in particular meningiomas, were the most common of these. The relationship between somatropin therapy and CNS tumor recurrence in adults is unknown. Monitor for progression or recurrence in patients receiving somatropin therapy who have a history of GH deficiency secondary to an intracranial neoplasm. Thoroughly consider the risks and benefits of starting somatropin in children at increased risk for developing malignancies due to certain rare genetic causes. These patients should be carefully monitored for development of neoplasms. Any pre-existing nevi should be monitored carefully for increased growth or malignant transformation
- **Impaired Glucose Intolerance and Diabetes Mellitus:** Previously undiagnosed impaired glucose tolerance and overt diabetes mellitus may be unmasked during somatropin treatment. New-onset type 2 diabetes mellitus has been reported. As a result, blood glucose concentrations should be monitored periodically in all patients taking somatropin, especially in those with risk factors for diabetes mellitus. Patients with pre-existing type 1 or type 2 diabetes mellitus or impaired glucose tolerance should be monitored closely during somatropin treatment
- **Intracranial Hypertension:** Intracranial hypertension with papilledema, visual changes, headache, nausea, and/or vomiting have been reported in a small number of patients treated with somatropin. Funduscopic examination is recommended at the initiation of and periodically during therapy. If papilledema is observed by funduscopy during treatment with somatropin, treatment should be stopped and the patient's condition should be reassessed before treatment is resumed
- **Fluid Retention:** Transient and dose-dependent fluid retention during somatropin replacement in adults may frequently occur
- **Hypopituitarism:** In patients with hypopituitarism, standard hormone replacement therapy should be monitored closely when somatropin therapy is administered
- **Hypothyroidism:** Patients treated with somatropin should have periodic thyroid function tests, and thyroid hormone replacement therapy should be initiated or appropriately adjusted in cases of unmasked or worsening hypothyroidism

Important Safety Information continued

- **Slipped Capital Femoral Epiphysis in Pediatric Patients:** Slipped capital femoral epiphysis may occur more frequently in patients with endocrine disorders and in patients undergoing rapid growth. Any pediatric patient with the onset of a limp or complaints of hip or knee pain during somatropin therapy should be carefully evaluated
- **Progression of Scoliosis in Pediatric Patients:** Progression of scoliosis can occur in patients who experience rapid growth. Because somatropin increases growth rate, patients with a history of scoliosis who are treated with somatropin should be monitored for progression of scoliosis. However, somatropin has not been shown to increase the occurrence of scoliosis
- **Confirmation of Childhood Onset Adult GHD:** Patients with epiphyseal closure who were treated with somatropin replacement therapy in childhood should be reevaluated before continuation of somatropin therapy at the reduced dose level recommended for GH deficient adults
- **Otitis Media and Cardiovascular Disorders in Patients with Turner Syndrome:** Patients with Turner Syndrome should be evaluated carefully for otitis media and other ear disorders as somatropin treatment may increase the occurrence of otitis media in these susceptible patients. In addition, patients with Turner Syndrome should be monitored closely for cardiovascular disorders (e.g., hypertension, aortic aneurysm or dissection, stroke) as they are at increased risk for these conditions
- **Local and Systemic Reactions:** Injection site should be rotated to avoid tissue atrophy. Patients should be informed that local or systemic allergic reactions may occur and that prompt medical attention should be sought in such cases
- **Laboratory Tests:** Serum levels of inorganic phosphorus, alkaline phosphatase, parathyroid hormone and IGF-I may increase after somatropin therapy
- **Pancreatitis:** Cases of pancreatitis have been reported rarely in children and adults receiving somatropin. Pancreatitis should be considered in any somatropin-treated patient, especially a child, who develops abdominal pain. Girls who have Turner Syndrome may be at greater risk than other somatropin-treated children
- **Benzyl Alcohol:** Benzyl alcohol, an ingredient in Omnitrope Cartridge 5 mg/1.5 mL and the diluent for Omnitrope for injection 5.8 mg/vial, has been associated with serious adverse events and death, particularly in pediatric patients and should not be used in premature babies or neonates. Consider the combined daily metabolic load of benzyl alcohol from all sources
- **Pregnancy/Nursing Mothers:** Somatropin should be used during pregnancy only if clearly needed and with caution in nursing mothers because it is not known whether somatropin is excreted in human milk
- **Special Populations:** The safety and effectiveness of somatropin in patients aged 65 years and over have not been evaluated in clinical studies. Elderly patients may be more sensitive to the action of somatropin and may be more prone to adverse reactions
- **Potential Drug Interactions:**
 - Somatropin inhibits 11 β -hydroxysteroid dehydrogenase type 1 (11 β HSD-1) in adipose/hepatic tissue and may significantly impact the metabolism of cortisol and cortisone. As a consequence, in patients treated with somatropin, previously undiagnosed central (secondary) hypoadrenalism may be unmasked, requiring glucocorticoid replacement therapy
 - Careful monitoring is advisable when growth hormone is administered in combination with insulin and/or other hypoglycemic agents, other drugs metabolized by CYP450 liver enzymes (e.g., hydrocortisone or other corticosteroids, sex steroids, anticonvulsants, cyclosporine), or other hormone replacement therapy

Adverse Reactions

- Common adverse reactions reported in adult and pediatric patients taking somatropin include injection site reactions/ rashes and lipoatrophy and headaches. Additional common adverse reactions include edema, arthralgia, myalgia, carpal tunnel syndrome, paresthesias, and hypothyroidism

Please see accompanying full Prescribing Information and Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch