Statement Of Medical Necessity

Omnitrope®
(somatropin) injection

See following pages for a list of documentation to accompany the Omnitrope® Statement of Medical Necessity (SMN).

SANDOZ

Please see Important Safety Information on pages 5-6 and click here for full Prescribing Information.

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.

	Omnitrope® (somatropin) Indications					
	Pediatric Patients					Adult Patients
Recommended Evaluations	Growth Hormone Deficiency (GHD)[1,2]	Idiopathic Short Stature[3,4]	Small for Gestational Age[5]	Prader-Willi Syndrome[6]	Turner Syndrome[7]	Growth Hormone Deficiency (GHD)[8]
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	✓			✓	✓	
MRI scan	✓[a]					✓
Cardiac evaluation					✓	
Lipid profile					✓	✓
History of head trauma						✓
DEXA scan						✓
Insulin tolerance test						✓
Assessment of pituitary gland						✓

[a]Per guidelines for the diagnosis and treatment of GHD in childhood and adolescence, an MRI is done for those with known or suspected intracranial tumors, optic nerve hypoplasia/septo-optic dysplasia or other structural or developmental anomaly.[2]

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.
- **Prader-Willi Syndrome in Children:** Somatropin should not be used in 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. Systemic hypersensitivity reactions have been reported with postmarketing use of somatropin products.

Please see additional Important Safety Information on pages 5-6 and click here for full Prescribing Information.

STATEMENT OF MEDICAL NECESSITY

Please fill out form completely and fax to 877.828.1052
Questions? Call OmniSource® at 877.456.6794, Monday-Friday, 8AM-8PM ET.

Omnitrope® (somatropin) injection

Patient Is: ☐ New to Omnitrope® ☐ Continuing Omnitrope ☐ Switching From Other Brand: _____

PATIENT INFORMATION

Patient Name (first and last): _____
Date of Birth: _____
Gender: ☐ M ☐ F
Address: _____
City: _____ State: _____ ZIP: _____
Indicating parent or guardian is suggested for patients under 18.

Contact Name (Parent[s] or Guardian[s]): _____
Relationship to Patient: _____
Primary Phone: _____ Preferred Time? ☐ Day ☐ Night
Primary Language: _____

INSURANCE

Primary/Medical Insurance: _____ Pharmacy/Rx Insurance: _____ ☐ Uninsured
Member Name: _____
Member ID #: _____
Policy/Group #: _____
Subscriber ID #: _____
Attach copies of BOTH sides of patient's insurance card(s), including medical and pharmacy/Rx cards.

PA Submitted: ☐ Y ☐ N
PA Approved: ☐ Y ☐ N Pursuing Appeal: ☐ Y ☐ N
PA Approval Dates: _____
Reference Number: _____

DIAGNOSIS

Please check the ICD-10 diagnosis code that applies. ☐ *Medical records are attached. See pg. 2 for suggested documentation to accompany the SMN.*

Pediatric growth hormone deficiency (GHD):
☐ E23.0 Hypopituitarism (includes isolated GHD)
☐ E23.0 Panhypopituitarism
☐ E23.1 Drug-induced hypopituitarism
☐ E89.3 Postprocedural hypopituitarism

Idiopathic short stature (ISS):
☐ R62.52 Short stature (child)

Small for gestational age (SGA):
☐ R62.52 Short stature/growth failure plus:
☐ P05.1 Newborn small for gestational age
☐ P05.9 Newborn affected by slow intrauterine growth, unspecified
☐ P05. _____

Turner syndrome (TS):
☐ Q96.0 ☐ Q96.1 ☐ Q96.2 ☐ Q96.3 ☐ Q96.4 ☐ Q96.8 ☐ Q96.9

Prader-Willi syndrome (PWS):
☐ Q87.1 Congenital malformation syndromes predominantly associated with short stature

Adult growth hormone deficiency (GHD):
☐ E23.0 Hypopituitarism

Other Diagnosis:
☐ ICD-10 code and description: _____

PRESCRIPTION

☐ **Omnitrope 5 mg Cartridge (NDC 0781-3001-07):**
☐ Omnitrope Pen 5 Device

☐ **Omnitrope 10 mg Cartridge (NDC 0781-3004-07):**
☐ Omnitrope Pen 10 Device

Cartridge BD Pen Needle Gauge:
☐ 29 Gauge (12.7 mm)
☐ 31 Gauge (5 mm)
☐ 31 Gauge (8 mm)
☐ Other: _____
☐ Ancillary Supplies (days' supply): _____

Pen Dose: _____ **mg**/day _____ Days/week
Dispense: _____ month(s) supply Refills: _____
Preferred Pharmacy (optional): _____

☐ **Omnitrope 5.8 mg Vial (NDC 0781-4004-36):**
☐ 3 cc Syringe With 18 Gauge 1" Needle (for mixing)
☐ 1 cc Syringe (mL syringe required for dosing)

Syringe Needle Gauge:
☐ 29 Gauge (12.7 mm)
☐ 31 Gauge (5 mm)
☐ 31 Gauge (8 mm)
☐ Other: _____
☐ Ancillary Supplies (days' supply): _____

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.

Vial Dose: _____ **mL**/day _____ Days/week
Dispense: _____ month(s) supply Refills: _____
Preferred Pharmacy (optional): _____

SERVICES

Services (check all that apply):
☐ Omnitrope Self Pay
☐ Quick Benefits Investigation
☐ Full Benefits Investigation
☐ PA Assistance
☐ Interim Drug (SOS)*
☐ Injection Training
Preferred Trainer: _____
☐ Co-Pay Savings Program†
☐ Patient Starter Kit

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 completing and faxing this form, I certify that my patient is aware of the disclosure of their personal health information to Sandoz and its business partners for Sandoz's patient support services, including reimbursement and verification services and the services provided by field reimbursement professionals in your office, as part of the patient's treatment with this product. I certify that I have obtained any required patient authorization. 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 that (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 for any government program or third-party insurer. For the purposes of transmitting prescriptions, I authorize Sandoz, and its affiliates, business partners, and agents to forward these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies on my behalf.

Name (print): _____ Practice: _____ DEA Number: _____
Address: _____ City: _____ State: _____ ZIP: _____
Office Contact: _____ Phone: _____ Fax: _____
Office Contact Email: _____ Provider Tax ID Number: _____ Provider NPI Number: _____

If NP or PA, Under Direction of Dr: _____ ☐ If Dispense as Written, Signature Required: _____

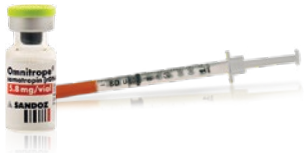
Signature: _____ **Date:** _____

Note: This form cannot be processed without the prescribing health care provider's signature and date. Stamps are not permissible.

ATTENTION:

FAX SMN AND ALL OTHER DOCUMENTS TO 877.828.1052

The following devices are available for Omnitrope® (somatropin)

	Device	Dosing Increments	Maximum 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 to:

- ☐ Copy the front and back of the patient's insurance card(s), including medical and pharmacy/Rx cards, and fax with this form.
- ☐ Check the correct diagnosis in the Diagnosis section. Please note: Providers should contact the patient's insurer to determine the appropriate diagnosis codes. Sandoz Inc. does not guarantee that the codes provided 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.
- ☐ Choose the appropriate delivery system (Omnitrope Pen 5, 10, or Vial) located in the Prescription section and indicate dosage, number of months' supply, and number of refills.
- ☐ Indicate the OmniSource® services requested for your patient by checking the appropriate box(es) in the Services section.
- ☐ Include the items below; they may be required for prior authorization approval.
  - Stim Test Results (<10 ng/mL; qty: 2) PGHD
  - Lab Test Results
  - Stim Test Results (<5 ng/mL; qty: 1) AGHD
  - IGF-1 (IGF-BP3)
  - MRI (if done)
  - Bone Age Results
  - Genetic Tests (when applicable)
  - Growth Chart

*SOS is available for a maximum of twelve (12) months to commercially insured patients with an FDA-approved Omnitrope indication during first-time benefits investigation and expired prior authorizations. SOS is also available for a maximum of two (2) months to government-insured patients with an FDA-approved Omnitrope indication during first-time benefits investigation only. This program is not health insurance. Product dispensed under SOS is not eligible for claim reimbursement and should not be submitted to any third party private payer. SOS does not require, nor will be made contingent on, purchase requirements of any kind. Sandoz reserves the right to amend, rescind, or discontinue this program at any time without further notice. Additional eligibility criteria may apply; contact OmniSource for further details.

†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. Omnitrope Co-Pay Savings Program has no cash value. Sandoz reserves the right to rescind, revoke, or amend this offer without further notice.

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.
- **Prader-Willi Syndrome in Children:** Somatropin should not be used in 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. Systemic hypersensitivity reactions have been reported with postmarketing use of somatropin products.

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 of short stature. These patients should be carefully monitored for development of neoplasms. Any pre-existing nevi should be monitored carefully for increased growth or potential malignant changes.
- **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. Patients with Turner syndrome and Prader-Willi Syndrome may be at increased risk for the development of intracranial hypertension.
- **Hypersensitivity:** Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with postmarketing use of somatropin products. Patients and caregivers should be informed that such reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs.
- **Fluid Retention:** Transient and dose-dependent fluid retention during somatropin replacement in adults may frequently occur.
- **Hypoadrenalism:** Monitor patients for reduced serum cortisol levels and/or need for glucocorticoid dose increases in those with known hypoadrenalism.
- **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.
- **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.

Please see additional Important Safety Information on page 6 and click here for full Prescribing Information.

Omnitrope®
(somatropin) injection

IMPORTANT SAFETY INFORMATION (continued)

- **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., stroke, aortic aneurysm or dissection, hypertension) as they are at increased risk for these conditions.
- **Lipoatrophy:** Injection site should be rotated to avoid tissue atrophy.
- **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 persistent severe 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 11β-hydroxysteroid dehydrogenase type 1 (11βHSD-1) in adipose/hepatic tissue and may significantly impact the conversion of cortisone to its active metabolite cortisol. 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 full Prescribing Information for Omnitrope.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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.

References: 1. Grimberg A, DiVall SA, Polychronakos C, et al; Drug and Therapeutics Committee and Ethics Committee of the Pediatric Endocrine Society. 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;86(6):361-397. **2.** GH Research Society. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. *J Clin Endocrinol Metab.* 2000;85(11):3990-3993. **3.** Cohen P, Rogol AD, Deal CL, et al; 2007 ISS Consensus Workshop participants. 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. **4.** Lee MM. Clinical practice. Idiopathic short stature. *N Engl J Med.* 2006;354(24):2576-2582. **5.** Clayton PE, Cianfarani S, Czernichow P, Johannsson G, Rapaport R, Rogol A. 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(3):804-810. **6.** Deal CL, Tony M, Höybye C, Allen DB, Tauber M, Christiansen JS; 2011 Growth Hormone in Prader-Willi Syndrome Clinical Care Guidelines Workshop Participants. 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. **7.** Bondy CA; Turner Syndrome Study Group. 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. **8.** Cook DM, Yuen KC, Biller BM, Kemp SF, Vance ML; American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients—2009 update. *Endocr Pract.* 2009;15(suppl 2):1-29.

Omnitrope® (somatropin) injection

07/23 140463-4

OmniSource® SANDOZ