Statement of Medical Necessity

Please fill out form completely and Fax to: 877.828.1052
Call 877.456.6794 Mon-Fri, 8am-8pm ET

OmniSource®

Omnitrope®
(somatropin [rDNA origin] for injection)

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: _____
Attach copies of BOTH sides of patient's Insurance Card(s) or patient demographic sheet, including Medical and Pharmacy Rx Cards. Subscriber ID #: _____

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)
- ☐ E23.1 Iatrogenic Hypopituitarism (253.7)
- ☐ E23.0 Growth Hormone Deficiency (253.3)
- ☐ R62.52 **Idiopathic Short Stature** – 2.25 SDS (783.43)

SGA:
- ☐ R62.52 Short Stature/Growth Failure (783.43), plus
- ☐ P05.00 Small for Dates (764.00) or
- ☐ P05.9 Intrauterine Growth Retardation, Unspecified (764.90)
- ☐ Q87.1 **Prader-Willi Syndrome** (759.81)
- ☐ Q96.9 **Turner Syndrome** (758.6)
- ☐ 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® 5.8mg 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)
- ☐ Patient Starter Kit
- ☐ Injection Training Preferred Trainer: _____
- ☐ Co-Pay Card #: _____

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 and its employees or agents 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*: _____

***This form cannot be processed without prescribing physician's full and usual signature. Actual signature is required – no stamps.**

ATTENTION:

FAX THE SMN FORM AND ALL OTHER DOCUMENTS TO 877.828.1052

OmniSource®

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

Device		Dosing Increments	Max Dose	NDC
Omnitrope® Pen 5		0.05mg	2.7mg	NDC 0781-3001-07
Omnitrope® Pen 10		0.1mg	5.4mg	NDC 0781-3004-07
Omnitrope® 5.8mg Vial		0.02mL	5mg/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), Starter Kit, Nurse Training, etc., please indicate by checking the appropriate boxes in the Prescription section.
- ☐ For Prior Authorization approval, the following items may be required—please attach them to this form before faxing if necessary:
  - 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

For further information on the transition from ICD-9 to ICD-10 please visit*:

- www.cms.gov/Medicare/Coding/ICD10/index.html
- www.cdc.gov/nchs/icd/icd10.htm
- apps.who.int/classifications/apps/icd/icd10training/
- www.aapc.com/ICD-10/
- www.himss.org/library/icd-10/playbook

*This information is taken from publicly available references. It is meant to be used as a guide only. Sandoz Inc. makes no promises or guarantees about, and disclaims responsibility for, reimbursement outcomes if these alternatives are utilized. It is the healthcare professional's responsibility to ensure that accurate coding and documentation are provided to managed care organizations.

Please see accompanying full Prescribing Information and Important Safety Information.

† Eligibility Requirements for Save As You Grow Program
Maximum benefit of $250 a month up to $3,000 annually. Prescription must be for an approved indication. This program is for insured patients and cash-paying patients only; uninsured patients are not eligible. 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. To receive savings, eligible patients must have a first use of the program by December 31 of the current year. Co-Pay Support 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. For more information, call your OmniSource Patient Support Specialist at 877.456.6794.

OmniSource
1670 Century Center Pkwy., Memphis, TN 38134

Omnitrope®
(somatropin [rDNA origin] for injection)

SANDOZ
a Novartis company

Biopharmaceuticals

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.
- **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 11β-hydroxysteroid dehydrogenase type 1 (11βHSD-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

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