INSTRUCTIONS: How to Complete the Statement of Medical Necessity (SMN) Nutropin® and Nutropin AQ® for the Pediatric Patient

Please write legibly and complete all sections to prevent delays. This instruction sheet may be used for guidance and as a checklist to assist in the completion of the SMN. IT DOES NOT NEED TO BE FAXED WITH THE SMN.

www.NutropinAccessSolutions.com

INSURANCE INFORMATION

- ❑ This section should include both primary and secondary insurance including any prescription cards to ensure that ALL potential coverage can be investigated.
- ❑ If available, please provide a front and back copy of the insurance card (enlarged and legible) and fax this information with the SMN and PAN.

DIAGNOSIS AND MEDICAL INFORMATION

Diagnosis

- ❑ Check the appropriate diagnosis code.
- ❑ If "other" is checked, ICD-9 code is required.

The following is a list of what is usually needed by diagnosis (provide on SMN or as a report as appropriate):
Please note that Nutropin® Access Solutions™ may need to request additional information from your office if required by an insurance company.

Isolated Growth Hormone Deficiency 253.3

- ❑ Two Stim Test Results
- ❑ Growth Chart (with at least two plots)
- ❑ Bone Age
- ❑ History and Physical (helpful)

Iatrogenic-Induced Hypopituitarism 253.7

- ❑ MRI
- ❑ Growth Chart (with at least two plots)
- ❑ Bone Age
- ❑ History and Physical (helpful)

Panhypopituitarism 253.2

- ❑ MRI
- ❑ Growth Chart (with at least two plots)
- ❑ History and Physical (helpful)
- ❑ Bone Age

Turner Syndrome 758.6

- ❑ Growth Chart (with at least two plots)
- ❑ Karyotype Report
- ❑ Bone Age

Chronic Renal Insufficiency 585.0

- ❑ Growth Chart (with at least two plots)
- ❑ Renal Function Studies
- ❑ History and Physical (helpful)
- ❑ Is Patient on Dialysis?
- ❑ Bone Age

Short Stature/Growth Failure 783.43

- ❑ Growth Chart (with at least two plots)
- ❑ Predicted Height From Progress Report
- ❑ Mid-Parental Height (may be helpful)
- ❑ Bone Age

Date Patient Last Seen/Date Therapy Initiated/Estimated Duration

- ❑ Please indicate the date you last saw the patient (date these results are from), the date therapy was originally initiated (or will be initiated) and the estimated duration of therapy (example: lifetime).

PRESCRIPTION

- ❑ Please ensure that you complete all areas of the prescription portion correctly and completely.
- ❑ A prescription cannot be processed with a stamped signature. The prescriber must sign and date the form to make the prescription valid.
- ❑ If you would like a Starter shipment sent to a patient who has never received one, please indicate by checking the box and advising when and where it should be shipped (examples: home or MD office).
  (The Starter shipment is a free, one-time, 30-day supply that is not meant for reselling or billing to a payer.)

ATTACH TO COMPLETED SMN

- ❑ Any report, demographic sheet or insurance cards that you feel would further your patient's treatment authorization
- ❑ If you have one, please attach a signed and dated PATIENT AUTHORIZATION AND NOTICE OF RELEASE OF INFORMATION (PAN) form. This form is needed to fully investigate coverage and to refer the patient to a patient assistance program.
- ❑ You may also attach recent visit notes and/or pertinent reports.
- ❑ Growth chart with at least two plots

REMINDER: The SMN form cannot be fully processed without a prescriber's signature and date, as well as a signed and dated PAN form.

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Statement of Medical Necessity

PEDIATRIC GROWTH HORMONE TREATMENT

Phone: **(866) NUTROPIN/(866) 688-7674** Fax: **(800) 545-0612**

PATIENT

Name (First and Last): Date of Birth (MM/DD/YY):

Patient's Address:

City/State/ZIP: Social Security Number: Male ❑ Female ❑

Primary Contact: Relationship:

Home Ph: ( ) Work Ph: ( ) Cell Ph: ( ) E-Mail:

INSURANCE

HMO/EPO ❑ PPO ❑ POS ❑ Medicaid ❑ Medicare ❑ No Insurance ❑

Primary Insurance: **See Attached ❑**

Phone: ( )

Subscriber:

Subscriber ID #: Pol/Grp #:

Employer: Retired ❑

HMO/EPO ❑ PPO ❑ POS ❑ Medicaid ❑ Medicare ❑ No Insurance ❑

Secondary Insurance: **See Attached ❑**

Phone: ( )

Subscriber:

Subscriber ID #: Pol/Grp #:

Employer: Retired ❑

DIAGNOSIS

Prescription Type: New Start ❑ Continued Tx ❑ Restart Tx ❑

Isolated Growth Hormone Deficiency	(253.3) ❑	Panhypopituitarism	(253.2) ❑
Iatrogenic-Induced Hypopituitarism	(253.7) ❑	Chronic Renal Insufficiency	(585) ❑
Turner Syndrome	(758.6) ❑	Short Stature/Growth Failure	(783.43) ❑

Other Disorder Due to Inadequacy of Endogenous Growth Hormone Secretion: Specify by ICD-9:

MEDICAL ASSESSMENT

Lab Results: (For Initial Diagnosis Only) See Attached ❑

GH Stimulation Test Date: GH Stimulation Test Date:

Agent: Peak Value: Agent: Peak Value:

Thyroid Test Results: IGF-BP3 Test Results:

Tanner Stage of Puberty: IGF-I Level:

Karyotype Results (Turner Syndrome Only): GFR (CRI Only):

Clinical Impression:

Date Patient Last Seen: **Date Therapy Initiated:** **Estimated Duration:**

Ht. **cm /** **%-ile**

Wt. **kg /** **%-ile**

Growth Velocity: **cm/yr**

SDS Score: **Epiphyses Open:**

Bone Age: **Yes❑ No❑**

Date of X-ray:

Growth Chart Attached ❑

PRESCRIPTION

Injection Training to Be Completed by: Office (by Office Staff) ❑ Home (Coordinated by Nutropin® Access Solutions™ or Pharmacy) ❑

Please Dispense: *Remember to dispense the corresponding pen if your patient doesn't already have one.*

Nutropin AQ Pen 10® ❑ Nutropin AQ Pen® 10-mg Cartridge [somatropin (rDNA origin) injection] ❑

Nutropin AQ Pen 20® ❑ Nutropin AQ Pen® 20-mg Cartridge [somatropin (rDNA origin) injection] ❑

BD Ultra-Fine™ (original) 29 g/12.7 mm Needles ❑ Other Needles ❑

Nutropin AQ® [somatropin (rDNA origin) injection] 10-mg Vial ❑

Nutropin® [somatropin (rDNA origin) for injection] 5 mg ❑ 10 mg ❑ Dilute: w/ mL

Dispense: Syringes for Inj. 0.3 mL 0.5 mL 1 mL **Other Insulin Syringe:**

Reconstitution Syringes as Needed 1 mL 3 mL

Dose: mg/injection (mL) **SubQ:** inj./week **Dispense:** months **Refill X** or **PRN**

Starter Rx* ❑ **Date to Be Shipped:** **Ship to:**

*The Starter shipment is a free, one-time, 30-day supply that is not for reselling or billing to any payer.

PRESCRIBER

Prescriber's Full Name: **DEA #:** **Tax ID #:**

State License #: **Exp Date:** **Prescriber NPI:** **Group Billing NPI:**

Address: **City/State/ZIP:** **Phone: ( )** **Fax: ( )**

UNAPPROVED USE WARNING: Please read the FDA-approved label for Nutropin before prescribing. If the indication for which you are prescribing Nutropin is not listed in the label, you are prescribing Nutropin for an "unapproved" use. The fact that the use for which you are prescribing Nutropin is not listed in the FDA-approved label indicates that the FDA has not approved the efficacy, dosage amount or safety of Nutropin when used for such a use. Nevertheless, Genentech® Access to Care Foundation will consider providing Nutropin for your patient with this admonition, based upon your medical order, within program requirements.

By signing below, I certify that (a) the above therapy is medically necessary, (b) I have received the necessary authorization to release the above referenced information and other protected health information (as defined in the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) to Genentech USA, Inc., Nutropin Access Solutions and contracted dispensing pharmacy or other contractors for the purpose of seeking reimbursement, assisting in initiating or continuing therapy and/or the evaluation of the patient's eligibility for the Genentech Access to Care Foundation program related to Genentech products as a break in treatment would negatively impact the patient's therapeutic outcome, (c) I will not sell or bill for any free product received in my office for patients from the Genentech Access to Care Foundation or Starter Programs, and (d) I appoint Nutropin Access Solutions solely to convey on my behalf to the pharmacy chosen by the above-named patient the prescription described herein.

I agree to comply with the program guidelines as established by Genentech USA, Inc. and understand that Genentech Access to Care Foundation, at its sole and absolute discretion, reserves the right to modify or discontinue the program at any time and to verify the accuracy of the information submitted.

Prescriber's Signature*: **Date:**

*This form cannot be processed without prescriber's signature.

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Fax: **(800) 545-0612**

PATIENT AUTHORIZATION AND NOTICE OF RELEASE OF INFORMATION

Dear Patient:

Nutropin® Access Solutions™ is a program sponsored by Genentech USA, Inc. that provides services such as benefits investigations, prior authorizations and appeals assistance at no charge to patients, and assists them in obtaining reimbursement for Nutropin products. If a patient does not have insurance or is deemed uninsured due to denial by private and public payers, and the patient meets certain financial criteria, the Genentech® Access to Care Foundation may provide Nutropin products free of charge. Additional information on this program can be found on www.NutropinAccessSolutions.com.

In order for Nutropin Access Solutions and Genentech Access to Care Foundation to provide these services, we will need to review, use and disclose your protected health information (PHI). By law, only with your prior written authorization may your health care provider, health plan or health insurer disclose your PHI to Nutropin Access Solutions and Genentech Access to Care Foundation.

You are not required to agree to this Authorization. However, failure to provide this Authorization may prevent you from becoming eligible for the Nutropin Access Solutions coverage and reimbursement assistance program or Genentech Access to Care Foundation patient assistance programs, which may result in your need to pay for certain products with your own funds. You will receive a copy of the Authorization you sign.

Please review this Authorization carefully. If you have any questions regarding this Authorization, please contact your health care provider's office or you can contact Nutropin Access Solutions directly at (866) NUTROPIN.

AUTHORIZATION

I. INFORMATION TO BE DISCLOSED OR USED AND PERSONS AUTHORIZED TO DISCLOSE SUCH INFORMATION

This Authorization permits my health care providers, health plans and health insurers, and others who may hold my PHI to use and disclose to Nutropin Access Solutions or Genentech Access to Care Foundation, its authorized agents and assignees, all medical records and financial information with respect to my treatment, which may have bearing on the benefits payable for services or products provided through my health care provider, health plan or insurer under any plan providing benefits or services, including, without limitation, the dollar balance of benefits remaining under any applicable lifetime maximum benefits provisions, or which may have a bearing on my medical condition or my therapy. All of this information may be considered PHI, and may, if relevant, include information about HIV/AIDS and/or other communicable diseases, mental health information and/or information concerning genetic test results.

II. PERSONS TO WHOM DISCLOSURE MAY BE MADE

The PHI identified in Paragraph I may be disclosed to and/or used by Nutropin Access Solutions or Genentech Access to Care Foundation, their sponsor Genentech USA, Inc., a biopharmaceutical manufacturer located at 1 DNA Way, Mail Stop #210, South San Francisco, CA 94080, and its related entities, their agents or assignees and certain Genentech business partners, as well as other companies involved in the administration of certain Genentech products.

III. DESCRIPTION OF EACH PURPOSE

My PHI may be used for the purposes of reimbursement and/or participation in a reimbursement assistance or patient assistance program administered by Nutropin Access Solutions and Genentech Access to Care Foundation, respectively. My PHI may also be used for purposes of tracking the general use of a Genentech product, assessing and improving Genentech's coverage and reimbursement and patient assistance services, and proper management and administration of Genentech's business.

IV. EXPIRATION DATE OR EVENT

California residents only: This Authorization will be effective, unless revoked by me in writing, until December 31, 2015. All other residents: This Authorization will be effective, unless revoked by me in writing, for up to one year from the date of this Authorization.

V. NOTICES

I understand that once my health information is disclosed pursuant to this Authorization, there is no guarantee under federal law that the recipient will not redisclose my health information to a third party. Any such third party may not be required to abide by this Authorization or applicable federal law governing the use and disclosure of my health information.

I understand that I may refuse to sign or may revoke (at any time) this Authorization for any reason and that such refusal or revocation will not affect the commencement, continuation or quality of my health care provider's treatment of me. If I refuse to sign or revoke this Authorization, however, I may be responsible for costs that may have otherwise been covered by Nutropin Access Solutions or Genentech Access to Care Foundation.

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Fax: **(800) 545-0612**

V. NOTICES (CONTINUED)

I understand that this Authorization will remain in effect until it expires as described above or I provide a written notice of revocation via mail to Nutropin Access Solutions, 1 DNA Way, Mail Stop #210, South San Francisco, CA 94080 or via fax to (800) 545-0612. The revocation will be effective immediately upon my health care provider's receipt of my written notice, except that the revocation will not have any effect on any action taken by my health care provider or others referenced in this Authorization, including without limitation, Nutropin Access Solutions or Genentech Access to Care Foundation, in reliance on this Authorization before my health care provider received my written notice of revocation.

VI. DISTRIBUTION ACKNOWLEDGMENT

I hereby state (or my parent/guardian hereby states) that if I should receive free product from Genentech Access to Care Foundation, I will utilize Nutropin for the reason that my physician has prescribed it to me. I will not sell or distribute Nutropin, as I acknowledge it is unlawful to do so. I will be responsible to ensure that Nutropin will be delivered to a secure address for purposes of receipt of shipment and I understand it is my duty to control Nutropin while it remains in my possession.

VII. SIGNATURE

I have read and understand the terms of this Authorization and I have had an opportunity to ask questions about the use and disclosure of my health information. By my signature below, I hereby, knowingly and voluntarily, authorize the use and/or disclosure of my health information in the manner described above.

REQUIRED

Print Patient's Name _____ Date _____

Signature of Patient or Guardian* _____ Relationship to Patient (self, parent, etc) _____

Patient/Guardian Address _____

*If the patient is an unemancipated minor or otherwise incapacitated (physically or mentally)

VIII. FINANCIAL INFORMATION

- Only uninsured patients (and patients whose insurance has denied treatment) who wish to apply to Genentech Access to Care Foundation for assistance need to fill out this section.
- There is no need to complete this section if the patient has insurance coverage for Nutropin.

COMPLETE IF NECESSARY

Household Adjusted Gross Income: ❑ $0-25K/yr ❑ $25,001-50K/yr ❑ $50,001-75K/yr ❑ $75,001-100K/yr

I understand that in order to qualify, my adjusted gross income may not exceed $100K/yr. I certify that the above statement of my previous year's income is true and that I have no medical insurance coverage for Nutropin, including Medicare, Medicaid or other public programs, and that I have insufficient financial resources to pay for the prescribed therapy. I also agree to furnish my IRS 1040 (or if none, then my Social Security Benefit Statement or W-2) within 45 days of the submission of this form. I understand that failure to provide this documentation may result in an interruption in therapy.

Signature of Patient (complete if applicable) _____ Date Signed (complete if applicable) _____

OPTIONAL

STEPPING STONES™ FREE PATIENT SUPPORT PROGRAM

I authorize Genentech USA, Inc. to enroll me/my child in a free patient support program. I understand my name, address, e-mail address, phone number and the name of my pharmacy, once identified, will be sent by Nutropin Access Solutions to the free patient support program to complete my enrollment. I agree that Genentech and its agents may contact me in the future by mail, e-mail and/or telephone concerning the free patient support program. I understand that all personally identifiable information will be kept strictly confidential and will not be distributed outside of Genentech or its agents, as the Genentech USA, Inc. privacy policy provides (available at www.steppingstones.nutropin.com). I also understand that I do not have to sign this Authorization in order to receive Nutropin or participate in the Nutropin Access Solutions/Genentech Access to Care Foundation programs and that I may cancel this Authorization at any time by giving written notice to Genentech/Nutropin through its agent at PO Box 29478, Mission, KS 66201-9907.

SIGNATURE OF PATIENT/GUARDIAN: _____

E-Mail Address: _____

Date: _____

I authorize Genentech USA, Inc. to notify my health care provider that I have enrolled in Stepping Stones, a free patient support program.

YES ❑ NO ❑

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FAX COVER SHEET

Attn: Nutropin® Access Solutions™	**Date:**
To:	**Fax #:** (800) 545-0612
From:	**Phone:**
	# Pages:

Growth Hormone

Patient's Name: **Date of Birth:**

Comments: