STATEMENT OF MEDICAL NECESSITY (SMN)

PEDIATRIC GROWTH HORMONE TREATMENT

NuAccess℠ Request Fax: (866) 924-8584* SMN Fax (non-NuAccess request): (800) 545-0612

Nutropin® [somatropin (rDNA origin) for injection]
Access Solutions™ Treatment made possible.

SERVICES REQUESTED† (check all that apply) ☐ BI/PA‡ ☐ Appeals Support ☐ Co-pay Assistance ☐ GATCF§ Patient Assistance ☐ Other‖:_____

PATIENT

Last name†:_____ First name†:_____ Gender†: ☐ Male ☐ Female Birth date†:_____
Street:_____ City:_____ State†:_____ ZIP:_____
Home phone: (_____)_____ Work/cell phone: (_____)_____ Email:_____
Primary contact last name:_____ First name:_____ Phone: (_____)_____
Relationship to patient:_____

INSURANCE: Is the patient insured? ☐ Yes ☐ No (Attach a copy of insurance card)
Is the patient pending Medicaid determination? ☐ Yes ☐ No

DIAGNOSIS

Prescription Type: ☐ New start ☐ Continued Tx ☐ Restart Tx

Where appropriate, please fill in the 4th digit of the ICD-9 code. Further information is available on the next page.

☐ Isolated growth hormone deficiency (253.3) ☐ Panhypopituitarism (253.2) ☐ Iatrogenic-induced hypopituitarism (253.7)
☐ Chronic renal insufficiency (chronic kidney disease [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-CM:_____

MEDICAL ASSESSMENT

Lab Results (for initial diagnosis only): See attached ☐

GH stimulation test date: _____
Agent: _____ Peak value: ____
GH stimulation test date: _____
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: _____

Epiphysis open: ☐ Yes ☐ No Growth chart attached: ☐ Yes ☐ No

	Baseline	Current
Date		
Height (cm)		
Height (%)		
Height SDS		
Weight (kg)		
Weight (%)		
Growth velocity		
Bone age		
Date of x-ray		

PRESCRIPTION

NuSpin Pen ☐ NuSpin Pen 20® 20-mg (0.2-mg dosing) ☐ NuSpin Pen 10® 10-mg (0.1-mg dosing) ☐ NuSpin Pen 5® 5-mg (0.05-mg dosing)

Needle ☐ BD Ultra-Fine® 29 g/12.7 mm ☐ BD Ultra-Fine III Short Pen Needle 31 g/8 mm ☐ NovoFine® Pen Needle 30 g/8 mm

AQ Pen & Cartridge ☐ Nutropin AQ Pen 10® ☐ 10-mg cartridge (0.1-mg dosing)
☐ Nutropin AQ Pen 20® ☐ 20-mg cartridge (0.2-mg dosing)

Needle ☐ BD Ultra-Fine 29 g/12.7 mm ☐ BD Ultra-Fine III Short Pen Needle 31 g/8 mm ☐ NovoFine Pen Needle 30 g/8 mm

Vial Nutropin AQ® [somatropin (rDNA origin) injection] ☐ 10-mg vial
Nutropin® [somatropin (rDNA origin) for injection] ☐ 10-mg vial ☐ 5-mg vial Dilute w/_____mL

Dispense _____syringes for inj_____0.3 mL _____0.5 mL _____1 mL with ☐ 30 g/12.7 mm needles ☐ 31 g/8 mm needles
Reconstitution syringes as needed:_____1 mL _____3 mL _____5 mL Other insulin syringe:_____

Dose: _____mg/inj (_____mL) **SubQ:**_____inj/week **Dispense:**_____months **Refill X**_____or_____**PRN**

SERVICES

Injection training to be arranged by: ☐ Office ☐ Home (Nutropin Access Solutions to coordinate) **Preferred agency:**_____
Preferred specialty pharmacy to dispense: OCEAN BREEZE PHARMACY

NUACCESS

NuAccess: Program ID # H2090001 ☐ 30-day supply

Product will be delivered to the patient's home. NuAccess is for patients who have been prescribed NuSpin or Nutropin AQ Pen and Cartridge only.

The NuAccess authorization sticker may be reused for 2 refills of the same dose for the same patient. One should not assume that a patient eligible for a NuAccess shipment in one instance will be eligible in future instances or that similar patients will be eligible.

Place NuAccess Authorization Sticker Here

PRESCRIBER

Prescriber's last name†:_____ First name†:_____
Practice name:_____ Specialty:_____
Street†:_____ City†:_____ State†:_____ ZIP†:_____
Phone: (_____)_____ Fax: (_____)_____ Prescriber tax ID:_____ Prescriber NPI¶:_____
DEA #†:_____ Group NPI:_____ State license #:_____ PTAN#:_____

By signing below, I certify that I am prescribing Nutropin therapy for the patient named above and that (a) the above therapy is medically necessary and that I will supervise the patient's treatment accordingly, (b) I am not prescribing Nutropin for any of the following purposes: (1) athletic performance, (2) athletic body building, (3) anti-aging or (4) cosmetic use, (c) 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, Inc., Nutropin Access Solutions and contracted dispensing pharmacy or other contractors for the purpose of seeking reimbursement, assisting in initiating or continuing therapy, including but not limited to the NuAccess Program, 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, (d) I will not sell or bill for any free product received in my office for patients from the Genentech Access to Care Foundation, Starter Programs or NuAccess Program and (e) I appoint Nutropin Access Solutions solely to convey on my behalf to the pharmacy chosen by the above-named patient the prescription prescribed herein. I agree to comply with the program guidelines as established by Genentech, Inc. and understand that the 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†_____
(Original or stamped signature required.)

*If applying for NuAccess, fax this completed form and supporting medical documentation to (866) 924-8584; for all other services, fax to (800) 545-0612. †Required field.
‡Benefits Investigation/Prior Authorization. §Genentech® Access to Care Foundation. ‖eg, NuAccess. ¶National Provider Identifier. #Provider Transaction Access Number.

INSTRUCTIONS: How to Complete the Statement of Medical Necessity (SMN) for Nutropin® [somatropin (rDNA origin) for injection] for the Pediatric Patient

Please write legibly and complete all required fields (†) 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.

SERVICES REQUESTED

☐ Check the appropriate services requested. Nutropin Access Solutions and/or GATCF cannot perform services without your specific authorization

INSURANCE INFORMATION

☐ If patient is insured, please provide a front and back copy of the insurance card (enlarged and legible) and fax this information with the SMN and PAN forms

DIAGNOSIS AND MEDICAL INFORMATION

☐ 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 report as appropriate):
Please note that Nutropin Access Solutions may request additional information from your office.

Isolated Growth Hormone Deficiency 253.3
- ☐ Two stim test results
- ☐ Growth chart (with at least two plots)
- ☐ Bone age
- ☐ History and physical (helpful)

Panhypopituitarism 253.2
- ☐ MRI
- ☐ 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)

Chronic Renal Insufficiency 585. ___
(Chronic Kidney Disease)
- ☐ Growth chart (with at least two plots)
- ☐ Renal function studies
- ☐ History and physical (helpful)
- ☐ Is patient on dialysis?
- ☐ Bone age

Turner Syndrome 758.6
- ☐ Growth chart (with at least two plots)
- ☐ Karyotype report
- ☐ 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

Please specify the 4th digit of the ICD-9 code for the Chronic Kidney Disease indication:

Stage 2: 585.2 **Stage 3:** 585.3 **Stage 4:** 585.4 **Stage 5:** 585.5 **End Stage:** 585.6

MEDICAL ASSESSMENT

☐ 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

SERVICES

☐ Nutropin Access Solutions or a specialty pharmacy will coordinate a home injection

NUACCESS

☐ If applying for NuAccess℠, affix authorization sticker and fax this completed form to (866) 924-8584

☐ NuAccess is for patients who have been prescribed NuSpin or Nutropin AQ Pen and Cartridge only

PRESCRIBER

☐ This form cannot be processed without an original or stamped signature

ATTACH TO COMPLETED SMN

☐ Attach a signed and dated Patient Authorization and Notice of Release of Information (PAN) form. Nutropin Access Solutions and/or GATCF cannot work with the insurance plan on your patient's behalf without a signed and dated PAN form

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

NutropinAccessSolutions.com
Phone: (866) NUTROPIN/(866) 688-7674 SMN Fax: (800) 545-0612

Nutropin®
[somatropin (rDNA origin) for injection]

Access Solutions™
Treatment made possible.

Genentech
A Member of the Roche Group

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