STATEMENT OF MEDICAL NECESSITY

PEDIATRIC GROWTH HORMONE TREATMENT

***= Required field** **SMN Fax: 800-545-0612** **Phone: 866-688-7674**

Nutropin AQ® NuSpin® (somatropin) injection, for subcutaneous use **Nutropin gps™**

PATIENT/INSURANCE INFORMATION

***Patient name** _____

***Date of birth** _____ ***Gender** ☐ **Male** ☐ **Female**

***Street address** _____

***City** _____ ***State** _____ ***Zip** _____

***Primary phone** _____ Alternate phone _____

Alternate contact name _____

Relationship to patient _____

***Is the patient insured?** ☐ **Yes** ☐ **No**
If yes, please attach front and back of insurance card, and pharmacy card if available.

***Prescription Type:**
- ☐ New to growth hormone
- ☐ Switch from alternative growth hormone
- ☐ Continue Nutropin AQ®
- ☐ _____ Conversion
  (Insurance name)

DIAGNOSIS

***Diagnosis:** *For CKD please use CKD-specific form*
- ☐ Hypopituitarism (Isolated GHD) (E23.0)
- ☐ Panhypopituitarism (E23.0)
- ☐ Drug-induced hypopituitarism (E23.1)
- ☐ Postprocedural hypopituitarism (E89.3)
- ☐ Hypothalamic dysfunction, not elsewhere classified (E23.3)
- ☐ Disorder of pituitary gland, unspecified (E23.7)

Turner Syndrome (Based on Karyotype):
- ☐ Q96.0 ☐ Q96.1 ☐ Q96.2 ☐ Q96.3 ☐ Q96.4 ☐ Q96.9
- ☐ Other variants of Turner Syndrome (Q96.8)
- ☐ Short stature (R62.52)
- ☐ Short stature due to endocrine disorder (E34.3)
- ☐ Other diagnosis/ICD-10 Code: _____ /_____

PRESCRIPTION

***Device/Product:**
- ☐ NuSpin® 20 (0.2 mg dosing increments)
- ☐ NuSpin® 10 (0.1 mg dosing increments)
- ☐ NuSpin® 5 (0.05 mg dosing increments)

Needles:
- ☐ BD Ultra-Fine™ III Short Pen Needle 31 g/8 mm (default if no needle is selected)
- ☐ BD Ultra-Fine™ 29 g/12.7 mm
- ☐ NovoFine® Pen Needle 30 g/8 mm
- ☐ NovoFine® Autocover® 30 g/8 mm
- ☐ Other: _____

Dose: _____ mg/inj
SubQ: _____ inj/week
Dispense: _____ month supply
Refill: x _____

SERVICES REQUESTED

☐ **PRIORITY REVIEW**
Complete the fields with *bold text only ***(see reverse/next page for requirements)***

☐ NuAccess℠ free goods program *(see reverse/next page for requirements)*

☐ All services below (or check services individually):
- ☐ Benefits investigation/prior authorization
- ☐ Appeals support
- ☐ Co-pay support
- ☐ Education kit
- ☐ Genentech® Access to Care Foundation patient assistance program
- ☐ Injection training/teach

Injection Training/Pharmacy
Injection training to be arranged by
☐ Office ☐ Nutropin GPS™ Case Manager

Preferred specialty pharmacy:
_____

MEDICAL ASSESSMENT

Attach applicable medical records:
- ☐ Growth chart
- ☐ History and physical

Thyroid test results normal? ☐ Yes ☐ No
Bone age: _____
Chronological age: _____
Epiphysis open? ☐ Yes ☐ No

Date patient last seen: _____/_____/_____
Height (cm): _____ Height (%): _____
Height SDS: _____
Weight (kg): _____ Weight (%): _____
Growth velocity: _____

☐ Other lab results to support diagnosis *(see reverse/next page for diagnosis-specific suggestions)*

GH stim test	GH stim test
Date: ____/____/____	____/____/____
Agent: _____	_____
Peak value: _____	_____

IGF-1: _____
IGFBP-3: _____

PRESCRIBER

***Prescriber's last name** _____
***Prescriber's first name** _____
***Address** _____
_____
***Fax** _____
Practice name _____

National Provider Identifier (NPI) _____
***Specialty** _____
State License Number (SLN) _____
Phone _____
Name of office contact _____
E-mail _____

PHYSICIAN CERTIFICATION: 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 authorizations, including those required by state law and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), to release the above-referenced information and other health and medical information of the patient to Genentech, Inc., its agents and the contracted dispensing pharmacy, for the purpose of requesting reimbursement support, assisting in initiating or continuing therapy and/or the evaluation of the patient's eligibility for GATCF, as a break in treatment would negatively impact the patient's therapeutic outcome; (d) I will not attempt to seek reimbursement for free product provided to the patient; and (e) I request Genentech, Inc., and its agents to convey 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. If applying for GATCF, I certify that (a) this patient has no medical insurance coverage or otherwise meets the financial criteria for the prescribed therapy, and is not eligible for other product financial support programs, and (b) the therapy identified above will not be used in a clinical trial. Note: Prescribers in all states must follow applicable law for a valid prescription and who is considered an authorized prescriber. For prescribers in states with official prescription form requirements, such as New York, please submit prescriptions on an official state prescription blank along with this form. Unapproved Use Warning: Please read the FDA-approved label for Genentech products before prescribing. If the indication for which you are prescribing is not listed in the FDA-approved label, you are prescribing the medication for an "unapproved" use, meaning that the FDA has not approved the efficacy, dosage amount or safety of this medication when used for such a use.

By signing below I request Lash to forward this Statement of Medical Necessity to a dispensing pharmacy on the behalf of my patient while ensuring that in doing so it remains unaltered.

***Prescriber's signature:** _____ ***Date:** _____/_____/_____
(Original or stamped signature required)

INSTRUCTIONS: How to complete the Statement of Medical Necessity for Nutropin AQ® (somatropin) injection, for subcutaneous use for the pediatric patient

PATIENT/INSURANCE INFORMATION
If attaching insurance information, please include cardholder name, employer, policy #, group #, and BIN # for the insurance and/or pharmacy benefit company. **If available, please attach the front and back of insurance cards and pharmacy cards.**

PRESCRIPTION
The following devices/products are available for Nutropin AQ.

Device/Product		Dosing Increments	NDC
NuSpin® 20		0.2 mg	50242-076-01
NuSpin® 10		0.1 mg	50242-074-01
NuSpin® 5		0.05 mg	50242-075-01

PRIORITY REVIEW
- Use Priority Review to determine if Nutropin AQ is available on formulary.
- For Priority Review, please complete the ***bolded** fields: patient name, date of birth, gender, street, city, state, ZIP, phone, prescription type, diagnosis, device, prescriber name, address, fax, specialty, prescriber signature, date. Check the "Priority Review" box and attach any insurance information.
- For a full benefits investigation, please complete all fields and indicate any services requested.

NuAccess℠
NuAccess℠ is a program providing medicine for patients for a limited time while their insurance coverage is being evaluated.

MEDICAL ASSESSMENT
- Please attach the requirements as suggested below.
- When possible, please provide lab results, height, weight, etc. by filling in the appropriate field/check box on the front of the SMN. If documentation is required, please only send what is requested or necessary per the criteria. Providing additional documents or information with this form may delay processing.
- Please use the Adult Statement of Medical Necessity for adults with childhood-onset GHD or panhypopituitarism.

	Hypopituitarism (Isolated GHD) E23.0	Panhypopituitarism E23.0	Drug-induced hypopituitarism E23.1 Postprocedural hypopituitarism E89.3	Turner syndrome Q96.0, Q96.1, Q96.2, Q96.3, Q96.4, Q96.8, Q96.9	Short stature R62.52	Short stature due to endocrine disorder E34.3
Growth Chart (at least 2 plots)	☐	☐	☐	☐	☐	☐
Bone Age	☐	☐	☐	☐	☐	☐
History and physical	☐	☐	☐	☐	☐	☐
MRI	☐	☐	☐			
IGF-1 and IGFBP-3	☐	☐	☐			
Two stim test results (peak value indicated)	☐					
Karyotype report				☐		
Predicted height					☐	
Pretreatment height/growth					☐	
List of hormonal deficiencies and/or replacements		☐				

If you have questions about insurance criteria, please ask Nutropin GPS™ to contact a Genentech reimbursement representative to discuss the criteria with your office representative.

Nutropingps.com Phone: 866-NUTROPIN 866-688-7674 SMN Fax: 800-545-0612