CKD

STATEMENT OF MEDICAL NECESSITY

PEDIATRIC NEPHROLOGY HORMONE TREATMENT

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

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

PATIENT/INSURANCE

*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: Chronic Kidney Disease (CKD)

- ☐ CKD, Stage II (Mild), (N18.2)
- ☐ CKD, Stage III (Moderate), (N18.3)
- ☐ CKD, Stage IV (Severe), (N18.4)
- ☐ CKD, Stage V (N18.5)
- ☐ End stage renal disease (N18.6)
- ☐ CKD, Unspecified (N18.9)

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 _____

†Recommended dose for CKD is 0.35 mg/kg/week divided into daily doses.

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
- ☐ GFR
- ☐ Creatinine

Thyroid test results normal?
☐ Yes ☐ No

Bone age: _____ Chronological age: _____

Epiphyses open?
☐ Yes ☐ No

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

Date patient last seen: ____/____/____

Height (cm): _____ Height (%): _____ Height SDS: _____

Weight (kg): _____ Weight (%): _____ Growth velocity: _____

Is patient on dialysis? ☐ Yes ☐ No
If yes, type:
- ☐ Hemodialysis ☐ Chronic Cycling Peritoneal Dialysis
- ☐ Chronic Ambulatory Peritoneal Dialysis

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 nephrology 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

DIALYSIS

In order to optimize therapy for patients who require dialysis, the following guidelines for injection schedule are recommended:

- Hemodialysis patients should receive their injection at night just prior to going to sleep or at least 3 to 4 hours after their hemodialysis.
- Chronic Cycling Peritoneal Dialysis (CCPD) patients should receive their injection in the morning after they have completed dialysis.
- Chronic Ambulatory Peritoneal Dialysis (CAPD) patients should receive their injection in the evening at the time of the overnight exchange.

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.

The following is a list of usual required clinical documentation:

- ☐ Growth chart
- ☐ Bone age
- ☐ History and physical
- ☐ Bilateral hip x-rays
- ☐ Renal function studies
- ☐ Thyroid levels (Undiagnosed/untreated hypothyroidism may prevent an optimal response to somatropin)

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

Nutropin AQ is indicated for the treatment of growth failure associated with CKD up to the time of renal transplantation. Nutropin AQ therapy should be used in conjunction with optimal management of CKD.

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.

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

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(somatropin) injection, for subcutaneous use