



STATEMENT OF MEDICAL NECESSITY
PEDIATRIC NEPHROLOGY HORMONE TREATMENT



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

PATIENT/INSURANCE	<p>*Patient name _____</p> <p>*Date of birth _____ *Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female</p> <p>*Street address _____</p> <p>*City _____ *State _____ *Zip _____</p> <p>*Primary phone _____ Alternate phone _____</p> <p>Alternate contact name _____</p> <p>Relationship to patient _____</p>	<p>*Is the patient insured? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please attach front and back of insurance card, and pharmacy card if available.</p> <p>*Prescription Type:</p> <p><input type="checkbox"/> New to growth hormone</p> <p><input type="checkbox"/> Switch from alternative growth hormone</p> <p><input type="checkbox"/> Continue Nutropin AQ®</p> <p><input type="checkbox"/> _____ Conversion <small>(Insurance name)</small></p>
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DIAGNOSIS	<p>*Diagnosis: Chronic Kidney Disease (CKD)</p> <p><input type="checkbox"/> CKD, Stage II (Mild), (N18.2) <input type="checkbox"/> CKD, Stage IV (Severe), (N18.4) <input type="checkbox"/> End stage renal disease (N18.6)</p> <p><input type="checkbox"/> CKD, Stage III (Moderate), (N18.3) <input type="checkbox"/> CKD, Stage V (N18.5) <input type="checkbox"/> CKD, Unspecified (N18.9)</p>
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PRESCRIPTION	<p>*Device/Product:</p> <p><input type="checkbox"/> NuSpin® 20 (0.2 mg dosing increments)</p> <p><input type="checkbox"/> NuSpin® 10 (0.1 mg dosing increments)</p> <p><input type="checkbox"/> NuSpin® 5 (0.05 mg dosing increments)</p>	<p>Needles:</p> <p><input type="checkbox"/> BD Ultra-Fine™ III Short Pen Needle 31 g/8 mm (default if no needle is selected)</p> <p><input type="checkbox"/> BD Ultra-Fine™ 29 g/12.7 mm</p> <p><input type="checkbox"/> NovoFine® Pen Needle 30 g/8 mm</p> <p><input type="checkbox"/> NovoFine® Autocover® 30 g/8 mm</p> <p><input type="checkbox"/> Other: _____</p>	<p>Dose[†]: _____ mg/inj</p> <p>SubQ: _____ inj/week</p> <p>Dispense: _____ month supply</p> <p>Refill: x _____</p> <p>[†]Recommended dose for CKD is 0.35 mg/kg/week divided into daily doses.</p>
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SERVICES REQUESTED	<p><input type="checkbox"/> PRIORITY REVIEW Complete the fields with *bold text only (see reverse/next page for requirements)</p> <p><input type="checkbox"/> NuAccessSM free goods program (see reverse/next page for requirements)</p>	<p><input type="checkbox"/> All services below (or check services individually):</p> <p><input type="checkbox"/> Benefits investigation/prior authorization</p> <p><input type="checkbox"/> Appeals support</p> <p><input type="checkbox"/> Co-pay support</p> <p><input type="checkbox"/> Education kit</p> <p><input type="checkbox"/> Genentech® Access to Care Foundation patient assistance program</p> <p><input type="checkbox"/> Injection training/teach</p>	<p>Injection Training/Pharmacy</p> <p>Injection training to be arranged by:</p> <p><input type="checkbox"/> Office <input type="checkbox"/> Nutropin GPS™ Case Manager</p> <p>Training to be performed at:</p> <p><input type="checkbox"/> MD Office</p> <p><input type="checkbox"/> Home (default if site not selected)</p> <p>Preferred specialty pharmacy: _____</p>
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MEDICAL ASSESSMENT	<p>Attach applicable medical records:</p> <p><input type="checkbox"/> Growth chart</p> <p><input type="checkbox"/> History and physical</p> <p><input type="checkbox"/> GFR</p> <p><input type="checkbox"/> Creatinine</p> <p>Thyroid test results normal?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Bone age: _____ Chronological age: _____</p> <p>Epiphyses open?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p><input type="checkbox"/> Other lab results to support diagnosis (see reverse /next page for diagnosis-specific suggestions)</p> <p>Date patient last seen: _____ / _____ / _____</p> <p>Height (cm): _____ Height (%): _____ Height SDS: _____</p> <p>Weight (kg): _____ Weight (%): _____ Growth velocity: _____</p> <p>Is patient on dialysis? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, type:</p> <p><input type="checkbox"/> Hemodialysis <input type="checkbox"/> Chronic Cycling Peritoneal Dialysis</p> <p><input type="checkbox"/> Chronic Ambulatory Peritoneal Dialysis</p>
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PRESCRIBER	<p>*Prescriber's last name _____</p> <p>*Prescriber's first name _____</p> <p>*Address _____</p> <p>*Fax _____</p> <p>Practice name _____</p>	<p>National Provider Identifier (NPI) _____</p> <p>*Specialty _____</p> <p>State License Number (SLN) _____</p> <p>Phone _____</p> <p>Name of office contact _____</p> <p>E-mail _____</p>
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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.

NuAccessSM

NuAccess is a program providing medicine for pediatric patients while their insurance coverage is being evaluated.

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

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Nutropin GPS is a trademark and NuAccess is a service mark of Genentech, Inc.
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