



## **Human Growth Hormone Prescriber Certification**

CuraScript is dedicated to providing best-in-class client service that ensures a superior level of knowledge and understanding of your unique specialty pharmacy needs. In our ongoing effort to provide your members with the best in specialty pharmacy care, following is information on our HGH specific policy designed to protect against the misuse of drugs that will continue to ensure our compliance with Federal law.

*Federal law, 21 U.S.C. § 333(e), provides controls and restrictions that limit the distribution and possession of human growth hormone (HGH) to the treatment of only those diseases or other recognized medical conditions for which human growth hormone has been approved by the U.S. Food and Drug Administration (FDA).*

In order to comply with this statute, CuraScript requires that documentation be on file for each patient that certifies for each physician that the Human Growth Hormone product is being prescribed for an FDA approved indication before Human Growth Hormone (HGH) prescriptions can be dispensed. If we cannot obtain this information we will not be able to fill the prescription.

To ensure your members' prescriptions are in compliance, CuraScript Specialty Pharmacy contacts the prescribing physician to obtain specific documentation that documents a prescribers certification to an approved FDA indication for the prescribed HGH product. CuraScript makes every attempt to avoid delays for your members however our ability to release an order is dependent on the responsiveness of the prescribing physician. Once received, the form is imaged in the patients' profile. We will only need a new form if the drug, prescriber, or approved indication changes.

Below you will find a FAQ document which will help answer some of the questions you may have. If you have additional questions or concerns please reach out to your account team for assistance.

**CuraScript Specialty Pharmacy**  
**Human Growth Hormone (HGH) Verification and Certification FAQ**

**Q. Why does CuraScript require the HGH Certification Letter?**

**A.** To comply with Federal Regulation 21 USC section 333 (e) (1), CuraScript Specialty Pharmacy has instituted a procedure for the certification of approved indication for dispensing of Human Growth Hormone Product.

**Q. What are some unapproved uses?**

**A.** CuraScript will not dispense HGH products for any unapproved use such as performance enhancement, anti-aging, cosmetic purposes or off label use.

**Q. Is this just related to CuraScript specifically or across all vendors of HGH products?**

**A.** The statute, 21 CFR USC § 333 (e) applies to all prescribers and dispensers of HGH. CuraScript has implemented the system described herein to assure compliance with 21 USC § 333 (e). It is possible that other dispensers have implemented a different system for compliance or will not implement any compliance system at all.

**Q. When is a HGH Certification Letter required?**

**A.** Certification letters are required for all new HGH patients. This includes new patients coming on service with CuraScript and existing patients where the drug or the prescriber changes. If a patient is on multiple HGH therapies and/or multiple prescribers, CuraScript must obtain a certification letter from each prescriber.

**Q. What medications when prescribed will require the HGH Certification Letter?**

**A.** Humatrope, Nutropin, Genotropin, Nordiflex, Saizen, Norditropin, Increlex, Serostim, Tev-Tropin, Omnitrope, Zorbtive, Protropin, Egrifta

**Q. Does CuraScript accept any other documentation in place of the HGH Certification Letter?**

**A.** Only approved Statements of Medical Necessity (SMN) from the manufacturer, manufacturer HUBs can be used for certification purposes. Your Account Manager can provide the most current list of approved forms.

**Q. Who completes the HGH Certification Letter?**

**A.** Forms must be signed by the prescriber. A stamped signature is not valid. Mid level practitioners, such as Nurse Practitioners or Physician Assistants registered under the prescriber of the growth hormone product can sign the form as well if they are permitted to by their corresponding state law.

**Q. How often does CuraScript renew the HGH Certification Letter?**

**A.** Once the HGH Certification Letter is obtained no further prescriber certification is required unless any of the following change: the prescriber, the HGH product, or the approved indication.

**Q. What is CuraScript's process for obtaining the HGH Certification Letter?**

**A.** Upon receiving a referral/order for a HGH medication CuraScript reviews the patient's profile for a valid HGH Certification Letter or a approved Statement of Medical Necessity (SMN). If no SMN or HGH

Certification Letter is on file CuraScript will initiate a request to the prescriber to complete for HGH Certification Letter. Once the completed and signed letter is received it is attached onto the patient's profile for future reference.

**Q. How does CuraScript request the HGH Certification Letter from the prescriber?**

**A.** There are two options for obtaining the HGH Certification Letter. We will fax a CuraScript SP Approved Indication for HGH Form (attachment 1 below) or we will obtain a verbal using the Verbal Certification for Approved Indication of HGH Form (attachment 2 below).

**Q. What information must be obtained for HGH Certification approval?**

**A.** ICD 9 Code, Name of physician, Name of Medication, Signature of Prescribing Physician. If any of this information is missing from the HGH Certification Letter CuraScript cannot release the patient's order until it is received.

**Q. What happens if the prescriber does not complete the HGH Certification Letter?**

**A.** CuraScript cannot release the patient's order until the HGH Certification Letter is received.

**Attachment 1**

**Prescriber Certification for Human Growth Hormone Indication**

Patient Name (Last, First): \_\_\_\_\_ Date of Birth \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_ Gender: M \_\_\_\_\_ F \_\_\_\_\_

Home Phone: \_\_\_\_\_ Cell Phone: \_\_\_\_\_

Human Growth Hormone Medication Prescribed: \_\_\_\_\_

**CuraScript Specialty Pharmacy does not dispense human growth hormone for anti-aging, cosmetic or performance enhancement purposes, pursuant to 21 U.S.C. § 333 (e)(1), which limits usage only to the treatment of disease or other recognized medical conditions authorized by the Secretary of Health and Human Services.**

**Diagnosis (Please check appropriate line):**

042 Human Immunodeficiency Syndrome _____	593.9 Chronic Renal Insufficiency _____
194.3 Pituitary Gland and Craniopharyngeal duct (pouch) _____	756.59 Other Congenital Osteodystrophies (SHOX deficiency) _____
227.3 Pituitary Gland and Craniopharyngeal duct (pouch) _____	758.60 Turner Syndrome _____
253.2 Panyhypopituitarism _____	759.81 Prader-Willi Syndrome _____
253.3 Isolated Growth Hormone Deficiency _____	764.0 Light-for-Dates weight NOS _____
253.4 Other Anterior Pituitary Disorders _____	764.04 Light-for-Dates 1000-1249G _____
253.7 Iatrogenic Pituitary Disorders _____	764.06 Light-for-Dates 1500-1749G _____
253.8 Other Disorders of the Pituitary _____	764.08 Light-for-Dates 2000-2499G _____
253.9 Unspecified Dyspituitarism _____	764.9 Fetal Growth Retardation, Unspecified _____
259.4 Dwarfism NOS, excludes pituitary _____	783.40 Lack of Expected Normal Physiological Development in Childhood _____
259.9 Unspecified Endocrine Disorder _____	783.41 Failure to Thrive _____
579.3 Short Bowel Syndrome _____	783.43 Short Stature/Growth Failure (SHOX deficiency) _____
582.0-9 Chronic Glomerulonephritis _____	799.4 Cachexia _____
585 Chronic Renal Failure _____	

**Prescriber Certification:**

**I certify that this medication is not being prescribed for anti-aging, cosmetic, or athletic performance. I further certify human growth hormone is being prescribed for the medical condition noted above and is medically necessary.**

Prescriber Signature \_\_\_\_\_ Date \_\_\_\_\_

Print Prescriber Name \_\_\_\_\_

Address \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

**Please fax completed form to CuraScript Specialty Pharmacy 800-451-5905**

Pharmacy Use Only:

Reviewed and Approved: \_\_\_\_\_ RPh Rx# \_\_\_\_\_ Date \_\_\_\_\_

**Prescriber Certification Review**

Patient Name (Last, First): \_\_\_\_\_

***Pharmacy Use Only:***

Reviewed and Approved \_\_\_\_\_ RPh Rx# \_\_\_\_\_ Date \_\_\_\_\_

Reviewed and Approved \_\_\_\_\_ RPh Rx# \_\_\_\_\_ Date \_\_\_\_\_

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Reviewed and Approved \_\_\_\_\_ RPh Rx# \_\_\_\_\_ Date \_\_\_\_\_

**Attachment 2**

**CuraScript SP Telephone Documentation of Approved Indication for Human Growth Hormone:**

Dear Dr.XXXXXX,

I am calling about patient \_\_\_\_\_ prescription for \_\_\_\_\_ (human growth hormone drug product). Federal law (21 U.S.C. § 333 (e) (1)) limits distribution of growth hormone to the treatment of disease or other recognized medical conditions approved by the FDA. Accordingly, CuraScript Specialty Pharmacy will not dispense human growth hormone for anti-aging, cosmetic or performance enhancement purposes, or for any other use (medical or non-medical) that has not been approved by the FDA.

The purpose of this call is obtain your certification that the prescription is for an FDA-approved indication, is medically necessary, and is not being prescribed for anti-aging, cosmetic or athletic performance purposes. (1) Please state the patient's medical condition. (Make sure the indication is listed below and mark the appropriate line with an "X".) (2) Is the prescription medically necessary to treat this condition? YES \_\_\_ or NO \_\_\_. (3) Is this prescription for anti-aging, cosmetic, or athletic enhancement purposes? YES \_\_\_ or NO \_\_\_. Thank you.

042 Human Immunodeficiency Syndrome _____	593.9 Chronic Renal Insufficiency _____
194.3 Pituitary Gland and Craniopharyngeal duct (pouch) _____	756.59 Other Congenital Osteodystrophies (SHOX deficiency) _____
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582.0-9 Chronic Glomerulonephritis _____	799.4 Cachexia _____
585 Chronic Renal Failure _____	

Date: \_\_\_\_\_ Time of Phone Call: \_\_\_\_\_ R.Ph. Name \_\_\_\_\_

Dr. Name \_\_\_\_\_ Patient Name \_\_\_\_\_

Drug Name \_\_\_\_\_ Dose and Regimen \_\_\_\_\_

**Standard Documentation Note:**

*Pharmacist Documentation Note to be placed in CuraScript system after the pharmacist verifies the HGH Medical Necessity Form or the Telephone HGH Form for each and every new and refill prescriptions for human growth hormone.*

I herby certify that I have personally reviewed and verified that: (1) a HGH certification form (manufacturer, CuraScript fax, or CuraScript phone) is on file; (2) the form states an approved FDA indication for Human Growth Hormone; (3) the form bears the signature of the prescriber (or pharmacist receiving the prescriber's authorization); (4) the patient's

name and the drug product match the prescription being filled or refilled; and (5) the regimen of the HGH prescription being filled or refilled is consistent with the designated FDA approved indication.

Dr. Name: \_\_\_\_\_ Patient Name: \_\_\_\_\_

Drug Product: \_\_\_\_\_ Dose: \_\_\_\_\_ Regimen: \_\_\_\_\_

Approved Indication: \_\_\_\_\_ Prescription #: \_\_\_\_\_

Pharmacist Name: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_