Growth Hormone

HMSACOM - PriorAuthorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-237-5512**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Patient's Phone Number: _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Additional Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*ft* _____*inches*

Indicate where the drug is being dispensed:

❑ Office ❑ Outpatient Hospital ❑ Ambulatory Surgical ❑ Inpatient Hospital
❑ Off Campus Outpatient Hospital ❑ Urgent Care ❑ Emergency Room ❑ Birthing Center
❑ Military Facility ❑ Skilled Nursing Facility ❑ Nursing Facility ❑ Hospice
❑ Inpatient Psychiatric ❑ Psychiatric Residential Treatment ❑ End Stage Renal Facility
❑ Psychiatric Facility ❑ Pharmacy ❑ Other

Indicate where the drug is being administered:

❑ Ambulatory surgical ❑ Home ❑ Inpatient Hospital
❑ Office ❑ Outpatient Hospital ❑ Pharmacy

What is the ICD-10 code? _____

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

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Criteria Questions:

1. What is the prescribed drug?

❒ Genotropin, *Continue to #2*

❒ Humatrope, *Continue to #100*

❒ Norditropin, *Continue to #100*

❒ Omnitrope, *Continue to #2*

❒ Saizen, *Continue to #2*

❒ Serostim, *Continue to #100*

❒ Zomacton, *Continue to #2*

❒ Zorbtive, *Continue to #2*

NON-PREFERRED EXCEPTIONS CRITERIA FOR APPROVAL

2. The preferred products for HMSA are Norditropin, Humatrope and Serostim. Can the patient's treatment be switched to one of the preferred products?

❒ Yes – Norditropin, *Continue to #100*

❒ Yes - Humatrope, *Continue to #100*

❒ Yes - Serostim, *Continue to #100*

❒ No, *Continue to #3*

3. What is the requested product?

❒ Genotropin, *Continue to #6*

❒ Omnitrope, *Continue to #6*

❒ Saizen, *Continue to #9*

❒ Zomacton, *Continue to #4*

❒ Zorbtive, *Continue to #5*

4. Is the diagnosis short stature homeobox-containing gene deficiency (SHOXD)?

❒ Yes, *Continue to #7*

❒ No, *Continue to #7*

5. Is the diagnosis short bowel syndrome (SBS)?

❒ Yes, *Continue to #100*

❒ No, *Continue to #100*

6. Is the diagnosis Prader-Willi syndrome (PWS)

❒ Yes, *Continue to #8*

❒ No, *Continue to #8*

7. Has the patient tried and experienced a documented inadequate response or intolerable adverse event to the preferred product, Humatrope? ***ACTION REQUIRED****: If yes, please submit supporting documentation*

❒ Yes, *Continue to #100*

❒ No, *Continue to #100*

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8. Has the patient tried and experienced a documented inadequate response or intolerable adverse event to the preferred product, Norditropin? ***ACTION REQUIRED:*** *If yes, please submit supporting documentation*

❒ Yes, *Continue to #100*

❒ No, *Continue to #100*

9. Has the patient tried and experienced a documented inadequate response or intolerable adverse event to the preferred products, Norditropin and Humatrope? ***ACTION REQUIRED****: If yes, please submit supporting documentation*

❒ Yes, *Continue to #100*

❒ No, *Continue to #100*

CRITERIA FOR APPROVAL

100. What is the diagnosis?

❒ Pediatric growth hormone (GH) deficiency, *Continue to #200*

❒ Idiopathic short stature (ISS), *Continue to #300*

❒ Small for gestational age (SGA), *Continue to #350*

❒ Turner syndrome (TS), *Continue to #400*

❒ Noonan syndrome (NS), *Continue to #400*

❒ Prader Willi syndrome (PWS), *Continue to #400*

❒ SHOX deficiency (SHOXD), *Continue to #400*

❒ Adult GH deficiency, *Continue to #700*

❒ HIV-associated wasting/cachexia, *Continue to #800*

❒ Short bowel syndrome (SBS), *Continue to #900*

❒ Treatment of extensive burns, *Continue to #950*

❒ Other, *Continue to #102*

102. Is the requested drug being prescribed for in-vitro fertilization use?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

INITIAL CRITERIA

Pediatric GH Deficiency

200. Is this request for a new start, restart (re-initiation), or continuation of GH therapy?
❒ New start, *Continue to #202*
❒ Restart, *Continue to #202*
❒ Continuation, *Continue to #201*

201. Was GH therapy previously authorized by HMSA/CVS for this member?
❒ Yes, *Continue to #600*
❒ No, *Continue to #202*
❒ Unknown, *Continue to #202*

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202. Did the member have a GH response of < 10 ng/mL (or otherwise abnormal as determined by the lab) to at least 2 GH stimulation tests? ***ACTION REQUIRED***: *Please submit results of GH stim tests.*
❒ Yes, *Continue to #209*
❒ No, *Continue to #203*

203. Did the member have a GH response of < 10 ng/mL to at least one GH stimulation test? ***ACTION REQUIRED****: Please submit results of GH stim tests.*
❒ Yes, *Continue to #204*
❒ No, *Continue to #205*

204. Does the member have a defined CNS pathology, history of cranial irradiation or a genetic condition associated with GH deficiency?
❒ Yes, *Continue to #209*
❒ No, *Continue to #206*

205. Did the member have a GH response of < 15 ng/mL to at least one GH stimulation test? ***ACTION REQUIRED:*** *Please submit results of GH stim tests.*
❒ Yes, *Continue to #206*
❒ No, *Continue to #207*

206. Does the member have both IGF-1 and IGFBP-3 levels below normal for age and gender? ***ACTION REQUIRED****: Please submit lab results.*
❒ Yes, *Continue to #209*
❒ No, *Continue to #207*

207. Does the member have 2 or more documented pituitary hormone deficiencies other than GH?
❒ Yes, *Continue to #209*
❒ No, *Continue to #208*

208. Did the member have an abnormally low GH level in association with neonatal hypoglycemia? ***ACTION REQUIRED:*** *Please submit lab results.*
❒ Yes, *Continue to #209*
❒ No, *Continue to #209*

209. Is the member's pretreatment height ≥ 2 SD below the mean for age and gender? ***ACTION REQUIRED****: Please submit growth chart.*
❒ Yes, *Continue to #213*
❒ No, *Continue to #210*

210. Is the member's pretreatment height ≥ 1 SD below the mean for age and gender? ***ACTION REQUIRED:*** *Please submit growth chart.*
❒ No, *Continue to #211*
❒ No, *Continue to #211*

211. Is the member's pretreatment growth velocity >1 SD below the mean for age and gender?
❒ Yes, *Continue to #212*
❒ No, *Continue to #212*

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212. Collection of growth data showing a consistent growth pattern is required for authorization. Will either of the following be submitted by the prescriber?

- At least 2 heights measured by an endocrinologist at least 6 months apart (data for a minimum of 1 yr)
- At least 4 heights measured by a primary care physician at least 6 months apart (data for a minimum

❒ Yes, *Continue to #213*
❒ No, *Continue to #213*

213. What is the member's age? _____ years, *Continue to #214*

214. Are the growth plates open? ***ACTION REQUIRED:*** *Please submit supporting documentation.*
❒ No, *Continue to #215*
❒ No, *Continue to #215*

215. Is this request for a new start, restart (re-initiation), or continuation of GH therapy?
❒ New start, *No Further Questions*
❒ Restart, *Continue to #601*
❒ Continuation, *Continue to #600*

Idiopathic Short Stature (ISS)

300. Is this request for a new start, restart (re-initiation), or continuation of GH therapy?
❒ New start, *Continue to #302*
❒ Restart, *Continue to #302*
❒ Continuation, *Continue to #301*

301. Was GH therapy previously authorized by HMSA/CVS for this member?
❒ Yes, *Continue to #600*
❒ No, *Continue to #302*
❒ Unknown, *Continue to #302*

302. Is the member's pretreatment height > 2.25 SD below the mean? ***ACTION REQUIRED:*** *Please submit growth chart.*
❒ Yes, *Continue to #303*
❒ No, *Continue to #303*

303. Has pediatric growth hormone (GH) deficiency been ruled out with a provocative GH test (peak GH level > 10ng/mL)?
❒ No, *Continue to #304*
❒ No, *Continue to #304*

304. Does the patient have a predicted adult height listed below?

- Less than 5'3" for boys
- Less than 4'11" for girls

❒ Yes, *Continue to #305*
❒ No, *Continue to #305*

305. Are the epiphyses open?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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Small for Gestational Age

350. s this request for a new start, restart (re-initiation), or continuation of GH therapy?

❒ New Start, *Continue to #352*

❒ Restart, *Continue to #352*

❒ Continuation, *Continue to #351*

351. Was GH therapy previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #600*

❒ No, *Continue to #352*

❒ Unknown, *Continue to #352*

352. Is the patient >2 years of age?

❒ Yes, *Continue to #353*

❒ No, *Continue to #353*

353. Does the patient meet at least one of the following?

- Birth weight < 2500 g at gestational age > 37 weeks
- Birth weight or length less than 3rd percentile for gestational age
- Birth weight or length ≥ 2 SD below the mean for gestational age

❒ Yes, *Continue to #354*

❒ No, *Continue to #354*

354. Has the patient failed to manifest catch-up growth by the age of 2 years old (i.e., pretreatment height >2 SD below the mean)?

❒ Yes, *Continue to #355*

❒ No, *Continue to #355*

355. Are the epiphyses open?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Turner Syndrome, Noonan Syndrome, Prader Willi Syndrome, and SHOX Deficiency

400. Is this request for a new start, restart (re-initiation), or continuation of GH therapy?

❒ New start, *Continue to #402*

❒ Restart, *Continue to #402*

❒ Continuation, *Continue to #401*

401. Was GH therapy previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #600*

❒ No, *Continue to #402*

❒ Unknown, *Continue to #402*

402. Is the member's pretreatment height below the 10th percentile for age? ***ACTION REQUIRED:*** *Please submit supporting documentation.*

❒ Yes, *Continue to #403*

❒ No, *Continue to #403*

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403. What is the member's age? _____ years, *Continue to #404*

404. Are the growth plates open? ***ACTION REQUIRED:*** *Please submit supporting documentation.*
❒ Yes, *Continue to #405*
❒ No, *Continue to #405*

405. Is this request for a new start, restart (re-initiation), or continuation of GH therapy?
❒ New start, *No Further Questions*
❒ Restart, *Continue to #601*
❒ Continuation, *Continue to #601*

Continuation Criteria

Pediatric GH Deficiency, ISS, SGA, Turner Syndrome, Noonan Syndrome, Prader Willi Syndrome, SHOX Deficiency

600. Is the member's growth velocity ≥ 2 cm per year while on GH therapy? ***ACTION REQUIRED:*** *Please submit supporting documentation.*
❒ Yes, *Continue to #601*
❒ No, *Continue to #601*

601. What is the member's age? _____ years, *Continue to #602*

602. Are the growth plates open?
❒ Yes, *Continue to #603*
❒ No, *Continue to #603*

603. Is the member's current height less than 59 inches (4'11") for a girl or less than 65 inches (5'5") for a boy (ie, less than 5th percentile of normal adult height for gender)? ***ACTION REQUIRED****: Please submit supporting documentation.*
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

ADULT GH DEFICIENCY

700. Is this request for a new start or continuation of GH therapy?
❒ New start, *Continue to #702*
❒ Continuation, *Continue to #701*

701. Was GH therapy previously authorized by HMSA/CVS for this member?
❒ Yes, *No Further Questions*
❒ No, *Continue to #702*
❒ Unknown, *Continue to #702*

702. Does the patient have a low pre-treatment IGF-1 (between 0 to 2 standard deviations below the mean)? ***ACTION REQUIRED:*** *If 'Yes', collect laboratory report or medical record of pretreatment IGF-1 level*

❒ Yes, *Continue to #703*

❒ No, *Continue to # 718*

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703. Has the patient had at least 2 pre-treatment pharmacologic provocative growth hormone (GH) tests or a pre-treatment test with the agent Macrilen? ***ACTION REQUIRED:*** *If 'Yes', collect and attach laboratory report or medical record of pre-treatment provocative test results*

❒ Yes, *Continue to #704*

❒ No, *Continue to #718*

704. What was the first agent used?

❒ Insulin tolerance test, *Continue to #705*

❒ Glucagon stimulation test, *Continue to #707*

❒ Macrilen test, *Continue to #706*

❒ None of the above, *Continue to #728*

705. What was the peak growth hormone (GH) level of the insulin tolerance test?

❒ Less than or equal to 5 ng/mL, *Continue to #711*

❒ Greater than 5 ng/mL, *Continue to #728*

706. What was the peak growth hormone (GH) level of the Macrilen test?

❒ Less than or equal to 2.8 ng/mL, *Continue to #711*

❒ Greater than 2.8 ng/mL, *Continue to # 728*

707. What is the patient's body mass index (BMI)?

❒ Less than 25 kg/m2, *Continue to #709*

❒ Greater than or equal to 25 kg/m2 but less than or equal to 30 kg/m2, *Continue to #708*

❒ Greater than 30 kg/m2, *Continue to #710*

708. Does the patient have a high pre-test probability of growth hormone deficiency (e.g., patient has acquired structural abnormalities)?

❒ Yes, *Continue to #709*

❒ No, *Continue to #710*

709. What was the peak growth hormone level with the glucagon stimulation test?

❒ Less than or equal to 3.0 ng/mL, *Continue to #711*

❒ Greater than 3.0 ng/mL, *Continue to # 728*

710. What was the peak growth hormone level with the glucagon stimulation test?

❒ Less than or equal to 1.0 ng/mL, *Continue to #711*

❒ Greater than 1.0 ng/mL, *Continue to # 727*

711. What was the second agent used?

❒ Insulin tolerance test, *Continue to #712*

❒ Glucagon stimulation test, *Continue to #714*

❒ Macrilen test, *Continue to #713*

❒ None of the above, *Continue to #727*

712. What was the peak growth hormone (GH) level of the insulin tolerance test?

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❒ Less than or equal to 5 ng/mL, *Continue to #727*

❒ Greater than 5 ng/mL, *Continue to #728*

713. What was the peak growth hormone (GH) level of the Macrilen test?

❒ Less than or equal to 2.8 ng/mL, *Continue to #727*

❒ Greater than 2.8 ng/mL, *Continue to # 728*

714. What is the patient's body mass index (BMI)?

❒ Less than 25 kg/m2, *Continue to #716*

❒ Greater than or equal to 25 kg/m2 but less than or equal to 30 kg/m2, *Continue to #715*

❒ Greater than 30 kg/m2, *Continue to #717*

715. Does the patient have a high pre-test probability (e.g., acquired structural abnormalities) of growth hormone deficiency?

❒ Yes, *Continue to #716*

❒ No, *Continue to #717*

716. What was the peak growth hormone level with the glucagon stimulation test?

❒ Less than or equal to 3.0 ng/mL, *Continue to #727*

❒ Greater than 3.0 ng/mL, *Continue to # 728*

717. What was the peak growth hormone level with the glucagon stimulation test?

❒ Less than or equal to 1.0 ng/mL, *Continue to #727*

❒ Greater than 1.0 ng/mL, *Continue to # 728*

718. Does the patient have a pretreatment insulin-like growth factor-1 (IGF-1) more than 2 standard deviations below the mean? ***Action Required***: *If 'Yes', collect laboratory report or medical record of pretreatment IGF-1 level*

❒ Yes, *Continue to #719*

❒ No, *Continue to #728*

719. Has the patient had at least 1 pre-treatment pharmacologic provocative growth hormone (GH) test or a pre-treatment test with the agent Macrilen? ***ACTION REQUIRED***: *If 'Yes', collect and attach laboratory report or medical record of pre-treatment provocative test results*

❒ Yes, *Continue to #720*

❒ No, *Continue to #728*

720. What was the agent used?

❒ Insulin tolerance test, *Continue to #721*

❒ Glucagon stimulation test, *Continue to #723*

❒ Macrilen test, *Continue to #722*

❒ None of the above, *Continue to #728*

721. What was the peak growth hormone (GH) level of the insulin tolerance test?

❒ Less than or equal to 5 ng/mL, *Continue to #727*

❒ Greater than 5 ng/mL, *Continue to #728*

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722. What was the peak growth hormone (GH) level of the Macrilen test?

❒ Less than or equal to 2.8 ng/mL, *Continue to #727*

❒ Greater than 2.8 ng/mL, *Continue to # 728*

723. What is the patient's body mass index (BMI)?

❒ Less than 25 kg/m2, *Continue to #725*

❒ Greater than or equal to 25 kg/m2 but less than or equal to 30 kg/m2, *Continue to #724*

❒ Greater than 30 kg/m2, *Continue to #726*

724. Does the patient have a high pre-test probability (e.g., acquired structural abnormalities) of growth hormone deficiency?

❒ Yes, *Continue to #725*

❒ No, *Continue to #726*

725. What was the peak growth hormone level with the glucagon stimulation test?

❒ Less than or equal to 3.0 ng/mL, *Continue to #727*

❒ Greater than 3.0 ng/mL, *Continue to # 728*

726. What was the peak growth hormone level with the glucagon stimulation test?

❒ Less than or equal to 1.0 ng/mL, *Continue to #727*

❒ Greater than 1.0 ng/mL, *Continue to # 728*

727. Are the laboratory reports of the pretreatment provocative tests for growth hormone (GH) and pretreatment insulin-like growth factor-1 (IGF-1) levels attached, if applicable?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

728. Does the patient have organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation)?

❒ Yes, *Continue to #729*

❒ No, *Continue to #732*

729. Does the patient have documented deficiencies of three or more pituitary hormones?

❒ Yes, *Continue to #730*

❒ No, *Continue to # 732*

730. Please indicate the deficient pituitary hormones

❒ Growth hormone, *Continue to #731*

❒ Adrenocorticotropic hormone (ACTH), *Continue to #731*

❒ Antidiuretic hormone (ADH), *Continue to #731*

❒ Follicle stimulating hormone (FSH), *Continue to #731*

❒ Luteinizing hormone (LH), *Continue to #731*

❒ Thyroid stimulating hormone (TSH), *Continue to #731*

❒ Prolactin, *Continue to #731*

❒ None of the above, *Continue to # 732*

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731. Does the patient have a pretreatment insulin-like growth factor-1 (IGF-1) more than 2 standard deviations below the mean for age and gender? ***ACTION REQUIRED****: If 'Yes', collect laboratory report or medical record of pretreatment IGF-1 level*

❒ Yes, *No Further Questions*

❒ No, *Continue to # 732*

732. Does the patient have a genetic or structural hypothalamic-pituitary defect (e.g., transcription factor defects, GHRH receptor-gene defects, GH-receptor/post-receptor defects, GH-gene defects associated with brain structural defects, single central incisor, cleft lip/palate)?

❒ Yes, *No Further Questions*

❒ No, *Continue to # 733*

733. Does the patient have childhood-onset growth hormone deficiency (GHD)?

❒ Yes, *Continue to #734*

❒ No, *Continue to #734*

734. Does the patient have a congenital abnormality of the CNS, hypothalamus, or pituitary gland?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

HUMAN IMMUNODEFICIENCY VIRUS (HIV)-ASSOCIATED WASTING/CACHEXIA

800. Is the patient currently on antiretroviral therapy?

❒ Yes, *Continue to #801*

❒ No, *Continue to #801*

801. Is this a request for new start or continuation of therapy?

❒ New start, *Continue to #804*

❒ Continuation, *Continue to #802*

802. Was GH therapy previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #803*

❒ No, *Continue to #804*

❒ Unknown, *Continue to #804*

803. Is the patient's current body mass index (BMI) less than 27 kg/m2?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

804. Has the patient trialed and experienced a suboptimal response to alternative therapies (e.g., cyproheptadine, dronabinol, megestrol acetate or testosterone if hypogonadal)?

❒ Yes, *Continue to #806*

❒ No, *Continue to #805*

805. Does the patient have a history of intolerance or contraindication ot alternative therapies?

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❒ Yes, *Continue to #806*

❒ No, *Continue to #806*

806. Is the patient currently on antiretroviral therapy?

❒ Yes, *Continue to #807*

❒ No, *Continue to #807*

807. Does/did the patient have a body mass index (BMI) less than 18.5 kg/m2 prior to initiating therapy with growth hormone?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

SHORT BOWEL SYNDROME

900. Is the patient dependent on intravenous parenteral nutrition for nutritional support?
❒ Yes, *Continue to #901*
❒ No, *Continue to #901*

901. Will GH be used in conjunction with optimal management of short bowel syndrome?
❒ No, *Continue to #902*
❒ No, *Continue to #902*

902. How many weeks of GH therapy has the member received? _____ weeks, *No Further Questions*

TREATMENT OF BURNS

950. Is GH prescribed for a member with extensive 3rd-degree burns?
❒ Yes, *Continue to #951*
❒ No, *Continue to #951*

951. Do the burns affect ≥ 40% of total body surface area?
❒ Yes, *Continue to #952*
❒ No, *Continue to #952*

952. Is this request for a new start or continuation of therapy?
❒ New start, *No Further Questions*
❒ Continuation, *Continue to #953*

953. Was GH therapy previously authorized by HMSA/CVS for this member?
❒ Yes, *No Further Questions*
❒ No, *Continue to #954*
❒ Unknown, *Continue to #954*

954. How many months of GH therapy has the member received? _____ months, *No Further Questions*

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Growth Hormone HMSA – 10/2024.