COVERAGE DETERMINATION REQUEST FORM

EOC ID:
Elixir Growth Hormone-10 STANDARD PA-ST

Phone: 800-361-4542 Fax back to: 866-414-3453

Elixir manages the pharmacy drug benefit for your patient. Certain requests for coverage require review with the prescribing physician. Please answer the following questions and fax this form to the number listed above. **Please note any information left blank or illegible may delay the review process.**

Patient Name:	**Prescriber Name:**	
Member/Subscriber Number:	Fax:	Phone:
Date of Birth:	Office Contact:	
Group Number:	NPI:	State Lic ID:
Address:	Address:	
City, State ZIP:	City, State ZIP:	
Primary Phone:	Specialty/facility name (if applicable):	

Please note that Elixir will process the request as written, including drug name, with no substitution.

☐ Expedited/Urgent

Drug Name and Strength:

Directions / SIG:

Please attach any pertinent medical history or information for this patient that may support approval. Please answer the following questions and sign.

Q1. Is this request for initial or continuing therapy?

☐ Initial therapy ☐ Continuing therapy

Q2. If the request is for CONTINUING THERAPY, please provide the start date (MM/YY):

Q3. Please indicate which medication is being requested:

☐ Humatrope
☐ Nutropin/Nutropin AQ
☐ Omnitrope
☐ Saizen
☐ Zomacton (Somatropin)
☐ Serostim
☐ Tev-Tropin
☐ Zorbtive
☐ Other

Q4. If medication is Other, please describe below:

Q5. Please indicate the patient's diagnosis below:

☐ Adult growth hormone deficiency
☐ Growth failure in chronic renal insufficiency (CKD)
☐ Growth hormone deficiency in children
☐ HIV associated wasting or cachexia
☐ Noonan syndrome
☐ Prader willi syndrome
☐ Short bowel syndrome
☐ Short-stature homeobox-containing gene (shox) deficiency
☐ Turner syndrome

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☐ Other

Q6. FOR ADULT GROWTH HORMONE DEFICIENCY, Does the prescriber attest that the patient had a negative response to 1 of the standard growth hormone stimulation tests listed below? Please check all that apply for this patient:

- ☐ Arginine-GHRH: peak GH is less than or equal to 11.0 micrograms/L
- ☐ Arginine-GHRH: peak GH is less than or equal to 8.0 micrograms/L
- ☐ Arginine-GHRH: peak GH is less than or equal to 4.0 micrograms/L
- ☐ Arginine-L-DOPA is < 1.5ng/ml
- ☐ Insulin - induced hypoglycemia is less than or equal to 5.0 micrograms/ml
- ☐ Glucagon is less than or equal to 3.0 ng/ml
- ☐ None of the above

Q7. FOR ADULT GROWTH HORMONE DEFICIENCY, Does the prescriber attest that the patient has any of the following pituitary hormone deficiencies? (please check all that apply):

- ☐ Adrenocorticotropin (ACTH) deficiency
- ☐ Arginine vasopressin (AVP) deficiency (central diabetes insipidus)
- ☐ Gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH])
- ☐ Macrilen (macimorelin)
- ☐ Thyroid stimulating hormone (TSH) deficiency
- ☐ None of the above

Q8. FOR ADULT GROWTH HORMONE DEFICIENCY, Does the prescriber attest that the patient's serum IGF-1 level is lower than the gender and age-specific lower limit of normal (< 2.5 percentile or < -2 SDS)?

☐ Yes ☐ No ☐ Unknown

Q9. FOR GROWTH FAILURE IN CHRONIC RENAL INSUFFICIENCY (CKD), Does the prescriber attest that the patient has not had a kidney transplant?

☐ Yes ☐ No ☐ Unknown

Q10. GROWTH HORMONE DEFICIENCY IN CHILDREN: Does the prescriber attest that growth hormone deficiency is defined by a diminished serum growth hormone response to stimulation testing of < 10 ng/ml for one of the following stimulation tests? Please indicate which tests were performed:

- ☐ levodopa
- ☐ insulin-induced hypoglycemia
- ☐ arginine
- ☐ clonidine
- ☐ glucagon
- ☐ None of the above

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Q11. GROWTH HORMONE DEFICIENCY IN CHILDREN, Does the prescriber attest that any of the following apply?

- ☐ The patients baseline height is less than the 3rd percentile for age and gender
- ☐ The patient is < 3 years of age and has a pretreatment growth rate of < 7 cm per year
- ☐ The patient is > 3 years of age and has a pretreatment growth rate of < 4 cm per year
- ☐ The patient is of any age with a growth velocity of < 10th percentile for age and gender (based on the last 6 months of data)
- ☐ None of the above

Q12. FOR HIV ASSOCIATED WASTING OR CACHEXIA, Does the prescriber attest that the following apply:

- ☐ Patient has a documented, unintentional weight loss defined as 10% weight loss from baseline
- ☐ Patient has a documented, unintentional weight loss defined as weight <90% of the lower limit of ideal body weight
- ☐ Patient has a documented, unintentional weight loss defined as BMI less than or equal to 20kg/m2
- ☐ Patient is able to consume or be fed through parenteral or enteral feedings for 75% or more of maintenance energy requirements based on current body weight
- ☐ Therapy will be limited to 24 weeks
- ☐ None of the above

Q13. FOR NOONAN'S SYNDROME, Does the prescriber attest that the patient's baseline height is < the 3rd percentile for age and gender (i.e., > 2 standard deviations [SD] below the mean for gender and age)?

☐ Yes ☐ No ☐ Unknown

Q14. FOR SHORT BOWEL SYNDROME, Does the prescriber attest that the following apply?

- ☐ Patient is receiving specialized nutritional support (defined as a high carbohydrate, low-fat diet that is adjusted for individual patient requirements and preferences)
- ☐ Therapy is limited to ONE 4-week course per year
- ☐ Patient is 18 years old or older
- ☐ None of the above

Q15. FOR SHOX deficiency, Does the prescriber attest that the diagnosis has been confirmed by chromosome analysis?

☐ Yes ☐ No

Q16. FOR TURNER SYNDROME, Does the prescriber attest that the diagnosis has been confirmed by chromosome analysis?

☐ Yes ☐ No

Q17. If the patient's diagnosis is OTHER, please specify below.

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Q18. Please select the current age of the patient:

- ☐ Less than 3 years of age
- ☐ 3- 17 years of age
- ☐ 18 years of age or older

Q19. Please indicate the patient's BMI:

- ☐ less than or equal to 20 kg/m2
- ☐ >20 kg/m2 to < 25 kg/m2
- ☐ 25 kg/m2 to < 30 kg/m2
- ☐ 30 kg/m2 to < 40 kg/m2
- ☐ 40 kg/m2 or greater

Q20. Please indicate the specialty of the prescribing physician:

☐ Endocrinologist ☐ Other

Q21. If the prescriber specialty is Other, please describe below:

Q22. Does the prescriber attest that the patient has an open-epiphyses?

☐ Yes ☐ No ☐ Not Applicable

Q23. Growth Hormones are excluded for use in the following situations. Please check all that apply to the patient:

- ☐ Acute critical illness
- ☐ Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment
- ☐ Active malignancy
- ☐ Active proliferative or severe non-proliferative diabetic retinopathy
- ☐ Children with closed epiphyses
- ☐ Used to improve functional status in elderly patients (antiaging)
- ☐ Used to enhance athletic ability
- ☐ Bone marrow transplantation without total body irradiation
- ☐ Patients with bony dysplasias (i.e., achondroplasia or hypochondroplasia)
- ☐ Use in children if burn injuries
- ☐ Use in central precocious puberty
- ☐ Use in chronic fatigue syndrome
- ☐ Use in congenital adrenal hyperplasia
- ☐ Use in Dilate cardiomyopathy and heart failure
- ☐ Use in Down's syndrome
- ☐ Use in ESRD in adults undergoing hemodialysis
- ☐ Use in Familial dysautonomia
- ☐ Use in fibromyalgia
- ☐ Use in HIV-associated adipose redistribution syndrome (HARS)
- ☐ Use in infertility
- ☐ Use in kidney or liver transplant patients
- ☐ Use in multiple system atrophy (MSA)
- ☐ Use in persons with myelomeningocele
- ☐ Use in obesity
- ☐ Use in osteogenesis imperfecta or osteoporosis
- ☐ Use in children with thalassemia
- ☐ Use in X-linked hypophosphatemic rickets
- ☐ None of the above

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☐ Use in corticosteroid-induced short stature
☐ Use in Crohn's disease
☐ Use in Cystic Fibrosis

Q24. Has the patient tried and failed any of the following? (please select all that apply):

☐ Genotropin ☐ Norditropin ☐ None of the above

Q25. If the patient has NOT tried any of the medications listed in the previous question, is there a reason these medications cannot be used (i.e. contraindication, history of adverse event, etc)?

Q26. FOR CONTINUING THERAPY (CHILDREN): Does the prescriber attest that the following apply?

☐ Growth rate has increased significantly (height velocity at least doubles by the end of the first year)
☐ The patients height velocity is 2.5 cm per year or greater
☐ None of the above

Q27. FOR CONTINUING THERAPY (ADULTS), Does the prescriber attest that the following apply?

☐ Patient has not reached the mid-parental height (Father's height + Mother's height/2 PLUS 2.5 inches for male or MINUS 2.5 inches for female)
☐ Goal of therapy is to reach middle of the normal range IGF-1 levels appropriate for the age and sex of the patient unless side effects are significant
☐ None of the above

Prescriber Signature

Date