Subject: **Growth Hormone (GH) Therapy***

Effective Date: **July 29, 2003**

Department(s): **Utilization Management**

Policy: Treatment with GH (**HCPCS J2941**) is reimbursable under Plans administered by QualCare, Inc. for the indications listed below.

Objective: To provide proper and consistent reimbursement for and to ensure appropriate utilization of a scarce and costly therapeutic agent.

Procedure:

I. A letter of medical necessity must document the presence of one of the following conditions:

A. Children and adolescents

1. Idiopathic GH deficiency (**ICD-9 253.3*;* ICD-10 E23.0**)with height less than the 3rd percentile for age and gender and growth velocity, tracked over at least one year, less than the 10th percentile for age and gender AND who have failed to respond to at least two standard GH stimulation tests (insulin, levodopa, arginine, propranolol, clonidine, or glucagon)

2. chronic renal insufficiency (**ICD-9 585.1- 585.5; ICD-10 N18.1- N18.5**) and growth retardation, prior to renal transplantation

3. Turner's syndrome (**ICD-9 758.6; ICD-10 Q96.0-Q96.9**) confirmed by genetic testing

4. Prader Willi syndrome (**ICD-9 759.81; ICD-10 Q87.1**)confirmed by genetic testing

5. Small for gestational age (**ICD-9 764.00 -764.09; ICD-10 P05.00- P05.18**) (weight or length ≥2 standard deviations below mean for gestational age with failure to manifest catch-up growth by age 2 years [height ≥2 standard deviations below mean for age and gender])

6. Short stature associated with Noonan Syndrome(**ICD-9 759.89; ICD-9 Q87.1**)

    a. Height ≥ 2 standard deviations below mean for gender and chronological age
    b. Growth–velocity in the year prior to beginning GH therapy that is ≥ 1 standard deviation below the mean for gender and chronological age, OR for children over 2 years of age, a decrease in growth velocity of more than 0.5 standard deviation measured over one year.

7. **Short Stature Homeobox-Containing** Gene (SHOX) Deficiency (**ICD-9 756.89; ICD-10 Q87.1**) if epiphyses are not yet closed.

8. A history of cranial or whole body radiation, with growth velocity deceleration and failure to respond to at least one standard GH stimulation tests (insulin, levodopa, arginine, propranolol, clonidine, or glucagon)(**ICD9- E926.3; ICD-10 W88.0XXs, W88.8XXS**)

B. Adults

1. Destructive lesions of or therapeutic destruction of the pituitary (**ICD-9 253.0-253.7*;* ICD-10 E22.0-E22.9, E23.0-E22.6, E34.4, E89.3**)who meet the following criteria:

    a. The patient is already receiving full supplementation of other deficient hormones (including but not limited to thyroid and adrenal hormones)

    b. There is written documentation of symptomatic GH deficiency AND at least one of the following:

        i. Severely decreased quality of life as assessed using the Adult Growth Hormone Deficiency Assessment or other validated similar tool

        ii. Bone mineral density 1 or more standard deviations below average for age and gender

        iii. Adverse cardiovascular risk profile (i.e., that would qualify for drug therapy)

        iv. Reduced exercise tolerance and cardiac de-compensation
        (NYHA Class II, III, or IV)

2. Idiopathic adult growth hormone deficiency (**ICD-9 253.3; ICD-10 E23.0**)
   when all of the following criteria are met:

    i. IGF-1 level below the lower limits of normal
    ii. Abnormal growth hormone response to two of the following provocative stimuli- insulin, arginine-GHRH, or glucagon
    iii. One of the criteria in section B1b above is met.

3. History of GH deficiency as children (**ICD-10 E23.6**)

AND

- continued manifestations of GH deficiency in adulthood, documented by lack of response to at least one standard GH stimulation test after stimulation with insulin, levodopa, arginine, propranolol, or glucagon

AND

- Symptomatic GH deficiency with at least one of the features under B.1.b.above.

4. AIDS-related wasting (**ICD-9 042, 799.4; ICD-10 B20, R64**) with **ALL** of the following:

- Documented CDC criteria meeting the definition of AIDS
- Weight loss of at least 10% from baseline or BMI <20 kg/m^2
- Exclusion of malnutrition, voluntary weight loss, psychiatric disease, endocrine disease or other definable cause of weight loss
- Failure of Megace or other appetite-stimulating drug or anabolic steroid
- Concomitant anti-retroviral therapy

II. Authorization will be reviewed at least annually to determine the continued medical necessity of GH therapy and to verify continued follow-up with the provider.

III. In children and adolescents, coverage of GH therapy will be discontinued if **ANY** of the following occurs:

- Increase in height velocity is <2 cm/year over 1 year of GH therapy

- Bone age is ≥14 years in girls or ≥16 years in boys

IV. GH therapy will not be covered for experimental, investigational, or unproven indications including but not limited to the following:

A. Age-related adult GH deficiency ("somatopause") (**ICD-9 259.8; ICD-10 E34.8,**)
B. Aging (**ICD-9 259.8; ICD-10 E34.8)** inhibition or retardation

C. Amphetamine-induced growth retardation (including but not limited to Ritalin, Adderall) (**ICD-9 969.72; ICD-10 T43.621A**)
D. Amyotrophic lateral sclerosis (**ICD-9 335.20; ICD-10 G12.21**)
E. Burn injuries (**ICD-9 942.0-942.09, 948.00-948.99, 949.0-949.5*;* ICD-10; T21.00XA-T21.09XA, T31.0-T31.99, T30.0**)
F. Chronic catabolic states, including but not limited to cardiac or pulmonary cachexia (**ICD-9 799.4; ICD-10 R64**), inflammatory bowel disease (**ICD-9 555.0-555.9; ICD-10 K50.00-K50.919**), and short-gut syndrome (**ICD-9 579.3; ICD-10 K91.2**)
G. Chronic fatigue syndrome (**ICD-9 780.71; ICD-10 R53.82**)
H. Constitutional delay of growth and development, including idiopathic or familial short stature (**ICD-9 783.43; ICD-10 R62.52**)
I. Corticosteroid-induced pituitary ablation (**ICD-9 253.7; ICD-10 E23.1**)
J. Cystic fibrosis (**ICD-9 277.00-277.09; ICD-10 E84.0-E84.9**)
K. Decreased libido (**ICD-9 799.81; ICD-10 R62.82**)
L. Depression (**ICD-9 296.20-296.99, 298.0-298.9; ICD-10 F30.10-F34.9**)
M. Down syndrome (**ICD-9 758.0; ICD-10 Q90.0-Q90.9**) or other syndromes associated with short stature that do not involve GH deficiency
N. Hypertension (**ICD-9 401.0-401.9; ICD-10 I10**)
O. Hypogonadism with onset in adulthood (**ICD-9 256.31, 256.39, 257.2; ICD-10 E28.310, E28.319, E28.39, E29.1**)

P. Hypophosphatemic rickets (**ICD-9 275.3; ICD-10 E83.30, E83.31, E83.39**)
Q. Infertility (**ICD-9 606.0-606.9, 628.0-628.9; ICD-10 N46.01-N46.9, N97.0-N97.9**)
R. Intrauterine growth retardation (**ICD-9 764.90-764.99*;* ICD-10 P05.00-P05.9**) or Russell-Silver syndrome
S. Juvenile rheumatoid arthritis (**ICD-9 714.30-714.33; ICD-10 M08.00-M08.80**)
T. Muscular dystrophy (**ICD-9 359.0-359.22; ICD-10 G71.0-G71.12**)
U. Obesity including morbid obesity (**ICD-9 278.00-278.02; ICD-10 E66.09-E66.9**)
V. Osteoporosis (**ICD-9 733.00 – 733.09; ICD-10 M81.0-M81.8**)
W. Post-traumatic stress disorder (**ICD-9 309.81; ICD-10 F43.10-F43.12**)
X. Precocious puberty (**ICD-9 259.1- ICD-10 E30.1, E30.8**)
Y. Skeletal dysplasias (including but not limited to achondroplasia (**ICD-9 756.4; ICD-10 Q77.0-QQ78.9**), osteogenesis imperfecta (**ICD-9 756.51**; **ICD-10 Q78.0*)***
Z. Spina bifida (**ICD-9 741.00-741.03; ICD-10 Q05.4, Q05.9**)

V. GH therapy will not be reimbursed when used to augment athletic training or to enhance linear growth solely to achieve a competitive height in an athlete.

VI. All requests for GH are subject to review by the Medical Director.

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*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.