Medical Coverage Policy

Self-Administered Human Growth Hormone

☐ Device/Equipment ☒ Drug ☐ Medical ☐ Surgery ☐ Test ☐ Other

Effective Date:	10/02/2007	Policy Last Updated:	5/14/2008

☐ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☒ **Prospective review is not required.**

Description:
The human growth hormone (GH) somatotropin is produced by the pituitary gland. It is essential for growth in children and plays a vital role in metabolism, not only during childhood, but also throughout adult life. GH deficiency occurs when the pituitary gland fails to produce enough hormones. GH deficiency may be categorized as either congenital or acquired. Congenital deficiencies are the result of genetic mutations or the absence of the pituitary gland; acquired deficiencies may result from radiation, trauma, or disease.

Growth Hormone Deficiencies in Children and Adults:
The lack of adequate GH results in a child being significantly shorter than their genetically determined height. Replacement GH therapy for pediatric patients with GH deficiency is used primarily for the treatment of short stature. It stimulates growth of linear bone, skeletal muscle, and organs. Initiation of GH therapy as early as possible and continuation through adolescence will ensure the best chance of achieving height potential.

Adults with GH deficiencies may have increased body fat, particularly central adiposity; decreased muscle mass; decreased bone density with an increased risk of fracture; increased LDL cholesterol and Apo B.; decreased HDL cholesterol; decreased cardiac muscle mass (especially in childhood onset somatotropin deficiency); impaired cardiac function; decreased total and extracellular fluid volume; decreased insulin sensitivity and increased prevalence of impaired glucose tolerance; increased concentration of plasma fibrinogen and plasminogen activator inhibitor type I; and accelerated atherogenesis.

Growth Hormone Conditions Include the Following:

- Prader-Willi Syndrome:

Prader-Willi Syndrome (PWS) is a complex multi-system genetic disorder characterized by decreased muscle tone, short stature, excessive appetite, hypothalamic obesity, developmental delay, and delayed or absent puberty. A PWS-like disorder can also be acquired after birth if damage occurs to the hypothalamus portion of the brain. GH testing is not necessary prior to treating children with PWS who have growth failure. GH therapy in children with PWS is used to improve growth failure and body composition as children with PWS often have too much body fat.

- Turner's Syndrome (TS):

Turner's syndrome a genetic disorder that is caused by abnormalities or the absence of an X chromosome, 45 X genotype. TS affect females only and are characterized by short stature. Other features that may be present are shortness of the neck, webbing of the skin of the neck, cubitus valgus deformity of the elbow, shortness of the fourth and fifth metacarpals and metatarsals, a shield shaped chest, and primary hypogonadism. Growth hormone secretion has been shown to be frequently abnormal, but classical GH deficiency is rare.

- Noonan Syndrome (NS):

Noonan Syndrome's abnormalities frequently resemble those in Turner's syndrome. One important distinction between the two is that patients with NS have normal karyotypes. NS patients are likely to have mild mental retardation and unusual features (e.g., hypertelorism, down-slanting eyes, webbed neck), congenital heart disease, short stature and chest deformity. GH secretion has been shown to be frequently abnormal, but classical GH deficiency is rare in NS.

- Children with Chronic Renal Insufficiency (CRI):

In individuals with chronic renal insufficiency (CRI), the kidneys lose the ability to excrete wastes, concentrate urine, and conserve salt and water. The kidney's role in the growth process is also compromised; which leads to growth failure in children. Chronic renal insufficiency is defined as a serum creatinine of greater than 1.5 mg/dl (1.4 for women and 1.7 for men), or a creatinine clearance less than 75ml/min per $1.73m^2$.

- AIDS Wasting Syndrome (AWS):

Individuals with AWS typically have depletion of lean body mass that may result in muscle weakness and other complications.

- Third Degree Burns:

GH therapy may be used in the promotion of wound healing in burn patients with third degree burns. The goal of GH therapy in severe burn patients is to improve nitrogen balance, reduce muscle catabolism, and increase wound healing.

- Short Bowel Syndrome:

Short bowel syndrome (SBS) is either a congenital or acquired deficiency of at least half of the small intestine, with or without loss of a portion of the large intestine. SBS causes malabsorption, a condition in which the body is unable to break down and/or absorb food. Symptoms of malabsorption include malnutrition, weight loss, diarrhea, abdominal bloating, and fatigue.

There are a number of synthetic GH preparations products available: Genotropin, Humatrope, Norditropin, Nutropin, Saizen, and Serostim. Synthetic GH (somatropin or somatrem) is produced by recombinant DNA technology and has a sequence identical to human GH. Synthetic GHs may be used as replacement therapy for patients with GH deficiency.

Medical Criteria:
Not applicable.

Policy:
Human growth hormone drugs classified as self administered can be purchased at a pharmacy and are covered under the member's pharmacy benefit.

Prior authorization is not required.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate member certificate or subscriber agreements/BlueCHiP for RIte Care contract for the applicable prescription drug benefit.

Coding:
J2941 Injection, somatropin, 1mg
Use this code for Humatrope, Genotropin Nutropin, Biotropin, Genotropin, Genotropin Miniquick, Norditropin, Nutropin, Nutropin AQ, Saizen, Saizen Somatropin RDNA Origin, Serostim, Serostim RDNA Origin, Zorbtive

J3490 Unclassified drugs is used in conjunction with the uncoded growth hormone drug (which will automaticaly suspend for IC claim review).

Typically used human growth hormone injectable drugs:
Genotropin (somatropin)
Geref (sermorelin)
Humatrope (somatropin)
Increlex (mecasermin)
Iplex (mecasermin rinfabate)
Norditropin (somatropin)
Nutropin (somatropin)
Nutropin AQ (somatropin)
Saizen (somatropin)
Sandostatin LAR Depot (octreotide acetate)
Serostim (somatropin)
Somatropin
Somavert (pegvisomant)
Tev-tropin (somatropin)
Zorbtive (somatropin)

Pellets:
Testopel Testostarene

Also Known As:
Somatotropin
Protropin
Humatropin/Humatrope
Recombinant human growth hormone replacement therapy
Growth hormone replacement therapy, recombinant human
Human growth hormone replacement therapy

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References:
Cook. D., Owens G. (2004). Appropriate use of growth hormone therapy in adults: A collaborative approach. *The American Journal of Managed Care,*10 (13), S416 Supplement.

Hardin D. S., Woo J., Butsch R., et al. Current prescribing practices and opinions about growth hormone therapy: Results of a nationwide survey of paediatric endocrinologists. *Clin Endocrinol 2007;*66 (1); 85-94. Retrieved 4/2/2007 from www.medscape.com/viewarticle/553884_print

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