MEDICAL POLICY

Date Reviewed: 02/25/00, 03/24/00, 08/23/02, 03/24/06, 04/24/09, 04/28/10, 04/15/11

Subject: Growth Hormone for Adults (Accretropin, Genotropin, Humatrope, NordiFlex, Nordipen, Norditropin, Nutropin, Omnitrope, Protropin, Saizen, Sermorelin, Serostim, Somatrem, Somatropin, Tev-Tropin, Zorbtive)

Description: Human growth hormone (HGH) is used to treat various growth and metabolic disorders. It is primarily used to increase low endogenous growth hormone levels in both children and adults.

Indications of Coverage:

The use of HGH for adults is considered medically necessary for an individual with growth hormone deficiency when the following criteria are met (see separate criteria for Zorbtive):

The medical record documents of one of the following conditions:

Growth hormone deficiency documented by an endocrinologist as due to disease of the pituitary or thalamic glands from known causes (for example, pituitary tumor, radiation therapy, surgery, trauma, or panhypopituitarism)

Childhood-onset growth hormone deficiency documented by an endocrinologist and previously treated with growth hormone replacement prior to the age of 18 (except for Turner's syndrome and idiopathic short stature (see Limitations of Coverage))

Two growth hormone stimulation tests performed by an endocrinologist after final height has been achieved confirm growth hormone deficiency. Growth hormone therapy should be discontinued for at least one month followed by appropriate testing to confirm the presence of a growth hormone deficiency prior to restarting growth hormone therapy. The preferred test to establish the diagnosis of adult growth hormone deficiency in patients with childhood-onset growth hormone deficiency is the insulin tolerance test (ITT). (The ITT is contraindicated in the presence of ischemic heart disease or seizures.) Acceptable alternative tests include the growth hormone releasing hormone plus arginine (GHRH+ARG) test, the glucagon test, and, rarely, the arginine (ARG) test alone. In patients with hypothalamic growth hormone deficiency (for example, idiopathic isolated growth hormone deficiency of childhood), the GHRH+ARG test may be misleading, so an ITT or glucagon test should be used. A growth hormone level deficiency is identified by the following test results:

Serum growth hormone level less than or equal to 5 micrograms per liter for the ITT

Serum growth hormone level less than or equal to .4 micrograms per liter for the ARG test

Serum growth hormone level less than or equal to 3 micrograms per liter for the glucagon test

Serum growth hormone level less than or equal to 11 micrograms per liter in individuals with a BMI less than 25, less than or equal to 8 micrograms per liter

in individuals with a BMI between 25 and 30, or less than or equal to 4 micrograms per liter in individuals with a BMI greater than 30 for the GHRH+ARG test

Note: Exceptions for discontinuation and retesting include individuals with known mutations, individuals with congenital defects, individuals with irreversible hypothalamic-pituitary structural lesions, and individuals with evidence of serum insulin-like growth factor one (IGF-I) levels below the age- and sex-appropriate reference range off GH therapy and panhypopituitarism (hormone deficiencies of a minimum of three of the following):

Adrenocorticotropic hormone (ACTH)

Thyroid-stimulating hormone (TSH)

Growth hormone (GH, human Growth Hormone, HGH, somatotropin)

Prolactin (PRL) (luteotropic hormone (LTH), luteinizing hormone (LH), interstitial cell stimulating hormone (ICSH))

Follicle stimulating hormone (FSH)

Oxytocin

Antidiuretic hormone (ADH) (vasopressin, arginine vasopressin(AVP))

If criteria are met, treatment may be approved for twelve months. Subsequent treatment may be approved in one year increments following discontinuation of therapy for one month and testing for reconfirmation of growth hormone deficiency when there is documentation of continued therapeutic response and consistent prescription medication use. Therapeutic response is defined as normalized serum insulin-like growth factor one (IGF-I) test results (test results in the middle of the laboratory's age- and sex-appropriate reference range) without unacceptable side effects, and improvement in the individual's Questions on Life Satisfaction-Hypopituitarism (QLS-H) score from baseline testing (or the improvement from baseline testing has been maintained).

The use of Zorbtive for adults is considered medically necessary when the following are met:

The patient has the diagnosis of Short Bowel Syndrome, requires specialized nutritional support, and has had optimal management such as dietary adjustments, enteral feedings, fluid and micronutrient supplements.

If criteria are met, treatment may be approved for up to 28 days.

Limitations of coverage:

Review contract for exclusions and benefits.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

HGH is considered not medically necessary in the following situations:

In individuals with a malignancy

In individuals with an acute critical illness due to complications from cardiac or abdominal surgery, trauma, or acute respiratory failure

When continuing growth hormone treatment is provided in adulthood for some conditions that may have been treated in childhood, such as Turner's syndrome and idiopathic short stature, since there is no proven benefit to continuing growth hormone treatment. (Retesting for these individuals when final height has been achieved would also be considered not medically necessary.)

When reconfirmation testing after twelve months of therapy (when required) does not establish the presence of a growth hormone deficiency

In individuals where no apparent or objective benefits of treatment are achieved after two years of treatment

The use of Zorbtive for more than 28 days or in pediatric patients with Short Bowel Syndrome is considered investigational as safety and effectiveness in these situations has not been established.

Documentation required:

Office notes

Growth hormone stimulation tests

Prescription medication use data

Rationale: Growth hormone is essential to maintain healthy body composition and metabolism. If the pituitary gland does not function correctly, it may be necessary to replace the growth hormone usually provided through this organ. A recent guideline published by the American Association Of Clinical Endocrinologists (AACE) clarified the indications for growth hormone therapy in adults.

Zorbtive is a man-made human growth hormone (HGH). Zorbtive is used to treat Short Bowel Syndrome (SBS) in patients who are on a specialized diet. When used with a special diet, Zorbtive may help the bowel take in more water, electrolytes and nutrients and lower the need for IV (intravenous) feedings.

References:

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Approved by the Medical Director