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Federal Employee Program.

GROWTH HORMONE (Adult therapy)

Genotropin, Humatrope, **Norditropin**, Omnitrope, Saizen, Sogroya, Zomacton

Preferred product: Norditropin

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Growth hormone deficiency (GHD) in adulthood, associated with hypothalamic-pituitary dysfunction is now widely accepted as a distinct clinical syndrome, and is linked to a substantial number of significant co-morbidities, many of which can be ameliorated with growth hormone replacement therapy (1).

The FDA has approved growth hormone replacement for use in adult patients with growth hormone deficiency. Approved indications are for the treatment of adults with either adult onset or childhood onset GHD. With the exception of idiopathic adult onset GHD, GHD should be confirmed as due to pituitary disease from known causes, including pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, trauma, or reconfirmed childhood GHD. Growth hormone should only be prescribed to patients with clinical features suggestive of adult GHD and biochemically proven evidence of adult GHD (1-8).

Regulatory Status

FDA-approved indications: Human growth hormone is indicated for treatment of adult patients with either childhood-onset or adult-onset GH deficiency (2-8).

The laboratory diagnosis of GHD in adults is determined by dynamic endocrine testing. Because growth hormone has a short half-life in blood growth hormone levels frequently are undetectable in blood samples obtained at random from normal subjects. For this reason, a stimulation test is needed to confirm the diagnosis. American Association of Clinical Endocrinologists (AACE) does not recommend growth hormone stimulation testing in patients with three or more pituitary hormone deficiencies and low IGF1 (2-8).

Use of any growth hormone in adults can cause a number of potentially serious adverse effects, therefore regular and routine monitoring is required. Sometimes treatment may need to be permanently stopped. These adverse effects include the development of impaired glucose tolerance and diabetes mellitus, upper airway obstruction and sleep apnea in patients with Prader-



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Willi syndrome, progression or recurrence of tumors in patients with preexisting tumors, intracranial hypertension, the worsening of hypothyroidism, and the worsening of pre-existing scoliosis, and pancreatitis (1-8).

The usefulness of growth hormone treatment in adults who have completed their structural growth derives from the role of growth hormone in the following processes: increasing bone density, increasing lean tissue, decreasing adipose tissue, bolstering cardiac contractility, improving mood and motivation, and enhancing exercise capacity (2-8).

Growth hormone (GH) is used off-label for cosmetic, anti-aging and performance enhancing purposes. These indications are not approved by the FDA and are not a covered benefit under the Service Benefit Plan.

Summary

Growth hormone deficiency (GHD) in adulthood, associated with hypothalamic-pituitary dysfunction is now widely accepted as a distinct clinical syndrome, and is linked to a substantial number of significant co-morbidities, many of which can be ameliorated with growth hormone replacement therapy. The FDA has approved growth hormone replacement for use in adult patients with growth hormone deficiency (1-8).

Growth hormone is used off-label for cosmetic, anti-aging and performance enhancing purposes. These indications are not approved by the FDA and are not a covered benefit under the Service Benefit Plan.

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of human growth hormone while maintaining optimal therapeutic outcomes.

References

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