

Growth Hormone and Increlex Criteria

Revised: 09/17/2024

GROWTH HORMONE AND INCRELEX

Length of Authorization: Initial – 6 months
Renewal – 1 year

GROWTH HORMONE

- Approvable diagnoses:
 - Growth hormone deficiency (GHD) – confirmed by testing
 - Pituitary Dwarfism
 - Panhypopituitarism
 - Turner’s Syndrome
 - Pre-transplant chronic renal insufficiency (CRI)
 - Prader-Willi Syndrome (PWS)
 - Neonatal hypoglycemia associated with growth hormone deficiency; **AND**
 - Noonan Syndrome (rare genetic disorder, patients with this condition may have short stature)
- Prescriber is a pediatric endocrinologist or pediatric nephrologist
- Male patient with bone age less than 16 years of age **or** female patient with bone age less than 14 years of age
- Open epiphyses

GROWTH HORMONE (CHILDREN) – CRITERIA TO APPROVE

Growth Hormone and Increlex: If the diagnosis is Idiopathic Short Stature (ISS) or Small for Gestational Age (SGA), forward to a pharmacist to be denied

GROWTH HORMONE (CHILDREN) – CRITERIA FOR RENEWAL

Above criteria must still be met as well as documented growth velocity > 2.5 cm/year.

INCRELEX (CHILDREN ONLY)

- Age is at least 2 years of age, but not older than 18 years of age on the date of the request.
- Approvable diagnoses:
 - Growth failure with a diagnosis of severe primary insulin-like growth factor deficiency (PIGFD) as defined **all** the following:
 - Height more than three (3) standard deviations (SD) below the mean for age.
 - IGF-1 level more than three (3) standard deviations (SD) below the mean for age; **AND**
 - Growth hormone (GH) gene deletion and has developed neutralizing antibodies to GH.
- Medication is being prescribed by, or in consultation with, an endocrinologist.

Increlex® should **not** be approved for patients with secondary forms of IGF-1 deficiency such as GH deficiency, malnutrition, hypothyroidism, chronic treatment with steroids. Thyroid and nutritional deficiencies should be corrected prior to initiation of therapy.

INCRELEX RENEWAL

Above criteria must still be met as well as documented growth rate.

GROWTH HORMONE (ADULTS) – CRITERIA TO APPROVE

- Growth hormone deficiency documented by a provocative stimulation test < 5 ng/mL. Insulin tolerance test is preferred. Clonidine testing is not acceptable. Other acceptable testing: L-Arginine HCl, L-Dopa, and Glucagon
- Patient is receiving full supplementation of deficient pituitary hormones, such as thyroid, glucocorticoids or gonadotropic hormone.
- Patient has at least **one** of the following abnormalities or elevated risk factors:
 - Reduced bone mineral density (BMD) of greater than 1 SD below the mean, using the WHO criteria (**see below**)
 - High risk lipid profile (total cholesterol level \geq 240 mg/dL or LDL level + or > 190 mg/dL; **OR**
 - At least 2 pituitary hormone deficiencies (other than GH) such as TSH, ACTH, gonadotropins or ADH

GROWTH HORMONE (ADULTS) – RENEWAL

- First year after initial approval, must have prescriber's office request to continue prior authorization for another year.
- Second year after initial approval, patient must show improvement in their original qualifying risk factor as compared to baseline.
 - Documented increase in bone mineral density (BMD) per DEXA scan; **OR**
 - At least a 5% reduction in lipid panel; **OR**
 - If patient had 2 pituitary hormone deficiencies, no BMD or lipid panel is required

WHO CRITERIA – WORLD HEALTH ORGANIZATION DEFINITIONS OF OSTEOPOROSIS BASED ON BONE DENSITY LEVELS

- The difference between your BMD and that of a healthy young adult is referred to as a standard deviation (SD). As outlined in the World Health Organization's diagnostic categories, individuals whose T-score is within one standard deviation of the "norm" are considered to have normal bone density.
- A T-score compares your bone density to the optimal peak bone density for your gender. It is reported as number of standard deviations below the average. A T-score of greater than minus -1 is considered normal. A T-score of -1 to -2.5 is considered osteopenia, and a risk for developing osteoporosis. A T-score of less than -2.5 is diagnostic of osteoporosis.

REVISION HISTORY

Date	Issues/Updates
03/31/2024	• Initial draft creation
09/17/2024	• Revision to include Increlex criteria (children)