Growth Hormones and Growth Factors

Effective 12/05/2007
Revised 10/03/2019

Preferred Agents
• Egrifta®
• Genotropin®
•Increlex®
• Norditropin FlexPro® Pen

Non-Preferred Agents
•Humatrope®
• Nutropin AQ® Nuspin® Pen
• Nutropin AQ® Pen
• Omnitrope®
• Saizen®
• Serostim®
• Zomacon®
• Zorbtive®

Approval Criteria

• Documented compliance on current therapy for Egrifta, Serostim, Zorbtive, and Increlex only (90 out of 120 days) OR
• Participant < 18 years of age OR
• For all agents in patients ≥ 18 years of age one of the following:
  o Diagnosis of HIV with cachexia in the last 2 years:
    ▪ Documented baseline body weight at initial request for 2 week approval
    ▪ At 2 week follow up, no documented weight loss from baseline for 10 week approval
    ▪ At 10 week follow up, documented stable weight for 12 week approval
    ▪ May be approved every 12 weeks with documented stable weight
  o Documented diagnosis of renal impairment or chronic renal disease in last 2 years and participant is pre-transplant
  o History of growth hormone deficiency in last 2 years documented by one of the following:
    ▪ Insulin Tolerance Test (ITT) OR
    ▪ GH Stimulation Panel (with arginine, glucagon, propranolol, or levodopa) OR
    ▪ Serum IGF-I concentration (if ITT contraindicated) OR
    ▪ Equivalent Diagnostic Test (subject to clinical review) AND
    ▪ After 1 year of therapy, documented IGF-1 level or equivalent GHD level in the past 6 months required for approval
  o Documented history of any of the following in the past 2 years (subject to clinical review):
    ▪ Prader-Willi Syndrome OR
    ▪ Turner Syndrome OR
    ▪ Crohns Disease OR
    ▪ Cardiomyopathy OR
    ▪ Short Bowel Syndrome OR
    ▪ Other medically accepted use as determined by clinical consultant

• For Egrifta only:
  o Participant ≥ 18 years of age AND
  o Documented diagnosis of excess abdominal fat in HIV infected patients with lipodystrophy in the past 2 years AND
- Documented compliance to antiretroviral therapy (90 out of 120 days) **AND**
- Clinical consultant review

**For Increlex only:**
- Participant ≥ 18 years of age **AND**
- Documented history of short stature in the past 2 years **AND**
- Clinical consultant review

**Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents**
- Documented trial period for preferred agents
- Documented ADE/ADR to preferred agents

### Denial Criteria

- Therapy will be denied if no approval criteria are met
- Increlex only: Documented secondary forms of IGF-1 deficiency:
  - Growth Hormone deficiency **OR**
  - Malnutrition **OR**
  - Hypothyroidism **OR**
  - Chronic treatment with pharmacologic doses of anti-inflammatory steroids

**Drug Prior Authorization Hotline:** (800) 392-8030