Drug Therapy Guidelines

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<th>Medical Benefit</th>
<th>Effective: 6/21/17</th>
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<td>Pharmacy- Formulary 1</td>
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<td>Pharmacy- Formulary 2</td>
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I. Medication Description

Increlex® is an injectable form of recombinant human insulin-like growth factor 1 (IGF-1). IGF-1 is the primary mediator of growth hormone and performs several metabolic functions to promote statural growth such as stimulating skeletal, organ, and other tissue growth, suppressing hepatic glucose production, and inhibiting insulin secretion. Severe primary IGF-1 deficiency is characterized in children with height and serum IGF-1 levels ≥ 3 standard deviations below normal in the presence of normal or elevated GH levels. Mecasermin is not a substitute for GH treatment.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided for Increlex® for the treatment of growth failure in children with severe primary IGF-1 deficiency OR growth hormone gene deletion in children who have developed neutralizing antibodies to growth hormone when the following criteria are met:

- Member is at least 2 years of age AND
- Member’s height standard deviation score must be ≤ -3.0 for age and sex AND
- The basal IGF-1 score must be below the lower limits of normal for the reporting lab AND
- The member must have normal (defined as stimulated serum GH level of greater than 10 ng/ml) or elevated growth hormone (except for members with growth hormone gene deletion) AND
- Epiphyses must be confirmed as open in members ≥ 10 years of age AND
- Diagnosis has been made by a pediatric endocrinologist AND
- Member is not receiving growth hormone therapy

IV. Quantity Limits

0.24 mg/kg/day

V. Coverage Duration

Coverage is approved for 12 months and may be renewed.
VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Epiphyses confirmed open AND
- Member has demonstrated a growth-response rate of ≥ 4.5 cm/yr (prepubertal growth) or ≥ 2.5 cm/yr (post-pubertal growth) AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as 40mg vials containing 10mg/ml solution

VIII. Summary of Policy Changes

- 4/1/11: Increlex moved from Growth Stimulating Drug policy
- 6/1/11: no changes
- 6/15/12: no changes
- 6/15/13: absence of concurrent growth hormone supplementation added to coverage criteria
- 6/15/14: diagnosis codes updated
- 7/1/15: formulary distinctions made
- 7/19/15: no policy changes
- 6/21/17: no policy changes

IX. References

1. UpToDate Online, retrieved February 2011
3. Facts and Comparisons Online, retrieved February 2011

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.