I. POLICY

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Mecasermin (Increlex) is subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the Prior Authorization process for Mecasermin (Increlex).

IV. SCOPE

This policy applies to the Pharmacy Services Department.
V. PROCEDURE

Criteria for Mecasermin (Increlex)

Mecasermin (Increlex) is indicated for the treatment of growth failure in children with severe primary insulin-like growth-factor 1 (IGF-1) deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

Mecasermin (Increlex) is considered medically necessary for members with growth failure who meet all of the following criteria:

**Initial Authorization**

- Member must have a confirming diagnosis of severe primary IGF-1 deficiency or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.
- Must be prescribed by a pediatric endocrinologist and must be used with appropriate physician (pediatric endocrinologist) follow-up.
- Members must be at least two (2) years of age for mecasermin.
- Has at least two of the following:
  - Present height <5th percentile for age/sex.
  - Pretreatment growth velocity is <10th percentile for age and gender or <4.5 cm/yr until age 10, and lower growth rates thereafter.
  - Comparison of skeletal (bone) age by x-ray of the left hand and wrist is ≥ 2 standard deviations below the chronological age.
- Basal serum IGF-1 level which is low for age (≥3 standard deviations below the normal level for age and gender, as measured in clinical laboratories where appropriate normative data are available).
- Normal or elevated growth hormone (GH) shown by growth stimulation tests, except for members with growth hormone gene deletion.
- Cannot have secondary forms of IGF-1 deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. If thyroid or nutritional deficiencies exist, this should be corrected before initiation with mecasermin treatment.
- Cannot be currently taking growth hormone treatment.
- Member cannot have closed epiphyses, presence of active or suspected neoplasia, or have an allergy to mecasermin as these are contraindications.
- Request must include a treatment plan outlining the dose, monitoring parameters, such as when the member will be seen for follow-up, methods for determining treatment response and anticipated duration of use.
- Authorization will be granted for up to one (1) year of therapy if the above criteria are met.
Reauthorization Criteria

- Reauthorization will be done annually to check for therapy benefit by reviewing a progress report, indicating growth and maturation. Therapy will not be considered medically necessary if one or any of the following discontinuation criteria is met:
  - Growth velocity while on therapy has not increased by at least 2 cm/year (suggests the need for assessment of compliance evaluation of other causes of growth failure).
  - Expected final adult height has been reached.
  - Growth plates have fused.
  - Bone age in females reaches age 14, in males age 16.

Limitations

If a member does not meet the above approval criteria, the request will be referred to a UPMC Health Plan Medical Director for review.

VI. BIBLIOGRAPHY