

HealthAlliance**MEDICARE**

PURPOSE OF THE POLICY

To define coverage criteria for mecasermin (Increlex®).

STATEMENT OF THE POLICY

Mecasermin will be covered for children if the following criteria are met, and will apply to new starts only for Medicare Part D members.

PROCEDURES

1. Inclusion criteria

- 1.1 Approved for FDA approved indications.
- 1.2 Must be prescribed by an endocrinologist, AND
- 1.3 Patient is a child and older than 2 years of age, AND
- 1.4 Must have documented diagnosis of:
 - severe primary insulin-like growth factor deficiency (IGFD), defined as
 - having height AND serum IGF-1 levels that are three or more standard deviations below normal ((based on lab reference range for age and sex), AND normal or elevated growth hormone (GH), or
 - growth hormone gene deletion who have developed neutralizing antibodies to growth hormone.

2. Exclusion criteria

- 2.1 Diagnosis of secondary IGF-a deficiency arising from growth hormone deficiency, uncorrected malnutrition, uncorrected hypothyroidism, or chronic corticosteroid therapy.
- 2.2 Patient with closed epiphyses.
- 2.3 Patient who has active or suspected neoplasia.

3. Authorization and Limitations

- 3.1 Initial authorization: Mecasermin may be authorized for a period of up to 12 months, when all criteria in 1. are met.
- 3.2 Discontinuation occurs when linear growth ceases.

REFERENCE

Insulin-Like Growth Factor I (IGF-I)

Females/Males (Age)	Range (ng/mL)
1-7 days	ND-26
8-15 days	11-41
15 days - 1 year	55-327
2 years	51-303
3 years	49-289
4 years	49-283
5 years	50-286
6 years	52-297
7 years	57-316
8 years	64-345
9 years	74-388
10 years	88-452

11 years	111-551
12 years	143-693
13 years	183-850
14 years	220-972
15 years	237-996
16 years	226-903
17 years	193-731
18 years	163-584
19 years	141-483
20 years	127-424
21-25 years	116-358
26-30 years	117-329
31-35 years	115-307
36-40 years	109-284
41-45 years	101-267
46-50 years	94-252
51-55 years	87-238
56-60 years	81-225
61-65 years	75-212
66-70 years	69-200
71-75 years	64-188
76-80 years	59-177
81-85 years	55-166

Nichols Institute Diagnostics (kit manufacturer) Directional Insert