Texas Vendor Drug Program

Drug Use Criteria: Mecasermin (Increlex®)

Publication History

1. Developed December 2006.
2. Revised May 2019; May 2016; August 2015; December 2013; February 2012; June 2010; May 2010; May 2007.

Notes: Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; prospective application is indicated with an asterisk [*]. The information contained is for the convenience of the public. The Texas Health and Human Services Commission is not responsible for any errors in transmission or any errors or omissions in the document.

Medications listed in the tables and non-FDA approved indications included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.

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1 Dosage

Mecasermin (Increlex®) is the recombinant DNA form of human insulin-like growth factor-1 (rhIGF-1). In normal circulation, over 98% of rhIGF-1 is available in bound form to IGFBP-3, which allows IGF-1 to remain inactive until released to target tissues. This reduces the potential for adverse events associated with free levels of IGF-1. In patients with growth hormone insensitivity syndrome, the serum half-life of unbound IGF-1 is decreased, as these patients have lower rhIGFBP-3 concentrations. Patients with IGF-1 gene deletion have normal levels of rhIGFBP-3. Mecasermin is FDA-approved for use in treating growth failure in children with severe primary IGF-1 deficiency (primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Mecasermin has also been evaluated for use in short children with low IGF-1 levels; results showed improvement in height velocities following mecasermin use compared to untreated patients after one year of treatment.[1-4]

1.1 Pediatrics

Mecasermin is approved for use in children 2 years of age and older but has not been studied in adults. Mecasermin should not be used in children whose bone growth plates are closed (epiphyseal closure), as linear growth is no longer possible in these patients. Additionally, mecasermin safety and efficacy have not been determined in children younger than 2 years of age. The recommended initial mecasermin dosage is 0.04 to 0.08 mg/kg twice daily subcutaneously, which can be titrated up in increments of 0.04 mg/kg, if tolerated, to a maximum dose of 0.12 mg/kg twice daily (total: 0.24 mg/kg/day). Patient profiles containing prescriptions for doses exceeding these recommendations will be reviewed.[1-4]

Mecasermin should be administered with food or a snack as IGF-1 decreases hepatic glucose production and increase peripheral glucose utilization and may induce hypoglycemia. Mecasermin administration should be withheld in patients unable or unwilling to eat a meal prior to mecasermin dosing.[1-4]

2 Duration of Therapy

Five clinical studies evaluated mecasermin use in 71 pediatric patients with severe primary IGF-1 deficiency (one double-blind, placebo-controlled trial and four open-label trials). Results revealed 61 patients completed at least one year of treatment and 13 patients received mecasermin therapy for 8 years. The mean change in height velocity significantly increased from baseline in mecasermin-treated patients for treatment years 1 through 6. Therapy continuation is recommended until epiphyses fuse and full growth potential is reached. However, a maximum treatment duration has not been defined for mecasermin.[4-8]

3 References

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