Clinical Policy Title:	mecasermin
Policy Number:	RxA.171
Drug(s) Applied:	Increlex®
Original Policy Date:	02/07/2020
Last Review Date:	12/05/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Severe Primary IGF-1 Deficiency (must meet all)**:**

1. Diagnosis of severe primary IGF-1 deficiency IGFD;
2. The epiphyses are open;
3. IGF-1 serum level is ≥ 3 standard deviations (SD) below the mean;
4. GH serum level is normal or elevated;
5. Height is ≥ 3 SD below the mean for age and sex;
6. Member does not have malignant neoplasia or a history of malignancy;
7. Somatropin (recombinant human GH) is not prescribed concurrently with Increlex®.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Growth Hormone (GH) Insensitivity (must meet all)**:**

1. Diagnosis of acquired GH insensitivity as evidenced by both of the following (a and b):
   a. Documentation of genetic GH deficiency due to a GH gene deletion;
   b. Documentation of presence of neutralizing GH antibodies;
2. The epiphysis are open;
3. Documentation of baseline height is provided at the time of request;
4. Member does not have malignant neoplasia or a history of malignancy;
5. Somatropin (recombinant human GH) is not prescribed concurrently with Increlex®.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Grimberg A, DiVall SA, Polychronakos C, et al. Growth Hormone Treatment for Growth Hormone Deficiency and Idiopathic Short Stature: New Guidelines Shaped by the Presence and Absence of Evidence. Curr Opin Pediatr. 2017 Aug; 29(4): 466–471. doi: 10.1097/MOP.0000000000000505. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5565215/. Accessed November 27, 2024.
2. Paulo F. Collett-Solberg, Madhusmita Misra, on behalf of the Drug and Therapeutics Committee of the Lawson Wilkins Pediatric Endocrine Society, The Role of Recombinant Human Insulin-Like Growth Factor-I in Treating Children with Short Stature, The Journal of Clinical Endocrinology & Metabolism, Volume 93, Issue 1, 1 January 2008, Pages 10–18. Available at: https://doi.org/10.1210/jc.2007-1534. Accessed November 27, 2024.
3. Steven D. Chernausek, Philippe F. Backeljauw, James Frane, Joyce Kuntze, Louis E. Underwood, Long-Term Treatment with Recombinant Insulin-Like Growth Factor (IGF)-I in Children with Severe IGF-I Deficiency due to Growth Hormone Insensitivity, The Journal of Clinical Endocrinology & Metabolism, Volume 92, Issue 3, 1 March 2007, Pages 902–910. Available at: https://doi.org/10.1210/jc.2006-1610. Accessed November 27, 2024.
4. Centers for Disease Control and Prevention, National Center for Health Statistics. CDC growth charts: United States. Available at: http://www.cdc.gov/growthcharts/. Accessed November 27, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy description table was updated. 2. Initial therapy and continued therapy approval duration for HIM was added. 3. Continuation therapy criteria II.A.1. was repharsed to" criteriaMember is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy". 4. References were updated.	07/09/2020	09/14/2020
Policy was reviewed: 1. References reviewed and updated.	03/31/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.4 & I.B.4: Updated to include new criteria the epiphysis are open. 2. Initial Approval Criteria, I.B.4.a,b,c,d,e: updated to remove Documentation of growth failure as indicated by any of the following (a, b, c, d, or e): a. Height > 3 SD below the mean; b. Height > 2 SD below the mean and one of the following (i or ii): i. Height velocity > 1 SD below the mean over 1 year; ii. Decrease in height SD > 0.5 over 1 year in children > 2 years of age; c. Height > 1.5 SD below midparental height; d. Height velocity > 2 SD below the mean over 1 year;	01/13/2022	04/18/2022

e. Height velocity > 1.5 SD below the mean over 2 years; 3. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.1.a, I.A.1.b & I.A.1.c: Updated to remove prior diagnosis evidence criteria " (i.e., inherited growth hormone insensitivity) and associated growth failure as evidenced by all of the following (a, b, and c): a. Basal IGF-1 standard deviations (SD) score is 3 at the baseline; b. Normal or elevated GH level; c. Height standard deviation score is ≤ 3.0 at baseline." 2. Initial Approval Criteria, I.A.5: Updated to include new lab values criteria IGF-1 serum level is ≥ 3 standard deviations (SD) below the mean. 3. Initial Approval Criteria, I.A.6: Updated to remove prior documentation criteria "Documentation of baseline height is provided at the time of request". 4. Initial Approval Criteria, I.A.6: Updated to include new lab values criteria GH serum level is normal or elevated. 5. Initial Approval Criteria, I.A.7: Updated to include new eligibility criteria Height is ≥ 3 SD below the mean for age and sex. 6. Initial Approval Criteria, I.A.8 and I.B.6: Updated to include new criteria pertaining to indication Severe Primary IGF-1 Deficiency and Growth Hormone Insensitivity, "Member does not have malignant neoplasia or a history of malignancy". 7. Initial Approval Criteria, II.A.4: Updated to include new criteria pertaining to indication Severe Primary IGF-1 Deficiency and Growth Hormone Insensitivity, "Member does not have malignant neoplasia or a history of malignancy". 8. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber restrictions. 2. Removed age restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed other reauthorization requirements including positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024

Updated Continued therapy approval to “Member is currently receiving medication that has been authorized..”	11/27/2024	12/05/2024