Clinical Policy Title:	repository corticotropin
Policy Number:	RxA.158
Drug(s) Applied:	Acthar® Gel
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. West Syndrome (Infantile Spasms) (must meet all)**:**

1. Diagnosis of West syndrome (infantile spasms);
2. Diagnosis is confirmed by electroencephalogram.

Approval Duration

All Lines of Business (except Medicare): 3 months

B. Multiple Sclerosis (MS) (must meet all)**:**

1. Diagnosis of MS;
2. Prescribed for acute exacerbations of MS;
3. Recent (within the last 30 days) trial and failure of at least a 7-day course of corticosteroid therapy for acute exacerbations of MS, unless contraindicated or clinically significant adverse effects are experienced;
4. Member has been adherent to disease modifying therapy for MS (e.g., Aubagio®, Avonex®, Betaseron®, Copaxone®, Gilenya®, Plegridy®, Rebif®).

Approval Duration

All Lines of Business (except Medicare): 21 days

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

Lines of Business (except Medicare): 12 months

References

1. Berkovich R, Agius M. Mechanisms of action of ACTH in the management of relapsing forms of multiple sclerosis. Ther Adv Neurol Disord. March 2014; 7(2): 83–96. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3932770/. Accessed August 28, 2024.
2. Beck L, Bomback AS, Choi M, et al. KDOQI commentary on the 2012 KDIGO clinical practice guidelines for glomerulonephritis. Am J Kidney Dis. 2013: 62(3): 403-441. Available at: https://kdigo.org/wp-content/uploads/2017/02/KDIGO-GN-GL-Public-Review-Draft_1-June-2020.pdf. Accessed August 28, 2024.

3. Hogan J, Bomback AS, Mehta K, et al. Treatment of idiopathic FSGS with adrenocorticotropic hormone gel. Clin J Am Soc Nephrol. December 6, 2013; 8(12): 2072- 2081. Available at: https://pubmed.ncbi.nlm.nih.gov/24009220/. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	1/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was updated to all line of business. 3. Initial and continued therapy approval was updated to include Medicaid approval duration. 4. "Other FDA Approved Indications" section was added to initial approval criteria and continued therapy. 5. Continued therapy criteria II.A.1. & II.C.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…" 6. References were reviewed and updated.	07/1/2020	09/14/2020
Policy was reviewed: 1. Clinical Policy title was updated. 2. Criteria for other FDA approved indications updated. 3. Continued Therapy criteria II.A.1, II.C.1, and II.D.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 4. References were reviewed and updated.	02/25/2021	06/10/2021
Policy was reviewed: 1. Clinical Policy Title: Updated from "repository corticotropin injection" to "repository corticotropin". 2. Initial Approval Criteria, I.C and Continued Approval Criteria II.C :Nephrotic Syndrome was removed from PA policy. 3. Continued Therapy Approval Criteria II.A.1, II.C.1 & II.D.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.	01/11/2022	04/18/2022
Policy was reviewed: 1. Clinical Policy Title, Drug(s) Applied: Updated from H.P. Acthar® Gel to Acthar® Gel. 2. Initial Approval Criteria, I.A.4: Updated to include new diagnosis confirmation criteria Diagnosis is confirmed by electroencephalogram. 3. Initial Approval Criteria, I.C: Updated to remove approval criteria for Other FDA Approved Indications. 4. Continued Therapy Approval Criteria II.C: Updated to remove approval criteria for Other FDA Approved Indications.	01/18/2023	04/13/2023

5. References were reviewed and updated.		
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 reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024