Pharmacy Management Drug Policy

SUBJECT: Repository Corticotropin Injection - for Infantile Spasms, Multiple Sclerosis Exacerbations
POLICY NUMBER: PHARMACY-01
EFFECTIVE DATE: 02/2012
LAST REVIEW DATE: 02/12/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Repository corticotropin injection (available as Acthar and Purified Cortrophin gel) is an adrenocorticotropic hormone (ACTH) analogue, which stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and other androgenic substances. Elevated plasma cortisol levels suppress ACTH release. Repository corticotropin is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin.

POLICY:

Based upon our assessment and review of the peer-reviewed literature repository corticotropin injection has been medically proven to be effective and therefore, **medically necessary** for the following:

A. Infantile spasms

1. Member must be followed by a neurologist **AND**
2. Member must be less than 2 years of age **AND**
3. Member must have diagnosed infantile spasms supported by documented electroencephalographic (EEG) features
4. Recommended dosage is 150U/m^2 (divided into twice daily intramuscular injections of 75U/m^2) over a two-week period.
   a. Taper as follows to avoid adrenal insufficiency: 30 U/m^2 in the morning for 3 days; 15 U/m^2 in the morning for 3 days; 10 U/m^2 in the morning for 3 days; and 10 U/m^2 every other morning for 6-days.
5. Coverage beyond 1 month (2-week treatment + 2-week recommended taper) will require submission of progress notes demonstrating taper schedule and failure or need for continued treatment.

B. Acute exacerbations of multiple sclerosis

1. Member must be followed by a neurologist **AND**
2. Member must be at least 18 years of age **AND**
3. Member must have had previous treatment with steroids and experienced unmanageable

side effects that required hospitalization or significant clinical intervention (examples include steroid induced mania, sepsis, etc.) **AND**

4. Member must demonstrate severe exacerbation symptoms including severe weakness, severe loss of vision, severe coordination problems, or severe walking impairment **AND**
5. Approval will be granted for 1 month
   a. Coverage for additional acute exacerbations will be evaluated with the above criteria from lines 1, 2 and 4. If the patient has met line 3 on the initial review, documentation of intolerance to steroids will not be required again for re-treatment.

Based upon our criteria and review of the peer-review literature, repository corticotropin injection for the treatment of all other indications is considered **not medically necessary** and will be excluded. There has been no guideline/literature support to indicate that repository corticotropin injection would be more effective or better tolerated than corticosteroids. The clinical evidence does not support the use of repository corticotropin injection for indications including, but not limited to, the following:

C. Nephrotic Syndrome

D. Rheumatic Disorders
Psoriatic Arthritis, Rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis

E. Collagen Diseases
Systemic lupus erythematosus, systemic dermatomyositis (polymyositis)

F. Dermatologic Disease
Severe erythema multiforme or Stevens-Johnson syndrome

G. Allergic States
Serum sickness

H. Ophthalmic Diseases
Acute and chronic allergic and inflammatory process involving the eye and its adexa

I. Respiratory Diseases
Sarcoidosis

POLICY GUIDELINES:

1. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
2. Quantity limit of 5 mL per 30-day supply.
3. Quantity limit for Acthar self-inject of 2 mL/30 days (4 injectors) for the 40 units/0.5 mL pen and 4 mL/30 days (4 injectors) for the 80 units/1mL pen.
4. Repository corticotropin can cause HPA suppression with the potential for adrenal insufficiency after withdrawal of medication. Patient must be monitored for signs of insufficiency including weakness, hyperpigmentation, weight loss, hypotension, and abdominal pain. Symptoms are often difficult of define in infants. Caregivers must be instructed on signs and symptoms of adrenal insufficiency
5. Tapering dose upon discontinuation of treatment can minimize adrenal insufficiency
6. Repository corticotropin can cause GI bleeding and gastric ulcer. Use cautiously in patients with certain GI disorders

7. Repository corticotropin may be associated with CNS effects (mood swings, insomnia, irritability, personality alterations, and depression). Cautiously use in patients with psychotic manifestations and hypothyroidism.
8. Multiple Sclerosis Corticosteroid-responsive condition policy rationale: Clinical studies evaluating the efficacy and use of Acthar gel are extremely limited. There have been no studies that show ACTH to be more effective than corticosteroids. Studies that do exist to compare corticosteroids to ACTH have found corticosteroids to be equally safe and effective for the treatment of acute MS exacerbations.[9,10, 13,14]
9. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines
10. Repository corticotropin may be covered under the pharmacy benefit (self-administered or caregiver administered) **OR** the medical benefit (administered by a healthcare professional).
11. For members with Medicare Part B, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
12. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
    - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
13. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
14. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
15. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

UPDATES:

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11/19/2025	Revised
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REFERENCES:

1. Ashwal S, Michelson D, Plawner L, Dobyns W. Practive Parameter: Evaulation of the child with microcephaly (an evidence based-review): Report of the Quality Standards Subcommittee of American Academy of Neurology and the Practice Committee of the Child Neurology Society. American Academy of Neurology: 2010;73:887-897.
2. Goodin D.S., Frohman E.M., et al. Disease modifying therapies in multiple sclerosis: Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. American Academy of Neurology. 2012;58:169-178.
3. H.P. Acthar Gel [package insert]. Hayward, CA. Questcor Pharmaceuticals, Inc; June 2011.
4. H.P. Acthar Gel [internet]. 2011. [cited 2012 Jan 13]. Available from: http://www.acthar.com.
5. Stafstrom C, Arnason B, et al. Treatment of Infantile Spasms: Emerging Insights from Clinical and Basic Science Perspectives. Journal of Child Neurology. 2011:1-11.
6. New Data on H.P. Acthar Gel in the Treatment of Nephrotic Syndrome Presented at the

American Societe of nephrology 43rd Annual Meeting [Press Release]. Questcor. November 2010. Available at http://ir.questcor.com/releasedetail.cfm?releaseid=532120.
7. Pellock JM, Hrachvoy R, Shinner S, et al. Infantile spasms: a U.S. consensus report. Epilepsia 2010;51(10):2175.
8. Filippini G, Brusaferri F, Sibley WA, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database Syst Rev. 2000
9. Abbruzzese G, Gandolfo C, Loeb C. "Bolus" methylprednisolone versus ACTH in the treatment of multiple sclerosis. Ital J Neurol Sci. 1983 Jun; 4(2):169-72.
10. Milanese C, La Mantia L, Salmaggi A, et al. Double-blind randomized trial of ACTH versus dexamethasone versus methylprednisolone in multiple sclerosis bouts. Clinical, cerebrospinal fluid and neurophysiological results. Eur Neurol 1989;29(1):10-4.
11. Sibley WA. Spotlight Series: Pivotal Trials through Today's Knowledge- Adrenocorticotrophic Hormone. The international MS Journal 2009: 16:42-46.
12. Schimmer B, Parker K, Adrenocorticotropic Homone; adrenocortical steroids and their synthetic analogs; inhibitors of the synthesis and actions of adrenocortical hormones. Goodman & Gilman's The Pharmacological Basis of Therapeutics 11th edition, 2006. p1588- 1612.
13. Barnes M, Bateman D, Cleland P, Dick D, Walls T, Newman P, Saunders m, Tilley P. Intravenous methylprednisolone for multiple sclerosis in relapse. J Neurol Neurosurg Psychiatry 1985: 48(2):157-9.
14. Thompson A, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. Neurology 1989: 39(7):969-71.
15. Cortese I, Chaudhry V, So Y, Cantor F, Cornblath D, Rae-Grant A. Evidence-based guideline update: Plasmapheresis in neurologic disorders: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2011:76(3):294.