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: 02/08/2024

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. 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
4. Tapering dose upon discontinuation of treatment can minimize adrenal insufficiency
5. Repository corticotropin can cause GI bleeding and gastric ulcer. Use cautiously in patients with certain GI disorders

6. 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.
7. 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]
8. 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
9. Repository corticotropin may be covered under the pharmacy benefit (self-administered or caregiver administered) **OR** the medical benefit (administered by a healthcare professional).
10. 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.

UPDATES:

Date:	Revision:
02/08/2024	Reviewed / P&T Committee Approval
12/11/2023	Revised
12/06/2023	Revised
04/01/2023	Revised
02/9/2023	Reviewed / P&T Committee Approval
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2/22	P&T Committee Approval / Reviewed
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12/21	Revised
5/21	P&T Approval/Reviewed
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5/19	P&T Approval/Reviewed
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11/13	Revised
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12/12	Revised
10/12	Revised
2/12	Created

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