Pharmacy Policy Bulletin: J-0192 Repository Corticotropin Injection – Commercial and Healthcare Reform	
Number: J-0192	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0192-016	**Original Date:** 05/01/2014
Effective Date: 04/25/2025	**Review Date:** 4/9/2025

Drugs Product(s):	• Acthar Gel Vial (repository corticotropin) • Acthar Gel SelfJect (repository corticotropin) • Purified Cortrophin Gel (repository corticotropin) • Purified Cortrophin Gel Prefilled Syringe (repository corticotropin)

FDA-Approved Indication(s):	• Acthar Gel
	  ○ Monotherapy treatment of infantile spasms in infants and children under 2 years of age
	  ○ Treatment of exacerbations of multiple sclerosis (MS) in adults
	  ○ May be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state
	• Purified Cortrophin Gel
	  ○ Treatment of exacerbations of multiple sclerosis (MS) in adults
	  ○ May be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state

Background:	• Acthar Gel is a naturally sourced complex mixture of adrenocorticotropic hormone (ACTH) analogs and other pituitary peptides. ACTH stimulates the adrenal cortex to secrete cortisol (hydrocortisone), corticosterone, aldosterone, and a number of weakly androgenic substances. • Purified Cortrophin Gel is a porcine derived purified corticotropin (ACTH) in a sterile solution of gelatin. It is made up of a complex mixture of ACTH, ACTH related peptides and other porcine pituitary derived peptides. • Acthar Gel and Purified Cortrophin Gel have limited therapeutic value in conditions responsive to corticosteroid therapy; in such cases, corticosteroid therapy is considered to be the treatment of choice. Acthar Gel or Purified Cortrophin Gel may be employed in the following disorders: ○ Multiple Sclerosis: acute exacerbations of multiple sclerosis in adults; Short-term use of corticotropin can speed the resolution of acute exacerbations of multiple sclerosis; however, it does not alter the natural course of the disease.

	○ Rheumatic Disorders: adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), and ankylosing spondylitis in adults and children > 2 years of age. Purified Cortrophin Gel has an additional indication for acute gouty arthritis. ○ Collagen Diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis) in adults and children > 2 years of age. ○ Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome in adults and children > 2 years of age. Purified Cortrophin Gel has an additional indication for severe psoriasis. ○ Allergic States: Serum sickness in adults and children > 2 years of age. Purified Cortrophin Gel has an additional indication for atopic dermatitis. ○ Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation in adults and children > 2 years of age. Purified Cortrophin Gel has an additional indication for allergic conjunctivitis. ○ Respiratory Diseases: Symptomatic sarcoidosis in adults and children > 2 years of age. ○ Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or due to lupus erythematosus in adults and children >2 years of age. • Prescribing Considerations: ○ Common adverse reactions for Acthar Gel are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain. ○ Acthar Gel for infantile spasms should be prescribed by a neurologist. ○ For the treatment of infantile spasms, 2 weeks of treatment is recommended, followed by a 2-week period of tapering and discontinuation. ○ Acthar vial is intended for either intramuscular (IM) or subcutaneous (SC) injection. Acthar Gel SelfJect is for SC administration by adults (18 years of age and older) only. For infantile spasms, doses must be administered IM using the vial. Acthar Gel SelfJect is not to be used for the treatment of infantile spasms.

Approval Criteria

I. Approval Criteria

When a benefit, coverage of Acthar Gel Vials may be approved when all of the following criteria are met: **(A. and B.):**

A. The member is less than 2 years of age.

B. The member has a documented diagnosis of infantile spams (specifically, West Syndrome) (ICD-10: G40.82).

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Purified Cortrophin Gel is not FDA-labeled for use in infantile spasms. Acthar Gel SelfJect is not to be used for the treatment of infantile spasms.
II. Acthar Gel and Purified Cortrophin Gel are considered **not medically necessary** as treatment of corticosteroid-responsive conditions. Use for corticosteroid-responsive conditions has not been shown to be more effective than the use of corticosteroids. There is a lack of evidence documenting effectiveness of Acthar Gel or Purified Cortrophin Gel in patients who have failed to respond to corticosteroids.
III. Acthar Gel and Purified Cortrophin Gel are considered **not medically necessary** for use in diagnostic testing of adrenocortical function.
IV. Except as noted above, use of Acthar Gel and Purified Cortrophin Gel are considered **investigational** for all other indications because its effectiveness for these indications has not been established.
V. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
VI. For members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and Healthcare Reform Plans: If approved, up to a 1 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Acthar Gel [package insert]. Bedminster, NJ: Mallinckrodt ARD LLC; February 2024.
2. Purified Cortrophin Gel [package insert]. Baudette, MN: Ani Pharmaceuticals, Inc.; February 2025.
3. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. Neurology. 1989;39:969-971.
4. Filippini G, Brusaferri F, Sibley WA, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database of Syst Rev. 2000;(4):CD001331.
5. Barnes MP, Bateman DE, Cleland PG, et al. Intravenous methylprednisolone for multiple sclerosis in relapse. J Neurol Neurosurg Psychiatry. 1985;48:157-159.
6. Milanese C, La Mantia L, Salmaggi A, et al. Double-blind randomized trial of ACTH versus dexamethasone versus methylprednisolone in multiple sclerosis bouts. Eur Neurol. 1989;29:10-14.
7. Burton JM, O'Connor PW, Hohol M, Beyene J. Oral versus Intravenous Steroids for Treatment of Relapses in Multiple Sclerosis. Cochrane Database of Systematic Reviews 2012, Issue 12. Art. No.: CD006921. DOI: 10.1002/14651858.CD006921.pub 3.
8. DRUGDEX [electronic version]. Greenwood Village, CO: IBM Watson Health; May 2021.
9. AHFS Drug Information. Bethesda, MD: American Society of Health-System Pharmacists; Accessed January 29, 2025.
10. Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: medical treatment of infantile spasms. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. Neurology 2012; 78:1974.