



## Medical Policy Manual **Draft Revised Policy: Do Not Implement**

### **Corticotropin-ACTH: [HP Acthar Gel (repository corticotropin injection), Purified Cortrophin® Gel (repository corticotropin injection)]**

#### **IMPORTANT REMINDER**

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:  
POLICY**

#### **I. INDICATIONS**

The Restricted Indication Enhanced Specialty Guideline Management (RI eSGM) program provides coverage for specific, but not all FDA labeled or compendial supported drug uses based on plan design and the scope of the pharmacy benefit. This program provides coverage for Acthar Gel for the treatment of infantile spasms if all of the approval criteria are met.

**Infantile spasms:** as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age

The use of Acthar and Purified Cortrophin Gel for the treatment of all other indications listed in the FDA product labeling has not been proven to be superior to conventional therapies (e.g., corticosteroids, immunosuppressive agents) and has a significantly higher cost than the standard of care agents. Use of Acthar and Purified Cortrophin Gel for these conditions is considered not medically necessary and is not a covered benefit:

##### **A. Acthar Gel:**

- Multiple Sclerosis:** treatment of acute exacerbations of multiple sclerosis in adults
- Rheumatic Disorders:** as 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; ankylosing spondylitis
- Collagen Diseases:** during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- Dermatologic Diseases:** severe erythema multiforme, Stevens-Johnson syndrome
- Allergic States:** serum sickness
- 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, anterior segment inflammation
- Respiratory Diseases:** symptomatic sarcoidosis
- Edematous State:** to induce a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

##### **B. Purified Cortrophin Gel:**

- Rheumatic Disorders:** as 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; ankylosing spondylitis; acute gouty arthritis

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2. **Collagen Diseases:** during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
3. **Dermatologic Diseases:** severe erythema multiforme (Stevens-Johnson syndrome), severe psoriasis
4. **Allergic States:** atopic dermatitis, serum sickness
5. **Ophthalmic Diseases:** severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
6. **Respiratory Diseases:** symptomatic sarcoidosis
7. **Edematous States:** to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
8. **Nervous system:** acute exacerbation of multiple sclerosis

**Note: Acthar Gel single-dose pre-filled SelfJect injector is not to be used for the treatment of infantile spasms.**

All other indications are considered experimental/investigational and not medically necessary.

### II. EXCLUSIONS

- A. Coverage of Purified Cortrophin Gel for the treatment of infantile spasms will be excluded.
- B. Use of Acthar Gel in combination with Purified Cortrophin Gel will be excluded.

### III. CRITERIA FOR INITIAL APPROVAL

#### **Infantile Spasms (Acthar Gel only)**

Authorization of 4 weeks may be granted for treatment of infantile spasms in members who are less than 2 years of age.

### IV. CONTINUATION OF THERAPY

#### **Infantile Spasms (Acthar Gel only)**

Authorization of 3 months may be granted to members requesting Acthar Gel for continuation of therapy when the member has shown substantial clinical benefit from therapy.

### **APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS**

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

### **ADDITIONAL INFORMATION**

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).



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### REFERENCES

1. Acthar Gel [package insert]. Bedminster, NJ: Mallinckrodt ARD LLC.; **February 2024**.
2. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. *Epilepsia*. 2010;51:2175-2189.
3. 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;78:1974-1980.
4. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. *Cochrane Database Syst Rev*. 2013;6:CD001770.
5. Riikonen R. Recent advances in pharmacotherapy of infantile spasms. *CNS Drugs* 2014; 28:279-290.
6. Pavone P, et al. Infantile spasms syndrome, West Syndrome and related phenotypes: what we know in 2013. *Brain & Development* 2014; 739-751.
7. Purified Cortrophin Gel [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; **October 2023**.

### EFFECTIVE DATE

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