

**Acthar Gel (repository corticotropin injection)
 Purified Cortrophin Gel (repository corticotropin injection)
 Effective 11/01/2024**

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A			
Contact Information	Medical Benefit Pharmacy Benefit		Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A			

Overview

Corticotropin is an adrenocorticotropin stimulating hormone

FDA-Approved Indications:

- Infantile Spasms (Acthar Gel only):** as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- Multiple Sclerosis:** treatment of acute exacerbations of multiple sclerosis in adults

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.

Acthar 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
- 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

Purified Cortrophin Gel:

1. **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.
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 include a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

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

Coverage Guidelines

Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all the following criteria are met:

Infantile Spasms (Acthar Gel vial only)

1. Member has a diagnosis of infantile spasms
2. Member is less than 2 years of age

Multiple Sclerosis

1. Member has a diagnosis of acute exacerbations of multiple sclerosis
2. Member is ≥ 18 years of age
3. Submission of documentation of member's inadequate response to a trial of IV methylprednisolone (for the current exacerbation), including dosage and duration of treatment

Exclusions

1. Coverage of Purified Cortrophin Gel for the treatment of infantile spasms will be excluded
2. Use of Acthar Gel in combination with Purified Cortrophin Gel will be excluded
3. Acthar Gel autoinjector will only be approved for patients 18 years of age and older

Continuation of Therapy

Infantile Spasms and Multiple Sclerosis

Reauthorization may be granted for members who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Limitations



1. Initial approvals and reauthorizations for Infantile Spasms will be granted for 4 weeks
2. Initial approvals and reauthorizations for Multiple Sclerosis will be granted for 3 weeks

References

1. Acthar Gel [package insert]. Bridgewater, NJ: Mallinckrodt Pharmaceuticals, Inc.; February 2024.
2. Berkovich R, Agius MA. Mechanisms of action of ACTH in the management of relapsing forms of multiple sclerosis. *Ther Adv Neurol Disord* 2014; 7(2):83-96.
3. Citterio A, La Mantia L, Ciucci G, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. *Cochrane Database Syst Rev* 4:CD001331.
4. Frohman EM, Shah A, Eggenberger E, et al. Corticosteroids for multiple sclerosis: I. Application for treatment exacerbations. *Neurotherapeutics* 2007; 4(4): 618-626.
5. 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.
6. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. [Cochrane Database Syst Rev](#). 2013;6:CD001770.
7. Pavone P, et al. Infantile spasms syndrome, West Syndrome and related phenotypes: what we know in 2013. *Brain & Development* 2014; 739-751.
8. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. *Epilepsia*. 2010;51:2175-2189.
9. Purified Cortrophin Gel [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; October 2023.
10. Riikonen R. Recent advances in pharmacotherapy of infantile spasms. *CNS Drugs* 2014; 28:279-290.
11. Sellebjerg F, Barnes D, Filippini G, et al. EFNS guidelines on treatment of multiple sclerosis relapses: report of an EFNS task force on treatment of multiple sclerosis. *European Journal of Neurology* 2005; 12:939-946.
12. 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.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

09/11/2024 – Reviewed and updated at September P&T. Updated Exclusions section of policy to indicate that Acthar Gel autoinjector will only be approved for the treatment of multiple sclerosis. Effective 11/1/2024.

