University of Michigan Health Plan

DRUG DETERMINATION POLICY

Title: DDP-34 Acthar Gel

Effective Date: 10/22/25

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by UM Health Plan and may not be covered by all UM Health Plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact UM Health Plan Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Acthar is a specialty drug indicated for a number of diagnoses and is associated with significant toxicity. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of toxicity, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. Supported Indications

A. Infantile Spasms. [must meet all listed below]

1. Age: less than two years.
2. Diagnosis and severity [must meet both listed below]:
   a. Monotherapy treatment of infantile spasms in infants and children.
   b. Electroencephalogram (EEG): intereictal EEG demonstrates hypsarrhythmia (very high voltage, random, slow waves, and spikes in the cortical area).
3. Dosage regimen: 150 units per m^2 divided into two equal daily doses (75 units per m^2) intramuscular for two weeks, then tapered dose over two weeks to discontinue.
4. Approval: one month.

B. Multiple Sclerosis [must meet all listed below]
    1. Age: Adults
    2. Diagnosis and severity [must meet all listed below]
        a. Acute exacerbation of Muscular Sclerosis: new or worsening set of neurological symptoms that last more than 24 hours in a person who lives with relapsing muscular sclerosis
        b. Adjunctive agent in patients whose disease is refractory to conventional treatments
    3. Other therapies
        a. High dose IV or oral methylprednisolone
    4. Dosage Regimen: 80 to 120units SQ per day for two weeks
    5. Approval
        a. Initial: two weeks
        b. Re-approval: Previous use was effective in reducing neurological symptoms and has been at least 30 days since last exacerbation

II. Non-supported use: Excluded from coverage
    A. General rationale: although FDA approved for the following conditions, available data to support use in this condition are limited and use has been replaced by other agents. Current guidelines for the management of these diseases do not include recommendations for the use of corticotropin in the treatment of these conditions.
    B. Atopic dermatitis (Purified Cortrophin): Treatment of atopic dermatitis.
        1. Other therapies: Although FDA approved for the treatment of atopic dermatitis, available data to support use in this condition are limited and use has been replaced by other agents.
        2. Current guidelines for the management of atopic dermatitis do not include recommendations for the use of corticotropin in the treatment of this condition (AAD [Sidbury 2014]).
    C. Collagen diseases**:** Treatment of exacerbations or maintenance therapy of systemic lupus erythematosus or systemic dermatomyositis (polymyositis).
        1. Other therapies: Although FDA approved for the treatment of collagen diseases, available data to support use in these conditions are limited and use has been replaced by other agents.
        2. Current guidelines for the treatment of systemic lupus erythematosus (EULAR [Fanouriakis 2019]) and recent guidance on the treatment of dermatomyositis and polymyositis (McGrath 2018; Yang 2019) and juvenile dermatomyositis (Bellutti Enders 2017) do not include recommendations for the use of corticotropin in the treatment of these conditions.
    D. Dermatologic diseases: Treatment of severe erythema multiforme, severe psoriasis (Purified Cortrophin only), or Stevens-Johnson syndrome.
        1. Other therapies: Although FDA approved for the treatment of dermatologic diseases, available data to support use in these conditions are limited and use has been replaced by other agents.
        2. Current guidelines for the treatment of psoriasis (AAD/NPF [Menter 2020]) and Stevens-Johnson syndrome and toxic epidermal necrolysis (BAD [Creamer 2016]) and recent guidance on the treatment of erythema multiforme (Trayes 2019) do not include recommendations for the use of corticotropin in the treatment of these conditions.

E. Diuresis in nephrotic syndrome**:** To induce a diuresis or remission of proteinuria in patients with nephrotic syndrome without uremia of the idiopathic type or due to lupus erythematosus.

1. Other therapies: Although FDA approved for diuresis in nephrotic syndrome, available data to support use in these conditions are limited and use has been replaced by other agents.
2. Current guidelines for the treatment of lupus nephritis (EULAR/ERA-EDTA [Fanouriakis 2020]) and the management of glomerular diseases (KDIGO 2021) do not include recommendations for the use of corticotropin.

F. Ophthalmic diseases: Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa (eg, allergic conjunctivitis, keratitis, iritis, iridocyclitis, diffuse posterior uveitis, choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation).

1. Other therapies: Although FDA approved for the treatment of ophthalmic diseases, available data to support use in these conditions are limited.

G. Rheumatic disorders**:** As adjunctive therapy for acute episodes/exacerbations of psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (select cases may require low-dose maintenance therapy), acute gouty arthritis (Purified Cortrophin only), and/or ankylosing spondylitis.

1. Other therapies: Although FDA approved for the treatment of rheumatic disorders, available data to support use in these conditions are limited and use has been replaced by other agents.
2. Current guidelines: for the treatment of psoriatic arthritis (ACR/NPF [Singh 2019]), rheumatoid arthritis (ACR [Fraenkel 2021]), juvenile idiopathic arthritis (ACR/AF [Ringold 2019]), gout (ACR [FitzGerald 2020]; EULAR [Richette 2017]), and ankylosing spondylitis (ACR/SAA/SRTN [Ward 2019]) do not include recommendations for the use of corticotropin in the treatment of these conditions.

H. Serum sickness: Treatment of serum sickness.

1. Other therapies: Although FDA approved for the treatment of serum sickness, available data to support use in this condition are limited and use has been replaced by other agents.
2. Current Guidelines: Available guidelines for the treatment of serum sickness do not include recommendations for the use of corticotropin (AAAAI/ACAAI 2010).

I. Sarcoidosis, pulmonary**:** Treatment of symptomatic sarcoidosis.

1. Other therapies: Although FDA approved for symptomatic sarcoidosis, available data to support use in this condition are limited and use has been replaced by other agents.
2. Current guidelines: for the management of sarcoidosis suggest that corticotropin may be considered for patients in whom treatment with glucocorticoids and/or antimetabolites has failed (ERS [Baughman 2021]).

IV. Exclusions.

A. Investigational, not responsive to corticosteroid conditions: e.g., acute gout, childhood epilepsy and use in tobacco cessation.

B. Diagnostic testing of adrenocortical function.

C. Contraindications:

1. Cardiovascular: congestive heart failure (CHF), uncontrolled hypertension, hypersensitivity.
2. Dermatology: scleroderma.
3. Endocrine/metabolism: osteoporosis primary adrenocortical insufficiency, adrenocortical hyper-function.
4. Gastrointestinal: peptic ulcer.
5. Hypersensitivity: to proteins of porcine origin.
6. Infections: systemic fungal infections, ocular herpes simplex, infants with suspected congenital infections, co-administration of live or live attenuated vaccines.
7. Other: recent surgeries, intravenous administration of Acthar.

4.0 Coding:

COVERED CODES				
Code	**Brand Name**	**Generic Name**	**Billing (1 unit)**	**Prior Approval**
J0800	Acthar Gel	corticotropin	40 units	Y

5.0 References, Citations & Resources:

1. H.P. Acthar Gel and Cosyntropin Review. P & T 2009;34(5):250-257.
2. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; H.P. Acthar gel, accessed September 2025.
3. ERS clinical practice guidelines on treatment of sarcoidosis. *Eur Respir J*. 2021;58(6):2004079. doi:10.1183/13993003.04079-2020[PubMed 34140301]
4. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis*. 2019;78(6):736-745. doi:10.1136/annrheumdis-2019-215089[PubMed 30926722]

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 04/27/2016

Next Review Date: 11/01/2026

Revision Date	Reason for Revision
8/19	Moved to new format; replaced abbreviations, clarified other therapies, formatted table, removed other therapies for infantile spasm due Acthar being first line treatment
4/20	Annual review: replaced abbreviations, clarified Infantile Spasm indication/age; changed other therapies language and instructions; added contraindications to exclusions section; changed B1 regarding use of Acthar in steroid-responsive conditions
5/21	Annual review, added general coverage considerations and modified other therapies to corticosteroid response conditions, reformatted; removed individual Corticosteroid responsive conditions

Revision Date	Reason for Revision
2/22	Annual review; clarified criteria instructions
1/23	Annual review
8/23	Annual review; changed section to Supported and non-supported indications. Added MS to supported indications, Added many disease states to non-supported indications
8/24	Annual review; delete Patient Safety and Monitoring Table
8/25	Annual review, updated reference, replaced abbreviation.