DRUG DETERMINATION POLICY

Title: DDP-34 Acthar Gel

Effective Date: 11/05/2019

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP 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 PHP 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:

A. Infantile Spasms.

   1. Indication: treatment of infantile spasms in children less than two years.

      a. Onset: usually at three to seven months (rare greater than 18 months).

      b. EEG (interictal): demonstrates hypsarrhythmia (very high voltage, random, slow waves and spikes in the cortical area).

   2. Dosage regimen: 150 units per m^2 divided two times daily (75 units per m^2) IM for two weeks, then tapered dose over two weeks to discontinue.

   3. Approval: one month.

B. Other Corticosteroid-Responsive Conditions.

1. Considered experimental and investigational for the following (not an all-inclusive list) because its effectiveness for these indications has not been established in the literature:

    a. Multiple Sclerosis: acute exacerbation in adults.

    b. Rheumatic diseases: adjunctive therapy for acute episodes or exacerbations of psoriatic arthritis (PA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS).

    c. Collagen Diseases: select cases of systemic lupus erythematous (SLE), systemic dermatomyositis and polymyositis.

    d. Dermatological diseases: severe erythema multiforme and Stevens-Johnson syndrome.

    e. Allergic state: serum sickness.

    f. Ophthalmic diseases: severe acute or chronic allergic and inflammatory processes including optic neuritis, keratitis and iritis.

    g. Symptomatic sarcoidosis.

    h. Nephrotic syndrome: to induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome without uremia or due to systemic lupus erythematous.

2. Two supporting articles from major peer-reviewed medical journals that support use in other corticosteroid-responsive conditions as safe and effective.

3. Other therapies: contraindicated, failed or had significant adverse effects (both below):

    a. Corticosteroids: other routes for corticosteroid administration (e.g., oral prednisone, IV methylprednisolone); must document why other well-established routes can't be used.

    b. Chronic traditional disease modifying anti-rheumatic agents (DMARDs): trial of two chronic DMARDs for specific disease state as supported in the literature.

4. Dosage: individualize depending on the disease state and medical condition of the patient; may need to taper the dose.

5. Approval: short-term individualized to disease state.

C. Exclusions.

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

2. Diagnostic testing of adrenocortical function.

4.0 Coding:

AFFECTED 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 2019.

6.0 Appendices:

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Acthar Gel corticotropin	• CV: HTN (11%) • CNS: seizure (12%) • Infection (20%)	• CV: BP, cardiac function • Endocrine: signs & symptoms of adrenal insufficiency or Cushing's Syndrome • Lab: serum glucose, electrolytes • Misc: weight	None needed

7.0 Revision History:

Original Effective Date: 04/27/2016

Next Review Date: 11/05/2020

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