DRUG DETERMINATION POLICY

Title: DDP-34 Acthar Gel

Effective Date: 2/22/23

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:

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

   A. Age: less than two years.

   B. Diagnosis and severity [must meet both listed below]:

      1. Monotherapy treatment of infantile spasms in infants and children.

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

   C. 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.

   D. Approval: one month.

II. Other Corticosteroid-Responsive Conditions [must meet all listed below]:

   A. General coverage considerations [must meet all listed below]:

1. Determination of medical necessity: use of Acthar in steroid-responsive conditions (both The Food and Drug Administration (FDA)-approved and Off-label use) is only considered medically necessary if there is a medical contraindication or intolerance to corticosteroids that are NOT associated with the use of Acthar.

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

3. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies.

B. Other therapies: contraindicated, inadequate response or significant adverse effects to two corticosteroid and two standard therapies:

1. Corticosteroids: oral and/or intravenous steroids.

2. Standard therapy: chronic formulary alternatives for specific disease state as supported in the peer reviewed literature.

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

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

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:

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 March 2022.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 04/27/2016

Next Review Date: 03/24/2024

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
2/22	Annual review; clarified criteria instructions
1/23	Annual review

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Acthar Gel corticotropin	• Cardiovascular: hypertension (11%) • Central Nervous System: seizure (12%) • Infection (20%)	• Cardiovascular: blood pressure, cardiac function • Endocrine: signs and symptoms of adrenal insufficiency or Cushing's Syndrome • Labs: serum glucose, electrolytes • Miscellaneous: weight	None needed