

Pharmacy Benefit Determination Policy

Policy Subject: H.P. Acthar Gel Policy Number: SHS PBD7 Category: Endocrine Policy Type: <input checked="" type="checkbox"/> Medical <input type="checkbox"/> Pharmacy Department: Pharmacy	Dates: Effective Date: April 27, 2016 Revision Date: May 15, 2017 Approval Date: June 27, 2018 Next Review Date: June 2019
Product (check all that apply): <input checked="" type="checkbox"/> Group HMO/POS <input checked="" type="checkbox"/> Individual HMO/POS <input checked="" type="checkbox"/> PPO <input checked="" type="checkbox"/> ASO	Clinical Approval By: Medical Directors PHP: Peter Graham, MD; Pharmacy and Therapeutics Committee PHP: Peter Graham, MD;

Policy Statement: Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover Acthar HP through the Medical Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding: J-code: J0800 (1U billable=40U)

Clinical Determination Guidelines: Document the following with chart notes A. Infantile Spasms <ol style="list-style-type: none"> 1. Indication: Treatment of infantile spasms in children < 2yo. <ol style="list-style-type: none"> a. Onset: Usually at 3-7 months (rare >18 months) b. EEG (Interictal): Demonstrates hypsarrhythmia (very high voltage, random, slow waves & spikes in the cortical area) 2. Previous therapies: Prednisolone treatment failure, contraindication or significant adverse effects 3. Dosage: 150U/m² divided 2x/day (75U/m²) IM x 2 wks, then tapered dose over 2 wks to D/C 4. Approval: 1 month

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B. Other Corticosteroid-Responsive Conditions

1. Considered experimental & investigational for the following (not an all-inclusive list) because its effectiveness for these indications has not been established:
 - a. MS: Acute exacerbation in adults
 - b. Rheumatic Diseases: Adjunctive therapy for acute episodes/exacerbations of psoriatic arthritis (PA), rheumatoid arthritis (RA) & ankylosing spondylitis (AS)
 - c. Collagen Diseases: Select cases of systemic lupus erythematosus (SLE), systemic dermatomyositis & polymyositis.
 - d. Dermatological Diseases: Severe erythema multiforme & Stevens-Johnson syndrome
 - e. Allergic State: Serum sickness
 - f. Ophthalmic Diseases: Severe acute/chronic allergic & inflammatory processes including optic neuritis, keratitis & iritis
 - g. Symptomatic sarcoidosis
 - h. Nephrotic syndrome: To induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome w/o uremia or due to SLE
2. Two supporting articles from major peer-reviewed medical journals that support use in other corticosteroid-responsive conditions as safe & effective.
3. Maximize other or previous therapies (must meet one of the below):
 - a. Other routes for corticosteroid administration (eg. oral prednisone, IV methylprednisolone): Must document why other well-established routes can't be used.
 - b. Corticosteroids (drug of choice): Treatment failure or significant adverse effects
4. Dosage: Individualize depending on the disease state & 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 & use in tobacco cessation.
2. Diagnostic testing of adrenocortical function

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Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Acthar HP corticotropin	<ul style="list-style-type: none"> • CV: HTN (11%) • CNS: Seizure (12%) • Infection (20%) 	<ul style="list-style-type: none"> • CV: BP, Cardiac function • Endocrine: Sx/S adrenal insufficiency or Cushing's Syndrome • Lab: Serum glucose, electrolytes • Misc: Weight 	None needed

References and 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 May 2018

Approved By:



6/27/18

Peter Graham, MD – PHP Executive Medical Director

Date

6/27/18

Human Resources (Kurt Batteen)

Date