Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***H.P. Acthar Gel (repository corticoptropin injection)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2011 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for H.P. Acthar Gel (repository corticoptropin injection).

H.P. Acthar Gel (repository corticoptropin injection) is indicated for:

- As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- For treatment of exacerbations of multiple sclerosis in adults

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to

make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, H.P. Acthar Gel (repository corticoptropin injection), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Infantile Spasms:**
   - Must be prescribed by a pediatric neurologist
   - Must have a diagnosis of infantile spasms confirmed by EEG
   - Must be under the age of 2 years
   - Must have no evidence of infection

2. **Multiple Sclerosis:**
   - Must be prescribed by a neurologist
   - Must have a diagnosis of multiple sclerosis
   - Must be experiencing an acute exacerbation of multiple sclerosis
   - Must be age 18 years or older
   - Must have an adequate trial of at least 2 IV corticosteroids with an inadequate response or significant side effects/toxicity
   - Must have no evidence of active infection

3. **Rheumatic Disorders, Collagen Diseases, Dermatologic Disorders, Allergic States, Ophthalmic Diseases, Respiratory Disease, and Edematous States:**
   - Must have an adequate trial of at least 2 IV corticosteroids with an inadequate response or significant side effects/toxicity for the following diagnoses:
   - Psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (select cases may require low-dose maintenance therapy), ankylosing spondylitis
     - Must be used as an adjunctive therapy for short-term administration (to tide patient over an acute episode or exacerbation)
     - Must be prescribed by a rheumatologist
   - Systemic lupus erythematosus or systemic dermatomyositis (polymyositis)
     - May be used during an exacerbation or maintenance therapy

    - Must be prescribed by a dermatologist or rheumatologist
- Severe erythema multiforme or Stevens-Johnsons syndrome
- Serum sickness
- Severe acute or chronic allergic or inflammatory processes involving the eye and its adnexa such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroditis, optic neuritis, chorioretinitis, anterior segment inflammation
    - Must be prescribed by an opthamologist
- Symptomatic sarcoidosis
- Nephrotic syndrome without uremia of the idiopathic type or lupus erythematosus
    - Must be used to induce a diuresis or remission of proteinuria.
    - Must be prescribed by a nephrologist
    - Must be experiencing an acute exacerbation of nephrotic syndrome
    - Must have a documented trial and failure of, intolerance to, or contraindication to treatment with a cytotoxic/immunosupressive regimen (i.e. cyclophosphamide, cyclosporine, mycophenolate)
    - Must currently be using conventional symptomatic therapy regimen (diuretics, ACE inhibitors, Angiotensin Receptor Blockers (ARBs), albumin)

Reauthorization Criteria:

All prior authorization renewals are reviewed on a case-by-case basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-month or 1-week intervals based upon the member's initial response to therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Infantile spasms: Up to 1 month • All other indications (Commercial members): Up 1 week • All other indications (Exchange members): Up to 1 month
Reauthorization	Same as initial
Quantity Level Limit	
Acthar Gel	3 vials per month

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. H.P. Acthar Gel [package insert]. Union City, CA: Questcor Pharmaceuticals, Inc. October 2010.
2. Hrachovy RA, Frost JD, Kellaway P, et al. Double-blind study of ACTH vs. prednisone therapy in infantile spasms. *J Pediatr* 1983;103:641-5
3. Hrachovy RA, Frost JD, Glaze DG. High-dose, long-duration versus low-dose, short duration corticotropin therapy for infantile spasms. *J Pediatr* 1994;124:803-6
4. Baram TZ, Mitchell WG, Tournay A, et al. High-dose corticotropin (ACTH) versus prednisone for infantile spasms: a prospective, randomized, blinded study. *Pediatrics* 1996;97:375-379
5. Mackay MT, Weiss SK, Adams-Webber T, et al. Practice parameter: medical treatment of infantile spasms: report of the American Academy of Neurology and the Child Neurology Society. *Neurology* 2004;62(10):1668-1681
6. Hancock EC, Osborne JP, Edwards SWl. Treatment of infantile spasms. *Cochrane Database of Systematic Reviews* 2008, Issue 4. Art. No.: CD001770. DOI: 10.1002/14651858.CD001770.pub2.
7. Filippini G, Brusaferri F, Sibley WA, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. *Cochrane Database of Systematic Reviews* 2000, Issue 4. Art. No.: CD001331. DOI: 10.1002/14651858.CD001331
8. Sellebjerg F, Barnes D, Fillippini, et al. EFNS guideline on treatment of multiple sclerosis relapses: report on an EFNS task force on treatment of multiple sclerosis. *European Journal of Neurology* 2005;12:939-946
9. Panitch H, Cohen J, Cross A, et al. National Clinical Advisory Boards of the National Multiple Sclerosis Society Treatment Recommendations for Physicians. Recommendations regarding corticosteroids in the management of multiple sclerosis. 2008. http://www.nationalmssociety.org/for-professionals/healthcare-professionals/publications/expert-opinion-papers/index.aspx. Accessed 12 December, 2010.
10. Berg A, Nilsson-Ehle P, Arnadottir M. ACTH-Induced Improvement in the Nephrotic Syndrome in Patients with a Variety of Diagnoses. Nephrology Dialysis Transplant. 2004; 19:1305-1307.
11. Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. Drug Des Devel Ther. 2011;5:147-153.
12. Nephrotic syndrome in adults: Diagnosis and management. Am Fam Physician. 2009 Nov 15;80(10):1129- 1134.
13. Vivekananad J, Ganguli A, Saha TK, et al. A randomized controlled trial of steroids and cyclophosphamide in adults with neprhotic syndrome caused by idiopathic membranous nephropathy. J Am Soc Nephrol 18: 1899–1904, 2007.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*
Criteria update	*07/16*