AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	HP Acthar	Page:	1 of 3
Effective Date:	11/1/2024	Last Review Date:	10/14/2024
Applies to:	☒Illinois ☒New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☒Virginia	☐Michigan ☒Florida Kids ☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for HP Acthar under the patient's prescription drug benefit.

Description:

The Restricted Indication Enhanced Specialty Guideline Management (RI eSGM) program provides coverage for specific, but not all FDA labeled or compendial supported drug uses based on plan design and the scope of the pharmacy benefit.

The use of Acthar and Purified Cortrophin Gel for the treatment of all other indications listed in the FDA product labeling has not been proven to be superior to conventional therapies (e.g., corticosteroids, immunosuppressive agents) and has a significantly higher cost than the standard of care agents.

All other indications are considered experimental/investigational and not medically necessary.

Note:

a) Acthar Gel single-dose pre-filled SelfJect injector is not to be used for the treatment of infantile spasms.
b) Coverage of Purified Cortrophin Gel for the treatment of infantile spasms will be excluded.
c) Use of Acthar Gel in combination with Purified Cortrophin Gel will be excluded.

Applicable Drug List:

HP Acthar

Policy/Guideline:

Criteria for Initial Approval:

A. This program provides coverage for Acthar Gel for the treatment of infantile spasms if the approval criteria is met:
1. Used as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age

B. Use of Acthar and Purified Cortrophin Gel for these conditions is considered not medically necessary and is not a covered benefit:
1. Acthar Gel
   a. **Multiple Sclerosis:** treatment of acute exacerbations of multiple sclerosis in adults

b. **Rheumatic Disorders:** as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis; ankylosing spondylitis
c. **Collagen Diseases:** during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
d. **Dermatologic Diseases:** severe erythema multiforme, Stevens-Johnson syndrome
e. **Allergic States:** serum sickness
f. **Ophthalmic Diseases:** severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
g. **Respiratory Diseases:** symptomatic sarcoidosis
h. **Edematous State:** to induce a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

2. Purified Cortrophin Gel**:**
   a. **Rheumatic Disorders**: as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis; ankylosing spondylitis; acute gouty arthritis
   b. **Collagen Diseases**: during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
   c. **Dermatologic Diseases**: severe erythema multiforme (Stevens-Johnson syndrome), severe psoriasis
   d. **Allergic States**: atopic dermatitis, serum sickness
   e. **Ophthalmic Diseases**: severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
   f. **Respiratory Diseases**: symptomatic sarcoidosis

g. **Edematous States**: to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
h. **Nervous system**: acute exacerbation of multiple sclerosis

Criteria for Continuation of Therapy:

Infantile Spasms (Acthar Gel only)

A. Authorization may be granted to members requesting Acthar Gel when the following criteria is met:
1. Member has shown substantial clinical benefit from therapy

Approval Duration and Quantity Restrictions:

Initial Approval: 4 weeks
Renewal Approval: 3 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Acthar Gel [package insert]. Bedminster, NJ: Mallinckrodt ARD LLC.; February 2024.
2. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. *Epilepsia*. 2010:51:2175-2189.
3. Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: Medical treatment of infantile spasms: Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2012;78:1974-1980.
4. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. *Cochrane Database Syst Rev*. 2013;6:CD001770.
5. Riikonen R. Recent advances in pharmacotherapy of infantile spasms. *CNS Drugs* 2014; 28:279-290.
6. Pavone P, et al. Infantile spasms syndrome, West Syndrome and related phenotypes: what we know in 2013. *Brain & Development* 2014; 739-751.
7. Purified Cortrophin Gel [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; October 2023.