TITLE: Corticotropin (H.P. ACTHAR GEL®)

EFFECTIVE DATE: May 1, 2015

DOCUMENT HISTORY
Original Endorsement Date: 1/30/14
Subsequent Endorsement Date(s): 2/5/15, 11/17/15

This policy was developed and approved by the Medica Pharmacy and Therapeutics Committee.

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE
To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determines the medical necessity of corticotropin (H.P. Acthar Gel®). The Coverage issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

MEDICAL NECESSITY CRITERIA

I. H.P. Acthar Gel® is considered medically necessary for the following indications:
   (1) Infantile Spasms (West Syndrome)
   (a) Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
   (2) Multiple Sclerosis
   (a) Treatment of acute exacerbations of multiple sclerosis in adults
   (3) Rheumatic Disorders
   (a) Short-term adjunct therapy in the treatment of acute exacerbations of rheumatic disorders such as psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, and ankylosing spondylitis in adults and children greater than 2 years of age
   (4) Collagen Disease
   (a) Treatment of acute exacerbations or as maintenance therapy of collagen disorders such as systemic lupus, erythematosus, and systemic dermatomyositis (polymyositis) in adults and children greater than 2 years of age
   (5) Dermatologic Disorders
   (a) Treatment of dermatologic diseases such as Stevens-Johnson syndrome and erythema multiforme in adults and children greater than 2 years of age
   (6) Allergic Reaction
   (a) Treatment of serum sickness in adults and children greater than 2 years of age
   (7) Ophthalmic Disorders
   (a) Treatment of 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, and anterior segment inflammation in adults and children greater than 2
years of age

(8) **Respiratory Disease**
   (a) Treatment of symptomatic sarcoidosis in adults and children greater than 2 years of age

(9) **Edematous State**
   (a) Induction of diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythematosus in adults and children greater than 2 years of age

II. Written documentation from the medical record must include:
   a. Documentation of Infantile Spasms (West Syndrome) as outlined in indication (1) **OR**
   b. Documentation confirming one of the diagnoses outlined in indications (2) through (9) **AND**
   c. Documentation of:
      i. Incomplete response to an adequate trial of corticosteroids **OR**
      ii. Medical contraindications or intolerance to corticosteroids that are not also expected to occur with use of repository corticotropin injection
   d. Renewal requests require written documentation of a new (different) episode of acute exacerbation of Multiple Sclerosis

**COVERAGE ISSUES**

1. Prior authorization is required.
2. Coverage may vary according to the terms of the member's coverage document.
3. When submitting a request for clinical review, Medica must receive a completed General Prior Authorization Form. Complete all fields and fax the form to the MedImpact Prior Authorization Department at 1-858-790-7100 or call 1-800-788-2949.
4. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s coverage document.
5. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica administrative handbook.

**References:**
1. H.P. Acthar Gel® Prescribing Information. Questcor Pharmaceuticals, Inc. Hayward, CA., September 2012
2. Micromedex. Truven Health Analytics. Last accessed 1/20/15