Clinical Policy: Corticotropin (H.P. Acthar)
Reference Number: ERX.SPMN.113
Effective Date: 10/16
Last Review Date: 09/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that corticotropin (H.P. Acthar®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Infantile Spasms (must meet all):
      1. Age < 2 years;
      2. Abnormal EEG confirming diagnosis of infantile spasms;
      3. H.P. Acthar Gel (IM injections) will be used as monotherapy;
      4. Prescribed daily dose does not exceed 150 U/m² administered (divided into twice daily intramuscular injections of 75 U/m²) over 2 weeks with an additional 2 weeks of taper.

   Approval duration: 4 weeks (one course)

   B. Multiple Sclerosis (MS) (must meet all):
      a. Age ≥ 18 years;
      b. Prescribed by or in consultation with a neurologist;
      c. Prescribed for acute exacerbations of MS;
      d. Documented adherent use of disease modifying therapy for MS;
      e. Inadequate response or significant intolerance/contraindication to injectable and oral corticosteroids;
      f. Prescribed daily dose does not exceed 80-120 units daily (IM or SC injections) administered over 2 to 3 weeks with tapering if necessary.

   Approval duration: up to 3 weeks (one course)

II. Continued Approval
Requests for continued treatment will be reviewed by a Medical Director on an individual case basis.

III. Other diagnoses/indications: It is the policy of health plans affiliated with US Script that HP Acthar is considered not medically necessary due to the lack of clinical studies establishing effectiveness and superiority over corticosteroids for the following conditions: Rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous states.
Background

Description/Mechanism of Action:
Corticotropin gel is an adrenocorticotropic hormone analogue for intramuscular or subcutaneous injection (repository corticotropin injection). Corticotropin and endogenous ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Prolonged administration of large doses of corticotropin gel induces hyperplasia and hypertrophy of the adrenal cortex and continuous high output of cortisol, corticosterone and weak androgens. The release of endogenous ACTH is under the influence of the nervous system via the regulatory hormone released from the hypothalamus and by a negative corticosteroid feedback mechanism. Elevated plasma cortisol suppresses ACTH release.

FDA Approved Indications:
H.P. Acthar is an adrenocorticotropic hormone (ACTH) analogue/intramuscular or subcutaneous injectable gel indicated for treatment of:
- Infantile spasms in infants and children under 2 years of age – as monotherapy (IM injections);
- Exacerbations of multiple sclerosis in adults (IM or SC injections);
H.P. Acthar Gel may also be used for the following disorders and diseases, although corticosteroid therapy is considered to be the treatment of choice and corticotropin should rarely be used:
- 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 (selected cases may require low-dose maintenance therapy); and ankylosing spondylitis.
- Collagen diseases: during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- Dermatologic diseases: severe erythema multiforme and Stevens-Johnson syndrome.
- Allergic states: serum sickness.
- 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; and anterior segment inflammation.
- Respiratory diseases: symptomatic sarcoidosis.
- Edematous state: 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.

Appendices

Appendix A: Abbreviation Key
ACE: angiotension-converting enzyme MS: multiple sclerosis
ACTH: adrenocorticotropic hormone RA: rheumatoid arthritis
ARB: angiotension II receptor blocker JRA: juvenile rheumatoid arthritis
IM: intramuscular SC: subcutaneous
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<th>Reviews, Revisions, and Approvals</th>
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<tr>
<td>Policy split from USS.CP.PHAR.56 H.P. Acthar and Sabril and converted to new template. Removed all requests for documentation and safety criteria. Removed labeled indications and criteria that do not have clinical studies showing effectiveness and superiority over corticosteroid therapy. Retained criteria for infantile spasms and MS. Infantile spasms: modified approval duration to 4 weeks. MS: added age/dosing and modified approval duration to max 3 weeks based on PI; added criteria for failure or contraindication of oral corticosteroids for MS; added requirement for adherent use of disease modifying therapy.</td>
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**References**

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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