

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG	H.P. Acthar® Gel (repository corticotrophin injection)
POLICY #	22100
INDICATIONS	<ol style="list-style-type: none"> 1. H.P. Acthar Gel is indicated for diagnostic testing of adrenocortical function 2. H.P. Acthar Gel has limited therapeutic value in those conditions responsive to corticosteroid therapy; in such cases, corticosteroid therapy is considered to be the treatment of choice. H.P. Acthar Gel may be employed in the following disorders: <ol style="list-style-type: none"> a. Nervous system diseases: Acute exacerbations of multiple sclerosis b. Rheumatic disorders: As adjunctive therapy for short-term administration (to tide patient over an acute episode or exacerbation) in: <ul style="list-style-type: none"> ▪ 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); <ul style="list-style-type: none"> ▪ Serum sickness e. Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: <ul style="list-style-type: none"> ▪ Allergic conjunctivitis ▪ Keratitis ▪ Iritis an iridocyclitis ▪ Diffuse posterior uveitis and choroiditis ▪ Optic neuritis ▪ Chorioretinis ▪ Anterior segment inflammation f. Respiratory diseases: <ul style="list-style-type: none"> ▪ Symptomatic sarcoidosis g. 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 h. Infantile Spasms (monotherapy)
CRITERIA	<p>ConnectiCare will consider H.P. Acthar to be medically necessary in members</p> <ul style="list-style-type: none"> • With chart note documentation of any of the above conditions (listed in 2a-2h above) that have intolerance or treatment failure of at least two other standard pharmacologic therapy <u>including</u> corticosteroid therapy, AND • Prescribing provider is a specialist in the disease state being managed <p>Some off-label use may be medically appropriate and rational in certain circumstances. Off-label drug use will be reviewed for evidence of therapeutic value according to the following criteria:</p>

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	<ol style="list-style-type: none"> 1. The drug is FDA-approved 2. The member has tried and failed established FDA approved and/or clinical guideline recommended therapy unless contraindicated 3. Phase III* FDA clinical studies to support the non-FDA approved use. 4. A. The drug is recognized for treatment of the requested indication in one of the standard reference compendia <ul style="list-style-type: none"> • American Hospital Formulary Service – Drug Information (AHFS-DI) • Thomson Micromedex DrugDex • Clinical Pharmacology (Gold Standard) • National Comprehensive Cancer Network (NCCN) • Facts & Comparisons <p>OR</p> <p>B. In the absence of being listed in above named sources, a minimum of at least two articles from major peer-reviewed journals (from the United States or great Britain) which supports the proposed use for the specific medical condition as safe and effective.</p> <p>Note: ConnectiCare requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended indication.</p> <p>*In Phase III trials, the experimental study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow the experimental drug or treatment to be used safely.</p>
LIMITATIONS	For members approved for therapy, there is a maximum of 1 vial dispensed per prescription
REFERENCES	1. H. P. Athcar Gel full prescribing information. Union City, CA. Questcor Pharmaceuticals.
P&T REVIEW HISTORY	9/07,6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 5/16, 5/17, 5/18
REVISION RECORD	11/15, 3/16, 5/17, 5/18