Updated: 04/2019
PARP Approved: 4/2019

Gateway Health
Prior Authorization Criteria
HP Acthar (corticotropin)

All requests for HP Acthar (corticotropin) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

HP Acthar (corticotropin) Prior Authorization Criteria:
Disclaimer: All requests for H.P. Acthar Gel (Corticotropin) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for H.P. Acthar Gel (Corticotropin) all of the following criteria must be met:

- Documentation of current height (cm) and weight (kg) are required
- Must be administered by intramuscular (IM) or subcutaneous (SQ) injection
- Cannot be administered in infants with suspected congenital infections or to members with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origin
- Cannot be administered with live or live attenuated vaccines

Coverage may be provided with a diagnosis of infantile spasms (West Syndrome) and the following criteria is met:

- Member is less than 24 months of age
- Prescribed by a neurologist
- Medication is used as monotherapy
- Diagnosis is supported by documentation of epileptic spasms, arrest of psychomotor development, and EEG pattern of hypsarrhythmia (Hypsarrythmia, which does not typically occur with other forms of epilepsy, can help to confirm a diagnosis of infantile spasms)
- Dosing does not exceed more than 75 units/m^2 intramuscularly twice daily for 14 days then tapered off (30 units/m^2 intramuscularly in the morning x 3 days, 15 units/m^2 intramuscularly in the morning x 3 days, 10 units/m^2 intramuscularly every morning x 3 days, then 10 units/m^2 intramuscularly every other morning x 6 days)
- **Initial Duration of Approval:** 1 month
- **Reauthorization criteria**
    - Dosing does not exceed FDA labeled dosing
    - Requires documentation showing the member's EEG with continued hypsarrhythmia after 2 weeks of treatment **OR** the member is continuing to experience spasms.
- **Reauthorization Duration of Approval:** 1 month

Gateway Health

Updated: 04/2019
PARP Approved: 4/2019

Coverage may be provided with a diagnosis of acute exacerbation of multiple sclerosis and the following criteria is met:

- Member is 18 years of age or older
- Must be prescribed by a neurologist or physician that specializes in the treatment of multiple sclerosis
- Member has tried and failed oral methylprednisone 0.5g daily for 5 days and intravenous methylprednisolone 1g/day for 3 to 5 days within the last 45 days or has a contraindication to corticosteroid therapy
- There is documentation or claims verifying the member is on a medication for the treatment of multiple sclerosis. If not on a disease modifying therapy, refer to care management
- Dosing is consistent with the FDA labeling and does not exceed 80-120 units intramuscularly or subcutaneously daily for 2-3 weeks.
- **Initial Duration of Approval:** 3 weeks
- **Reauthorization criteria**
    - Dosing does not exceed FDA labeled dosing
    - Documentation of disease response with treatment as indicated by resolution of symptoms
    - Absence of unacceptable toxicity from the drug (e.g. GI bleeding, gastric ulcer, hypertension, hypokalemia, severe depression, frank psychotic manifestations, posterior subcapsular cataracts, glaucoma)
- **Reauthorization Duration of Approval:** 3 weeks

Coverage may be provided with a diagnosis of moderately to severely active psoriatic arthritis and the following criteria is met:

- Must provide documentation of at least 6 tender and 6 swollen joint counts and ≥ 30 minutes of morning joint stiffness
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- Member has tried and failed three disease modifying anti-rheumatic drugs (DMARD) with a different mechanism of action for at least 12 weeks or has a contraindication to DMARD therapy
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Must provide documentation of 70% improvement in tender or swollen joint counts were achieved as well as a 70% improvement in at least three of the following criteria:
        - Patient assessment
        - Physician assessment
        - Pain scale
        - Disability/functional questionnaire
        - Acute phase reactant (ESR or CRP)
- **Reauthorization Duration of Approval:** 1 year

Gateway Health

Updated: 04/2019
PARP Approved: 4/2019

Coverage may be provided with a diagnosis rheumatoid arthritis or juvenile rheumatoid arthritis and the following criteria is met:

- Must be prescribed by a rheumatologist
- Member must have rheumatoid arthritis of at least 2 years duration
- Member has tried and failed three biologics with a different mechanism of action for at least 12 weeks or has contraindications to biologic therapy
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- Must have active disease as defined by at least 6 tender and 6 swollen joints
- Must provide laboratory documentation with an ESR rate of at least 28mm/hr or CRP at least 1.2 times the upper limit of normal
- Must be stable on a DMARD and prednisone for at least 4 weeks
- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
    - Must provide documentation of reductions in tender joint count and swollen joint count
- **Reauthorization Duration of Approval:** 1 year

Coverage may be provided with a diagnosis of ankylosing spondylitis and the following criteria is met:

- Must be prescribed by a rheumatologist
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- Member has tried and failed two nonsteroidal anti-inflammatory drugs (NSAIDs) or has a contraindication to NSAID therapy
- Member has tried and failed two tumor necrosis factor alpha antagonists (anti-TNF-alpha) or has a contraindication to anti-TNF-alpha therapy
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Must provide chart documentation demonstrating clinical benefit and tolerance to H.P. Acthar
- **Reauthorization Duration of Approval:** 1 year

Coverage may be provided with a diagnosis of systemic lupus erythematosus and the following criteria is met:

- Must be prescribed by a rheumatologist
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- Member has tried and failed prednisone or has a contraindication to prednisone
- Member has tried and failed two steroid-sparing immunosuppressive agents (e.g. azathioprine, cyclophosphamide, or methotrexate) or has a contraindication to all immunosuppressive agents
- Must provide chart documentation confirming at least 4 of the American College of Rheumatology (ACR) SLE Criteria (See Table 1)

- Must provide baseline Physician Global Assessment, Patient Global Assessment, or SLEDAI-2K score
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Must provide chart documentation demonstrating a decrease in Physician Global Assessment, Patient Global Assessment, or SLEDAI-2K score
- **Reauthorization Duration of Approval:** 1 year

Coverage may be provided with a diagnosis of systemic dermatomyositis (polymyositis) and the following criteria is met:

- Must be prescribed by a rheumatologist
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- Member has tried and failed two steroid-sparing immunosuppressive agents (e.g. azathioprine, tacrolimus, or methotrexate) for at least 12 weeks or has a contraindication to all immunosuppressive agents
- Member has tried and failed rituximab for at least 12 weeks or has a contraindication to rituximab
- Member has tried and failed intravenous immune globulin (IVIG) therapy for at least 12 weeks or has a contraindication to IVIG
- Must have documentation of active myositis defined as one of the following:
    - Baseline Manual Muscle Testing (MMT-8) no greater than 125/150 and at least 2 of the following:
        - Patient global with a minimum value of 2.0 cm on a 10 cm visual analog scale (VAS)
        - Physician global with a minimum value of 2.0 cm on a 10 cm VAS scale
        - Health Assessment Questionnaire (HAQ) disability index with a minimum value of 0.25
        - Elevation of at least one of the muscle enzymes [which includes creatine kinase (CK), aldolase, lactate dehydrogenase (LDH), alanine aminotransferase (ALT) and aspartate aminotransferase (AST)] at a minimum level of 1.3 times the upper limit of normal.
        - Global extramuscular disease activity score with a minimum value of 1.0 cm on a 10 cm VAS scale [this measure is the physician's composite evaluation and is based on assessments of activity scores on the constitutional, cutaneous, skeletal, gastrointestinal, pulmonary and cardiac scales of the Myositis Disease Activity Assessment Tool (MDAAT)].
    - Cutaneous VAS score on MDAAT > 3 cm on a 10 cm VAS scale and at least 3 of the following:
        - Patient global with a minimum value of 2.0 cm on a 10 cm visual analog scale (VAS)
        - Physician global with a minimum value of 2.0 cm on a 10 cm VAS scale
        - Health Assessment Questionnaire (HAQ) disability index with a minimum value of 0.25

        - Elevation of at least one of the muscle enzymes [which includes creatine kinase (CK), aldolase, lactate dehydrogenase (LDH), alanine aminotransferase (ALT) and aspartate aminotransferase (AST)] at a minimum level of 1.3 times the upper limit of normal.
        - Global extramuscular disease activity score with a minimum value of 1.0 cm on a 10 cm VAS scale [this measure is the physician's composite evaluation and is based on assessments of activity scores on the constitutional, cutaneous, skeletal, gastrointestinal, pulmonary and cardiac scales of the Myositis Disease Activity Assessment Tool (MDAAT)].
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Must provide chart documentation demonstrating a decrease in Physician Global Assessment, Patient Global Assessment, or SLEDAI-2K score
- **Reauthorization Duration of Approval:** 1 year

Coverage may be provided with a diagnosis of severe erythema multiforme or Stevens-Johnson syndrome and the following criteria is met:

- Must be prescribed by a rheumatologist, allergist, or dermatologist
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
    - Must provide chart documentation demonstrating clinical benefit and tolerance to H.P. Acthar
- **Reauthorization Duration of Approval:** 3 months

Coverage may be provided with a diagnosis of serum sickness and the following criteria is met:

- Must be prescribed by an allergist or immunologist
- Must provide laboratory documentation demonstrating neutropenia, development of reactive plasmacytoid lymphocytes, and elevated erythrocyte sedimentation rate or C-reactive protein.
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
    - Must provide chart documentation demonstrating clinical benefit and tolerance to H.P. Acthar
- **Reauthorization Duration of Approval:** 3 months

Coverage may be provided with a diagnosis 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 and the following criteria is met:

- Must be prescribed by an ophthalmologist

- Member has tried and failed two topical glucocorticoids or has a contraindication to topical glucocorticoid therapy
- Member has tried and failed two steroid-sparing immunosuppressive agents (e.g. azathioprine, mycophenolate, or methotrexate) or has a contraindication to all immunosuppressive agents
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
    - Must provide chart documentation demonstrating clinical benefit and tolerance to H.P. Acthar
- **Reauthorization Duration of Approval:** 3 year

Coverage may be provided with a diagnosis of sarcoidosis and the following criteria is met:

- Must be prescribed by a rheumatologist or pulmonologist
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- Member must have been on a stable dose of ≥ 5 mg prednisone for ≥ 3 months
- Must have documentation of deterioration of pulmonary disease as defined by a decrease of 5% forced vital capacity (FVC) in the previous year
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Documentation of reduction in concurrent prednisone dose
    - Must provide chart documentation demonstrating clinical benefit and tolerance to H.P. Acthar
- **Reauthorization Duration of Approval:** 1 year

Coverage may be provided with a diagnosis of nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus and the following criteria is met:

- 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/immunosuppressive regimen (e.g. cyclophosphamide, cyclosporine, mycophenolate)
- Must currently be using conventional symptomatic therapy regimen (diuretics, ACE inhibitors, Angiotensin Receptor Blockers (ARBs), albumin)
- Member has tried and failed two intravenous corticosteroids or has a contraindication to intravenous corticosteroid therapy
- Must provide baseline 24-hour proteinuria level or urine protein:creatinine ratio
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Must provide chart documentation of reduction in 24-hour proteinuria level or urine protein:creatinine ratio

- **Reauthorization Duration of Approval:** 1 year

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Table 1. 1997 Update of the 1982 American College of Rheumatology Revised Criteria for Classification of Systemic Lupus Erythematosus

Criterion	Definition
Malar Rash	Fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds
Discoid Rash	Erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions
Photosensitivity	Skin rash as a result of unusual reaction to sunlight, by patient's history or physician's observation
Oral Ulcers	Oral or nasopharyngeal ulceration, usually painless, observed by a physician
Arthritis	Nonerosive arthritis involving two or more peripheral joints, characterized by tenderness, swelling or effusion
Serositis	a) Pleuritis-convincing history of pleuritic pain or rub heard by a physician or evidence of pleural effusion *or* b) Pericarditis-documented by ECG or rub or evidence of pericardial effusion
Renal Disorder	a) Persistent proteinuria greater than 0.5 g per day or greater than 3+ if quantitation not performed *or* b) Cellular casts-may be red cell, hemoglobin, granular, tubular or mixed
Neurologic Disorder	a) Seizures-in the absence of offending drugs or known metabolic derangements; eg uremia, ketoacidosis, or electrolyte imbalance *or* b) Psychosis-in the absence of offending drugs or known metabolic derangements, eg uremia, ketoacidosis, or electrolyte imbalance
Hematologic Disorder	a) Hemolytic anemia-with reticulocytosis *or* b) Leukopenia-less than 4000=mm3 total on two or more occasions *or* c) Lymphopenia-less than 1500=mm3 on two or more occasions *or* d) Thrombocytopenia-less than 100 1000=mm3 in the absence of offending drugs

Immunologic Disorder	a) Anti-DNA-antibody to native DNA in abnormal titer *or* b) Anti-SM-presence of antibody to Sm nuclear antigen *or* c) Positive finding of antiphospholipid antibodies based on: 1. An abnormal serum level of IgG or IgM anticardiolipin antibodies *or* 2. A positive test result for lupus anticoagulant using a standard method *or* 3. 3 A false positive serologic test for syphilis known to be positive for at least six months and confirmed by *Treponema pallidum* immobilization or fluorescent treponemal antibody absorption test
Antinuclear Antibody	An abnormal titer of antinuclear antibody by immunofluorescence or an equivalent assay at any point in time and in the absence of drugs known to be associated with drug induced lupus syndrome

Gateway Health

Updated: 04/2019
PARP Approved: 4/2019

Acthar H.P. (corticotropin)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE):_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Please check the applicable diagnosis:

☐ **Infantile Spasms (West Syndrome)**
- Does the patient have epileptic spasms? ☐ Yes ☐ No
- Is treatment being used as monotherapy? ☐ Yes ☐ No
- Has an EEG pattern shown hypsarrhythmia? ☐ Yes ☐ No
- Is there an arrest of psychomotor development? ☐ Yes ☐ No

☐ **Multiple Sclerosis (MS), acute exacerbation**
- Has the patient tried and failed or have a contraindication to corticosteroids? ☐ Yes ☐ No

☐ **Other:** _____

Does the patient have any of the following conditions?

☐ Systemic fungal infection ☐ Ocular Herpes Simplex ☐ History or presence of peptic ulcer
☐ Uncontrolled hypertension ☐ Osteoporosis ☐ Scleroderma
☐ Congestive heart failure ☐ Primary adrenocortical insufficiency or hyperfunction

Is the prescribing physician a neurologist or MS Specialist? ☐ Yes ☐ No, provide specialty_____

Will the patient be administered via intravenous route? ☐ Yes ☐ No

Gateway Health

Updated: 04/2019
PARP Approved: 4/2019

Acthar H.P. (corticotropin)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Continued)

Has the patient been administered or will be administered live or live attenuated vaccines?
☐ Yes, Provide vaccine and date: _____ ☐ No
If the patient is less than 2 years old, are they suspected to have any congenital infections?
☐ Yes, provide suspected congenital infection _____ ☐ No
Has the patient had surgery recently? ☐ Yes, Provide date: _____ ☐ No
Does the patient have a sensitivity of porcine origin? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe or provide documentation:_____
_____
_____

If used for Infantile Spasms (West Syndrome):
Is the member still experiencing spasms? ☐ Yes ☐ No
Does the member have continued hypsarrhythmia after 2 weeks of treatment? ☐ Yes ☐ No
If yes, please provide the member's EEG report.

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date