

Request for Prior Authorization for Corticotropin (H.P. Acthar, Purified Cortrophin Gel)
Website Form – www.wv.highmarkhealthoptions.com

Submit request via: Fax - 1-833-547-2030.

All requests for Corticotropin (H.P. Acthar, Purified Cortrophin Gel) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Corticotropin (H.P. Acthar, Purified Cortrophin Gel) Prior Authorization Criteria:

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

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines. If a requested dose is above these recommendations, medical rationale must be submitted.
- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- For H.P. Acthar Gel requests excluding diagnosis of infantile spasms, member must use Purified Cortrophin Gel unless contraindicated or clinically significant adverse effects are experienced.

Coverage may be provided with a <u>diagnosis</u> of infantile spasms (West Syndrome) and the following criteria is met (H.P. Acthar **ONLY**):

- 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)
- Documentation of current height (cm) and weight (kg) are required
- Initial Duration of Approval: 1 month
- Reauthorization criteria
 - o Dosing does not exceed FDA labeled dosing
 - o 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

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

• 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
- 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 <u>diagnosis</u> 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

Coverage may be provided with a <u>diagnosis</u> 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 <u>diagnosis</u> 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 therapy
- Reauthorization Duration of Approval: 1 year

Coverage may be provided with a <u>diagnosis</u> 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
 - o 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 <u>diagnosis</u> 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:
 - o 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
 - o 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 <u>diagnosis</u> 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 therapy
- **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 therapy
- **Reauthorization Duration of Approval:** 3 months

Coverage may be provided with a <u>diagnosis</u> 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 therapy
- **Reauthorization Duration of Approval:** 3 months

Coverage may be provided with a <u>diagnosis</u> 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
 - o Documentation of reduction in concurrent prednisone dose
 - Must provide chart documentation demonstrating clinical benefit and tolerance to therapy
- Reauthorization Duration of Approval: 1 year

Coverage may be provided with a <u>diagnosis</u> 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.



Corticotropin (H.P. Acthar, Purified Cortrophin Gel) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart

	documentation as applicable to Highmark Health Options Pharmacy Services. FAX: (833)-547-2030.				
If needed, you may call to speak to a Pharmacy Services Representative. PHONE : 1-844-325-6251 Mon – Fri 8 am to 7 pm					
	PROVIDER INFORMATION				
Requesting Provider:		NPI:			
Provider Specialty:		Office Cor			
Office Address:		Office Phone:			
		Office Fax	:		
Manchan Nama	MEMBER INFORMATION	DOD.			
Member Name: Member ID:		DOB: Member	Height:		
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	REQUESTED DRUG INFORMATION	_			
Medication:		Strength:			
Directions:		Quantity:	Refills:		
Is the member currently receiving rec	quested medication? Yes No		Iedication Initiated:		
	ronic or long-term condition for which th	e medication ma	ay be necessary for the		
life of the patient? Yes No					
Billing Information					
This medication will be billed: at a pharmacy OR medically, JCODE:					
Place of Service: Hospital Provider's office Member's home Other					
Name:	Place of Service Information	NPI:			
Address:		Phone:			
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MEDICAL HISTORY (Complete for ALL requests)					
Diagnosis:		ICD Code:			
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Prescribing Provider Signature	Date

