



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	April 20, 2009 April 24, 2012; September 28, 2012; April 29, 2013, February 20, 2018

H.P. Acthar Gel (repository corticotropin injection)

LENGTH OF AUTHORIZATION: Per Titration Schedule (length of approval shall not exceed the quantity (mL) required to properly treat and taper)

REVIEW CRITERIA:

Collagen disease:

- Patient must be ≥ 2 years old.
- Treatment of acute exacerbations or maintenance therapy.
- Must have a diagnosis of a collagen disorder (e.g. systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- Patient must have failed corticosteroid therapy (e.g. dexamethasone, hydrocortisone, methylprednisolone, prednisone . . .).
- Medication must be prescribed by rheumatologist or a specialist in this field of study.

Disorder of eye:

- Patient must be ≥ 2 years old.
- Use for 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.
- Patient must have failed corticosteroid therapy (e.g. dexamethasone, hydrocortisone, methylprednisolone, prednisone . . .).
- Medication must be prescribed by ophthalmologist or a specialist in this field of study.

Disorder of skin:

- Patient must be ≥ 2 years old.
- For the treatment of dermatologic diseases such as erythema mutlifforme and Stevens-Johnson syndrome.

Infantile Spasms:

- Patient must be less than 2 years old.
- Must have a diagnosis of **West Syndrome (infantile spasms)** verified by progress notes, discharge notes, or health conditions.
- Medication must be prescribed by neurologist or a specialist in this field of study.

Acute Exacerbations in Adults with Multiple Sclerosis:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of **Multiple Sclerosis** verified by progress notes, discharge notes, or health conditions.
- Patient must have failed corticosteroid therapy (e.g. dexamethasone, hydrocortisone, methylprednisolone, prednisone . . .).
- Medication must be prescribed by neurologist or a specialist in this field of study.

Acute Exacerbations of Inflammatory disorder of musculoskeletal system:

- Patient must be ≥ 2 years old.
- Must be diagnosed with a musculoskeletal disease (e.g. psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, or ankylosing spondylitis) verified by progress notes, discharge notes, or health conditions.
- Treatment is for acute exacerbations, short term adjunct therapy.
- Medication must be prescribed by rheumatologist or a specialist in this field of study.
- Patient must have failed corticosteroid therapy (e.g. dexamethasone, hydrocortisone, methylprednisolone, prednisone....).

Nephrotic syndrome:

- Patient must be ≥ 2 years old.
- Must have a diagnosis of nephrotic syndrome, idiopathic, without uremia or due to lupus erythematosus verified by progress notes, discharge notes, or health conditions.
- Medication must be prescribed by nephrologist or a specialist in this field of study.
- Patient must have failed corticosteroid therapy (e.g. dexamethasone, hydrocortisone, methylprednisolone, prednisone....).

Sarcoidosis:

- Patient must be ≥ 2 years old.
- Must have the diagnosis of sarcoidosis verified by progress notes, discharge notes, or health conditions.
- Medication must be prescribed by rheumatologist or a specialist in this field of study.
- Patient must have failed corticosteroid therapy (e.g. dexamethasone, hydrocortisone, methylprednisolone, prednisone....).

Transfusion reaction due to serum protein reaction:

- Patient must be ≥ 2 years old.
- Must have a diagnosis of serum sickness.

DOSING AND ADMINISTRATION:

Collagen disease, Disorder of eye, Disorder of skin, Acute Exacerbations of Inflammatory disorder of musculoskeletal system, Nephrotic syndrome, Sarcoidosis, Transfusion reaction due to serum protein reaction:

- 40-80 units subcutaneously (SQ) or intramuscularly (IM) every 24 to 72 hours.

Infantile Spasms:

- 150 U/m² divided into twice daily IM injections of 75 U/m² (after 2 weeks of treatment, dosing should be gradually tapered)
 - Dose may be tapered after 2 weeks by reducing dose by one third every 5 days OR
 - Patient switched to prednisone as taper therapy after 2 weeks treatment.

Acute Exacerbations in Adults with Multiple Sclerosis:

- 80-120 units/day IM for 2-3 weeks for acute exacerbations.
- Dosage should be individualized according to the medical condition of each patient. Frequency and dose of the drug should be determined by considering the severity of the disease and the initial response of the patient.

Dosage Form: 5 mL multi-dose vial containing 80 USP Units per mL