| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
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| Original Development Date:<br>Original Effective Date:<br>Revision Date: | April 20, 2009<br><br>April 24, 2012; September 28, 2012; April 29, 2013, February 20, 2018, July 15, 2020, September 22, 2020, March 11, 2022 |

# H.P. Acthar Gel (repository corticotropin injection) and Purified Cortrophin Gel (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 (Approve for 3 months):**

- 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).
- If the diagnosis is systemic lupus erythematosus, patient has had a trial of 1 agent from each of the following, and experienced inadequate response or intolerance:
    a) Corticosteroid: prednisone, intravenous dexamethasone
    b) Hydroxychloroquine, azathioprine, cyclosporine, cyclophosphamide, or mycophenolate
    c) Intravenous methylprednisolone
- For other diagnoses of collagen disorder, 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 (Approve for 3 months):**

- 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 (Approve for 3 months):**

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

**Infantile Spasms (Approve for 3 months):**

- 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 (MS) (Approved for one month):**

- Patient must be ≥ 18 years old.
- Must have a diagnosis of acute exacerbation of MS verified by progress notes, discharge notes, or health conditions.
- Failure of a recent (within the last 30 days) trial of at least 3 day course of corticosteroid therapy (e.g. dexamethasone, hydrocortisone, methylprednisolone, prednisone . . .). for acute exacerbations of MS, unless contraindicated or clinically significant adverse effects are experienced.
- Patient is adherent to disease modifying treatment (e.g. Aubagio, Avonex Betaseron, Copaxone, Gilenya, Rebif, Tecfidera,).
- Medication must be prescribed by neurologist or a specialist in this field of study.

**Acute Exacerbations of Inflammatory disorder of musculoskeletal system (Approve for 3 months):**

- 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 (Approve for 3 months):**

- 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 (Approve for 3 months):**

- 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 (Approve for 3 months):**

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

**CONTINUATION OF THERAPY (UP TO 3 MONTHS):**

Non-acute indications:

- Patient met initial review requirements
- Positive response to therapy submitted (supporting documentation required)
- Dosage and administration does not exceed FDA approved maximum for the patient's indication.
- Supporting documentation if dose requested exceeds FDA approved maximum.

**DOSING AND ADMINISTRATION:**

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/