Acthar Gel

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Repository corticotropin injection as monotherapy for the treatment of infantile spasms (West syndrome) meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes for up to 4 weeks when **ALL** the following criteria are met (FDA H.P. Acthar Gel, 2010):

1. Diagnosis of infantile spasms (i.e., West Syndrome); **AND**
2. Individual is less than 2 years old **AND**
3. Will **not** be used for any of the following:
   a. Diagnostic testing of adrenocortical function **OR**
   b. Conditions that are not responsive to corticosteroid therapy including but not limited to:
      i. Use in tobacco cessation **OR**
      ii. Use in acute gout **OR**
      iii. Use in childhood epilepsy **AND**
4. Must be dosed in accordance with FDA.

Dosing and Administration
Dosing per FDA Guidelines

Initial Dose: 75 U/square meters intramuscular twice daily for 2 weeks

After 2 weeks, dose should be tapered according to the following schedule: 20 U/square meters IM in the am for 3 days, then 15 U/square meters IM in the am for 3 days.

Repository corticotropin injection is available as 5 mL multi-dose vial containing 80 USP units per mL.

Please refer to a separate policy on Site of Care or Site of Service Review (policy #2018030) for pharmacologic/biologic medications.

Does Not Meet Primary Coverage Criteria Or Is Not Medically Necessary or Investigational For Contracts Without Primary Coverage Criteria

The use of repository corticotropin injection for any indication or circumstance other than those described above including but not limited to corticosteroid-responsive conditions, does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes and is considered **investigational**.

For members with contracts without primary coverage criteria, repository corticotropin injection for any indication or circumstance other than those described above including but limited to corticosteroid-responsive conditions is considered **investigational**.

Investigational services are specific contract exclusions in most member benefit certificates of coverage.