

Corticotropin injection gel (Acthar Gel, Cortrophin Gel)

Coverage Criteria:

Corticotropin injection gel may be approved for patients when they meet the following:

1. Patient has been diagnosed with infantile spasms; and,
2. Prescribed by Neurology; and,
3. Prescribed within the FDA approved dosing regimen.

Renewal Criteria:

Reauthorizations will be limited to patients with infantile spasms, who have demonstrated positive response to treatment, with documented clinical rationale to support continued use is required.

Coverage Duration:

Approvals are limited to 28 days.

Other Criteria:

Multiple Sclerosis

Corticotropin injection gel is considered not medically necessary for Multiple Sclerosis. There are no studies demonstrating improved outcomes for corticotropin injection gel when compared to alternative appropriate therapies such as methylprednisolone, which is much more affordable than corticotropin injection gel. There are no contraindications to methylprednisolone for which corticotropin injection gel would not also be contraindicated. There are no studies that suggest that patients who have had an inadequate response to methylprednisolone are likely to respond to corticotropin injection gel. Disease modifying treatments, steroids, and re-trial of steroids are medically necessary alternatives in patients with a multiple sclerosis exacerbation.

All Other Indications

Corticotropin injection gel is considered not medically necessary in all other uses, even those with FDA approval, because there is insufficient evidence in the form of high-quality, prospective, peer-reviewed literature. The FDA Product Label does not include any clinical trial evidence to support use in any indication other than infantile spasms. There are no studies demonstrating improved outcomes for corticotropin injection gel when compared to alternative appropriate therapies.

Medical Contraindications per Prescribing Information

Acthar Gel single-dose pre-filled SelfJect injector is not to be used for the treatment of infantile spasms.