Medical Necessity Guidelines:
Acthar (corticotropin)

Effective: January 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

Applies to:

Commercial Products
☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products
☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products
☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) Approved Indications:
- Infantile spasms
  - As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- Multiple sclerosis
  - For the treatment of acute exacerbations of multiple sclerosis in adults.

Controlled trials have shown corticotropin to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

The recommended dosage regimen for infantile spasms is a daily dose of 150 U/m2 (divided into twice daily intramuscular injections of 75 U/m2) administered over a two-week period. Dosing should then be gradually tapered over a two week period to avoid adrenal insufficiency.

The recommended dosage regimen for acute exacerbations of multiple sclerosis is a daily intramuscular or subcutaneous dose of 80 to 120 units for two to three weeks for acute exacerbations. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

Clinical Guideline Coverage Criteria

The Plan may cover Acthar (corticotropin) when all the following clinical criteria is met:

Infantile spasms
1. Documented diagnosis of infantile spasms (i.e., West Syndrome)
   AND
2. Documentation the Member is ≤2 years of age

**Multiple sclerosis**

1. Documented diagnosis of an acute exacerbation of multiple sclerosis
   AND
2. The medication is prescribed by a neurologist with expertise in treatment of multiple sclerosis
   AND
3. Documentation the Member is ≥18 years of age
   AND
4. Documentation of one of the following:
   a. Previous failure of both intravenous and oral corticosteroid therapy
   b. Intolerance or contraindication to corticosteroid therapy
   AND
5. If the request is for Acthar, documented previous failure or adverse event, or contraindication to Cortrophin

**Limitations**

- Repository Corticotropin Injection is unproven for treatment of conditions other than infantile spasms and multiple sclerosis. Requests for coverage of all other indications will be reviewed for medical necessity. If the request is for Acthar, documentation of previous failure or adverse event, or contraindication to Cortrophin is required.
- For infantile spasms, approval duration is 6 months.
- For multiple sclerosis, approval duration is 1 month.
- For all indications other than infantile spasms or multiple sclerosis, approval duration is 6 months.

**Codes**

The following code(s) require prior authorization:

**Table 1: HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J0800</td>
<td>Injection, corticotropin, up to 40 units</td>
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**References:**


Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.