Acthar Gel (repository corticotropin injection) will be considered for coverage when the following criteria are met:

**Infantile Spasms (West syndrome, X-linked infantile spasms syndrome)**

For **initial** authorization:
1. Member is an infant or a child under 2 years of age; AND
2. Medication must be prescribed by a pediatric neurologist or an epileptologist; AND
3. Member has documented diagnosis of infantile spasms in chart notes; AND
4. Member’s body surface area (BSA, m²) or height and weight have been provided to determine the appropriate dosage.
5. Medication is used as monotherapy; AND
6. **Dosage allowed/Quantity limit:** The recommended regimen is a maximum daily dose of 150 U/m² (divided into twice daily injections of 75 U/m²) for 2 weeks. After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period. Quantity Limit: 3 vials (15 mL total) per 28 days.

*If all the above requirements are met, the medication will be approved for 1 month.*
For **reauthorization**:  
1. Member must be under 2 years of age; AND  
2. Chart notes demonstrate clinical benefit from the initial use of medication (e.g., suppression of spasm symptoms); AND  
3. Member experienced a relapse in spasm symptoms after Acthar was discontinued.

*If all the above requirements are met, the medication will be approved for an additional month.*

### Multiple Sclerosis

For **initial** authorization:  
1. Member is at least 18 years of age or older; AND  
2. Medication must be prescribed by a neurologist; AND  
3. Member must have documentation of a current acute exacerbation of MS; AND  
4. Member must have a previous 3-day trial and failure of intravenous methylprednisolone at a dose of at least 1000 mg daily; AND  
Medication is being used as add-on treatment to disease modifying therapy (ex. Copaxone, Gilenya, Plegridy, etc.)  
5. Member does not have ANY of the following:  
   a. Scleroderma  
   b. Osteoporosis  
   c. Systemic fungal infections  
   d. Ocular herpes simplex  
   e. History of or the presence of a peptic ulcer  
   f. Congestive heart failure  
   g. Primary adrenocortical insufficiency or adrenocortical hyperfunction  

7. **Dosage allowed/Quantity limit:** Administer 80-120 units daily intramuscularly for 2-3 weeks.  
 Quantity Limit: 7 vials per 21 days.

*If all the above requirements are met, the medication will be approved for 3 weeks.*

For **reauthorization**:  
1. Acthar gel will not be reauthorized for chronic use.

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**CareSource considers Acthar Gel (repository corticotropin injection) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/08/2018</td>
<td>New policy for H.P.Acthar created. Policy placed in the new format.</td>
</tr>
<tr>
<td>01/22/2021</td>
<td>Changed name to Acthar. Increased the quantity limit to 3 vials (15 mL) per 28 days. Adjusted specialist name. Added that BSA or height/weight must be provided to calculate quantity. Reworded reauth requirement to be more specific. Added member must be under 2 years of age for reauth. Added that member must experience relapse in spasm symptoms after Acthar was discontinued. Updated references.</td>
</tr>
<tr>
<td>05/05/2022</td>
<td>Transferred to new format. Updated references. Added medication must be used as monotherapy.</td>
</tr>
<tr>
<td>03/16/2023</td>
<td>Added diagnosis of multiple sclerosis (MS). Added references. Updated background information to include MS.</td>
</tr>
</tbody>
</table>
References:


Effective date: 04/14/2023
Revised date: 03/16/2023