Louisiana Medicaid Repository Corticotropin (Acthar® Gel, <u>Cortrophin[™] Gel</u>)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for repository corticotropin (Acthar® Gel, <u>Cortrophin[™] Gel</u>).

Additional Point-of-Sale edits may apply.

This agent may have a **Black Box Warning**, and/or may be subject to **Risk Evaluation and Mitigation Strategy** (**REMS**) under FDA safety Regulations. Please refer to individual prescribing information for details.

Approval Criteria

- The recipient has a diagnosis of infantile spasms (Acthar® gel only); AND
- The recipient is less than 2 years of age on the date of the request; AND
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with a neurologist;

OR

- The recipient is 18 years of age or older on the date of the request: AND
- The recipient is being treated for an acute exacerbation of multiple sclerosis; AND
- The recipient has tried and failed an IV corticosteroid for this exacerbation occurrence or has a contraindication or intolerance to corticosteroid therapy (must be **stated on the request**); **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with a neurologist;

AND

- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet all initial approval criteria; AND
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: For infantile spasms: 12 months OR until the child's second birthday, whichever is less For multiple sclerosis: 1 month

References

Acthar Gel (repository corticotropin) [package insert]. Bedminster, NJ: Mallinckrodt Pharmaceuticals; October 2021. <u>https://www.acthar.com/pdf/Acthar-PI.pdf</u>

Cortrophin Gel (repository corticotropin) [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; November 2021. https://cortrophin.com/pdfs/purified-cortrophin-gel-prescribinginformation.pdf

Olek, M. Howard, J. Treatment of acute exacerbations of multiple sclerosis in adults. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2019.

Cortrophin Gel (repository corticotropin) [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; November 2021. https://cortrophin.com/pdfs/purified-cortrophin-gel-prescribinginformation.pdf

Revision / Date	Implementation Date
Policy created	October 2019
Formatting changes, updated references / December 2021	July 2022
Added wording for Cortrophin TM / July 2022	October 2022