

Corticotropin Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
12-15-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Acthar ; Cortrophin	corticotropin inj gel	80 UNIT/ML	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Acthar ; Cortrophin	corticotropin inj gel	80 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PREFERRED AGENTS

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval				
	<table border="1"> <thead> <tr> <th>Preferred Target Agent(s)</th> <th>Non-Preferred Target Agent(s)</th> </tr> </thead> <tbody> <tr> <td>Acthar Gel (repository corticotropin)</td> <td>Purified Cortrophin Gel (repository corticotropin)</td> </tr> </tbody> </table> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of infantile spasms AND 2. The patient is less than 24 months of age AND 	Preferred Target Agent(s)	Non-Preferred Target Agent(s)	Acthar Gel (repository corticotropin)	Purified Cortrophin Gel (repository corticotropin)
Preferred Target Agent(s)	Non-Preferred Target Agent(s)				
Acthar Gel (repository corticotropin)	Purified Cortrophin Gel (repository corticotropin)				

Module	Clinical Criteria for Approval
	<p>3. ONE of the following:</p> <ul style="list-style-type: none"> A. The requested agent is a preferred agent OR B. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR C. The prescriber states the patient is currently being treated with the requested agent AND the patient is currently stable on the requested agent OR D. The patient has tried and had an inadequate response to ONE preferred agent for the requested indication OR E. ONE preferred agent for the requested indication was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event OR F. The patient has an intolerance or hypersensitivity to ONE preferred agent for the requested indication that is NOT expected to occur with the requested agent OR G. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication that is NOT expected to occur with the requested agent OR H. ONE preferred agent for the requested indication is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm OR I. ONE preferred agent for the requested indication is not in the best interest of the patient based on medical necessity OR J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent for the requested indication and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event AND <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>5. ONE of the following:</p> <ul style="list-style-type: none"> A. The requested quantity (dose) is within FDA labeled dosing for the requested indication OR B. There is support for therapy with a higher dose for the requested indication <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL and BCBSMT: 12 months ALL other plans: 3 months</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ul style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ul style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ul style="list-style-type: none"> A. The patient has another FDA labeled indication for the requested agent and route of administration OR B. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 2. ALL of the following: <ul style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following:

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Target Agent(s) will NOT be approved and are NOT medically necessary for all other indications including but not limited to:</p> <ol style="list-style-type: none"> 1. Multiple Sclerosis 2. Rheumatic Disorders 3. Collagen diseases 4. Dermatologic diseases 5. Allergic states 6. Ophthalmic diseases 7. Respiratory diseases 8. Edematous states <p>The effectiveness of repository corticotropin has not been demonstrated as clinically superior to conventional corticosteroids and/or immunosuppressive therapy for uses other than infantile spasms.</p>