

Alhemo Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
02-01-2026

Date of Origin
02-13-2025

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Alhemo	concizumab-mtci soln pen-injector	150 MG/1.5ML ; 300 MG/3ML ; 60 MG/1.5ML	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Alhemo	concizumab-mtci soln pen-injector	150 MG/1.5ML ; 300 MG/3ML ; 60 MG/1.5ML	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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval		
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> ONE of the following: <ol style="list-style-type: none"> The requested agent is eligible for continuation of therapy AND the following: <div style="text-align: center;"> <table border="1" style="margin: 0 auto;"> <tr> <td>Agents Eligible for Continuation of Therapy</td> </tr> <tr> <td>Alhemo</td> </tr> </table> </div>	Agents Eligible for Continuation of Therapy	Alhemo
Agents Eligible for Continuation of Therapy			
Alhemo			

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed OR B. ALL of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of Hemophilia A (factor VIII deficiency) confirmed by blood coagulation testing AND BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent will be used for ONE of the following: <ol style="list-style-type: none"> A. Primary prophylaxis in patients with severe factor VIII deficiency (factor VIII level of less than 1%) OR B. Secondary prophylaxis in patients with at least TWO episodes of spontaneous bleeding into joints AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has factor VIII inhibitors AND ALL of the following: <ol style="list-style-type: none"> 1. A current or historical inhibitor titer of greater than or equal to 5 Bethesda units (BU) AND 2. Previous prophylaxis therapy AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) OR B. The patient has an inhibitor level greater than or equal to 200 BU (medical records required) OR C. There is support for why the patient is NOT a candidate for ITI OR B. The patient does NOT have factor VIII inhibitors AND ONE of the following: <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 2. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 3. The patient has tried and had an inadequate response to TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) [chart notes required] OR 4. TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 5. The patient has an intolerance or hypersensitivity to TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) [chart notes required] OR 6. The patient has an FDA labeled contraindication to BOTH Hemlibra AND

Module	Clinical Criteria for Approval
	<p>ALL antihemophilic factor VIII agents [chart notes required] OR</p> <ol style="list-style-type: none"> 7. TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) are 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 [chart notes required] OR 8. TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) are not in the best interest of the patient based on medical necessity [chart notes required] OR 9. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND <p>B. The patient has a diagnosis of Hemophilia B (factor IX deficiency) confirmed by blood coagulation testing AND BOTH of the following:</p> <ol style="list-style-type: none"> 1. The requested agent will be used for ONE of the following: <ol style="list-style-type: none"> A. Primary prophylaxis in patients with severe factor IX deficiency (factor IX level of less than 1%) OR B. Secondary prophylaxis in patients with at least TWO episodes of spontaneous bleeding into joints AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has factor IX inhibitors AND ALL of the following: <ol style="list-style-type: none"> 1. A current or historical inhibitor titer of greater than or equal to 5 Bethesda units (BU) AND 2. The patient has had previous prophylaxis therapy AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) OR B. The patient has an inhibitor level greater than or equal to 200 BU (medical records required) OR C. There is support for why the patient is NOT a candidate for ITI OR B. The patient does NOT have factor IX inhibitors AND ONE of the following: <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-

Module	Clinical Criteria for Approval
	<p>ERISA ASO/Self-insured Municipalities/Counties member OR</p> <ol style="list-style-type: none"> 2. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 3. The patient has tried and had an inadequate response to an antihemophilic Factor IX agent [chart notes required] OR 4. ONE antihemophilic Factor IX agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 5. The patient has an intolerance or hypersensitivity to an antihemophilic Factor IX agent [chart notes required] OR 6. The patient has an FDA labeled contraindication to ALL antihemophilic Factor IX agents [chart notes required] OR 7. ONE antihemophilic Factor IX agent 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 [chart notes required] OR 8. ONE antihemophilic Factor IX agent is not in the best interest of the patient based on medical necessity [chart notes required] OR 9. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE antihemophilic Factor IX agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND <p>C. If the patient has an FDA labeled indication, then ONE of the following:</p> <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND D. The requested agent will be used as prophylaxis to prevent or reduce the frequency of bleeding episodes AND E. The requested agent will NOT be used for the treatment of breakthrough bleeding AND F. The patient is NOT pregnant AND <ol style="list-style-type: none"> 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., prescriber working in a hemophilia treatment center, hematologist with hemophilia experience), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 3. The requested agent will NOT be used in combination with immune tolerance induction with clotting factor products (i.e., factor VIII or factor IX concentrates) as prophylactic therapy, hemophilia bypassing agent prophylaxis (i.e., factor VIIa or anti-inhibitor

Module	Clinical Criteria for Approval
	<p>coagulant complex), or emicizumab for hemophilia A with inhibitors (Note: Factor VIII or factor IX products can be administered for the treatment of breakthrough bleeds while receiving Alhemo) AND</p> <ol style="list-style-type: none"> 4. The patient does NOT have any FDA labeled contraindications to the requested agent AND 5. The requested quantity (dose) is within FDA labeled dosing for the requested indication <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL, BCBSMT, and BCBSTX: 12 months</p> <p>BCBSNM: 3 months</p> <p>ALL other plans: 8 Weeks</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] 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] AND D. There is support for an age in the patient's given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). 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] OR 2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol 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: <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. ALL of the following: <ol 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: <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]

Module	Clinical Criteria for Approval
	<p>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> <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</p> <p>ALL other plans: 12 months</p> <p>Renewal Evaluation</p> <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 been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. ONE of the following:(medical records required) <ol style="list-style-type: none"> A. The patient has had improvement or stabilization with the requested agent as indicated by the number of breakthrough bleeding episodes OR B. There is support for the continued use of the requested agent AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., prescriber working in a hemophilia treatment center, hematologist with hemophilia experience), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The requested agent will NOT be used in combination with immune tolerance induction with clotting factor products (i.e., factor VIII or factor IX concentrates) as prophylactic therapy, hemophilia bypassing agent prophylaxis (i.e., factor VIIa or anti-inhibitor coagulant complex), or emicizumab for hemophilia A with inhibitors (Note: Factor VIII or factor IX products can be administered for the treatment of breakthrough bleeds while receiving Alhemo) AND 5. There is an absence of unacceptable toxicity from the drug (e.g., thromboembolic events, hypersensitivity) AND 6. The plasma concentration of concizumab is at least 200 ng/ml AND 7. The patient does NOT have any FDA labeled contraindications to the requested agent AND 8. The requested quantity (dose) is within FDA labeled dosing for the requested indication <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p>

