



Agamree Emflaza Prior Authorization with Quantity Limit 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
Emflaza	deflazacort susp ; deflazacort tab	18 MG ; 22.75 MG/ML ; 30 MG ; 36 MG ; 6 MG	M ; N ; O ; Y	O ; Y		
Agamree	vamorolone oral susp	40 MG/ML	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Agamree	vamorolone oral susp	40 MG/ML	300	mLs	30	DAYS			
Emflaza	Deflazacort Tab 18 MG	18 MG	30	Tablets	30	DAYS			
Emflaza	Deflazacort Tab 6 MG	6 MG	60	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Agamree	vamorolone oral susp	40 MG/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 ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Emflaza	deflazacort susp ; deflazacort tab	18 MG ; 22.75 MG/ML ; 30 MG ; 36 MG ; 6 MG	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 ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Agamree	vamorolone oral susp	40 MG/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
Emflaza	Deflazacort Tab 18 MG	18 MG	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 ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Emflaza	Deflazacort Tab 6 MG	6 MG	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"> 1. ALL of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of Duchenne Muscular Dystrophy confirmed by genetic analysis (i.e., dystrophin deletion or duplication mutation) [genetic test required] OR 2. The patient has another FDA labeled indication for the requested agent and route of administration AND B. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> 1. The patient's age is within FDA labeling for the requested indication for the requested agent OR 2. There is support for the use of the requested agent for the patient's age for the requested indication AND C. 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 are required] OR 3. The patient has tried and had an inadequate response after 6 months of therapy with ONE prerequisite agent (i.e., generic prednisone or prednisolone) [chart notes are required] OR 4. ONE prerequisite agent (i.e., generic prednisone or prednisolone) was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR

Module	Clinical Criteria for Approval				
	<p>5. The patient has an intolerance or hypersensitivity to ONE prerequisite agent (i.e., generic prednisone or prednisolone) [chart notes are required] OR</p> <p>6. The patient has an FDA labeled contraindication to ONE prerequisite agent (i.e., generic prednisone or prednisolone) [chart notes are required] OR</p> <p>7. ONE prerequisite agent (i.e., generic prednisone or prednisolone) 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 are required] OR</p> <p>8. ONE prerequisite agent (i.e., generic prednisone or prednisolone) is NOT in the best interest of the patient based on medical necessity [chart notes are required] OR</p> <p>9. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE prerequisite agent (i.e., generic prednisone or prednisolone) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] AND</p> <p>2. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:</p> <table border="1" data-bbox="235 915 948 993"> <thead> <tr> <th data-bbox="235 915 592 949">Brand</th> <th data-bbox="592 915 948 949">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 949 592 993">Emflaza</td> <td data-bbox="592 949 948 993">deflazacort</td> </tr> </tbody> </table> <p>A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR</p> <p>C. The patient has tried and had an inadequate response to the generic equivalent [chart notes are required] OR</p> <p>D. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>E. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent [chart notes are required] OR</p> <p>F. The patient has an FDA labeled contraindication to the generic equivalent that is NOT expected to occur with the brand agent [chart notes are required] OR</p> <p>G. The generic equivalent 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 are required] OR</p> <p>H. The generic equivalent is NOT in the best interest of the patient based on medical necessity [chart notes are required] OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>J. There is support for the use of the requested brand agent over the generic equivalent AND</p> <p>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p>	Brand	Generic Equivalent	Emflaza	deflazacort
Brand	Generic Equivalent				
Emflaza	deflazacort				

Module	Clinical Criteria for Approval
	<p data-bbox="277 180 1382 239">5. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient's weight</p> <p data-bbox="228 275 500 304">Length of Approval:</p> <p data-bbox="228 342 634 401">BCBSOK: 36 months BCBSIL and BCBSMT: 12 months</p> <p data-bbox="228 436 987 466">All other plans: 6 months for Agamree, 12 months for Emflaza</p> <p data-bbox="228 501 1078 531">NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.</p> <p data-bbox="228 630 1247 659">The requested agent will also be approved when ALL the following are met:</p> <ol data-bbox="277 695 1390 1129" style="list-style-type: none"> <li data-bbox="277 695 743 724">1. The member resides in Ohio AND <li data-bbox="277 726 915 756">2. The plan is Fully Insured or HIM Shop (SG) AND <li data-bbox="277 758 1354 816">3. The patient does NOT have any FDA labeled contraindications to the requested agent AND <li data-bbox="277 819 1390 1129">4. ONE of the following: <ol data-bbox="391 842 1354 1129" style="list-style-type: none"> <li data-bbox="391 842 1354 900">A. The patient has another FDA labeled indication for the requested agent and route of administration OR <li data-bbox="391 903 1321 961">B. The patient has another indication that is supported in compendia for the requested agent and route of administration OR <li data-bbox="391 963 1390 1129">C. 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 data-bbox="228 1167 1390 1226">Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p data-bbox="228 1264 1382 1348">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 data-bbox="228 1386 500 1415">Length of Approval:</p> <p data-bbox="228 1453 553 1512">BCBSOK: 36 months All other plans: 12 months</p> <p data-bbox="228 1547 1078 1577">NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p data-bbox="228 1675 500 1705">Renewal Evaluation</p> <p data-bbox="228 1740 1078 1770">Target Agent(s) will be approved when ALL of the following are met:</p> <ol data-bbox="277 1808 1403 1978" style="list-style-type: none"> <li data-bbox="277 1808 1370 1892">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 <li data-bbox="277 1894 1403 1978">2. The patient has had improvements or stabilization with the requested agent (e.g., improved strength, timed motor function, pulmonary function; reduced need for scoliosis surgery) AND

Module	Clinical Criteria for Approval				
	<p>3. If the request is for one of the following brand agents with an available generic equivalent, then ONE of the following:</p> <table border="1" data-bbox="235 279 950 352"> <thead> <tr> <th data-bbox="235 279 592 310">Brand</th> <th data-bbox="592 279 950 310">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 310 592 352">Emflaza</td> <td data-bbox="592 310 950 352">deflazacort</td> </tr> </tbody> </table> <p>A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR</p> <p>C. The patient has tried and had an inadequate response to the generic equivalent [chart notes are required] OR</p> <p>D. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>E. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent [chart notes are required] OR</p> <p>F. The patient has an FDA labeled contraindication to the generic equivalent that is NOT expected to occur with the brand agent [chart notes are required] OR</p> <p>G. The generic equivalent 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 are required] OR</p> <p>H. The generic equivalent is NOT in the best interest of the patient based on medical necessity [chart notes are required] OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>J. There is support for the use of the requested brand agent over the generic equivalent AND</p> <p>4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., pediatric neurologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>6. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient’s weight</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>	Brand	Generic Equivalent	Emflaza	deflazacort
Brand	Generic Equivalent				
Emflaza	deflazacort				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested agent strength does not have a program quantity limit OR 3. The request agent is Emflaza and ONE of the following: <ol style="list-style-type: none"> A. The requested agent is Emflaza SUSPENSION OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the program quantity limit AND 2. The requested quantity (dose) cannot be achieved with a lower quantity of any combination of the four Emflaza tablet strengths OR

Module	Clinical Criteria for Approval
	<p>4. ALL of the following:</p> <ul style="list-style-type: none">A. The requested quantity (dose) exceeds the program quantity limit ANDB. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication ANDC. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit <p>Approval Length: 12 months</p>