

Iron Chelation Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
11-01-2025

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
Exjade ; Jadenu ; Jadenu sprinkle	deferasirox granules packet ; deferasirox tab ; deferasirox tab for oral susp	125 MG ; 180 MG ; 250 MG ; 360 MG ; 500 MG ; 90 MG	M ; N ; O ; Y	O ; Y		
Ferriprox ; Ferriprox twice-a-day	deferiprone (twice daily) tab ; deferiprone oral soln ; deferiprone tab	100 MG/ML ; 1000 MG ; 500 MG	M ; N ; O ; Y	N ; O ; Y		

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
Exjade	Deferasirox Tab For Oral Susp 125 MG	125 MG	30	Tablets	30	DAYS			
Exjade	Deferasirox Tab For Oral Susp 250 MG	250 MG	30	Tablets	30	DAYS			
Exjade	Deferasirox Tab For Oral Susp 500 MG	500 MG	90	Tablets	30	DAYS			
Ferriprox	Deferiprone Oral Soln 100 MG/ML	100 MG/ML	2700	mLs	30	DAYS			
Ferriprox	Deferiprone Tab 1000 MG	1000 MG	270	Tablets	30	DAYS			
Ferriprox	Deferiprone Tab 500 MG	500 MG	540	Tablets	30	DAYS			
Ferriprox twice-a-day	Deferiprone (Twice Daily) Tab 1000 MG	1000 MG	270	Tablets	30	DAYS			
Jadenu	Deferasirox Tab 180 MG	180 MG	30	Tablets	30	DAYS			
Jadenu	Deferasirox Tab 360 MG	360 MG	180	Tablets	30	DAYS			
Jadenu	Deferasirox Tab 90 MG	90 MG	30	Tablets	30	DAYS			
Jadenu sprinkle	Deferasirox Granules Packet 180 MG	180 MG	30	Packets	30	DAYS			
Jadenu sprinkle	Deferasirox Granules Packet 360 MG	360 MG	180	Packets	30	DAYS			

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
Jadenu sprinkle	Deferasirox Granules Packet 90 MG	90 MG	30	Packets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Exjade ; Jadenu ; Jadenu sprinkle	deferasirox granules packet ; deferasirox tab ; deferasirox tab for oral susp	125 MG ; 180 MG ; 250 MG ; 360 MG ; 500 MG ; 90 MG	IL HMO Performance Annual ; 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 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
Ferriprox ; Ferriprox twice-a-day	deferiprone (twice daily) tab ; deferiprone oral soln ; deferiprone tab	100 MG/ML ; 1000 MG ; 500 MG	IL HMO Performance Annual ; 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 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

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Exjade	Deferasirox Tab For Oral Susp 125 MG	125 MG	IL HMO Performance Annual ; Balanced ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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 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
Exjade	Deferasirox Tab For Oral Susp 250 MG	250 MG	IL HMO Performance Annual ; 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 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
Exjade	Deferasirox Tab For Oral Susp 500 MG	500 MG	IL HMO Performance Annual ; 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 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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Ferriprox	Deferiprone Oral Soln 100 MG/ML	100 MG/ML	IL HMO Performance Annual ; 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 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
Ferriprox	Deferiprone Tab 1000 MG	1000 MG	IL HMO Performance Annual ; 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 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
Ferriprox	Deferiprone Tab 500 MG	500 MG	IL HMO Performance Annual ; 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 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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			2026 ; Topaz ; Whole Foods
Ferriprox twice-a-day	Deferiprone (Twice Daily) Tab 1000 MG	1000 MG	IL HMO Performance Annual ; 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 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
Jadenu	Deferasirox Tab 180 MG	180 MG	IL HMO Performance Annual ; 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 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
Jadenu	Deferasirox Tab 360 MG	360 MG	IL HMO Performance Annual ; 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 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 ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Jadenu	Deferasirox Tab 90 MG	90 MG	IL HMO Performance Annual ; 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 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
Jadenu sprinkle	Deferasirox Granules Packet 180 MG	180 MG	IL HMO Performance Annual ; 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 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
Jadenu sprinkle	Deferasirox Granules Packet 360 MG	360 MG	IL HMO Performance Annual ; 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 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 ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Jadenu sprinkle	Deferasirox Granules Packet 90 MG	90 MG	IL HMO Performance Annual ; 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 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
Exjade, Jadenu	<p>Initial Evaluation</p> <p>Exjade (deferasirox) or Jadenu (deferasirox) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis) AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient’s baseline (pretreatment) serum ferritin is greater than 1,000 mcg/L AND 2. If the patient has been treated with a deferasirox agent within the past 90 days, the patient’s current (within the last 30 days) serum ferritin is greater than 500 mcg/L OR B. The patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome AND BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient’s baseline (pretreatment) liver iron (FE) concentration (LIC) is at least 5 mg FE/g of dry weight OR B. The patient’s serum ferritin is greater than 300 mcg/L OR C. MRI confirmation of iron deposition AND 2. If the patient has been treated with a deferasirox agent within the past 90 days, the LIC is greater than 3 mg FE/g of dry weight OR C. The patient has another FDA approved indication for the requested agent and route of administration OR D. The patient has another indication that is supported in compendia for the requested agent and route of administration AND 2. If the patient has an FDA approved indication, then ONE of the following:

Module	Clinical Criteria for Approval					
	<p>A. The patient’s age is within FDA labeling for the requested indication for the requested agent OR</p> <p>B. There is support for using the requested agent for the patient’s age for the requested indication AND</p> <p>3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:</p> <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. BOTH of the following:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR <p>C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR</p> <p>D. The patient has tried and had an inadequate response to the generic equivalent [chart notes required] OR</p> <p>E. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>F. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent [chart notes required] OR</p> <p>G. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent [chart notes required] OR</p> <p>H. 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 required] OR</p> <p>I. The generic equivalent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>J. 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 required] OR</p> <p>K. There is support for the use of the requested brand agent over the generic equivalent AND</p> <table border="1" data-bbox="235 1533 1227 1675"> <thead> <tr> <th data-bbox="235 1533 732 1570">Brand</th> <th data-bbox="732 1533 1227 1570">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 1570 732 1608">Exjade (deferasirox)</td> <td data-bbox="732 1570 1227 1608" rowspan="2">Generic deferasirox</td> </tr> <tr> <td data-bbox="235 1608 732 1675">Jadenu (deferasirox)</td> </tr> </tbody> </table> <p>4. The patient does NOT have severe hepatic impairment (Child-Pugh-Turcotte C) AND</p> <p>5. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., hematologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>6. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program AND</p> <p>7. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS, or DrugDex 1, 2a, or 2b level of evidence</p>	Brand	Generic Equivalent	Exjade (deferasirox)	Generic deferasirox	Jadenu (deferasirox)
Brand	Generic Equivalent					
Exjade (deferasirox)	Generic deferasirox					
Jadenu (deferasirox)						

Module	Clinical Criteria for Approval
	<p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</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 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 2. 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] 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</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p>

Module	Clinical Criteria for Approval
	<p>Exjade (deferasirox) or Jadenu (deferasirox) 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: <ol style="list-style-type: none"> A. The patient has a diagnosis of chronic iron overload due to blood transfusions, AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has had a decrease in serum ferritin from baseline (pretreatment) AND 2. The patient's current serum ferritin is greater than 500 mcg/L OR B. The patient has a diagnosis of non-transfusional iron overload due to thalassemia syndromes AND the patient's current serum ferritin is greater than 300 mcg/L OR C. The patient has another diagnosis and has had clinical benefit with the requested agent AND 3. The patient does NOT have severe hepatic impairment (Child-Pugh-Turcotte C) AND 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 5. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please see Quantity Limit Criteria</p>
Ferriprox	<p>Initial Evaluation</p> <p>Ferriprox (deferiprone) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of transfusional iron overload with thalassemia syndromes OR B. The patient has a diagnosis of transfusional iron overload with sickle cell disease or other anemias AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient does NOT have myelodysplastic syndrome AND 2. The patient does NOT have Diamond Blackfan anemia OR C. The patient has another FDA approved indication for the requested agent and route of administration OR D. The patient has another indication that is supported in compendia for the requested agent and route of administration AND 2. The patient has an absolute neutrophil count (ANC) greater than or equal to $1.5 \times 10^9/L$ AND 3. If the patient has an FDA approved indication, then ONE of the following: <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 4. If the request is for a brand agent, then ONE of the following: <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following:

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> A. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR D. The patient has tried and had an inadequate response to a generic deferiprone [chart notes required] OR E. A generic deferiprone was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR F. The patient has an intolerance or hypersensitivity to a generic deferiprone that is not expected to happen with the requested agent [chart notes required] OR G. The patient has an FDA labeled contraindication to a generic deferiprone that is not expected to happen with the requested agent [chart notes required] OR H. A generic deferiprone 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 I. A generic deferiprone agent is not in the best interest of the patient based on medical necessity [chart notes required] OR J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as generic deferiprone and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR K. There is support for the use of the requested brand agent over a generic deferiprone (NOTE: patient compliance will only be accepted after a trial of a generic) AND 5. ONE of the following: <ul style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. BOTH of the following: <ul style="list-style-type: none"> 1. ONE of the following: <ul style="list-style-type: none"> A. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR D. The patient has tried and had an inadequate response to Exjade (deferasirox) or Jadenu (deferasirox) [chart notes required] OR E. Exjade (deferasirox) or Jadenu (deferasirox) was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR F. The patient has an intolerance or hypersensitivity to Exjade (deferasirox) or Jadenu (deferasirox) [chart notes required] OR

Module	Clinical Criteria for Approval
	<p>G. The patient has an FDA labeled contraindication to BOTH Exjade (deferasirox) AND Jadenu (deferasirox) [chart notes required] AND</p> <p>H. Exjade (deferasirox) or Jadenu (deferasirox) 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</p> <p>I. Exjade (deferasirox) or Jadenu (deferasirox) is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as Exjade (deferasirox) or Jadenu (deferasirox) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</p> <p>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>7. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program AND</p> <p>8. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS, or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please see Quantity Limit Criteria</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 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 2. 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] supporting the proposed use(s) as generally safe and effective. Accepted

Module	Clinical Criteria for Approval
	<p>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>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p> <p>Ferriprox (deferiprone) 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. The patient has had clinical benefit with the requested agent AND 3. The patient has an absolute neutrophil count (ANC) greater than or equal to $1.5 \times 10^9/L$ AND 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 5. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please see Quantity Limit Criteria</p>

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 quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR

Module	Clinical Criteria for Approval
	<p>B. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR <p>C. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication <p>Length of Approval: 12 months</p>