



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 7/16/2015
LAST REVIEW DATE: 11/19/2020
LAST CRITERIA REVISION DATE: 11/19/2020
ARCHIVE DATE:

IRON CHELATING AGENTS:

EXJADE® (deferasirox) tablet for oral suspension

JADENU® (deferasirox) tablet for oral use

JADENU® Sprinkle (deferasirox) granules for oral use

FERRIPROX® (deferiprone) tablet for oral use and oral solution

DEFERIPRONE tablet for oral use

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.



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Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

EXJADE® (deferasirox) tablet for oral suspension **JADENU® (deferasirox) tablet for oral use** **JADENU® Sprinkle (deferasirox) granules for oral use**

Criteria:

- **Criteria for initial therapy:** Exjade (deferasirox) tablets for suspension or Jadenu (deferasirox) oral tablets or oral granules is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
 1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with Hematologist or Oncologist
 2. A confirmed diagnosis of chronic iron overload due to **ONE** of the following:
 - a. **Transfusional hemosiderosis** in an individual 2 years of age or older with **ALL** of the following:
 - i. Evidence of transfusion related iron overload that includes transfusion with at least 100 mL/kg of packed red blood cells (PRBC) (at least 20 units of PRBC for a 40-kg person) **or** a history of frequent blood transfusions that have resulted in chronic iron overload
 - ii. **Serum ferritin consistently > 1,000 mcg/L**
 - b. **Non-transfusional thalassemia (NTDT) syndromes** in an individual is 10 years of age or older with **ALL** of the following:
 - i. **Serum ferritin consistently > 300 mcg/L** on at least 2 measurements at least one month apart
 - ii. **Liver iron concentration (LIC) is ≥ 5 mg Fe/g dry weight** by biopsy or by an FDA-cleared or approved method
 - c. **ONE** of the following International Prognostic Scoring System (IPSS) low-risk or intermediate-risk **myelodysplastic syndrome (MDS)** patients:
 - i. Received or are anticipated to receive greater than 20 units of PRBC transfusions
 - ii. Serum ferritin level is greater than 2,500 ng/mL
 3. **ALL** of the following baseline tests have been obtained before initiation of therapy:
 - a. Comprehensive metabolic panel
 - b. Serum creatinine is measured in duplicate

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- c. Estimated glomerular filtration rate (eGFR)
 - d. Urinalysis
 - e. Complete blood count with differential
 - f. Auditory examination
 - g. Ophthalmic examination including slit lamp examination and dilated funduscopy
 - h. When used for iron overload in myelodysplastic syndrome (MDS), **ALL** of the following:
 - i. IPSS or IPSS-R score (score must be submitted with request)
 - ii. Performance status (score must be submitted with request) using **ONE** of the following:
 - 1. ECOG **or** Karnofsky score **or** for age ≤ 10 a Lansky Play score
4. There are **NO** contraindications:
- a. Contraindications include:
 - i. Known hypersensitivity to deferasirox
 - ii. eGFR < 40 mL/min/1.73 m²
 - iii. Individual with a platelet count of $< 50 \times 10^9/L$
 - iv. High-risk MDS defined by either IPSS or IPSS-R
 - v. Individuals with advanced malignancies
 - vi. Poor performance status defined by **ONE** of the following:
 - 1. ECOG score ≥ 3 **or** Karnofsky score $< 70\%$ **or** for age ≤ 10 , Lansky Play $< 70\%$
5. Will not be used in individuals with severe hepatic impairment (Child-Pugh Class C)
6. Will not be used in combination with other iron chelation therapies

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Exjade (deferasirox) tablets or Jadenu (deferasirox) tablets or granules is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
- 1. Individual continues to be seen by a physician specializing in the patient's condition or is in consultation with a Hematologist or Oncologist
 - 2. Individual's condition responded while on therapy
 - a. Response is defined as:
 - i. For transfusional hemosiderosis:
 - 1. Serum ferritin decreased over baseline but is still > 500 mcg/L, if ferritin is consistently < 500 mcg/L, Exjade (deferasirox) or Jadenu (deferasirox) must be discontinued
 - 2. Con
 - 3. Platelet count is $> 50 \times 10^9/L$
 - 4. eGFR > 40 mL/min/1.73 m²
 - ii. For NTDT: (if a serum ferritin and LIC is submitted, the LIC is used for determination)

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1. Serum ferritin decreased over baseline but is still > 300 mcg/L, if ferritin is consistently < 300 mcg/L, Exjade (deferasirox) or Jadenu (deferasirox) must be discontinued
 2. LIC decreased over baseline but is still ≥ 5 mg Fe/g dw, if LIC is consistently < 3 mg Fe/g dw, Exjade (deferasirox) or Jadenu (deferasirox) must be discontinued
 3. Platelet count is > $50 \times 10^9/L$
 4. eGFR > 40 mL/min/1.73 m²
- iii. For MDS:
1. Achieved and maintains a serum ferritin level of less than 1,000 ng/mL
3. Individual has been adherent with the medication
 4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
 - a. Contraindications as listed in the criteria for initial therapy section
 - b. Significant adverse effect:
 - i. Severe cutaneous adverse reactions (SCARs) including Stevens Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, or drug reaction with eosinophilia and systemic symptoms (DRESS)
 - ii. Severe hypersensitivity reaction
 - iii. Acute renal injury, including acute renal failure requiring dialysis and renal tubular toxicity including Fanconi syndrome
 - iv. Hepatic toxicity
 - v. GI bleeding, ulceration, or perforation
 - vi. Bone marrow suppression
 - vii. Severe auditory abnormalities
 - viii. Severe ocular abnormalities
 5. Will not be used in individuals with severe hepatic impairment (Child-Pugh Class C)
 6. Will not be used in combination with other iron chelation therapies
 7. There are no significant interacting drugs

Renewal duration: 12 months

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Ferriprox (deferiprone) oral tablet and oral solution Deferiprone oral tablet

Criteria:

- **Criteria for initial therapy:** Ferriprox (deferiprone) or deferiprone is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's condition or is in consultation with a Hematologist or Oncologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of **transfusional iron overload due to thalassemia syndromes** and **serum ferritin levels are consistently > 2,500 mcg/L**
 4. Chelation therapy with Exjade (deferasirox) or Jadenu (deferasirox) resulted in an inadequate response, or significant intolerance, or are contraindicated
 5. **All** of the following baseline tests have been obtained before initiation of therapy:
 - a. Complete blood count with differential
 - b. Absolute neutrophil count is $> 1.5 \times 10^9/L$
 - c. Liver enzymes
 - d. Negative pregnancy test in a woman of child bearing potential
 6. Will not be used in individuals with severe hepatic impairment (Child-Pugh Class C)
 7. Will not be used in combination with other iron chelation therapies

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Ferriprox (deferiprone) or deferiprone is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's condition or is in consultation with a Hematologist or Oncologist
 2. Individual's condition responded while on therapy
 - a. Response is defined as:
 - i. Serum ferritin decreased over baseline but is still > 500 mcg/L, if ferritin is consistently less than 500 mcg/L, Ferriprox (deferiprone) must be discontinued
 - ii. ANC is $> 1.5 \times 10^9/L$
 3. Individual has been adherent with the medication

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4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
 - a. Significant adverse effect:
 - i. Agranulocytosis/neutropenia
 - ii. Hepatic impairment
5. Will not be used in individuals with severe hepatic impairment (Child-Pugh Class C)
6. Will not be used in combination with other iron chelation therapies
7. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Exjade (deferasirox) tablet for oral suspension, Jadenu (deferasirox) oral tablets & Jadenu (deferasirox) Sprinkles are indicated for the treatment of chronic iron (Fe) overload in patients 2 years of age and older whose iron overload is due to blood transfusions (transfusional hemosiderosis) with at least 100 mL/kg of packed red blood cells and have a serum ferritin that is consistently greater than 1,000 mcg/L. Both are also indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes with liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L.

Ferriprox (deferiprone) (tablet and solution) or derferiprone tablet, is another oral iron chelating agent indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. The safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias.

An injectable iron chelating agent, deferoxamine (Desferal and generics), is available and is administered intramuscularly, subcutaneously, or intravenously. It is indicated for the treatment of acute iron intoxication and of chronic iron overload due to transfusion-dependent anemias.

Iron, iron overload, & iron chelation

- All body cells need iron
 - It is crucial for oxygen transport, energy production, and cellular growth and proliferation
- The human body contains an average of 3.5 g of iron (males 4 g, females 3 g)
- Iron is bound and transported in the body by the glycoprotein carrier protein transferrin and it is stored in ferritin molecules
 - Ferritin is particularly abundant in the liver and heart
- When there is an excess of iron, the body responds by producing more ferritin to facilitate iron storage

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- When iron concentrations exceed the storage capacity of ferritin molecules, unbound iron deposits in many organs and causes free-radical formation in cells, resulting in membrane lipid peroxidation, cellular injury, and organ dysfunction
- Iron overload may result from either inherited or acquired disorders such as transfusion dependent anemia, various liver diseases, hemolytic anemia, thalassemia, sickle cell anemia and excessive iron ingestion
- Determination of iron status can be accomplished by several methods
 - Serial measurement of serum ferritin is a reliable and the easiest method to evaluate iron overload
 - Elevated serum ferritin is a sensitive test for iron overload, but it is not very specific
 - The normal range for ferritin in plasma or serum is approximately 40-200 mcg/L (40-200 ng/mL; 89.9-449.4 picomoles/L)
 - A ferritin level ≥ 200 to 300 mcg/L in a man (or ≥ 150 to 200 mcg/L in a woman) is consistent with iron overload, and a level below these values is good evidence that the patient does not have iron overload
 - Ferritin levels in iron overload may range of up to 2000 to 3000 mcg/L (ng/mL)
 - Determination of liver iron concentration (LIC) can be done via a liver biopsy but it is an invasive procedure with the possibility of complications
 - Recently, nuclear magnetic resonance imaging techniques for assessing total body iron has become available
 - R2 and T2* parameters have been validated for liver iron concentration
- LIC estimated by MRI $> 2-7$ mg Fe/g dry weight (equivalent to approximately 53-125 micromol/g dry weight) indicates the presence of hepatic iron overload
 - A cardiac T2* by MRI < 20 milliseconds (normal: > 20) indicates the presence of cardiac iron overload
 - Values < 10 milliseconds have been associated with severe myocardial iron loading and the development of cardiac failure
- Myelodysplastic syndrome (MDS) refers to a heterogeneous group of clonal hematopoietic disorders with the potential to transform into acute myelocytic leukemia (AML)
 - Anemia is often seen and may require red blood cell (RBC) transfusions and subsequent iron overload
- Guidelines suggest the use of iron chelating agents in patients with MDS and iron overload, although the benefit of iron chelation in MDS is unproven and the optimal agent to use is unclear at this time
- Prophylactic or therapeutic iron chelation treatment is suggested for low risk MDS who have had, or are anticipated to have, prolonged red cell transfusion requirements (more than 20-30 transfusions), demonstrate evidence of iron overload (serum ferritin > 1000 mcg/L), the LIC is > 3 mg Fe/g dry weight, and/or the cardiac T2* is < 20 milliseconds

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- The International Prognostic Scoring System (IPSS) and a revised IPSS (IPSS-R) use cytogenetic, morphologic, and clinical data to define MDS risk groups
 - IPSS for MDS stratifies patients into four distinctive risk groups in terms of both survival and AML evolution
 - The IPSS-R defines five risk groups
 - The IPSS-R has been validated in a number of studies
- The latest National Comprehensive Cancer Network (NCCN) Guidelines Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes (Version 1.2018, Aug 29, 2017) states daily chelation therapy should be considered if > 20-30 RBC transfusions have been received to decrease iron overload, particularly for patients who have lower-risk MDS or who are potential transplant candidates LOW/INT-1

Definitions:

The Child-Pugh classification system: A scoring system used to determine the prognosis of individuals with cirrhosis. Scoring is based upon several factors: albumin, ascites, total bilirubin, prothrombin time, and encephalopathy, as follows:

	Score: 1 point	Score: 2 points	Score: 3 points
Serum Albumin (g/dL)	>3.5	3.0 - 3.5	<3.0
Serum Bilirubin (mg/dL)	<2.0	2.0 - 3.0	>3.0
Prothrombin time (seconds)	1 - 4	4 - 6	>6
Ascites	none	moderate	severe
Encephalopathy	none	mild	severe

The three classes and their scores are:

- **Class A** is score 5 – 6: Well compensated
- **Class B** is score 7 – 9: Significant functional compromise
- **Class C** is score >9: Decompensated disease

Methods for measuring iron overload:

Liver iron concentration (LIC) by biopsy
Magnetic resonance imaging with R2* or T2*
R2 technique

Thalassemia syndromes:

Alpha-thalassemia silent carrier	Mild Hb-E / Beta-thalassemia
Alpha-thalassemia trait (minor)	Moderately severe Hb-E / Beta-thalassemia
Hemoglobin H disease	Severe Hb-E / Beta-thalassemia
Hemoglobin Bart's Hydrops fetalis syndrome	Delta-thalassemia
Beta-thalassemia trait (minor)	Hemoglobin S thalassemia
Thalassemia intermedia	Hemoglobin C thalassemia
Beta-thalassemia major (Cooley's anemia)	Hemoglobin D thalassemia
Beta-thalassemia minor	Delta-thalassemia
Hemoglobin E (Hb-E) thalassemia	Hereditary persistence of fetal hemoglobin (HPFH)

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Myelodysplastic syndrome (MDS):

A heterogeneous group of clonal hematopoietic disorders with the potential to transform into acute myelocytic leukemia (AML). MDS include, *but are not limited to*:

- del 5q syndrome
- Refractory anemia
- Refractory anemia with:
 - Ringed sideroblasts
 - Excess blasts 1 and 2
- Refractory cytopenia with multilineage dysplasia or ring sideroblasts

International Prognostic Scoring System for MDS:

International Prognostic Scoring System (IPSS)					
Survival and AML evolution					
	Score value				
Prognostic variable	0	0.5	1	1.5	2
Bone marrow blasts (%)	< 5	5-10	--	11-20	21-30
Karyotype	Good	Intermediate	Poor	--	--
Cytopenias	0/1	2/3	--	--	--
Prognosis					
Overall Score	IPSS Group	Median survival (y)	25% AML progression (y)		
0	Low	5.7	9.4		
0.5-1	Intermediate-1	3.5	3.3		
1.5-2	Intermediate-2	1.1	1.1		
> 2.5	High	0.4	0.2		
<p>Scoring system: A score from 0 to 2 is determined for each of the three variables; the three values are added to obtain the IPSS score. Example, a patient with 12 percent bone marrow blasts (score 1.5), complex chromosomal changes (poor karyotype score 1), neutrophil count of 1000/microL, and platelet count of 50,000/microL (two cytopenias = score 0.5) would have an IPSS score of 3 (= high risk).</p> <p>Patients with 20-30% blasts may be considered to have MDS (FAB) or AML (WHO)</p> <p>Karyotype-Cytogenetics: [Excludes karyotypes t(8;21), inv16, and t(15;17) which are considered to be AML and not MDS]</p> <p>Good = normal, -Y alone, del(5q) alone, or del(20q) alone</p> <p>Poor = complex (≥ 3 abnormalities) or chromosome 7 anomalies</p> <p>Intermediate = other abnormalities</p> <p>Cytopenias:</p> <p>Absolute neutrophil count < 1,800/mcL</p> <p>Platelets < 100,000 mcL</p> <p>Hb < 10 g/dL (100 g/L)</p>					

Revised International Prognostic Scoring System (IPSS-R)							
Prognostic variable	0	0.5	1	1.5	2	3	4
Cytogenetic	Very good	-	Good	-	Intermediate	Poor	Very poor
Bone marrow blasts (%)	≤ 2	-	> 2- < 5	-	5-10	> 10	-
Hemoglobin	≥ 10	-	8- < 10	< 8	-	-	-
Platelets	≥ 100	50- < 100	< 50	-	-	-	-
ANC	≥ 0.8	< 0.8	-	-	-	-	-



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Prognosis			
Overall Score	IPSS-R Group	Median survival (y)	25% AML progression (y)
≤ 1.5	Very low	8.8	Not reached
> 1.5- ≤ 3	Low	5.3	10.8
> 3- ≤ 4.5	Intermediate	3	3.2
> 4.5- ≤ 6	High	1.6	1.4
> 6	Very high	0.8	0.7

Cytogenetic risks:
Very good = -Y, del(11q)
Good = normal del(5q), del(12p), del(20q), double including del(5q)
Intermediate = del(7q), +8, +19, i(17q), any single or double independent clones
Poor = -7, inv(3)/t(3q)/del(3q), double including -7/del(7q), complex: 3 abnormalities
Very poor = complex: 3 abnormalities

Performance scores:

Eastern Cooperative Oncology Group (ECOG) Score (also known as Zubrod Score)	
0	Asymptomatic, fully active, able to carry on all pre-disease performance without restriction
1	Symptomatic, fully ambulatory, restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example light house work or office work
2	Symptomatic, in bed less than 50% of the day, ambulatory and capable of all self-care but unable to carry out any work activities
3	Symptomatic, confined to bed or chair more than 50% of the day but not bedridden, capable of only limited self-care
4	Bedridden, cannot perform any self-care, completely disabled
5	Dead

Karnofsky Performance Score:	
100%	Able to carry on normal activity, no evidence of disease
90%	Able to carry on normal activity, minor signs or symptoms of disease
80%	Normal activity with effort, some signs and symptoms of disease
70%	Cares for self, unable to carry on normal activity or to work
60%	Requires occasional assistance from others but able to care for most needs
50%	Requires considerable assistance from others and frequent medical care
40%	Disabled, requires special care and assistance
30%	Severely disabled, hospitalization indicated, though death not imminent
20%	Very sick, hospitalization indicated, active support treatment necessary
10%	Moribund
0%	Dead

Lansky Play Score (Also known as Lansky Play - Performance Scale):	
100	Fully active, normal
90	Minor restrictions in physically strenuous activity
80	Active, but tires more quickly
70	Both greater restriction of and less time spent in play activity
60	Up and around, but minimal active play; keeps busy with quieter activities
50	Gets dressed but lies around much of the day, no active play but able to participate in all quiet play and activities



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40	Mostly in bed; participates in quiet activities
30	In bed; needs assistance even for quiet play
20	Often sleeping; play entirely limited to very passive activities
10	No play; does not get out of bed
0	Unresponsive

Resources:

Exjade (deferasirox) product information, revised by manufacturer Novartis Pharmaceuticals Corporation 07-2020, at DailyMed <http://dailymed.nlm.nih.gov> accessed October 01, 2020.

Jadenu (deferasirox) product information, revised by manufacturer Novartis Pharmaceuticals Corporation 07-2020, at DailyMed <http://dailymed.nlm.nih.gov> accessed October 01, 2020.

Ferriprox (deferiprone) product information, revised by manufacturer Apo Pharma USA Inc 02-2020, at DailyMed <http://dailymed.nlm.nih.gov> accessed October 01, 2020.

Deferiprone product information, revised by manufacturer Taro Pharmaceuticals USA Inc 03-2020, at DailyMed <http://dailymed.nlm.nih.gov> accessed September 21, 2020.

Bacon BR, Kwiatkowski JL. Approach to the patient with suspected iron overload. In: UpToDate, Mentzer WC, Mahoney DH, Tirnauer JS, Kunins L (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Accessed on October 01, 2020.

Bacon BR. Iron chelators: Choice of agent, dosing, and adverse effects. In: UpToDate, Mentzer WC, Tirnauer JS (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Accessed on October 01, 2020.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Myelodysplastic Syndromes Version 1.2021 – Updated September 11, 2020 ; <https://www.nccn.org>. Accessed October 7, 2020.