Pharmacy Medical Necessity Guidelines:
Iron Chelating Agents (Ferriprox®, Jadenu®)

Effective: December 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Ferriprox (deferiprone) tablet is indicated for the treatment of patients with transfusional iron overload with thalassemia syndromes, sickle cell disease, or other anemias. Ferriprox tablets are approved for patients 8 years of age and older, while the oral solution is approved in patients 3 years of age and older.

Ferriprox is available as 500 mg and 1,000 mg tablets and well as 100 mg/mL solution. The 500 mg tablets are approved to be administered three times per day. There are two formulations of the 1,000 mg tablets: one formulation (Ferriprox Twice-a-Day) is approved for twice daily administration and another is approved for three times daily administration. Ferriprox solution is approved to be administered three times per day.

Jadenu (deferasirox) is an iron chelator indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older. Jadenu is also indicated for the treatment of chronic overload in patients 10 years of age and older with non-transfusion dependent thalassemia (NTDT) syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (Fe/g dw) and a serum ferritin greater than 300 mcg/L. Controlled clinical trials of Jadenu in patients with myelodysplastic syndrome (MDS) and chronic iron overload due to blood transfusion have not been performed. Also, safety and efficacy of Jadenu when administered with other iron chelation therapy have not been established.

COVERAGE GUIDELINES

The plan may authorize coverage of Ferriprox (deferiprone) and Jadenu (deferasirox) for Members when **ALL** of the following criteria are met:

Ferriprox (deferiprone):

1. Documented diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias

AND

2. Member has had an inadequate response, intolerance, or contraindication to deferasirox

AND

3. **Ferriprox Twice-A-Day:** Documentation that Member has had adherence issues with the Ferriprox formulation administered three times per day

AND

4. **Ferriprox Oral Solution:** Provider indicates clinical inappropriateness of therapy with deferiprone oral tablet formulation administered three times per day

Jadenu (deferasirox):

1. Member has a diagnosis of iron overload due to transfusions

AND

The Member has had a transfusion of at least 100 mL/kg of packed red blood cells

AND

The Member has a serum ferritin level consistently greater than 1000 mcg/L

OR

2. Member has a diagnosis of chronic iron overload in non-transfusion-dependent thalassemia syndrome

AND

The Member's liver iron concentration (LIC) is at least 5 milligrams of iron per gram of dry liver tissue weight

AND

The Member's serum ferritin is > 300 mcg/L

Reauthorization:

1. Documentation of an adequate response based on a reduction in serum ferritin level from pretreatment.

LIMITATIONS

1. Ferriprox and Jadenu will be authorized for 3 months initially.
2. Requests for brand-name products, with AB-rated generics, will also be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. DeBaun MB, Chou ST. Transfusion in sickle cell disease: management of complications including iron overload. UpToDate. Available at: www.uptodate.com. Accessed 31 July 2023.
2. Ferriprox (deferiprone) solution [prescribing information]. Cary, NC: Chiesi USA, Inc.; November 2021.
3. Ferriprox (deferiprone) tablet [prescribing information]. Cary, NC: Chiesi USA, Inc July 2023 .
4. Jadenu (deferasirox) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024 .
5. Pennell DJ, Udelson JE, Arai AE, et al. Cardiovascular function and treatment in β-thalassemia major. *Circulation*. 2013;128:281-308.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: No changes.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes
4. September 15, 2026: Effective December 1, 2026, updated coverage criteria for Ferriprox to include prerequisite trial with deferasirox and require clinical inappropriateness with deferiprone oral tablet formulation administered three times per day for Ferriprox oral solution.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of

benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services