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

*Effective: November 16, 2020*

| | | | |
|---|---|---|---|
| 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:

**Commercial Products**

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**
RXUM: 617.673.0988

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

## OVERVIEW

### FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Ferriprox (deferiprone) is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. Approval is based on a reduction in serum ferritin levels. There are no controlled trials demonstrating a direct benefit, such as improvement in disease-related symptoms, functioning, or increased survival.

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 (defasirox) 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 (defasirox) for Members when **all of** the following criteria are met:

**Ferriprox (deferiprone):**

1. Documented diagnosis of transfusional iron overload due to thalassemia syndromes

**AND**

2. Previous iron chelation therapy has failed or is considered to be inadequate due to poor tolerance (serum ferritin level >2,500 µg/L).

**AND**

3. **Ferriprox Twice-A-Day:** Documentation that Member has had adherence issues with the Ferriprox 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-transfusional-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

## LIMITATIONS

1. The initial authorization will be for a period of 3 months. Subsequent authorization will require documentation of an adequate response based on a reduction in serum ferritin level from pretreatment.
2. Requests for brand-name products, with AB-rated generics, will also be reviewed according to Brand Name criteria.

## CODES

None

## REFERENCES


1. Ceci A, Mangiarini L, Felisi M, et al. The management of iron chelation therapy: preliminary data from a national registry of thalassaemic patients. Anemia. 2011; 2011: 435683. URL: ncbi.nlm.nih.gov/pmc/articles/PMC3123832/?tool=pubmed. Available from Internet. Accessed January 2016.
2. Ferriprox (deferiprone) solution [prescribing information]. Weston, FL: ApoPharma USA, Inc.; May 2017.
3. Ferriprox (deferiprone) 500 mg tablet [prescribing information]. Weston, FL: ApoPharma USA, Inc.; May 2020.
4. Ferriprox (deferiprone) 1,000 mg tablet [prescribing information]. Cary, NC: Chiesi USA, Inc.; May 2020.
5. Pennell DJ, Udelson JE, Arai AE, et al. Cardiovascular function and treatment in β-thalassemia major. *Circulation*. 2013;128:281-308.
6. Jadenu (deferasirox) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2019.


## APPROVAL HISTORY

September 16, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2016: Administrative change to rebranded template.
2. March 8, 2016: No changes
3. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Renamed MNG "Iron Chelating Agents." Added criteria for Jadenu.
4. May 8, 2018: No changes.
5. March 12, 2019: Administrative changes made to template.
6. January 14, 2020: Administrative update, added "Requests for brand-name products, with AB-rated generics, will also be reviewed according to Brand Name criteria" to the limitations section of the MNG.
7. November 10, 2020: Added criteria for Ferriprox Twice-A-Day to the MNG.

## 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