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5.99.009

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Miscellaneous Products	**Original Policy Date:**	June 7, 2012
Subject:	Ferriprox	**Page:**	1 of 6

Last Review Date: March 7, 2025

Ferriprox

Description

Ferriprox (deferiprone)

Background
Ferriprox (deferiprone) is an iron chelator used to treat patients with iron overload. Ferriprox is a chelating agent with an affinity for ferric ions (ion III) and binds with ferric ions to form neutral 3:1 (deferiprone:iron) complexes that are stable at physiological pH (1).

Regulatory Status
FDA-approved indications: Ferriprox is an iron chelator indicated for: (1)

- the treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes.
- the treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with sickle cell disease or other anemias.

Limitations of Use:
Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia (1).

Monitor serum ferritin concentration every two to three months to assess the effects of Ferriprox on body iron stores. Dose adjustments should be tailored to the individual patient's response and therapeutic goals (maintenance or reduction of body iron burden). If the serum ferritin falls consistently below 500 mcg/L, consider temporarily interrupting Ferriprox therapy. Monitor

serum liver transaminase levels monthly during therapy and consider interrupting treatment if there are consistently elevated transaminase levels (1).

Ferriprox carries a boxed warning regarding agranulocytosis that can lead to serious infections and death. Neutropenia may precede the development of agranulocytosis. Measure the absolute neutrophil count (ANC) before starting Ferriprox therapy and monitor the ANC weekly during therapy. Interrupt Ferriprox therapy if neutropenia develops (ANC <1.5 x 10^9/L). If infection develops, interrupt Ferriprox and monitor the ANC more frequently. Advise patients taking Ferriprox to report immediately any symptoms indicative of infection (1).

Ferriprox can cause fetal harm when administered to a pregnant woman. Women of reproductive potential should be advised of the potential hazard to the fetus and to avoid pregnancy while on this drug (1).

The safety and effectiveness of Ferriprox tablets in pediatric patients less than 8 years of age have not been established (1).

Related policies
Exjade/Jadenu, Zynteglo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ferriprox may be considered **medically necessary** if the conditions indicated below are met.

Ferriprox may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 8 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Iron overload due to blood transfusions associated with thalassemia syndromes

2. Iron overload due to blood transfusions associated with sickle cell disease or other anemias

AND ALL of the following:

a. Initial ANC ≥ 1.5x 10^9/L and physician agrees to monitor ANC level weekly while on therapy and to interrupt therapy if neutropenia or signs of infection develop
b. Physician agrees to measure initial serum ferritin level, to monitor levels every 2-3 months while on therapy, and to consider interrupting treatment if serum ferritin falls consistently below 500 mcg/L
c. **NO** concurrent therapy with another iron chelating agent (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 8 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Iron overload due to blood transfusions associated with thalassemia syndromes
2. Iron overload due to blood transfusions associated with sickle cell disease or other anemias

AND ALL of the following:

a. Documented response to treatment as shown by a decrease in the serum ferritin level
b. Physician agrees to continue to monitor ANC and serum ferritin level and consider interrupting treatment if serum ferritin falls consistently below 500 mcg/L
c. **NO** concurrent therapy with another iron chelating agent (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Ferriprox (deferiprone) is an iron chelator approved for the treatment of patients with transfusional iron overload. Ferriprox can cause agranulocytosis that can lead to serious infections and death. Neutropenia may precede the development of agranulocytosis. The safety and effectiveness of Ferriprox tablets for oral use in pediatric patients less than 8 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Ferriprox while maintaining optimal therapeutic outcomes.

References

1. Ferriprox [package insert]. Toronto, ON: Apotex Inc.; November 2021.

Policy History

Date	Action/Reason
June 2012	New Policy
December 2012	Annual editorial review and reference update
June 2014	Annual editorial review and reference update
September 2015	Annual editorial review and reference update
December 2016	Annual editorial review and reference update Addition of age to the renewal section Policy code changed from 5.11.09 to 5.99.09
June 2017	Annual editorial review and reference update
June 2018	Annual editorial review and reference update
June 2019	Annual editorial review. Addition of requirement of no concurrent therapy with another iron chelating agent and addition of Appendix 1
June 2020	Annual review
March 2021	Annual editorial review and reference update

May 2021	Addition of indication: Iron overload due to blood transfusions associated with sickle cell disease or other anemias. Changed age requirement from 18 and older to 8 and older per new package insert
September 2021	Annual review
March 2022	Annual review and reference update
December 2022	Annual editorial review. Changed policy number to 5.99.009. Per FEP, removed initiation requirement to t/f Exjade, Jadenu, or Desferal
March 2023	Annual review
March 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.

Appendix 1 - List of Iron Chelating Agents

Generic Name	Brand Name
deferasirox	Exjade
deferasirox	Jadenu
deferiprone	Ferriprox