
5.99.09

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Miscellaneous Products	Original Policy Date:	June 7, 2012
Subject:	Ferriprox	Page:	1 of 5

Last Review Date: March 12, 2021

Ferriprox

Description

Ferriprox (deferiprone)

Background

Ferriprox (deferiprone) is an iron chelator to treat patients with iron overload due to blood transfusions in patients with thalassemia, a genetic blood disorder that causes anemia, who had an inadequate response to prior chelation therapy. Patients with thalassemia have excess iron in the body from the frequent blood transfusions (transfusional iron overload), a condition that is serious and can be fatal. These patients also have a risk of developing liver disease, diabetes, arthritis, heart failure or an abnormal heart rhythm. The standard of care to treat transfusional iron overload is chelation therapy – chemical agents that are used to remove heavy metals from the body. Ferriprox is intended for use when chelation therapy is inadequate (1).

Regulatory Status

FDA-approved indication: Ferriprox is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate (2).

Limitations of Use:

Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias (2).

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

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Miscellaneous Products	Original Policy Date:	June 7, 2012
Subject:	Ferriprox	Page:	2 of 5

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. (2)

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 $<1.5 \times 10^9/L$). If infection develops, interrupt Ferriprox and monitor the ANC more frequently. Advise patients taking Ferriprox to report immediately any symptoms indicative of infection (2).

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 (2).

The safety and effectiveness of Ferriprox tablets for oral use in pediatric patients have not been established (2).

Related policies

Exjade, Jadenu

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** in patients 18 years of age or older with iron overload due to blood transfusions associated with thalassemia syndromes and if the conditions indicated below are met.

Ferriprox may be considered **investigational** in patients who are less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Miscellaneous Products	Original Policy Date:	June 7, 2012
Subject:	Ferriprox	Page:	3 of 5

Patient must have the following:

Iron overload due to blood transfusions associated with thalassemia syndromes

AND ALL of the following:

1. Inadequate response or a clinically significant adverse effect to currently available products including Exjade, Jadenu (desferasirox) and/or Desferal (deferoxamine)
2. Initial ANC $\geq 1.5 \times 10^9/L$ and physician agrees to monitor ANC level weekly while on therapy and to interrupt therapy if neutropenia or signs of infection develop
3. 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
4. **NO** concurrent therapy with another iron chelating agent (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

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

1. Iron overload secondary to blood transfusion associated with thalassemia syndromes
2. Documented response to treatment as shown by a decrease in the serum ferritin level
3. Physician agrees to continue to monitor ANC and serum ferritin level and consider interrupting treatment if serum ferritin falls consistently below 500 mcg/L
4. **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

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Miscellaneous Products	Original Policy Date:	June 7, 2012
Subject:	Ferriprox	Page:	4 of 5

Rationale

Summary

Ferriprox (deferiprone) is an iron chelator approved for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemia's. 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 have not been established (2).

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

References

1. Porter J, Viprakasit V. Iron Overload and Chelation. Guidelines for the Management of Transfusion Dependent Thalassemia: 3rd edition. Thalassemia International Federation; 2014. Accessed February 2021.
2. Ferriprox [package insert]. Toronto, ON: Apotex Inc.; May 2020.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

Section: Prescription Drugs **Effective Date:** April 1, 2021
Subsection: Miscellaneous Products **Original Policy Date:** June 7, 2012
Subject: Ferriprox **Page:** 5 of 5

Appendix 1 - List of Iron Chelating Agents

Generic Name	Brand Name
deferasirox	Exjade
deferasirox	Jadenu
deferiprone	Ferriprox