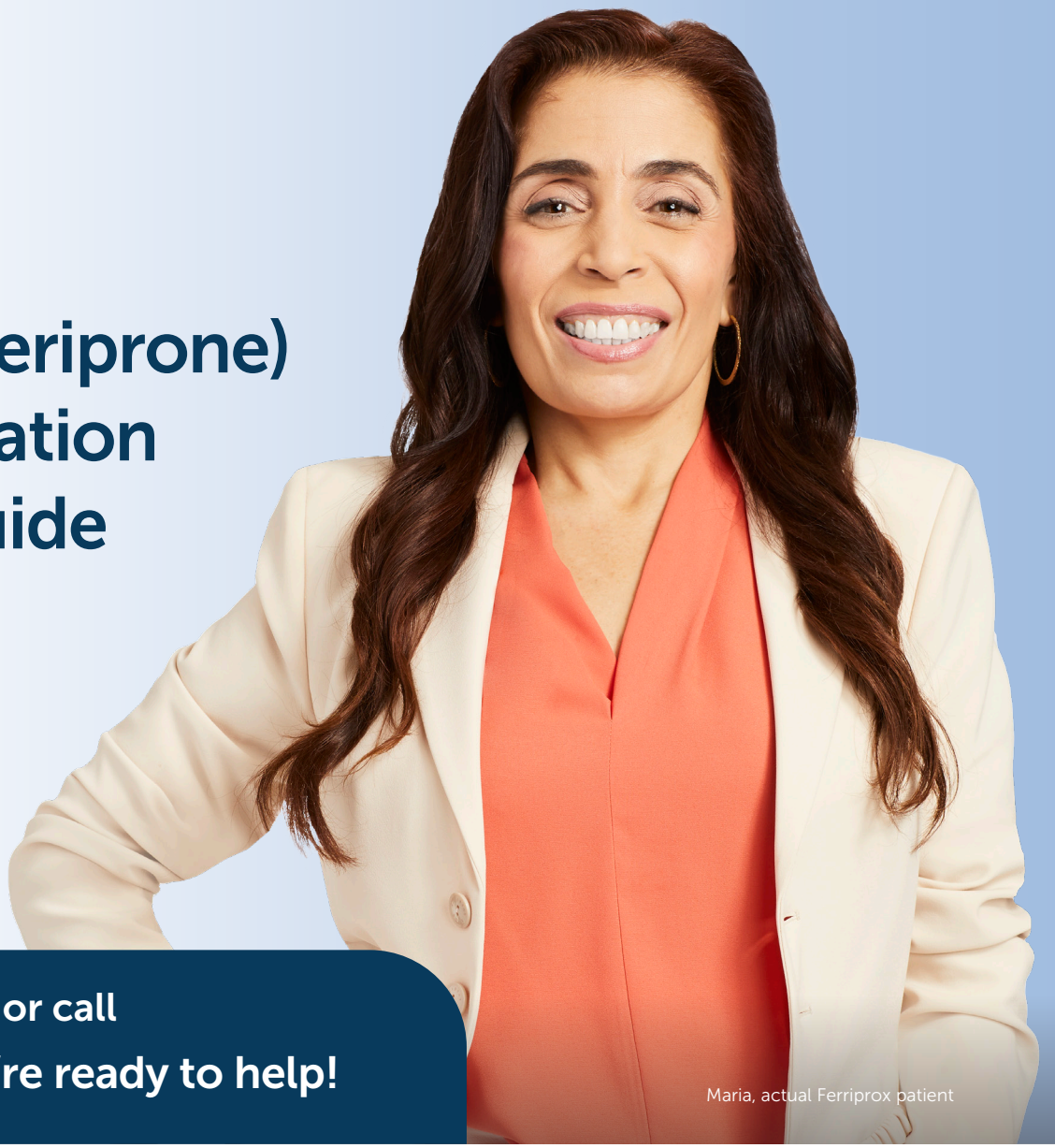
Chiesi TOTAL care℠

Ferriprox® (deferiprone) Prior Authorization and Access Guide



Visit chiesitotalcare.com or call

1-866-758-7071 – we're ready to help!

Indication

Ferriprox® (deferiprone) is an iron chelator indicated for the treatment of transfusional iron overload in patients with:

- thalassemia syndromes
- sickle cell disease or other anemias

Ferriprox Tablets are indicated in adult and pediatric patients ≥8 years of age; Ferriprox Oral Solution is indicated in patients ≥3 years of age.

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.

Important Safety Information

WARNING: AGRANULOCYTOSIS AND NEUTROPENIA

- **Ferriprox can cause 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 and monitor regularly while on therapy.**
- **Interrupt Ferriprox therapy if neutropenia develops.**
- **Interrupt Ferriprox if infection develops, and monitor the ANC more frequently.**
- **Advise patients taking Ferriprox to report immediately any symptoms indicative of infection.**

Please see full Prescribing Information, including boxed WARNING and Medication Guide inside.

Ferriprox® TWICE-A-DAY
deferiprone
1000 mg tablets

Ferriprox®
deferiprone
1000 mg tablets
500 mg tablets
Oral solution 100 mg/mL

Chiesi Total Care℠ will submit for insurance reimbursement and help you navigate prior authorization (PA).

HERE'S A STEP-BY-STEP LOOK AT THE PROCESS

1

SUBMISSION

Your Chiesi Total Care Team starts the process when a new Rx form has been submitted.

The Chiesi Total Care team helps you submit PA.

2

MONITORING PA

Chiesi Total Care monitors and tracks PA submission until an outcome is determined by payor.

3

PA IS APPROVED

- Your office and/or patient is notified

PA IS DENIED

- Send denial documentation to Chiesi Total Care
- Chiesi Total Care can help in denial situations with a high success rate

APPEAL

Based on the letter, Chiesi Total Care can submit a patient level appeal with signed patient consent.

OR

Your office can submit a physician level appeal. Chiesi Total Care can assist and coach on best practices.*

*Chiesi Total Care assistance is neither medical guidance nor a suggestion that you submit an appeal. The resources and information provided in this guide is general in nature and is not intended to be conclusive or exhaustive. As the patient's healthcare provider, you are responsible for applying your clinical judgment regarding appropriate care and treatment of each patient.

4

PA OR APPEAL IS APPROVED

Pharmacy fills Rx and medication is dispensed to the patient

Contact your dedicated Chiesi Total Care program specialist with any questions you may have about your case.

PA denied? Chiesi Total Care is here to help.

It's not uncommon for the first PA submission to be denied. With a long track record of success in gaining PA and appeal approvals, Chiesi Total Care is here to provide assistance with the appeal process. Chiesi Total Care will assist in providing additional resources and/or publications depending on the reasons for denial. To request a copy of an additional resource or publication, please reach out directly to us.medical@chiesi.com.

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Chiesi Total Care can help improve compliance and adherence.

Chiesi TOTAL care℠

We provide updates on your patient's therapy and alert the office should there be an issue with compliance. We also help patients stay compliant by helping them cope with side effects and answering questions.

We can help by:

- Alerting when to refill or when refills are being missed
- Counseling patients on managing side effects
- Providing 24/7 pharmacist access
- Enrolling patients in the Ferriprox Copay Program – patients may pay as little as $0 if eligible†

Lesa, Chiesi Total Care Pharmacist

† Please refer to the full Terms and Conditions in the back pocket for additional eligibility requirements.

Here is a checklist of best practices for Prior Authorization submission:

- ☐ Write "Dispense as written" on prescription Rx form
- ☐ Include pertinent clinical notes, dates, and laboratory findings
- ☐ Include prescribing practitioner NPI number and contact information
- ☐ Include medical rationale for why the patient cannot use generic or preferred formulary drugs
- ☐ Include therapeutic alternatives that were tried in the past, include documentation as to why it was inadequate

Important Safety Information

Avoid co-administration of Ferriprox with other drugs known to be associated with neutropenia or agranulocytosis; however, if this is unavoidable, closely monitor the absolute neutrophil count. Avoid co-administration with UGT1A6 inhibitors. Allow at least a 4-hour interval between administration of Ferriprox and drugs or supplements containing polyvalent cations (e.g., iron, aluminum, or zinc).

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Ferriprox is contraindicated in patients with known hypersensitivity to deferiprone or to any of the excipients in the formulations.

In pooled clinical trials, 7.5% of 642 patients with thalassemia syndromes treated with Ferriprox developed increased ALT values. Four (0.62%) Ferriprox-treated subjects discontinued the drug due to increased serum ALT levels and 1 (0.16%) due to an increase in both ALT and AST. In pooled clinical trials, 7.7% of 196 patients with sickle cell disease or other anemias treated with Ferriprox developed increased ALT values. Monitor serum ALT values monthly during therapy with Ferriprox and consider interruption of therapy if there is a persistent increase in the serum transaminase levels. Decreased plasma zinc concentrations have been observed on deferiprone therapy. Monitor plasma zinc annually, and supplement in the event of a deficiency.

Ferriprox can cause fetal harm. Advise females of reproductive potential to use an effective method of contraception during treatment with Ferriprox and for at least six months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with Ferriprox and for at least three months after the last dose. Advise females not to breastfeed during treatment with Ferriprox and for at least 2 weeks after the last dose.

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The most common adverse reactions in patients with thalassemia (incidence ≥6%) are nausea, vomiting, abdominal pain, arthralgia, ALT increased and neutropenia. The most common adverse reactions in patients with sickle cell disease or other anemias (incidence ≥6%) are pyrexia, abdominal pain, bone pain, headache, vomiting, pain in extremity, sickle cell anemia with crisis, back pain, ALT increased, AST increased, arthralgia, oropharyngeal pain, nasopharyngitis, neutrophil count decreased, cough and nausea.

Inform patients that their urine might show a reddish/brown discoloration due to the excretion of the iron-deferiprone complex. This is a very common sign of the desired effect, and it is not harmful.

Advise patients to avoid alcohol while taking Ferriprox tablets (twice-a-day). Consumption of alcohol while taking Ferriprox tablets (twice-a-day) may result in more rapid release of deferiprone.

Please see full Prescribing Information, including boxed WARNING and Medication Guide inside.

For more information, visit ferriprox.com.
Chiesi Total Care℠ Program offered through EVERSANA Life Science Services Specialty Pharmacy

Ferriprox® is a registered trademark of CHIESI FARMACEUTICI S.p.A.
Chiesi Total Care℠ is a service mark of CHIESI FARMACEUTICI S.p.A.
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