Clinical Policy: Deferiprone (Ferriprox)

Reference Number: CP.PHAR.147
Effective Date: 11.15
Last Review Date: 11.17
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Deferiprone (Ferriprox®) is an iron chelator.

FDA Approved Indication(s)
Ferriprox is indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

Limitation of use: Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Ferriprox is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Transfusional Iron Overload Due to Thalassemia Syndromes (must meet all)**:**

1. Diagnosis of transfusional iron overload due to thalassemia;
2. Age ≥ 18 years;
3. Documentation shows a transfusion history of ≥ 100 mL/kg of packed red blood cells (pRBCs) (e.g., ≥ 20 units of pRBCs for a 40 kg person or more in individuals weighing more than 40 kg) and a serum ferritin level > 1,000 mcg/L;
4. Failure of Desferal (deferoxamine), and Exjade/Jadenu (deferasirox), unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 99 mg/kg/day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Transfusional Iron Overload Due to Thalassemia Syndromes (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;

2. Current documentation (within the last 30 days) shows a serum ferritin level ≥ 500 mcg/L.
3. If request is for a dose increase, new dose does not exceed 99 mg/kg/day.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
pRBCs: packed red blood cells

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Transfusion iron overload due to thalassemia syndromes	Recommended initial dose of Ferriprox is 25 mg/kg, orally, three times per day for a total of 75 mg/kg/day.	33 mg/kg, three times per day for a total of 99 mg/kg/day

VI. Product Availability

Oral solution: 100 mg/mL
Tablets: 500 mg

VII. References

1. Ferriprox Prescribing Information. Rockville, MD: ApoPharma USA, Inc.; February 2015. Available at http://www.ferriprox.com/us/pdf/ferriprox_full_pi.pdf. Accessed May 8, 2017.
2. Ferriprox Oral Solution Prescribing Information. Rockville, MD: ApoPharma USA, Inc.; September 2015. Available at http://www.ferriprox.com/us/pdf/ferriprox_full_pi.pdf. Accessed May 8, 2017.
3. Desferal Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2011. Available at https://dailymed.nlm.nih.gov/dailymed/. . Accessed May 8, 2017.
4. Exjade Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016. Available at http://www.us.exjade.com/. Accessed May 8, 2017.
5. Jadenu Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016. Available at https://www.jadenu.com/. Accessed May 8, 2017.

6. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Cross-talk between available guidelines for the management of patients with beta-thalassemia major. Acta Haematol. 2013; 130: 64-73. DOI: 10.1159/000345734.
7. Hoffbrand AV, Taher A, Cappellini MD. How I treat tranfusional iron overload. Blood. November 1, 2012; 120(18): 3657-3669.

Reviews, Revisions, and Approvals	Date	Approval Date
Moved Ferriprox to independent policy Ferriprox criteria - added age criteria (adults); removed requests for documentation; reformatted using appendices and added question about ferritin levels in the continuation of therapy section.	11.15	11.15
Converted policy to new template. Age removed and documentation requests added; "current documentation" is defined as "within the last 30 days" for follow-up serum ferritin levels and recommended monthly ferritin tests. Initiation of therapy: transfusion history and serum ferritin level per the PI dosing information; the wording "and consistent ferritin levels >1,000" is changed to "or a serum ferritin level >1,000."	10.16	11.16
Converted to new template. Approval duration extended to 6 and 12 months, from 3 and 6 months initial and re-auth respectively. Added weight-based max dose per PI; safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.	05.17	P&T: 08.17 CPC: 11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.