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Effective Date: 4/16/2020

Desferal® (deferroxamine)

FDA approval: April 1, 1968

HCPCS: J0895

Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Desferal
 - i. Treatment of acute iron intoxication
 - ii. Chronic iron overload due to transfusion-dependent anemias > 3 years of age
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: FDA approved dosing
 - b. Initial Authorization Period: 1 year
 - c. Renewal Criteria: Documentation of tolerance of the medication and continued success assessed by:
 - i. Decrease in LICs from baseline OR
 - ii. Decrease in serum ferritin levels
 - iii. Stable ANC
 - d. Renewal Authorization Period: 1 year
- C. Desferal is considered investigational when used for all other conditions, including but not limited to:
 - a. Any other indication or iron storage disorder

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

- A. **FDA approved indication / Diagnosis**
 - a. The treatment of acute iron intoxication and of chronic iron overload due to transfusion-dependent anemias.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

**Please refer to most recent prescribing information.*

<https://www.fda.gov/>

B. Background Information

- a. Chronic iron overload can occur as a result of frequent blood transfusions due to disease states such as thalassemia, sickle cell disease (SCD), and myelodysplastic syndrome (MDS). SCD is the most common inherited hemoglobinopathy in the United States affecting around 70,000 to 100,000 individuals. In addition, chronic iron overload can be due to non-transfusion dependent thalassemia (NTDT) which is a subset of patients that do not require transfusions.
- b. Iron overload occurs when iron levels exceed the body's transferrin binding capacity resulting in increased serum iron levels. As a result, circulating free iron can deposit in vital organs such as the liver and heart putting patients at risk of developing liver disease, diabetes, arthritis, heart failure or an abnormal heart rhythm, and death. The standard of care to treat transfusional iron overload is chelation therapy.
- c. The level of evidence for initiating chelation therapy is variable dependent on the different disorders associated with iron overload. There are few clinical trials to show the impact that iron chelation therapy has on the clinical course of patients with SCD and iron overload. It is considered an important component of the transfusion program in this disorder for patients with stroke who are on a regular transfusion regimen.
- d. Therapy should be considered when patients have evidence of chronic transfusional iron overload. This is evidenced by a transfusion of at least 100 mL/kg of packed red blood cells (PRBCs) and a serum ferritin consistently greater than 1000 mcg/L.
- e. For patients with NTDT syndromes, chelation therapy should be considered when a patient has a liver iron concentration (LIC) of at least 5 mg Fe/g dry weight (dw) and a serum ferritin greater than 300 mcg/L.
- f. A baseline serum ferritin level, serum creatinine, serum transaminases and bilirubin, as well as auditory and ophthalmic examinations (and baseline LIC for NTDT patients) should be obtained prior to starting therapy.
- g. Serum ferritin should be monitored monthly with dosage adjustments made every 3 to 6 months based on serum ferritin trends for patients with transfusional iron overload. In addition, monitor LIC every 6 months for patients with NTDT syndrome.
- h. Currently available guidelines for the clinical management of thalassemia from the Thalassemia International Federation recommend deferoxamine or deferasirox as first-line chelation therapy.
- i. The National Institute of Health (NIH), National Heart, Lung, and Blood Institute guidelines on the Management of Sickle Cell Disease has not been updated since 2002 and do not include deferasirox.
- j. Current NCCN guidelines for MDS consider iron chelation therapy a supportive care.

Cross References	
Drug Review	P&T Committee Meeting
Feriprox (deferiprone)	02/09/2012
Exjade (deferasirox)	05/02/2013
Jadenu (deferasirox)	02/11/2016

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

a. Dosing:

- i. Subcutaneous: 20-40 mg/kg/day (1000-2000 mg) over 8-24 hours for adults and pediatric patients 3 years of age and older
- ii. Intramuscular: 500 mg to 1000 mg (total daily dose not to exceed 1000 mg) for adults and pediatric patients 3 years and older
- iii. Intravenous: 20-40 mg/kg/day (pediatric); 40-50 mg/kg/day for adults (not to exceed 60 mg/kg/day) over 8-12 hours (rate not to exceed 15 mg/kg/hr) for 5-7 days/week

**Please refer to most recent prescribing information.*

F. How supplied

- a. 500 mg and 2 gm vials

References:

1. Jadenu [package insert]. East Hanover, NJ. Novartis; July 2019.
2. Exjade [package insert]. East Hanover, NJ. Novartis; July 2019.
3. Ferriprox [package insert]. Rockville, MD. ApoPharma; May 2017.
4. Desferal [package insert]. East Hanover, NJ. Novartis; December 2011.
5. © 2015 OmedaRx-InsightsRx™ Abbreviated Medication Assessments: Electrolytes: Iron Chelator Therapies. July 2015.
6. © 2015 Highmark Class Review: Toxicology Agents: Heavy Metal Antagonists/Chelating Agents: Key Focus: deferiasirox (Jadenu™). July 2015.
7. Capellini MD, Cohen AR, et al. Guidelines for the clinical management of thalassemia. 2nd rev edition. Nicosia, Cyprus: Thalassaemia International Federation. 2008.
8. National Institute of Health. The management of sickle cell disease. NIH publication No 02-2117.2002.
9. National Comprehensive Cancer Network. Myelodysplastic Syndromes. Clinical Practice Guidelines in Oncology. 2015; v 1.2016.
10. Brittenham GM. Iron-Chelating Therapy for Transfusional Iron Overload. *N Engl J Med*. 2011; 364(2): 146-156.
11. Saliba AN, Harb AR, and Taher AT. Iron chelation therapy in transfusion-dependent thalassemia patients: current strategies and future directions. *Journal of Blood Medicine*. 2015; 6: 197-209.
12. Taher AT, Musallam KM, et al. Optimal management of β thalassemia intermedia. *British Journal of Hematology*. 2011; 152: 512-523.
13. Taher AT, Viprakasit V, et all. Treating iron overload in patients with non-transfusion-dependent thalassemia. *Am J Hematol*. 2013; 88: 409-415.
14. Ferriprox solution [prescribing information]. Rockville, MD. ApoPharma USA Inc; September 2015..

Policy History												
#	Date	Change Description										
1.5	Effective Date: 04/16/2020	Annual Review										
1.4	Effective Date: 05/09/2019	Annual Review of Medical Policy										
1.3	Effective Date: 05/03/2018	Annual Review of Medical Policy										
1.2	Effective Date: 05/04/2017	Annual Review of Medical Policy										
1.1	Effective Date: 05/05/2016	Policy update to include new formulation (Ferriprox oral solution)										
1.0	Effective Date: 02/11/2016	New Coverage Guidelines<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.