Mass General Brigham
Health Plan

Exjade (deferasirox)
Jadenu (deferasirox)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

FDA-Approved Indications

1. Chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older
2. Chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Chronic Iron Overload due to Blood Transfusions (transfusional iron overload)

Authorization may be granted when the following criteria is met:

1. Member has a diagnosis of chronic iron overload due to blood transfusions.
2. Submission of documentation that shows pretreatment serum ferritin level is consistently greater than 1000 mcg/L.
3. Dose of deferasirox tablet for suspension/Exjade will not exceed 40 mg/kg per day, dose of deferasirox/Jadenu will not exceed 28 mg/kg per day.

Chronic Iron Overload in Patients with Non-transfusion Dependent Thalassemia Syndromes

Authorization may be granted when the following criteria is met:

1. Member has a diagnosis of non-transfusion dependent thalassemia syndromes.
2. Submission of documentation that shows pretreatment serum ferritin level is greater than 300 mcg/L.
3. Submission of documentation that shows pretreatment liver iron concentration (LIC) is at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw).
4. Dose of deferasirox tablet for suspension/Exjade will not exceed 20 mg/kg per day, dose of deferasirox/Jadenu will not exceed 14 mg/kg per day.

Hereditary Hemochromatosis
Authorization may be granted when the following criteria is met:

1. Member has a diagnosis of hereditary hemochromatosis.
2. Phlebotomy is not an option (e.g., poor venous access, poor candidate due to underlying medical disorders) OR the member had an unsatisfactory response to phlebotomy.

Continuation of Therapy
Chronic Iron Overload due to Blood Transfusions (transfusional iron overload)
Reauthorization may be granted for continued treatment when the following criteria are met:

1. Member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.
2. For chronic iron overload due to blood transfusions (transfusional iron overload), serum ferritin level is not consistently below 500 mcg/L.
3. For chronic iron overload in patients with non-transfusion dependent thalassemia syndromes, serum ferritin level is not consistently below 300 mcg/L.

Limitations

1. Initial approvals and reauthorizations will be granted for 6 months.

References

1. Exjade [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
2. Jadenu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
3. Deferasirox tablet for suspension [package insert]. North Wales, PA: Actavis Pharma, Inc; August 2021.
4. Deferasirox tablet [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; January 2021.
5. Deferasirox granule [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; August 2021
6. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the management of transfusion dependent thalassaemia (TDT) 4th Edition [Internet]. Thalassaemia International Federation 2021;20:1-351.
7. Hoffbrand AV, Taher A, Cappellini MD. How I treat transfusional iron overload. Blood 2012;120(18):3657-69.
8. Taher A, Musallam K, Cappellini M, et al. Guidelines for the management of non-transfusion dependent thalassaemia (NTDT) 2nd Edition. Thalassaemia International Federation 2018;1-117.
9. Phatak P, Brissot P, Bonkovsky H et al. A phase I/II, open-label, dose-escalation trial of once daily oral chelator deferasirox to treat iron overload in HFE-related hereditary hemochromatosis: Final Results of the Core Study. Blood 2009;114: 1514.
10. Adams P, Barton J, et al. How I Treat Hemochromatosis. Blood 2010;(116): 317-325.
11. Kowdley, Kris V. MD, FACG1; Brown, Kyle E. MD, MSc2,3,4; Ahn, Joseph MD, MS, MBA, FACG (GRADE Methodologist)5; Sundaram, Vinay MD, MSc6 ACG Clinical Guideline: Hereditary Hemochromatosis, The American Journal of Gastroenterology: August 2019 - Volume 114 - Issue 8 - p 1202-1218

Review History
12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024