PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Chelating Agents – Iron Chelators (Oral) Preferred Specialty Management Policy
- Exjade® (deferasirox tablets for suspension – Novartis, generic)
- Jadenu® (deferasirox tablets – Novartis, generic)
- Jadenu® Sprinkle (deferasirox granules for oral use – Novartis, generic)
- Ferriprox® (deferiprone tablets and oral solution – Chiesi, generic [tablets only])

REVIEW DATE: 02/05/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Exjade, Jadenu (granules and tablets), and Ferriprox (granules and oral solution) are orally administered iron chelators used for the treatment of **iron overload**.[1-4] Exjade and Jadenu have the same chemical entity (deferasirox) in different formulations.[1,2]

Deferasirox (Exjade, Jadenu/Sprinkle; generics) is indicated for the following uses:[1,2]
- **Chronic iron overload due to blood transfusions** (transfusional hemosiderosis), in patients ≥ 2 years of age.
- **Chronic iron overload with non-transfusion-dependent thalassemia syndromes**, in patients ≥ 10 years of age with a liver iron concentration of

at least 5 mg of iron per gram of liver dry weight and a serum ferritin > 300 mcg/L.

Limitations of Use: The safety and efficacy of deferasirox when administered with other iron chelation therapy have not been established.[1,2]

Deferiprone tablets (Ferriprox tablets, generic) are indicated for the following uses:[3]

- **Transfusional iron overload with thalassemia syndromes**, in patients ≥ 8 years of age.
- **Transfusional iron overload with sickle cell disease or other anemias**, in patients ≥ 8 years of age.

Ferriprox (deferiprone) oral solution is indicated for the following uses:[4]

- **Transfusional iron overload with thalassemia syndromes**, in patients ≥ 3 years of age.
- **Transfusional iron overload with sickle cell disease or other anemias**, in patients ≥ 3 years of age.

Limitations of Use: Safety and effectiveness of deferiprone have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.[3,4]

Table 1. Availability of Oral Iron Chelators.[1-4]

Exjade (deferasirox tablets for suspension)	Ferriprox (deferiprone tablets and oral solution)		Jadenu/Sprinkle (deferasirox granules and tablets)	
• 125 mg • 250 mg • 500 mg	**Tablets** • 500 mg • 1000 mg	**Solution** • 100 mg/mL	**Granules** • 90 mg • 180 mg • 360 mg	**Tablets** • 90 mg • 180 mg • 360 mg

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all products (Preferred and Non-Preferred), the patient is required to meet the respective standard *Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy* criteria. The program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted below.

Preferred Products: Generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, generic deferiprone tablets

Non-Preferred Products: Exjade, Ferriprox (tablets and oral solution), Jadenu, Jadenu Sprinkle

Chelating Agents – Iron Chelators (Oral) Preferred Specialty Management Policy non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Exjade, Ferriprox tablets, Jadenu, Jadenu Sprinkle	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the respective standard *Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy* criteria; AND **B)** Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets.
Ferriprox oral solution	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets; OR **ii.** The dose prescribed cannot be attained with deferiprone tablets; OR **iii.** Patient cannot swallow or has difficulty swallowing deferiprone tablets.

REFERENCES

1. Exjade® tablets for suspension [prescribing information]. East Hanover, NJ: Novartis; July 2024.
2. Jadenu® tablets and Jadenu® Sprinkle for oral use [prescribing information]. East Hanover, NJ: Novartis; July 2024.
3. Ferriprox® tablets [prescribing information]. Rockville, MD: Chiesi; July 2023.
4. Ferriprox® oral solution [prescribing information]. Rockville, MD: Chiesi; November 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/18/2023
Annual Revision	No criteria changes.	01/31/2024
Annual Revision	No criteria changes.	02/05/2025