

CARE VALUE POLICY

- POLICY:** Chelating Agents – Iron Chelators (Oral) Care Value Policy
- Exjade® (deferasirox tablets for suspension – Novartis, generic)
 - Ferriprox® (deferiprone tablets and oral solution – ApoPharma USA, generic [500 mg tablets only])
 - Jadenu® (deferasirox tablets – Novartis, generic)
 - Jadenu® Sprinkle (deferasirox granules for oral use – Novartis, generic)

REVIEW DATE: 02/24/2021

OVERVIEW

Exjade, Jadenu (granules and tablets), and Ferriprox (tablets 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

The specific indication for treatment of iron overload differs among the products. Exjade and Jadenu (granules and tablets) are 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.

Ferriprox (tablets and oral solution) is indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.^{3,4} The recommended dosing for Ferriprox is weight-based, adjustments are based on response and therapeutic goals (maintenance or reduction of body iron burden). The maximum dose is 33 mg/kg actual body weight, three times per day for a total of 99 mg/kg/day.

Table 1. Availability of Oral Iron Chelating Agents.¹⁻⁴

Exjade® (deferasirox tablets for suspension)	Ferriprox® (deferiprone tablets and oral solution)		Jadenu®/Sprinkle (deferasirox granules and tablets)	
<ul style="list-style-type: none"> • 125 mg • 250 mg • 500 mg 	<u>Tablets</u> <ul style="list-style-type: none"> • 500 mg • 1000 mg 	<u>Solution</u> 100 mg/mL	<u>Granules</u> <ul style="list-style-type: none"> • 90 mg • 180 mg • 360 mg 	<u>Tablets</u> <ul style="list-style-type: none"> • 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 medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *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.

Automation: None.

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

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Exjade	<ol style="list-style-type: none"> 1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND B) Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets.
Ferriprox tablets	<ol style="list-style-type: none"> 1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND B) Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets.
Ferriprox solution	<ol style="list-style-type: none"> 1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND B) Patient meets ONE of the following (i, ii, <u>or</u> iii): <ol style="list-style-type: none"> 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.
Jadenu	<ol style="list-style-type: none"> 1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND B) Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets.
Jadenu Sprinkle	<ol style="list-style-type: none"> 1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND B) Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets.

REFERENCES

1. Exjade® tablets for suspension [prescribing information]. East Hanover, NJ: Novartis; December 2020.
2. Jadenu® tablets and Jadenu® Sprinkle for oral use [prescribing information]. East Hanover, NJ: Novartis; July 2020.
3. Ferriprox® tablets [prescribing information]. Rockville, MD: ApoPharma USA, Inc.; May 2020.
4. Ferriprox® oral solution [prescribing information]. Rockville, MD: ApoPharma USA, Inc.; February 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/24/2021