

## 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**.<sup>1-4</sup> Exjade and Jadenu have the same chemical entity (deferasirox) in different formulations.<sup>1-2</sup>

The specific indication for treatment of iron overload differs among the products. Exjade and Jadenu (granules and tablets) are indicated for the following uses:<sup>1,2</sup>

- Chronic iron overload due to blood transfusions (transfusional hemosiderosis), in patients  $\geq 2$  years of age.
- Chronic iron overload with non-transfusion-dependent thalassemia syndromes, in patients  $\geq 10$  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.<sup>3,4</sup> 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.**<sup>1-4</sup>

Exjade® (deferasirox tablets for suspension)	Ferriprox® (deferiprone tablets and oral solution)		Jadenu®/Sprinkle (deferasirox granules and tablets)	
<ul style="list-style-type: none"> <li>• 125 mg</li> <li>• 250 mg</li> <li>• 500 mg</li> </ul>	<u>Tablets</u> <ul style="list-style-type: none"> <li>• 500 mg</li> <li>• 1000 mg</li> </ul>	<u>Solution</u> 100 mg/mL	<u>Granules</u> <ul style="list-style-type: none"> <li>• 90 mg</li> <li>• 180 mg</li> <li>• 360 mg</li> </ul>	<u>Tablets</u> <ul style="list-style-type: none"> <li>• 90 mg</li> <li>• 180 mg</li> <li>• 360 mg</li> </ul>

### 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"> <li>1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B):               <ol style="list-style-type: none"> <li>A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND</li> <li>B) Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets.</li> </ol> </li> </ol>
Ferriprox tablets	<ol style="list-style-type: none"> <li>1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B):               <ol style="list-style-type: none"> <li>A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND</li> <li>B) Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets.</li> </ol> </li> </ol>
Ferriprox solution	<ol style="list-style-type: none"> <li>1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B):               <ol style="list-style-type: none"> <li>A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND</li> <li>B) Patient meets ONE of the following (i, ii, <u>or</u> iii):                   <ol style="list-style-type: none"> <li>i. Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets; OR</li> <li>ii. The dose prescribed cannot be attained with deferiprone tablets; OR</li> <li>iii. Patient cannot swallow or has difficulty swallowing deferiprone tablets.</li> </ol> </li> </ol> </li> </ol>
Jadenu	<ol style="list-style-type: none"> <li>1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B):               <ol style="list-style-type: none"> <li>A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND</li> <li>B) Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets.</li> </ol> </li> </ol>
Jadenu Sprinkle	<ol style="list-style-type: none"> <li>1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B):               <ol style="list-style-type: none"> <li>A) Patient meets the standard <i>Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy</i> criteria; AND</li> <li>B) Patient has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets.</li> </ol> </li> </ol>

**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