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

<table>
<thead>
<tr>
<th>Exjade® (deferasirox tablets for suspension)</th>
<th>Ferriprox® (deferiprone tablets and oral solution)</th>
<th>Jadenu®/Sprinkle (deferasirox granules and tablets)</th>
</tr>
</thead>
<tbody>
<tr>
<td>125 mg</td>
<td>Tablets</td>
<td>Granules</td>
</tr>
<tr>
<td>250 mg</td>
<td>500 mg</td>
<td>90 mg</td>
</tr>
<tr>
<td>500 mg</td>
<td>1000 mg</td>
<td>180 mg</td>
</tr>
<tr>
<td></td>
<td>Solution 100 mg/mL</td>
<td>360 mg</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Non-Preferred Product</th>
<th>Exception Criteria</th>
</tr>
</thead>
</table>
| **Exjade** | 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 has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets. |
| **Ferriprox tablets** | 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 has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets. |
| **Ferriprox 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. |
| **Jadenu** | 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 has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets. |
| **Jadenu Sprinkle** | 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 has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets. |
REFERENCES

HISTORY

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes</th>
<th>Review Date</th>
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<tr>
<td>New Policy</td>
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<td>02/24/2021</td>
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