Cigna National Formulary Coverage Policy

Preferred Specialty Management
Chelating Agents – Iron Chelators (Oral)

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Product Identifier(s)

| 90673 |

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. 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.

National Formulary Medical Necessity

Drugs Affected

- Exjade® (deferasirox tablets for suspension, generic)
- Ferriprox® (deferiprone tablets and oral solution, generic [500 mg tablets only])
- Jadenu® (deferasirox tablets, generic)
- Jadenu® Sprinkle (deferasirox granules for oral use, generic)

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the individual is required to meet the respective standard Prior Authorization Policy criteria. The program also directs the individual 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 Product(s): Generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, generic deferiprone tablets

Non-Preferred Product(s): Exjade, Ferriprox (tablets and oral solution), Jadenu, Jadenu Sprinkle
Cigna covers Non-Preferred Products as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

<table>
<thead>
<tr>
<th>Non-Preferred Product</th>
<th>Exception Criteria</th>
</tr>
</thead>
</table>
| Exjade                | 1. Approve for 1 year if the individual meets BOTH of the following (A and B):  
  A) Individual meets the standard Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy criteria; AND  
  B) Individual 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 individual meets BOTH of the following (A and B):  
  A) Individual meets the standard Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy criteria; AND  
  B) Individual 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 individual meets BOTH of the following (A and B):  
  A) Individual meets the standard Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy criteria; AND  
  B) Individual meets ONE of the following (i, ii, or iii):  
  i. Individual 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. Individual cannot swallow or has difficulty swallowing deferiprone tablets. |
| Jadenu                | 1. Approve for 1 year if the individual meets BOTH of the following (A and B):  
  A) Individual meets the standard Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy criteria; AND  
  B) Individual 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 individual meets BOTH of the following (A and B):  
  A) Individual meets the standard Chelating Agents – Iron Chelators (Oral) Prior Authorization Policy criteria; AND  
  B) Individual has tried ONE of generic deferasirox tablets, generic deferasirox tablets for suspension, generic deferasirox granules, or generic deferiprone tablets. |

**Conditions Not Covered**

Any other exception is considered not medically necessary.

**Background**

**Overview**

Exjade, Jadenu (granules and tablets), and Ferriprox (tablets and oral solution) are orally administered iron chelators used for the treatment of iron overload.\(^1\)\(^2\)\(^4\) 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. 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.

<table>
<thead>
<tr>
<th></th>
<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 500 mg</td>
<td>Solution 100 mg/mL</td>
<td>Granules 90 mg</td>
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<tr>
<td>250 mg</td>
<td>Tablets 500 mg</td>
<td></td>
<td>180 mg</td>
</tr>
<tr>
<td>500 mg</td>
<td>Tablets 1000 mg</td>
<td></td>
<td>360 mg</td>
</tr>
<tr>
<td>Solution</td>
<td></td>
<td></td>
<td>Tablets 90 mg</td>
</tr>
<tr>
<td>100 mg/mL</td>
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<td>180 mg</td>
</tr>
<tr>
<td>Granules</td>
<td></td>
<td></td>
<td>360 mg</td>
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References


Revision History

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