Venofer (iron sucrose)

Full Safety and Drug Utilization Review Provided in Background Materials

Pediatric Advisory Committee Meeting, March 24, 2015
Venofer (iron sucrose) - Background

• Venofer is indicated for the treatment of iron deficiency anemia patients with chronic kidney disease (CKD).

• 9/21/2012 approved pediatric labeling for iron maintenance treatment in patients ≥2 years of age with hemodialysis dependent chronic kidney disease (HDD-CKD).

• Venofer is also approved for iron maintenance treatment in patients ≥2 years of age with non-dialysis dependent or peritoneal dialysis dependent CKD treated with erythropoietin.

• The labeled pediatric dose for iron maintenance therapy is 0.5 mg/kg.
Venofer
20 Serious pediatric adverse events 11/6/2000 – 7/31/2014

• 1 death, reported as possible “cardiovascular collapse or systemic embolism”; insufficient information to fully assess cause of death.

• non-fatal SAEs:
  – Labeled events: 8 hypersensitivity reactions, 3 iron overload; 1 each of syncope, fever, hypoglycemia
  – Unlabeled events: 2 thrombotic events, 1 each of DRESS, rhabdomyolysis, decreased hemoglobin

• Majority of reports describe known or expected events for users of IV iron products.

• Unlabeled events had either insufficient information to assess causality or were likely due to patient comorbidities.

• No new safety signal identified
Venofer Pediatric Drug Utilization Review

Use in pediatrics is extremely low, <1%.

Total number of patients with a prescription and/or procedure claim* for Venofer® from a sample of non-retail settings, stratified by patient age**, September 2009 through August 2014, aggregate

<table>
<thead>
<tr>
<th></th>
<th>September 2009 - August 2014</th>
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<tbody>
<tr>
<td></td>
<td>Patients N</td>
</tr>
<tr>
<td><strong>Venofer® Total Patients</strong></td>
<td>654,294</td>
</tr>
<tr>
<td>0-16 years</td>
<td>1,820</td>
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<tr>
<td>0-1 year</td>
<td>125</td>
</tr>
<tr>
<td>2-16 years</td>
<td>1,695</td>
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<tr>
<td>17 years and older</td>
<td>652,468</td>
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<tr>
<td>Unspecified age</td>
<td>6</td>
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</tbody>
</table>

* Claims are from U.S. commercial, Medicare Part D, Cash, and Medicaid plans.

** Age is at first claim during examined time period. Patient age groups are inclusive of all patients up to the day before their next birthday. For example, patients aged 0-16 years include patients less than 17 years of age (16 years and 11 months).

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FDA will continue its standard ongoing safety monitoring.

Does the Committee concur?