SmartPA Criteria Proposal

Drug/Drug Class: Iron – Injectable Step Therapy Edit

First Implementation Date: November 19, 2020

Revised Date: November 11, 2021

Prepared for: MO HealthNet

Prepared by: MO HealthNet/Conduent

Criteria Status: ☒ Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of injectable iron therapy

Why Issue Selected: Iron deficiency anemia is the most common nutritional disorder in the world, accounting for approximately 50% of anemia cases. It is estimated that there are 8–9 million patients in the U.S. who suffer from iron deficiency anemia. Also, the most common reversible cause of chronic anemia or worsening anemia in patients with chronic kidney disease (CKD), other than anemia related directly to CKD, is iron deficiency anemia. Once discovered, the underlying cause of anemia should be treated. Oral iron therapy is used initially to replenish the body’s iron stores; injectable iron therapy may be used in patients who cannot tolerate or absorb the oral agents. Due to the high cost, MO HealthNet will impose clinical criteria to ensure appropriate utilization of injectable iron therapies.

Program-Specific Information:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date Range FFS 4-1-2020 to 3-31-2021</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FFS Claims</td>
</tr>
<tr>
<td>FERAHEME 510 MG/17 ML VIAL</td>
<td>492</td>
</tr>
<tr>
<td>FERRLECIT 62.5 MG/5 ML VIAL</td>
<td>2,509</td>
</tr>
<tr>
<td>INFED 100 MG/2 ML VIAL</td>
<td>426</td>
</tr>
<tr>
<td>INJECTAFER 750 MG/15 ML VIAL</td>
<td>527</td>
</tr>
<tr>
<td>MONOFERRIC 1,000 MG/10 ML VIAL</td>
<td>0</td>
</tr>
<tr>
<td>TRIFERIC 27.2 MG/5 ML AMP</td>
<td>0</td>
</tr>
<tr>
<td>TRIFERIC 272 MG PWD PKT</td>
<td>0</td>
</tr>
<tr>
<td>VENOFER 100 MG/5 ML VIAL</td>
<td>10,418</td>
</tr>
<tr>
<td>VENOFER 200 MG/10 ML VIAL</td>
<td>282</td>
</tr>
<tr>
<td>VENOFER 50 MG/2.5 ML VIAL</td>
<td>7,059</td>
</tr>
</tbody>
</table>

Type of Criteria: ☒ Appropriate Indications

Data Sources: ☒ Only Administrative Databases

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### Setting & Population

- Drug class for review: Injectable iron therapy
- Age range: All appropriate MO HealthNet participants

### Approval Criteria

- Claim for Ferrlecit, Infed, Triferic, or Venofer **OR**
- Claim for Feraheme, Injectafer, **or Monoferic**:
  - Participant aged 18 years or older **AND**
  - Documented diagnosis of iron deficiency anemia **AND**
  - Documented adequate therapeutic trial, intolerance, or contraindication to oral iron therapy (defined as 60 days in the past 90 days) **AND**
  - Documented adequate therapeutic trial, intolerance, or contraindication to at least 2 of the following agents: Infed, Ferrlecit, or Venofer (trial defined as 1 claim in the past 90 days) **AND**
  - Participant is dialysis dependent: Feraheme only

### Denial Criteria

- Therapy will be denied if no approval criteria are met
- Claim for Injectafer **or Monoferic**: participant is dialysis dependant
- Claim exceeds approved dosing limitations:
  - Feraheme: 2 vials per 25 days
  - Injectafer: 30 ml per 25 days
  - **Monoferic**: 10 ml per 25 days

### Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
<th>MedWatch Form:</th>
<th>Other:</th>
</tr>
</thead>
</table>

### Disposition of Edit

Denial: Exception code “0681” (Step Therapy)
Rule Type: CE

### Default Approval Period

6 months

### References