

This document applies to the following:

Product	Applies
Medicare Part B	<input checked="" type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input checked="" type="checkbox"/>

# Medicare Part B Step Therapy Intravenous Iron

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with Medicare Part B and Medicare Part B Advanced Biosimilars First.

## Plan Design Summary

This program applies to the intravenous iron products specified in this document. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a non-preferred product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

## Table. Intravenous Iron Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	<ul style="list-style-type: none"><li>Ferrlecit (sodium ferric gluconate complex)</li><li>Infed (iron dextran)</li><li>Sodium ferric gluconate</li><li>Venofer (iron sucrose)</li></ul>

Reference number(s)
5895-D

	Product(s)
Non-preferred	<ul style="list-style-type: none"> <li>Feraheme (ferumoxytol)</li> <li>Injectafer (ferric carboxymaltose)</li> <li>Monoferric (ferric derisomaltose)</li> </ul>

## Step Therapy Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for any of the preferred products.

Coverage for a non-preferred product is provided when any of the following criteria is met:

- Member has received treatment with the non-preferred product in the past 365 days.
- The requested product is Feraheme and the member meets any of the following:
  - Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed.
  - Member has a diagnosis of hemodialysis-dependent chronic kidney disease and is receiving supplemental epoetin therapy and has had a documented inadequate response or intolerable adverse event with both Ferrlecit and sodium ferric gluconate.
  - Member has a diagnosis of chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.
- The requested product is Injectafer and the member meets any of the following:
  - Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed.
  - Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.
  - Member has a diagnosis of iron deficiency with heart failure categorized as New York Heart Association class II/III.
- The requested product is Monoferric and the member meets any of the following:
  - Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed.
  - Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.

## References

- Ferrlecit [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; March 2022.

Reference number(s)
5895-D

2. Infed [package insert]. Madison, NJ: Allergan USA, Inc.; August 2024.
3. Sodium Ferric Gluconate [package insert]. Berkley Heights, NJ: Hikma Pharmaceuticals USA, Inc.; January 2021
4. Venofer [package insert]. Shirley, NY: American Regent, Inc.; June 2022.
5. Feraheme [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2022.
6. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; January 2025.
7. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics, Inc.; February 2022