EXCEPTIONS CRITERIA

INTRAVENOUS IRON

PREFERRED PRODUCTS: FERRLECIT, INFED, SODIUM FERRIC GLUCONATE, VENOFER

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

PLAN DESIGN SUMMARY

This program applies to the intravenous iron products specified in this policy. Coverage for targeted 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 targeted product for the first time.

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

Table. Complement Inhibitor Products

	Product(s)
Preferred*	Ferrlecit (sodium ferric gluconate complex)
	Infed (iron dextran)
	Sodium ferric gluconate
	Venofer (iron sucrose)
Targeted	Feraheme (ferumoxytol)
	Injectafer (ferric carboxymaltose)
	Monoferric (ferric derisomaltose)

^{*}Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

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

Coverage for a targeted product is provided when any of the following criteria is met:

- A. Member has received treatment with the targeted product in the past 365 days.
- B. The requested product is Feraheme and the member meets any of the following:
 - 1. 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.

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- 2. 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.
- 3. Member has a diagnosis of chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.
- C. The requested product is Injectafer and the member meets any of the following:
 - 1. 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.
 - 2. Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.
- D. The requested product is Monoferric and the member meets any of the following:
 - 1. 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.
 - 2. 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

- 1. Ferrlecit [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; March 2022.
- 2. Infed [package insert]. Madison, NJ: Allergan USA, Inc.; September 2021.
- 3. Sodium Ferric Gluconate [package insert]. Berkley Heights, NJ: Hikma Pharmaceuticals USA, Inc.; January 2021
- 4. Venofer [package insert]. Shirley, NY: American Regent, Inc.; July 2020.
- 5. Feraheme [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2022.
- 6. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; February 2022.
- 7. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics, Inc.; February 2022.

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