



RX.PA.095.CCH MEDICAL DRUG STEP THERAPY POLICY

The purpose of this policy is to define the step therapy process for the following drugs:

- Intravenous Iron Products – Ferrlecit (sodium ferric gluconate), Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose)
- Siklos (hydroxyurea)

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drugs listed above are subject to the step therapy process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be used for an FDA-approved or compendia supported use
- *FDA-approved indications ONLY:* Must be prescribed at a dose within the manufacturer’s dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must have failed, is intolerant to, OR have a contraindication to all preferred products within the same category below

Preferred Drugs	Non-Preferred Drugs
Iron Products	
Infed (J1750) Venofer (J1756)	Ferrlecit (J2916) Feraheme (Q0138) Injectafer (J1439) Monoferric (J1437)
Hydroxyurea Products	
Generic hydroxyurea Droxia (adults only)	Siklos (S0176)

MEDICAL DRUG STEP THERAPY POLICY

POLICY NUMBER: *RX.PA.095.CCH*

REVISION DATE: *04/2024*

PAGE NUMBER: 2 of 3

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J1437	Monoferric	Injection, ferric derisomaltose, 10mg
J1439	Injectafer	Injection, ferric carboxymaltose, 1 mg
J2916	Ferrlecit	Injection, sodium ferric gluconate complex in sucrose injection, 12.5mg
Q0138	Feraheme	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-esrd use)
S0176	Siklos	Hydroxyurea, oral, 500 mg

References:

1. Monoferric (ferric derisomaltose) [prescribing information]. Morristown, NJ: Pharmacosmos Therapeutics Inc; August 2022.
2. Injectafer (ferric carboxymaltose) [prescribing information]. Shirley, NY: American Regent Inc; May 2023.
3. Ferrlecit (sodium ferric gluconate complex in sucrose) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; March 2022.
4. Feraheme (ferumoxytol) [prescribing information]. Waltham, MA: AMAG Pharmaceuticals, Inc; June 2022.
5. Siklos (hydroxyurea) [prescribing information]. Rosemont, PA: Medunik USA Inc; November 2023.

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POLICY NUMBER: *RX.PA.095.CCH*

REVISION DATE: *04/2024*

PAGE NUMBER: 3 of 3

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	04/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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