

DOCUMENT REVISION HISTORY LOG

<div><div><div>DO NOT DISTRIBUTE OR RELEASE</div><div>Document Revision History Log is for internal use only and not considered part of the policy</div></div></div>		
<div><div>MEMORIAL HERMANN HEALTH PLAN HOLDINGS, LLC</div><div>POLICY</div><div><div>POLICY TITLE:</div><div>MHHP MEDM-MA IRO-003 Intravenous Iron Step Therapy Criteria</div></div><div><div>PUBLICATION DATE:</div><div>05/26/2025</div></div><div><div>LAST REVIEW DATE:</div><div>05/26/2025</div></div><div><div>VERSION:</div><div>1</div></div></div>		
Version	Change Summary	Revised By
1	Legacy document; Approved by P&T Committee 5/7/2025	D. Pierce/ S. Soman

DO NOT DISTRIBUTE OR RELEASE
Document Revision History Log is for internal use only and not considered part of the policy

**MEMORIAL HERMANN HEALTH SYSTEM
MEMORIAL HERMANN HEALTH PLAN HOLDINGS, LLC
POLICY**

POLICY TITLE: MHHP MEDM-MA IRO-003 Intravenous Iron
Step Therapy Criteria

PUBLICATION DATE: 05/26/2025

LAST REVIEW DATE: 05/26/2025

VERSION: 1

POLICY PURPOSE:

The Memorial Hermann Health Intravenous Iron Step Therapy Criteria policy aims to advise providers of preferred drug products and outline the exceptions to preferred drug products during the prior authorization process. Step therapy criteria is applied in conjunction with any relevant National Coverage Determinations (NCD), Local Coverage Determination (LCD), InterQual and other MHHP internal medical necessity and or Part B drug criteria.

DEFINITIONS: None

SCOPE:

This policy applies to Memorial Hermann Medicare plans.

POLICY STATEMENT

The step therapy program applies intravenous iron as described in this policy. Requested Part B drug coverage must comply with step criteria in this policy. If approved, authorizations will be approved for 6 months. If a provider administers a non-preferred drug without obtaining prior authorization, the request for coverage may be denied. Preferred drugs may still require prior authorization. This policy applies to all Medicare members who are new to treatment with a non-preferred drug. A member will not be required to change the current drug treatment. For the purposes of this policy, "current drug treatment" is defined as either a paid claim for the drug or clinical documentation confirming that the member has been using the non-preferred drug within the past 365 days. In addition, there must be evidence of regular follow-up visits with the prescribing physician within the last 6 months. The member must also

demonstrate clinical improvement as a result of the ongoing treatment. If a new plan member is currently using a particular drug, MHHP will not require the member to switch to the preferred drug upon enrollment. An existing member currently using a particular drug will not be required to change drug/products if this policy is updated. Not all indications for the non-preferred drug are listed in this policy. Sufficient documentation of extenuating circumstances related to the use of the non-preferred vs. the preferred drug will be considered on a case by case scenario by The Plan. The documentation must include that the preferred drug has been attempted and what the outcome of that attempt was or why the preferred drug cannot be attempted. Indications and medications listed in this policy may change upon varying factors and should be evaluated by guidelines, the FDA and manufacturer package insert to verify appropriate use at the time of review.

Intravenous Iron for Iron Deficiency Anemia

- After trial, failure, and or intolerance of oral supplementation

Initial (New Starts) Authorization Criteria	
Preferred drug (s): Ferrlecit (iodium ferric gluconate complex) INFeD (iron dextran complex) Venofer (iron sucrose)	
2nd Preferred drug (s): Injectafer (ferric carboxymaltose)	
Non-preferred drug(s): Feraheme (ferumoxytol) Monoferric (ferric derisomaltose) Triferic (ferric pyrophosphate)	
<i>(Note: Any drugs not listed as preferred will be considered non-preferred until the next policy update)</i>	
Criteria: Coverage for the non-preferred drugs (s) is provided when there is clinical documentation to support one or more of the following criteria:	
1. The member has received the requested non-preferred drugs in the past 365 days and there is objective evidence of clinical benefit via imaging, lab results, or clinical assessment	
OR	

2. There is an inadequate response to the preferred drug

OR

3. There has been an adverse event related to the preferred drug (s)

OR

4. There is a contraindication to the preferred drugs

AND

5. Dosing must be in accordance with FDA approved labeling or otherwise supported by approved compendia and disease specific treatment guidelines.

Related documents

MHHP MEDM-MA 303 Medical Necessity Determinations

REFERENCES

1. Feraheme (ferumoxytol) injection [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; FDA label website: [Feraheme FDA Label](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022180s025lbl.pdf)
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022180s025lbl.pdf,
Accessed April 2025

2. Ferrlecit (sodium ferric gluconate complex in sucrose) injection [package insert]. Bridgewater, NJ: SanofiAventis US LLC; March 2022. FDA label website:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020955s020lbl.pdf
Accessed April 2025

3. Infed (iron dextran) injection [package insert]. Madison, NJ: Allergan USA, Inc.; September 2020. FDA label website:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/017441s178lbl.pdf
Accessed April 2025

4. Injectafer (ferric carboxymaltose) injection [package insert]. Shirley, NY: American Regent, Inc.; February 2022. FDA label website:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/203565s014lbl.pdf
Accessed April 2025

5. Monoferric (ferric derisomaltose) injection [package insert]. Morristown, NJ: Pharmacosmos Therapeutics Inc.; February 2022. FDA label website:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208171s000lbl.pdf
Accessed April 2025

6. Venofer (iron sucrose) injection [package insert]. Shirley, NY: American Regent, Inc.; June 2022 FDA label website: <https://www.venofer.com/pdfs/venofer-prescribing-information.pdf> Accessed April 2025

7. Triferic (ferric pyrophosphate citrate) injection [package insert]. Wixom, MI: Rockwell Medical, Inc.; March 2020; FDA label website: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212860s000lbl.pdf Accessed April 2025