Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	X	X	X	X

Agents for Iron Deficiency Anemia

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 3 months Continuation requests: 3 months Dialysis-dependent use: 1 year

Medications	Comments	Quantity Limit
Ferrlecit (sodium ferric gluconate/sucrose complex) Infed (iron dextran) Venofer (iron sucrose)	Preferred	May be subject to quantity limit*
Feraheme (ferumoxytol) Injectafer (ferric carboxymaltose) Monoferric (ferric derisomaltose) Triferic, Triferic AVNU (ferric pyrophosphate citrate)	Non-Preferred	

*Use in dialysis-dependent individuals excluded from quantity limits.

APPROVAL CRITERIA

Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate/sucrose complex), Infed (iron dextran), Injectafer (ferric carboxymaltose), Venofer (iron sucrose)

Requests for Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate/sucrose complex), Infed (iron dextran), Injectafer (ferric carboxymaltose), Venofer (iron sucrose) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic kidney disease (CKD); **AND**
   A. Individual is dialysis dependent;

Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	X	X	X	X

OR

II. Individual has a diagnosis of iron deficiency anemia (IDA); **AND**
III. Individual is non-dialysis dependent; **AND**
IV. Diagnosis is confirmed by one of the following:
   A. For IDA associated with CKD or inflammatory conditions (for example, inflammatory bowel disease [IBD], heart failure), individual meets *one* of the following (De Franceschi 2017):
      1. Serum ferritin levels less than 100 ng/mL; **OR**
      2. TSAT levels less than 20%; **OR**
      3. Serum ferritin is less than or equal to 500 ng/mL ***and*** TSAT is less than or equal to 30% (KDIGO 2012); **OR**
      4. Bone marrow demonstrates inadequate iron stores; **OR**
   B. For IDA associated with cancer/chemotherapy or non-inflammatory conditions (for example, blood loss, malabsorption, malnutrition), individual meets *one* of the following (NCCN 2020, De Franceschi 2017):
      1. Serum ferritin levels less than 30 ng/mL; **OR**
      2. TSAT levels less than 20%; **OR**
      3. Bone marrow demonstrates inadequate iron stores; **AND**
V. Individual has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (NCCN 2020, KDIGO 2012).

Requests for Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate/sucrose complex), Infed (iron dextran), Injectafer (ferric carboxymaltose), or Venofer (iron sucrose) may not be approved when the above criteria are not met and for all other indications.

Monoferric (ferric derisomaltose)

Requests for Monoferric (ferric derisomaltose) may be approved if the following criteria are met:

I. Individual has a diagnosis of iron deficiency anemia (IDA); **AND**
II. Individual is non-dialysis dependent; **AND**
III. Diagnosis is confirmed by one of the following:
   A. For IDA associated with CKD or inflammatory conditions (for example, inflammatory bowel disease [IBD], heart failure), individual meets *one* of the following (De Franceschi 2017):
      1. Serum ferritin levels less than 100 ng/mL; **OR**
      2. TSAT levels less than 20%; **OR**

Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	X	X	X	X

3. Serum ferritin is less than or equal to 500 ng/mL ***and*** TSAT is less than or equal to 30% (KDIGO 2012); **OR**
4. Bone marrow demonstrates inadequate iron stores; **OR**

B. For IDA associated with cancer/chemotherapy or non-inflammatory conditions (for example, blood loss, malabsorption, malnutrition), individual meets *one* of the following (NCCN 2020, De Franceschi 2017):
1. Serum ferritin levels less than 30 ng/mL; **OR**
2. TSAT levels less than 20%; **OR**
3. Bone marrow demonstrates inadequate iron stores; **AND**

IV. Individual has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (NCCN 2020, KDIGO 2012).

Requests for Monoferric (ferric derisomaltose) may not be approved when the above criteria are not met and for all other indications

Triferic/Triferic AVNU (ferric pyrophosphate citrate)

Requests for Triferic/Triferic AVNU (ferric pyrophosphate citrate) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic kidney disease (CKD); **AND**
A. Individual is hemodialysis dependent.

Requests for Triferic/Triferic AVNU (ferric pyrophosphate citrate) may not be approved for the following:

I. Peritoneal dialysis; **OR**
II. When the above criteria are not met and for all other indications.

Requests for a non-preferred iron deficiency anemia agent [Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), Monoferric (ferric derisomaltose), Triferic, Triferic AVNU (ferric pyrophosphate citrate)] must also meet following criteria:

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to two (2) preferred agents;

Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	X	X	X	X

OR

II. The preferred agent(s) are not acceptable due to concomitant clinical conditions, including but not limited to known hypersensitivity to any active or inactive component which is not also associated with the requested non-preferred agent;

OR

III. Individual is dialysis-dependent and using iron in conjunction with dialysis.

Key References:

1. Auerbach M. Causes and diagnosis of iron deficiency and iron deficiency anemia in adults. Last updated June 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 13, 2020.
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4. De Franceschi L, Iolascon A, Taher A, Cappellini MD. Clinical management of iron deficiency anemia in adults: Systemic review on advances in diagnosis and treatment. Eur J Intern Med. 2017;42:16–23.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
9. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 13, 2020.
    a. Hematopoietic Growth Factors. V2.2020. Revised January 27, 2020.
10. Peyrin-Biroulet L, Williet N, Cacoub P. Guidelines on the diagnosis and treatment of iron deficiency across indications: a systematic review. Am J Clin Nutr. 2015;102(6):1585–1594.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.