SAMPLE CMS-1450 CLAIM FORM FOR FERAHEME® (FERUMOXYTOL INJECTION)

Medicare and Medicaid

Although this sheet provides information that should facilitate the claims process, all coding information is for reference purposes only.

Box 42: Enter the appropriate revenue code corresponding with the HCPCS code in box 44, 0510 for clinic services and 0636 revenue code for pharmacy drugs that require detailed coding.

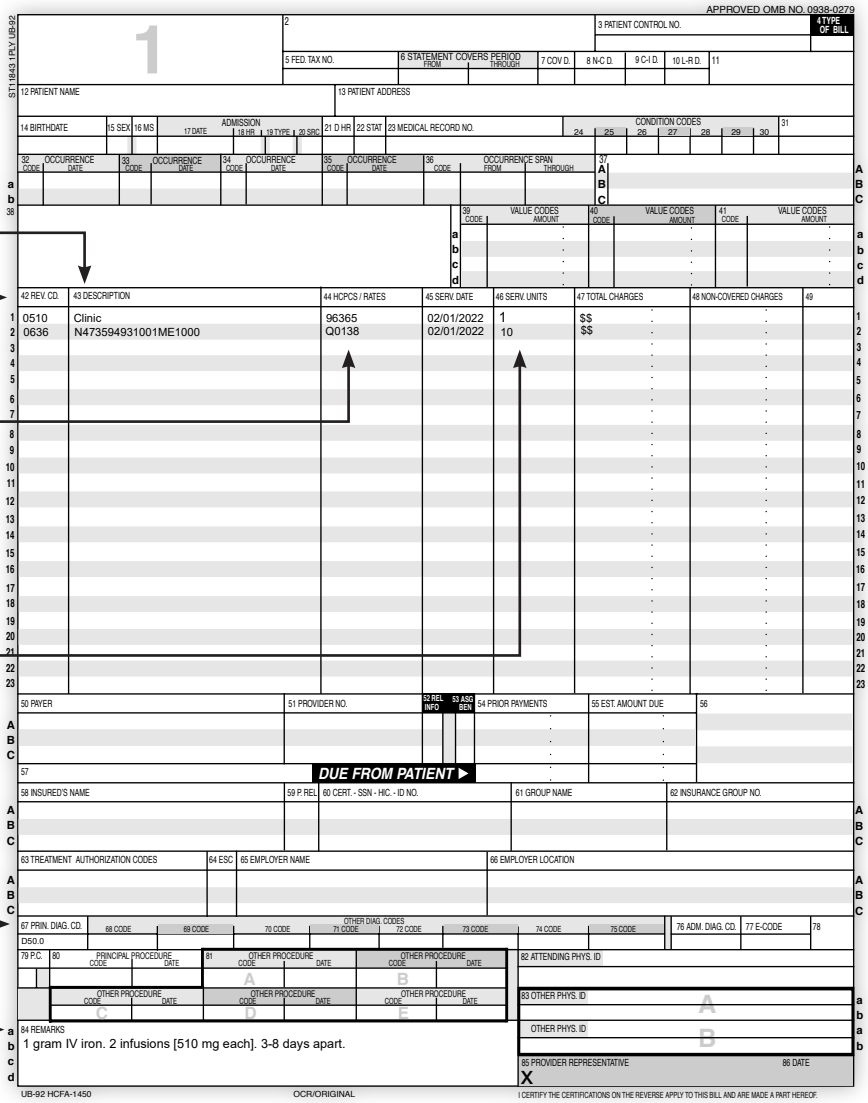
Box 43: Enter a detailed drug description: the N4 indicator, the 11-digit National Drug Code number, a code describing the unit of measurement qualifier (eg, ME for milligrams), and the unit quantity. Example: N59338077501ME510.

Box 44: Enter the appropriate, HCPCS code for Feraheme, Q0138, ferumoxytol injection. To report the administration procedure, enter an appropriate CPT code (e.g., 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)).[1]

Box 46: Enter the total number of units of service for Feraheme, Q0438, ferumoxytol injection, 1 mg. The payer may refer to the actual quantity administered via Box 43 and Box 80.

Box 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code (eg, D50.0 for iron deficiency anemia secondary to blood loss (chronic)). Code to the highest level of specificity.

Box 84: Enter additional details including the drug name, administered dose, route of administration, and NDC number.



1. Find-A-Code. 96365 - CPT® Code in category: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug). InnoviHealth Systems, Inc. https://www.findacode.com/code.php?set=CPT&c=96365. Updated 2018 Updated 2018. Accessed November 5, 2021.

Please see Important Safety Information on next page and Full Prescribing Information including Boxed Warning at www.feraheme.com.

To order Feraheme please call our product line: 877-411-2510

PP-FRH-US-00432

Feraheme® (ferumoxytol injection) Important Safety Information

WARNING: RISK FOR SERIOUS HYPERSENSITIVITY/ANAPHYLAXIS REACTIONS

Fatal and serious hypersensitivity reactions including anaphylaxis have occurred in patients receiving Feraheme. Initial symptoms may include hypotension, syncope, unresponsiveness, cardiac/cardiorespiratory arrest.

- Only administer Feraheme as an intravenous infusion over at least 15 minutes and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.
- Observe for signs or symptoms of hypersensitivity reactions during and for at least 30 minutes following Feraheme infusion including monitoring of blood pressure and pulse during and after Feraheme administration.
- Hypersensitivity reactions have occurred in patients in whom a previous Feraheme dose was tolerated.

Indication and Dosing

Feraheme is indicated for the treatment of iron deficiency anemia (IDA) in adult patients:

- Who have intolerance to oral iron or have had unsatisfactory response to oral iron or
- Who have chronic kidney disease (CKD)

The recommended dose of FERAHEME is an initial 510 mg dose followed by a second 510 mg dose as early as 3 days and up to 8 days later, each dose infused over at least 15 minutes while the patient is in a reclined or semi-reclined position.

Contraindications

Feraheme is contraindicated in patients with known hypersensitivity to Feraheme or any of its components or a history of allergic reaction to any intravenous iron product.

Warnings and Precautions Hypersensitivity:

In addition to the fatal and serious adverse reactions in the Boxed Warning, other adverse reactions associated with hypersensitivity have occurred (pruritus, rash, urticaria, and wheezing). Allergic reactions have occurred following the first dose or subsequent doses in patients in whom a previous dose was tolerated. Patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products. Carefully consider the potential risks and benefits before administering Feraheme to these patients. Elderly patients with multiple or serious co-morbidities who experience hypersensitivity reactions and/or hypotension following administration of Feraheme may have more severe outcomes.

Hypotension: Feraheme may cause clinically significant hypotension. Monitor patients for signs and symptoms of hypotension following each Feraheme administration.

Iron Overload: Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Regularly monitor the hematologic response during parenteral iron therapy. Do not administer Feraheme to patients with iron overload.

Magnetic Resonance (MR) Imaging Test Interference: Administration of Feraheme may transiently affect the diagnostic ability of MR imaging. Alteration of MR imaging studies may persist for up to 3 months following the last Feraheme dose. Maximum alteration of vascular MR imaging is anticipated to be evident for 1 – 2 days following Feraheme administration.

Adverse Reactions

The most common adverse reactions (≥ 2%) are diarrhea, headache, nausea, dizziness, hypotension, constipation, and peripheral edema.

You may report an adverse event related to AMAG Pharmaceuticals' products by calling 1-877-411-2510 or emailing medinfoUS@covispharma.com. If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly at fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information, including Boxed Warning at www.feraheme.com.

COVIS PHARMA

Feraheme® ferumoxytol injection