PRIOR AUTHORIZATION CHECKLIST

Prior authorization (PA) is a routine process used by insurers to confirm that certain drugs or services are used correctly and only when medically necessary. Insurers may require a prior authorization as part of a claim submission. Though coverage criteria may vary, many requirements are common across health plans. The following guidance identifies helpful practices for submitting PA requests for FERAHEME accurately and completely.

A key step in the process is to review the PA guidelines on the insurer's website or to contact the insurer's customer service for process information, including forms and contacts.

Tips for Submitting Prior Authorization

Complete a PA form. Some plans accept a standardized form; others require you to complete a form they provide.

Tip: Your Feraheme Assist Care Manager can help you locate the correct form

Make sure you include:

- Patient and provider contact information
- The health care provider's signature to attest to the validity and accuracy of the information provided
- Attach copies of the front and back of the patient's health plan card
- Write a letter of medical necessity, if required
- Provide information that supports your treatment rationale, such as:
  - » Patient's diagnosis using appropriate ICD-10-CM code(s)
  - » Contraindications to prior therapies

Common Reasons for Denial

Be sure to double check documentation and paperwork for errors or incomplete information that may lead to a denial. Reasons for denial may include:

- An administrative error, such as including an incorrect ICD-10-CM code
- Lack of supporting clinical documentation such as recent laboratory results
- Documentation that was submitted did not support health plan's criteria for approval, for example:
  - » The patient was not treated with prior therapies required by the health plan (eg, oral iron)
  - » No reason was given for discontinuing previous therapies

IMPORTANT NOTE: Use of the resource does not guarantee that the insurance company will provide reimbursement for the medicine requested and is not intended to be a substitute for or an influence on the independent medical judgment of the healthcare provider. This is a guide and is not to be taken as a specific recommendation.

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

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