Effective January 1, 2010

Feraheme®-specific Q-codes:

- **Q0138 for NDD-CKD (non-ESRD and HOPPS billing)**
- **Q0139 for DD-CKD (ESRD dialysis billing only)**

New

Feraheme®

ferumoxytol injection

Feraheme® (ferumoxytol) Injection

For Intravenous (IV) use

A new IV iron approved for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD)

Feraheme Provides:

- 510-mg undiluted IV push that may be delivered in under 1 minute[1]
  - — Deliver at a rate of up to 1 mL/sec (30 mg/sec)[1]
  - — Second dose should be delivered 3 to 8 days after the first dose[1]
- Proven safety in both non-dialysis dependent CKD (NDD-CKD) patients and dialysis dependent CKD (DD-CKD) patients[1]
- Significantly increased hemoglobin (Hgb) and transferrin saturation (TSAT) across the spectrum of CKD[1,2,a]

[a]Hgb was the primary efficacy endpoint and TSAT was an additional efficacy endpoint in 3 randomized, open-label, controlled clinical trials.[2]

Feraheme-specific Q-codes

Q-Code	Product	Usage
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg	NDD-CKD: non-ESRD and HOPPS billing
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg	DD-CKD: ESRD dialysis billing only

- These codes may only be used for *Feraheme* administered on or after January 1, 2010

HOPPS Pass-through Status Implications

- CMS documents the pass-through status for *Feraheme* using HCPCS code Q0138, ferumoxytol, 1 mg, non-ESRD (CKD) use
- *Feraheme*, non-ESRD (CKD) use will have pass-through status for 2 to 3 years in the Medicare hospital outpatient prospective payment system (HOPPS)

CMS=Centers for Medicare & Medicaid Services; ESRD=end-stage renal disease.

For more information, please visit www.feraheme.com.

For full Prescribing Information, click here.

Important Safety Information

Indication and contraindications

Feraheme is indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. *Feraheme* is contraindicated in patients with evidence of iron overload, known hypersensitivity to *Feraheme* or any of its components, and patients with anemia not caused by iron deficiency.

Warnings and precautions

In clinical studies, serious hypersensitivity reactions were reported in 0.2% (3/1,726) of subjects receiving *Feraheme*. Other adverse reactions potentially associated with hypersensitivity (e.g., pruritus, rash, urticaria or wheezing) were reported in 3.7% (63/1,726) of subjects. Patients should be observed for signs and symptoms of hypersensitivity for at least 30 minutes following *Feraheme* injection and the drug should only be administered when personnel and therapies are readily available for the treatment of hypersensitivity reactions. 1.9% (33/1,726) of *Feraheme*-treated subjects experienced hypotension. Please monitor for signs and symptoms of hypotension following each *Feraheme* injection. Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Patients should be regularly monitored for hematologic response during parenteral iron therapy, noting that lab assays may overestimate serum iron and transferrin bound iron values in the 24 hours following administration of *Feraheme*. As a superparamagnetic iron oxide, *Feraheme* may transiently affect magnetic resonance diagnostic imaging studies for up to 3 months following the last *Feraheme* dose. *Feraheme* will not affect X-ray, CT, PET, SPECT, ultrasound, or nuclear imaging.

Adverse reactions

In clinical trials, the most commonly occurring adverse reactions in *Feraheme* treated patients versus oral iron treated patients reported in ≥ 2% of chronic kidney disease patients were diarrhea (4.0% vs. 8.2%), nausea (3.1% vs. 7.5%), dizziness (2.6% vs. 1.8%), hypotension (2.5% vs. 0.4%), constipation (2.1% vs. 5.7%) and peripheral edema (2.0% vs. 3.2%). In clinical trials, adverse reactions leading to treatment discontinuation and occurring in 2 or more *Feraheme*-treated patients included hypotension, infusion site swelling, increased serum ferritin level, chest pain, diarrhea, dizziness, ecchymosis, pruritus, chronic renal failure, and urticaria.

References: 1. Feraheme® Prescribing Information. **2.** Data on file. AMAG Pharmaceuticals, Inc.

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