Injectafer® (ferric carboxymaltose) – New indication

- On November 19, 2021, the FDA approved American Regent's Injectafer (ferric carboxymaltose), for the treatment of iron deficiency anemia (IDA) in adults and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron.
    - Injectafer was previously approved for this indication in adult patients only.
- Injectafer is also approved for the treatment of IDA in adult patients who have non-dialysis dependent chronic kidney disease.
- The use of Injectafer for the expanded indication is supported by evidence from adequate and well-controlled studies of Injectafer in adults with additional pharmacodynamic and safety data in pediatric patients aged 1 year and older.
- The most common adverse reactions (≥ 4%) with Injectafer use in pediatric patients were hypophosphatemia, injection site reactions, rash, headache, and vomiting.
- For pediatric patients weighing 50 kg or more, the recommended dosage of Injectafer is 750 mg intravenously (IV) in two doses separated by at least 7 days for a total cumulative dose of 1,500 mg of iron per course. For pediatric patients weighing less than 50 kg, the recommended dosage is Injectafer 15 mg/kg body weight IV in two doses separated by at least 7 days per course.
    - Refer to the Injectafer drug label for additional dosing in adults.