Injectafer® (ferric carboxymaltose) – New indication

- On May 31, 2023, the FDA approved Daiichi Sankyo's Injectafer (ferric carboxymaltose), for the treatment of iron deficiency in adult patients with heart failure and New York Heart Association (NYHA) class II/III to improve exercise capacity.

- Injectafer is also approved for the treatment of iron deficiency anemia in:

  - Adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron
  - Adult patients who have non-dialysis dependent chronic kidney disease.

- The approval of Injectafer for the new indication was based on CONFIRM-HF, a randomized, double-blind, placebo-controlled study in 304 patients with iron deficiency and chronic heart failure with left ventricular ejection fraction of < 45% and NYHA class II/III. The primary endpoint was exercise capacity measured as change from baseline to 24 weeks in 6-minute walk distance (6MWD).

  - The mean change in 6MWD from baseline to week 24 in Injectafer-treated patients was 18 meters, and placebo-treated patients was -7 meters, with between group difference of 25 meters (95% CI: 7, 43; p = 0.007), favoring Injectafer.

- The recommended dose of Injectafer for the treatment of patients with iron deficiency with heart failure is based on weight and hemoglobin (Hb) levels.

	Weight less than 70 kg			Weight 70 kg or more		
	Hb g/dL			Hb g/dL		
	< 10	10 to 14	> 14 to < 15	< 10	10 to 14	> 14 to < 15
Day 1	1,000 mg	1,000 mg	500 mg	1,000 mg	1,000 mg	500 mg
Week 6	500 mg	No dose	No dose	1,000 mg	500 mg	No dose

  - A maintenance dose of 500 mg should be administered at 12, 24 and 36 weeks if serum ferritin < 100 ng/mL or serum ferritin 100 to 300 ng/mL with transferrin saturation < 20%.
  - There are no data available to guide dosing beyond 36 weeks or with Hb ≥ 15 g/dL.

- Refer to the Injectafer drug label for dosing for its other indications.