SUMMARY

ferric carboxymaltose

FERINJECT 50 mg/ml

dispersion for injection/infusion

Reassessment at pharmaceutical company's request

Original French opinion adopted by the Transparency Committee on 14 February 2024

The legally binding text is the original French opinion version

Summary of opinion

Maintenance of favourable opinion for reimbursement in the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used or there is a clinical need to deliver iron rapidly by the IV route.

Transparency Committee's conclusions

Clinical Benefit

Considering all these elements, the Committee deems that the new data from the AFFIRM-AHF trial, which assessed FERINJECT 50 mg/ml (ferric carboxymaltose) dispersion for injection/infusion in adult patients with heart failure with a reduction in ventricular ejection fraction and concomitant iron deficiency (defined as ferritin <100 µg/L, or 100–299 µg/L with transferrin saturation <20%, with or without anaemia) hospitalised and stabilised after an episode of cardiac decompensation, are not of a nature to modify its previous conclusions.

The clinical benefit remains substantial in the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used or there is a clinical need to deliver iron rapidly by the IV route.

➔ Public health benefit

Considering:

- the seriousness of iron deficiency and its high prevalence, particularly in patients with heart failure;
- the medical need partially met by other injectable iron products;
- the lack of evidence of an additional impact on morbidity and mortality compared to oral iron or injectable iron sucrose and the lack of evidence of an impact on quality of life to date;
- the lack of evidence of an additional impact on the organisation of care and the patient's life or care pathway (in particular, on the reduction of hospitalisations),

FERINJECT 50 mg/ml (ferric carboxymaltose) is unlikely to have an additional impact on public health.

Clinical Added Value

Considering all these elements, the Committee deems that the new data from the AFFIRM-AHF trial, which assessed FERINJECT 50 mg/ml (ferric carboxymaltose) dispersion for injection/infusion in adult patients with heart failure with a reduction in ventricular ejection fraction and concomitant iron deficiency (defined as ferritin <100 µg/L, or 100–299 µg/L with transferrin saturation <20%, with or without anaemia) hospitalised and stabilised after an episode of cardiac decompensation, are not of a nature to modify the its previous conclusions.

FERRINJECT continues to provide no clinical added value (CAV V) in the care pathway.