SUMMARY

ferric carboxymaltose

FERINJECT 50 mg/ml

dispersion for injection/perfusion

Indication extension

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

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

- At an advanced stage, iron deficiency can cause iron-deficiency anaemia (microcytic, hypochromic, aregenerative and hyposideraemic), with a risk of impaired psychomotor and neurocognitive development.
- The proprietary medicinal product FERINJECT 50 mg/ml (ferric carboxymaltose) is a curative medicinal product.
- Considering:
  - the lack of evidence of a superiority of ferric carboxymaltose compared to the oral route in children and adolescents with iron-deficiency anaemia,
  - the lack of representativity of the study patients with respect to the population targeted by the indication,
  - a generally satisfactory safety but a risk of rare but potentially serious anaphylactic reactions in view of the intravenous administration,
  - uncertainties with respect to the long-term safety in the paediatric population,

  the efficacy/adverse effects ratio is moderate.
- FERINJECT 50 mg/ml (ferric carboxymaltose) is a first-line treatment when oral iron preparations are ineffective or cannot be used or there is a clinical need to deliver iron rapidly by the IV route in children aged 1 to 13 years with iron deficiency.

➔ Public health benefit

Considering:

- the seriousness of iron deficiency in the absence of treatment and its prevalence in children,
- the medical need partially met by other injectable iron sucrose products (VENOFER (iron hydroxide-sucrose complex) and other injectable iron sucrose products),
- the lack of additional response to the identified need given:
  - the lack of evidence of an additional impact on morbidity compared to oral iron,
  - the lack of evidence of an additional impact on quality of life,
  - the lack of evidence of an additional impact of the organisation of care or on the patient's care and life pathway,

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

Considering all these elements, the Committee deems that the clinical benefit of FERINJECT 50 mg/ml (ferric carboxymaltose) dispersion for injection/infusion is moderate 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, in patients aged 1 to 13 years.

The Committee issues a favourable opinion for inclusion of FERINJECT 50 mg/ml (ferric carboxymaltose) dispersion for injection/for infusion in the list of covered drugs for inpatients approved for use 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, in patients aged 1 to 13 years and at the MA dosages.

Clinical Added Value

Considering:

- the results of the randomised, double-blind, phase 3 1VIT17044 study revealing no significant difference compared to oral iron in terms of mean change in Hb levels at D35 compared to baseline (2.22 g/dl versus 1.92 g/dl, p = 0.3108) in children aged 1 to 17 years with iron-deficiency anaemia;
- inclusion of a population partially representative of the population targeted by the indication:
  - only 22% of the patients included in the study were aged 1 to 12 years (25% in the ferric carboxymaltose group) and only 20% of the patients were male;
  - the study protocol scheduled the inclusion of patients with iron deficiency with anaemia only, whereas the indication also targets patients with iron deficiency without anaemia;
  - inclusion of patients with a documented history of an episode of inadequate response to all oral iron therapy at least 8 weeks (56 days) prior to randomisation and who responded to oral treatment during the study, raising the hypothesis of poor treatment compliance;
- the absence of specific data in children aged 1 to 13 years with haemodialysis-dependent chronic kidney disease;
- the absence of data in patients in whom there is a clinical need to deliver iron rapidly;
- the lack of long-term efficacy and safety data (follow-up duration of 6 weeks);
- the absence of comparative data versus the other injectable iron products;

the Committee deems that FERINJECT 50 mg/ml (ferric carboxymaltose) dispersion for injection/infusion provides no clinical added value (CAV V) in the current care pathway in patients aged 1 to 13 years, which includes the relevant comparators VENOFER (iron hydroxide-sucrose complex) and other injectable iron sucrose products.