

14.03 FERRIC CARBOXYMALTOSE

Injection 1,000 mg (iron) in 20 mL, Ferinject[®], Vifor Pharma Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested the listing of ferric carboxymaltose 1,000 mg/20 mL (Ferinject[®]), in addition to the already listed 500 mg/10 mL presentation, on the General Schedule as an unrestricted benefit for the treatment of iron deficiency anaemia (IDA).

2 Requested Listing:

- 2.1 The requested listing is shown below.
- 2.2 The sponsor noted that the maximum quantity for the 500 mg/10 mL presentation of ferric carboxymaltose is two vials, whereas for the 1,000 mg/20 mL vial, the maximum quantity will be one vial. This allows for a 1:1 of substitution of 1 x 1,000 mg/20 mL for 2x 500 mg/10 mL vials.

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer	
IRON Iron (as ferric carboxymaltose) 1000 mg/20 mL injection, 1 x 20 mL vial	1	1	1	Ferinject [®]	Vifor Pharma

Max = maximum; Qty = quantity; Rpts = repeats

3 Background

- 3.1 At its November 2013 meeting, the PBAC recommended listing ferric carboxymaltose (Ferinject[®]) 500 mg/10 mL for the treatment of iron deficiency anaemia (IDA) as an unrestricted benefit. Ferric carboxymaltose was listed on the PBS in June 2014.
- 3.2 Ferric carboxymaltose 1,000 mg/20 mL was approved by the TGA on 5 June 2018.
- 3.3 The sponsor proposed that listing a 1,000 mg/20 mL vial on the PBS would align with Quality Use of Medicines as 93.5% of patients prescribed I.V. iron receive a 1,000 mg dose (based on PBS 10% sample data) and a 1,000 mg vial would deliver this amount of iron in a single prescription.

4 Pricing considerations

- 4.1 Ferinject[®] is subject to a current Deed of Agreement, and the 1,000 mg/20 mL vial will be subject to this agreement.
- 4.2 The sponsor proposed an equivalent price per milligram for the 1,000 mg/20 mL vial relative to the 500 mg/10 mL vial.

- 4.3 Given the 1:1 substitution of ferric carboxymaltose 1 x 1,000 mg/20 mL vial for 2 x 500 mg/10 mL vials, with an equivalent price per milligram, there is expected to be no financial impact as a result of the inclusion of the 1,000 mg/20 mL vial on the PBS.

Estimated PBS usage & financial implications

- 4.4 The submission noted that the inclusion of ferric carboxymaltose 1,000 mg/20 mL will not increase the current market, instead providing an alternative to 2 x 500 mg/10 mL vials. It is expected to have no financial impact.

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of ferric carboxymaltose 1,000mg/20 mL in addition to the existing 500 mg/10 mL presentation, on the General Schedule as an unrestricted benefit for the treatment of iron deficiency anaemia (IDA).
- 5.2 The PBAC noted that the sponsor had proposed an equivalent price per milligram for the 1,000 mg/20 mL vial relative to the 500 mg/10 mL vial, and that the new presentation would provide a substitute for prescribing 2 x 500 mg/10 mL vials. The PBAC noted that there was expected to be no financial impact associated with the new listing.

Outcome:

Recommended

6 Recommended listing

- 6.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer	
IRON					
Iron (as ferric carboxymaltose) 1000 mg/20 mL injection, 1 x 20 mL vial	1	1	1	Ferinject®	Vifor Pharma

Max = maximum; Qty = quantity; Rpts = repeats

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

Vifor Pharma welcomes the recommendation to include the 1,000mg/20mL vial on the PBS.