14.03 FERRIC CARBOXYMALTOSE
Injection 1,000 mg (iron) in 20 mL,
Ferinject®, Vifor Pharma Pty Ltd

# Purpose of Application

* 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).

# Requested Listing:

* 1. The requested listing is shown below.
	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.

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| --- | --- | --- | --- | --- |
| **Name, Restriction,****Manner of administration and form** | **Max.****Qty (Packs)** | **Max.****Qty (Units)** | **No. of****Rpts** | **Proprietary Name and Manufacturer** |
| IRONIron (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 |

# Background

* 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.
	2. Ferric carboxymaltose 1,000 mg/20 mL was approved by the TGA on 5 June 2018.
	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.

# Pricing considerations

* 1. Ferinject® is subject to a current Deed of Agreement, and the 1,000 mg/20 mL vial will be subject to this agreement.
	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.
	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

* 1. 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.

# PBAC Outcome

* 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).
	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

# Recommended listing

* 1. Add new item:

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

# Sponsor’s Comment

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