NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

29 July 2014

Decision to list ferric carboxymaltose (Ferinject) for use in DHB hospitals

PHARMAC is pleased to announce the approval of an agreement with Vifor Pharma Pty Ltd to list Ferinject in Section H of the Pharmaceutical Schedule from 1 August 2014.

This proposal was the subject of a consultation letter dated 16 May 2014, available on PHARMAC's website at http://www.pharmac.health.nz/news/consultation-2014-05-16-ferric-carboxymaltose/.

Following consideration of consultation feedback, a restriction has been added to the Section H listing.

Details of the decision

- Ferinject will be listed in Part II of Section H (the Hospital Medicines List; HML) of the Pharmaceutical Schedule from 1 August 2014 at the following price (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price
Ferric carboxymaltose	Inj 50 mg per ml, 10 ml vial	Ferinject	1	$150.00

- Ferinject will be listed in Section H of the Pharmaceutical Schedule from 1 August 2014, subject to the following restriction.

  Restricted
  Treatment with oral iron has proven ineffective, or is clinically inappropriate.

- A confidential rebate will apply to Ferinject, reducing its net price.

- Ferinject will have subsidy and delisting protection until 1 July 2017.

- Ferinject 10 ml vial contains ferric carboxymaltose 180 mg per ml (1800 mg per 10 ml) which is equal to elemental iron 50 mg per ml (500 mg per 10 ml).

- PHARMAC has negotiated with Vifor for an option to extend funding to the community and will be undertaking more analysis and having further discussions with stakeholders to determine whether a proposal to list Ferinject in Section B of the Pharmaceutical Schedule could be progressed at a later date.

- For the avoidance of doubt there is no change to the listing of iron polymaltose or iron sucrose. Iron polymaltose remains listed in both Section B and Section H of the Pharmaceutical Schedule and iron sucrose remains listed in Section H. Therefore clinicians can continue to choose which iron preparation to prescribe, depending on the clinical situation.

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Feedback received

PHARMAC received a large number of detailed responses to this proposal. We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 30 May 2014 were considered in their entirety in making a decision on the proposal. Responses were overwhelmingly supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Concern that usage will increase compared to existing treatments. Although this is acceptable, there is a need for guidelines to be in place to ensure indications for intravenous (IV) iron are maintained to where the oral route is unavailable, ineffective, severity of anaemia requires rapid correction or intervention is scheduled over a time course where oral iron would be ineffective. Concern that listing just in Section H would encourage current infusions for IV iron that occur in community to be referred to DHBs.	PHARMAC has negotiated a cost neutral proposal for ferric carboxymaltose (FCM) in the HML. Market growth was factored into the calculations. PHARMAC recognises there may be increased demand for FCM in hospitals, and has added a restriction to the HML listing to limit use to patients where treatment with oral iron has proven ineffective, or is clinically inappropriate. PHARMAC considers it would be appropriate for DHBs to create their own iron deficiency guidelines to ensure use of FCM and other iron products is clinically appropriate. PHARMAC will be conducting further work on a proposal for community listing.
Restrictions should be developed for inclusion in Section H.	A restriction has been added to the Section H Listing. PHARMAC notes that DHB hospitals can also create local restrictions under rule 7 of the General Rules of Section H.
Can the confidential rebate and net cost of ferric carboxymaltose (FCM) be clarified? It makes it difficult to determine thresholds for using FCM compared to other IV agents. The pricing schedule should be the same for Section H and B, regardless of place of delivery.	PHARMAC notes the comments regarding the confidential rebate, however this is commercially sensitive information. Rebates collected in relation to hospital medicines are distributed on a quarterly basis to each relevant DHB hospital on the basis of its usage (refer to rule 21 of the General Rules of Section H). Pricing of Ferinject would be the same for Section H and Section B (if progressed).
Blood transfusions are often used as an alternative to IV iron infusions. Patient outcomes are improved when blood transfusion can be avoided. The cost of blood transfusions far exceeds that of iron.	Noted. PHARMAC considered the benefits and cost savings from avoiding blood products when modelling the cost-effectiveness of this proposal.
Many obstetric and gynaecological patients would benefit from parenteral iron. At present IV iron is rarely used and patients are disadvantaged. Day admission for iron polymaltose is difficult to organise.	Noted. Patients meeting the restriction would be eligible for funded treatment.

Theme	Comment
Reported data on hypersensitivity to IV iron polymaltose and iron sucrose in obstetric population. The alternative is blood transfusion which is costly and may cause harm. Published data is available supporting use of FCM in obstetric population. The proposal would improve access to iron treatment for this group.	Pregnant women with iron deficiency anaemia would have access to FCM as a result of this decision.
Some people may continue to use iron polymaltose or iron sucrose. Will these products still be available?	There is no proposal to change access to iron polymaltose or iron sucrose at this time and therefore clinicians would be able to choose which iron preparation to prescribe depending on the clinical situation.
Request for a smaller vial size 100 mg for small doses (examples include home dialysis patients). Access for home haemodialysis patients should be prioritised to enable them to have prescription for FCM dispensed from community pharmacies.	At this time PHARMAC has been unable to reach a commercial arrangement with the supplier for a smaller presentation (100mg vial). Iron Sucrose and iron polymaltose remain on the HML for those patients requiring a small dose of iron. PHARMAC notes that access for home haemodialysis patients to FCM via a community listing is desirable. PHARMAC will be conducting further work on a proposal for community listing.
Not all DHB hospitals have implemented the rapid iron polymaltose infusion protocol as some consider it inappropriate, outside of the manufacturer recommendations and based on a single clinical trial.	PHARMAC is aware that the rapid iron infusion protocol is not used in all hospitals. PHARMAC considers that the current proposal would represent a cost neutral listing for FCM in the HML compared to the rapid iron protocol but acknowledges that savings may be significantly greater for some DHB hospitals.
Feedback specific to a community listing	
Supportive of extending the availability of FCM to the community. Despite the cost FCM is already being used in primary care for patients unable to tolerate oral iron. The cost of infusion is prohibitive to some patients who may benefit from receiving it.	PHARMAC acknowledges that some primary care organisations are offering iron infusion services to patients who pay for their treatment. As part of our further work on a proposal for community listing we plan to discuss the issues around publicly funded community based infusion services with a number of stakeholders.
There is no subsidised medicine administration for infusions in the community and this cost shifts to the patient. Consideration needs to be given to the cost of administration and the consequences for the population, e.g. inequity of access.	As above.
Community access would provide cheaper, more convenient outcomes for patients and allow pre-procedural optimisation in the community. Community based treatment is a goal for many health care funders. Listing in community would reduce hospital admissions/referrals, demand for hospital resources and cancelled elective surgeries. It would improve access, particularly for people who live outside of a major centre.	Noted. PHARMAC will be conducting further work on a proposal for community listing.

Theme	Comment
Concern that inclusion of FCM in the community may place additional expectations on DHBs with regard to funding the cost of the IV infusion within primary care (in a similar manner to the expectations that occurred after the inclusion of zoledronic acid). It would be useful to see an estimation of patient numbers that may be eligible for IV infusion in a community setting (by DHB) if FCM were to be added to the community schedule.	PHARMAC notes these concerns and would endeavour to provide further information to DHBs to help them assess the impact of a possible community listing of FCM as part of our further work on a proposal for community listing.
Concern that the real gains are by moving this medicine out of hospitals and into the community. There are endless differences in clinical care and service provision amongst practitioners of all craft groups and it is unclear why service provision is an issue when it is just normal variation of practice.	PHARMAC consider that there are gains both to listing FCM in hospital and in community. We consider that it is appropriate to address community infusion service issues as best we can before further developing a proposal for a community listing.
Access to FCM in the community should be via Special Authority criteria.	PHARMAC considers funding restrictions would be required should FCM be listed in the community. PHARMAC intends to work on appropriate criteria with the advice of PTAC and its Subcommittees. Any Special Authority criteria or restrictions proposed for a community listing would be publicly consulted on.
Recommends GPs receive training and experience in infusion protocols. Equipment upgrades may also be required.	PHARMAC acknowledges the importance of appropriate training in infusion services for all clinicians and notes that a number of GPs already provide this service. PHARMAC plans to discuss training requirements for community infusion services with relevant stakeholders.
Recommends FCM should only be available in facilities where risk of administration can be managed appropriately. The UK Medicines and Healthcare Products Regulatory Agency's (MHRA) recommendations for IV iron administration include the immediate availability of personnel, equipment and drugs to treat any severe reaction. This may reduce more widespread use in community.	PHARMAC note the comments regarding safe administration and the MHRA and Medsafe datasheet recommendations that resuscitation facilities must be available. PHARMAC will consider this information carefully when conducting further work on a proposal for community listing.
The need for resuscitation equipment and presence of a doctor for iron sucrose and polymaltose, costs and logistics of these should be considered, especially as FCM is less likely to cause an anaphylactic reaction.	Resuscitation facilities are also recommended for FCM, however PHARMAC recognises the reduced infusion time would improve access to such facilities for patients via the Section H listing.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.