Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

ferric carboxymaltose (Ferinject)

(CSL Behring Canada Inc.)

Indication: For the treatment of iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older when oral iron preparations are not tolerated or are ineffective.

November 28, 2024

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0842-000
Brand name (generic)	Ferinject® (ferric carboxymaltose)
Indication(s)	Iron deficiency anemia
Organization	Gastrointestinal Society
Contact information[a]	Jaymee Maaghop

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

We agree with the recommendation. CDEC acknowledges that Ferinject® addresses significant unmet needs, such as being the only IV iron therapy approved for children and pregnant individuals. While other IV iron products have been used off-label for these populations, clinicians have stated that they are often hesitant to use them in children. This recommendation is particularly valuable because it offers a safe, convenient, and effective treatment option for iron deficiency anemia (IDA) in these vulnerable groups.

Additionally, the recognition that the infusion time is only 15 minutes is important and the draft recommendation noted that this can improve patient access to treatment and increases convenience by reducing the need for frequent, long visits, ultimately benefiting both patients and the healthcare system by saving time and costs.

Ferinject® provides another effective IV iron option that delivers a high dose quickly. The only other comparable treatment for high-dose IV iron is ferric derisomaltose, so having multiple treatment options is crucial. This flexibility allows patients to switch therapies if one becomes ineffective or intolerable. This is particularly important for those who do not respond to oral iron supplements, as Ferinject® can address urgent needs for rapid replenishment of iron stores in the body.

We also appreciate the recommendation to monitor for hypophosphatemia. We have voiced this in our input since the Product Monograph has identified inflammatory bowel disease (IBD) as a risk factor for developing this condition.

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐

We value the transparency from drug programs on potential challenges with implementation, particularly with the variability in definitions of IDA. It was noted that Saskatchewan uses a different definition of IDA compared to the Product Monograph. However, Saskatchewan includes a broader patient population. We also know that there have been recent movements in Ontario on a redefinition of IDA. We want to ensure that no patient is left behind and that all unmet needs are addressed. We also appreciate the clarity provided on implementation challenges, particularly the variability in funding for outpatient centres, which can create barriers for IV infusion services. Additionally, the difficulty in assessing intolerance to oral iron was highlighted. The clinical expert noted that for certain populations, such as those with a history of bariatric surgery, gastrectomy, IBD, or small bowel resection, oral iron may not be a viable option. This makes access to alternative treatments even more crucial. We hope that drug programs will carefully consider these factors and provide coverage for patients who require IV iron without requiring them to fail oral iron treatments first.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

[a] CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Jaymee Maaghop*
Position	*Health Policy & Outreach Manager*
Date	*26-11-2024*
☒	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☐
	Yes	☒

D. New or Updated Conflict of Interest Declaration

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0842
Name of the drug and Indication(s)	Ferinject
Organization Providing Feedback	Formulary Working Group (FWG)

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	☐
	No requested revisions	☐X

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons
Please provide details regarding the information that requires clarification.
c) Implementation guidance
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
Support strategy
3. Do you have any preferences or suggestions on how CADTH should address these issues?
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.