

BC PharmaCare Drug Information

The drug below is being considered for coverage under the BC PharmaCare program. PharmaCare is a government-funded drug plan that helps B.C. residents with the cost of eligible prescription drugs and medical supplies. For more information about PharmaCare, visit the PharmaCare website.

PharmaCare reviews each drug for treating a specific illness or medical condition (also called an "indication"). If PharmaCare decides to cover a drug, that coverage applies only to the indication(s) specified. In some cases, PharmaCare covers a drug only for people who have not responded to other drugs that treat the same indication.

More information about the PharmaCare drug review process is provided on the last page of this document.

| Drug information | | | |
|---|--|--|--|
| Generic name (scientific name) | ferric carboxymaltose | | |
| Brand name | Ferinject [®] | | |
| Manufacturer | CSL Vifor | | |
| Indication | Iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older | | |
| Has the drug been reviewed by CDA-AMC, or will CDA-AMC be reviewing it? (See note below.) | Yes For more information about the CDA-AMC Reimbursement Review (CRR) of ferric carboxymaltose (Ferinject), Search the CDA-AMC Reports. | | |
| Public input start date | Wednesday, September 25, 2024 | | |
| Public input closing date | Tuesday, October 22, 2024, at 11:59 pm | | |
| How is the drug taken? | Ferric carboxymaltose is given by intravenous (IV) infusion. It is delivered directly into a vein through a needle. | | |
| How often is the drug taken? | Ferric carboxymaltose infusions are given a minimum of 7 days apart from one another until the patient's prescribed dosage of iron is met. The dosage is based on a patient's body weight and hemoglobin (Hb) level. | | |

General drug and/or drug study information

Ferric carboxtmaltose is being reviewed by PharmaCare for the treatment of IDA in adult and pediatric patients 1 year of age and older when oral iron preparations are not tolerated or are ineffective. The diagnosis of iron deficiency must be based on laboratory tests.

This medication is also being reviewed by PharmaCare for the treatment of iron deficiency (ID) in adult patients with heart failure and New York Heart Association (NYHA) class II/III^a to improve exercise capacity. This survey is for IDA. There is a second survey, also posted on the Your Voice webpage, for ID in adult patients with heart failure.

Anemia is a condition in which the blood has reduced capacity to carry oxygen due to low hemoglobin (Hb) levels. Hb is a protein found in red blood cells whose main job is to carry oxygen from the lungs to the rest of the body. Anemia has a range of causes, but ID is the most common. ID is most often caused by blood loss or an underlying factor such as poor iron absorption or poor dietary intake. Patients with chronic kidney disease, inflammatory bowel disease, cancer, and rheumatoid arthritis are also at an increased risk of developing iron deficiency anemia. Patients with IDA often suffer from fatigue, paleness, shortness of breath, and headaches.

Ferric carboxymaltose replenishes the body's iron stores. Iron is needed to make Hb, which allows red blood cells to carry oxygen throughout the body.

Studies looked at the following:

- Changes from baseline in Hb, including:
 - Number of patients with greater than or equal to a 10 gram per liter (g/L) increase in Hb at Week 4
 - Number of patients with greater than or equal to a 20 g/L increase in Hb at Week 12
 - Number of patients with greater than or equal to a 20 g/L increase in Hb at any time to Week 8
 - Average change from baseline in Hb
- Changes from baseline to week 12 in health-related quality of life (HRQoL) as measured by the 36-Item Short Form Health Survey (SF-36) mental and physical components, and the 32-Item Inflammatory Bowel Disease Questionnaire (IBDQ-32)
- Average change from baseline in serum ferritin^b in micrograms per liter (mcg/L)

| Drug information | | | |
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| | Changes from baseline in transferrin saturation (TSAT)^c, including the number of patients with a normal TSAT level of 20% to 50% at weeks 4 or 12. Non-anemic patients: The percentage of patients who were non-anemic (Hb greater than or equal to 120 g/L for males or greater than or equal to 130 g/L for females) at week 12 | | |
| | Bad reactions | | |
| | Serious bad reactions | | |
| | Patients leaving the trial due to bad reactions | | |
| | Bad reactions of special interest: hypophosphatemia, a condition where there is too little phosphate in the blood. | | |
| Other considerations | None | | |

Note:

CDA-AMC (<u>Canada's Drug Agency-L'Agence des Médicaments du Canada</u>) is a national organization that reviews drugs on behalf of Canadian public sector plans when drug manufacturers want those plans to provide coverage for the drug. For detailed information about the PharmaCare drug review process, including the role of the CDA-AMC Reimbursement Review (CRR) in that process, visit <u>How PharmaCare Decides Which Drugs to Cover</u>.

| Cost of the drug compared to other drugs used to treat the same indication | | | | | |
|--|--|------------------------------------|--|--|--|
| Generic Name (Brand Name) of Drug Comparator | PharmaCare Status (if and how the drug is already covered) | Dosage Form | Usual Dose | Cost per Course of Therapy ^d | |
| ferric carboxymaltose (Ferinject) | Under Review | Single use vial for IV infusion | Dosage based on patient body weight and hemoglobin level. Infusions not to exceed maximum | \$97 to \$972° | |

^a The NYHA classification system is used to assess the severity of heart failure based on physical activity limitations. NYHA Class II patients have slight limitations to their activities, while Class III indicates more significant limitations in daily activities.

^b Ferritin is a protein that stores iron in your cells. A ferritin blood test can tell whether you are getting too much or too little iron.

^c The TSAT test measures how much iron is bound to a protein called transferrin in the blood. This test gives doctors information about a patient's iron levels.

^d All prices as per PharmaCare Formulary, unless otherwise specified.

^e Manufacturer's submitted price plus 8% markup.

| Cost of the drug compared to other drugs used to treat the same indication | | | | |
|--|--|------------------------------------|---|--|
| Generic Name (Brand Name) of Drug Comparator | PharmaCare Status (if and how the drug is already covered) | Dosage Form | Usual Dose | Cost per Course of Therapy ^d |
| | | | recommended single dose. Additional infusions should be kept a minimum of 7 days apart. | |
| Actual practice (off- | label use) except for | ferric derisomaltose j | for adult use | T |
| Ferric derisomaltose (Monoferric) ^f | Limited Coverage | Single use vial for IV infusion | Dosage based on patient body weight and hemoglobin level. Infusions not to exceed maximum recommended single dose. Additional infusions should be kept a minimum of 7 days apart. | \$243 to \$972 |
| iron sucrose (generic) ^{fg} | Limited Coverage | Single use vial for IV infusion | Dosage based on patient body weight and hemoglobin level. Infusions not to exceed maximum recommended single dose. Additional | \$149 to \$416 |

^{£ . .}

^f Health Canada has not authorized use for pediatric population.

^g Health Canada has not authorized use for adults without chronic kidney disease (CKD).

| Cost of the drug compared to other drugs used to treat the same indication | | | | |
|--|--|----------------------|---|--|
| Generic Name (Brand Name) of Drug Comparator | PharmaCare Status (if and how the drug is already covered) | Dosage Form | Usual Dose | Cost per Course of Therapy ^d |
| | | | infusions should be kept a minimum of 7 days apart. | |
| sodium ferric gluconate complex (Ferrlecit) ^f | Non-Benefit | Vial for IV infusion | Administered 8 times at sequential dialysis treatments | \$453 or more ^h |

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^h Price as per CDA-AMC Pharmacoeconomic Review Report for ferric carboxymaltose for the treatment of IDA.

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the <u>Drug Benefit Council (DBC)</u> gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called <u>Canada's Drug Agency-L'Agence des médicaments</u> du Canada (CDA-AMC)
- what the drug costs and whether it is a good value to the citizens of B.C.
- ethical considerations related to covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare to treat similar medical conditions
- the overall cost of covering the drug

For more information about the drug review process in B.C., visit: the <u>How PharmaCare decides which</u> drugs to cover.

This document provides information only.

It does not take the place of advice from a physician or other qualified health care provider.