

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 in adult patients with heart failure			
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 carboxymaltose is being reviewed by PharmaCare for the treatment of iron deficiency (ID) in adult patients with heart failure (HF) and New York Heart Association (NYHA) class II/III^a to improve exercise capacity. The diagnosis of ID must be based on laboratory tests.

This medication is also being reviewed by PharmaCare 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. This survey is for ID in adult patients with HF. There is a second survey, also posted on the Your Voice webpage, for adult and pediatric patients with IDA.

HF is a condition in which the heart is unable to pump blood well enough to meet the needs of the body. Symptoms can include breathlessness, fatigue, exercise intolerance, and fluid build-up, which can lead to swelling of the feet, ankles, legs, and the accumulation of fluid in the lungs.

ID can worsen heart failure by reducing oxygen delivery in the body. Iron is essential for producing hemoglobin (Hb) in red blood cells, which carries oxygen. Low oxygen levels caused by ID make the heart work harder to supply the body with oxygen, straining the heart further. In addition, adequate iron levels are needed for optimal heart muscle function. Treating iron deficiency may help improve HF symptoms.

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 NYHA Class at weeks 24 and 52
- Changes from baseline in 6-minute walk test (6MWT) in average meters at weeks 24 and 52
- Health-related quality of life (HRQoL) as measured by changes from baseline to weeks 24 and 52 in the Kansas City Cardiomyopathy Questionnaire (KCCQ)
- Changes from baseline to weeks 24 and 52 in Fatigue Scores
- Changes from baseline to weeks 24 and 52 in Serum Ferritin^b
- Hospitalization due to any cardiocascular (CV) reason (event rate per 100 patient-years) at weeks 26 and 52.
- Mortality due to any CV reason at weeks 26 and 52
- Bad reactions

BC PharmaCare Drug Information — ferric carboxymaltose (Ferinject®) continued...

Drug information					
	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					

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>.

Generic Name (Brand Name) of Drug Comparator Of Drug Comparator Usual Dose (if and how the drug is already covered) Dosage Form Usual Dose of Therapys of Therapy	Cost of the drug compared to other drugs used to treat the same indication						
ferric carboxymaltose (Ferinject) Under Review Under Review Under Review Single use vial for IV infusion Single use vial for IV infusion Single dose. Additional infusions should be kept a minimum of	(Brand Name) of	Status (if and how the drug is already	Dosage Form	Usual Dose	-		
	carboxymaltose	Under Review		patient body weight and hemoglobin level. Infusions not to exceed maximum recommended single dose. Additional infusions should be kept a minimum of	\$243 to \$972 ^d		

^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 All prices as per PharmaCare Formulary, unless otherwise stated.

^d Manufaturer'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 ^c		
Ferric derisomaltose (Monoferric) ^e	Limited Coverage for the treatment of adult patients with IDA	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 ^f (generic)	Limited Coverage for the treatment of adult patients with IDA	Single use vial for IV infusion	Dosage based on hemoglobin level. Infusions not to exceed maximum recommended single dose. Administration follows the recommended intervals.	\$297		
sodium ferric gluconate complex (Ferrlecit)	Non-Benefit	Single use vial for IV infusion	Administered 8 times at sequential dialysis treatments	\$453 or more ^g		

^e Health Canada has not authorized use for treatment of ID in HF.

^f Health Canada has not authorized use for treatment of ID in HF without chronic kidney disease (CKD).

^g Price as per CDA-AMC Pharmacoeconomic Review Report for ferric carboxymaltose for IDHF.

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> <u>du Canada (CDA-AMC)</u>
- 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.