

BC PharmaCare Drug Information

The drug below is being considered for possible coverage under the B.C. PharmaCare program. PharmaCare is a government-funded drug plan that helps British Columbians with the cost of eligible prescription drugs and specific medical supplies. For more information on PharmaCare, visit Ministry of Health - PharmaCare.

PharmaCare reviews each drug for treating a specific illness or medical condition (known as an "indication"). If a decision is made to cover the drug, it will be only for that illness or condition.

In some cases, PharmaCare may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition.

For more information on PharmaCare's drug coverage review process, see the last page of this information sheet.

| Information about the drug | | | |
|--|--|--|--|
| Generic name (scientific name) | insulin icodec | | |
| Brand name | Awiqli® | | |
| Manufacturer | Novo Nordisk Canada Inc. | | |
| Indication | Once-weekly treatment of adults with type 2 diabetes mellitus (T2D) to improve glycemic control | | |
| Has the drug been reviewed by Canada's Drug and Health Technology Agency (CADTH)? (see the note below this table.) | Yes For more information about the CADTH Reimbursement Review (CRR) of insulin icodec, you can Search the CADTH Reports. | | |
| Public input start date | Wednesday, March 27, 2024 | | |
| Public input closing date | Tuesday, April 23, 2024, AT 11:59 PM | | |
| How is the drug taken? | Insulin icodec is given by subcutaneous (under the skin) injection. | | |
| How often is the drug injected? | Insulin icodec is injected once weekly. | | |

Information about the drug

General drug and/or drug study information

Insulin icodec is being reviewed by PharmaCare for the once-weekly treatment of adults with type 2 diabetes mellitus (T2D) to improve blood sugar (glycemic) control. Type 2 diabetes is a lifelong disease that affects the way the body uses sugar for energy. The disease develops when the cells of the body become resistant to insulin and/or when the pancreas cannot make enough insulin.

Insulin is a hormone that helps the body's cells get needed energy from sugar. When insulin is not able to do its job, too much sugar builds up in the blood. Over time, this extra sugar can damage the eyes, heart, blood vessels, nerves, and kidneys.

Insulin icodec is similar to the insulin made by the body and helps to reduce blood sugar levels and maintain them over 7 days.

Studies looked at the following outcomes in both insulin-naïve and insulinexperienced patients:

- Percent change from baseline in glycated hemoglobin (A1C) at 26 or 52 weeks.^a
- Percent time spent in range^b (3.9 to 10 millimoles per liter (mmol/L)) at 26 or 52 weeks
- Percent time spent below range (less than 3.0 mmol/L) at 26 or 52 weeks
- Percent time spent above range (above 10.0 mmol/L) at 26 or 52 weeks
- Mortality and morbidity (fatal and non-fatal health issues), including all-causes of death
- Changes from baseline in body weight, in kilograms, at 26 or 52 weeks
- Treatment satisfaction and compliance, as measured by changes from baseline in the Diabetes Treatment Satisfaction Questionnaire (DTSQ) at 26 or 52 weeks, and Treatment Related Impact Measure for Diabetes (TRIM-D) scores at 52 weeks (TRIM-D scores were only measured in one of the clinical trials [ONWARDS 5]. Patients in this trial were insulin naïve.)

^a The A1C test, also known as the hemoglobin A1C or HbA1c test, is a simple blood test that measures a person's average blood sugar levels over the past 3 months.

^b Time in range is the amount of time spent in the target blood glucose range.

| Information about the drug | | | | |
|----------------------------|---|--|--|--|
| | Proportion of patients experiencing at least 1 clinically significant or severe hypoglycemia event^c at 26 weeks or 52 weeks | | | |
| | Bad reactions | | | |
| | Serious bad reactions | | | |
| | Patients leaving the trial due to bad reactions | | | |
| | Bad reactions of special interest, such as hypersensitivity, injection site reactions, hypoglycemia (low blood sugar), and nocturnal hypoglycemia (low blood sugar while sleeping at night) | | | |
| Other considerations | None | | | |

Note:

Canada's Drug and Health Technology Agency (CADTH) is a national organization that reviews drugs on behalf of Canadian public sector plans when manufacturers want to have the jurisdictions provide coverage for the drugs. For detailed information on B.C. PharmaCare's drug review process, including the role of the CADTH Reimbursement Review (CRR) in that process, see <a href="https://doi.org/10.1007/jhc.200

| Cost of the drug under review 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 | Annual Cost of Therapy ^d | |
| Insulin icodec (Awiqli) | Under Review | Prefilled pen | Once weekly. Maintenance dose is adjusted according to the metabolic needs of the patient and the glycemic control target. | \$1,085 to \$1,357 | |
| Long-acting insulin analogues (Basal) | | | | | |

^c Clinically significant hypoglycemic episodes (level 2) were defined as less than 3.0 mmol/L confirmed by blood glucose (BG) meter. Severe hypoglycemic episodes (level 3) were defined as any hypoglycemic event requiring active assistance of another person, for instance to administer corrective actions or receive medical care.

^d All prices as per CADTH Pharmacoeconomic Review Report for insulin icodec, unless otherwise specified.

| Cost of the drug under review 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 | Annual Cost of Therapy ^d | |
| Insulin degludec (Tresiba) | Non-Benefit | Cartridge Prefilled pen | Once daily. Maintenance dose is adjusted according to the metabolic needs of the patient and the glycemic control target. | \$1,085 to \$1,357 | |
| Insulin detemir (Levemir) | <u>Limited Coverage</u> | Cartridge Prefilled pen | | \$1,085 to \$1,357 | |
| Insulin glargine (Basaglar) | <u>Limited Coverage</u> | Cartridge Prefilled pen | | \$741 to \$926 | |
| Insulin glargine (Lantus) | Non-Benefit | Vial Cartridge Prefilled pen | | \$904 to \$1,130 | |
| Insulin glargine (Semglee) | <u>Limited Coverage</u> | Prefilled pen | | \$621 to \$777 | |
| Insulin glargine (Toujeo) | Non-Benefit | Prefilled pen | By weight in kilograms, once daily. Maintenance dose is adjusted according to the metabolic needs of the patient and the glycemic control target. | \$858 to \$1,072 | |
| Rapid-acting insulin | analogues (Bolus) | | | | |
| Insulin aspart (Trurapi) | Regular Benefit | Vial Cartridge Prefilled pen | Dosage is individualized and determined, based on the treating physician's advice, in accordance with the needs of the patient. Bolus insulin should be | \$131 to \$164 | |
| Insulin glulisine (Apidra) | Regular Benefit | Vial Cartridge Prefilled pen | | \$155 to \$194 | |
| Insulin lispro (Admelog) | Regular Benefit | Vial Cartridge Prefilled pen | | \$131 to \$164 | |

| Cost of the drug under review 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 | Annual Cost of Therapy ^d | |
| Regular human insulin (Humulin R) | Regular Benefit | Vial Cartridge | added before or after meals. | \$119 to \$149 | |
| Regular human insulin (Novolin ge Toronto) | Regular Benefit | Vial Cartridge | | \$106 to \$133 | |
| Basal + bolus insulin analogues | | | | | |
| Insulin icodec + bolus insulin analogues | | | | \$1,184 to \$1,551 | |
| Insulin degludec (Tresiba) + bolus insulin analogues | | | | \$1,184 to \$1,551 | |
| Insulin detemir (Levemir) + bolus insulin analogues | | | | \$1,184 to \$1,551 | |
| Insulin glargine (Basaglar) + bolus insulin analogues | | | | \$840 to \$1,121 | |
| Insulin glargine (Lantus) + bolus insulin analogues | | | | \$1,003 to \$1,324 | |
| Insulin glargine (Semglee) + bolus insulin analogues | | | | \$720 to \$971 | |
| Insulin glargine (Toujeo) + bolus insulin analogues | | | | \$957 to \$1,267 | |

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 and Health Technology Agency</u> (<u>CADTH</u>)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with 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:

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

For more information about the B.C. Drug Review Process, visit: <u>The Drug Review Process in B.C. -</u> Overview.

This document is intended for information only.

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