BRITISH COLUMBIA | Ministry of Health

Drug Coverage Decision for B.C. PharmaCare

About PharmaCare B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Details of Drug Reviewed

Drug	**semaglutide**
Brand Name	Rybelsus®
Dosage Form(s)	3 mg, 7 mg, and 14 mg oral tablets
Manufacturer	Novo Nordisk Canada Inc.
Submission Type	**New Submission**
Use Reviewed	For the treatment of Type 2 Diabetes Mellitus (T2DM).
Canadian Agency for Drugs and Technologies in Health (CADTH) Reimbursement Reviews (CRR)	Yes, the CRR recommended: **to Reimburse with clinical criteria and/or conditions**. Visit the CRR website for more details: www.cadth.ca/reimbursement-review-reports
Provincial Review	The Drug Benefit Council (DBC) now screens drug submissions under review by the CRR to determine whether or not a full DBC review is necessary, based on past DBC reviews, recommendations, and existing PharmaCare coverage. If a full DBC review is determined to not be required, the Ministry of Health's (Ministry) drug coverage decision will be based on the Canadian Drug Expert Committee (CDEC) recommendation and an internal review only. The DBC screened Rybelsus on December 7, 2020. The DBC advised that because Rybelsus is similar to some of the other drugs used for the treatment of T2DM, the Ministry may accept the CDEC's recommendation for Rybelsus.

Drug Coverage Decision	**Non-Benefit**
Date	**January 31, 2023**
Reason(s)	**Drug coverage decision is consistent with the CDEC recommendation**. • The CDEC recommended that Rybelsus be listed for the treatment of T2DM if the drug plan cost of treatment with Rybelsus does not exceed the drug plan cost of treatment with the least costly glucagon-like peptide-1 receptor agonist (GLP-1 RA), dipeptidyl peptidase-4 (DPP-4) inhibitor, or sodium-glucose cotransporter-2 inhibitors (SGLT-2) inhibitor classes of anti-diabetes drugs currently reimbursed for the treatment of T2DM. • The efficacy and safety of Rybelsus was reviewed in nine PIONEER randomized clinical trials (RCTs) in patients with T2DM either as a monotherapy, as an add-on to 1-2 oral anti-diabetic drugs, and as a combination therapy with basal insulin. • Based on the PIONEER RCTs, Rybelsus demonstrated statistically significantly greater reductions in glycated hemoglobin (HbA1c) levels versus two oral anti-diabetic drugs commonly used in the management of T2DM: sitagliptin, a DPP-4 inhibitor, and empagliflozin, an SGLT2 inhibitor. Rybelsus was also shown to be similar to liraglutide, an injectable GLP-1 RA, for reductions in HbA1c levels. • Based on the PIONEER-6 RCT, Rybelsus was similar to placebo with the risk of major adverse cardiovascular events (MACE). Therefore, based on currently available evidence, cardiovascular (CV) benefit with Rybelsus cannot be claimed. • At the submitted price per tablet (regardless of the dose), the daily cost of Rybelsus is more costly than all SGLT-2 inhibitors, DPP-4 inhibitors, and some GLP-1 RAs, depending on the dose. • The pan-Canadian Pharmaceutical Alliance (pCPA) and Business Management were involved in negotiations with the manufacturer for Rybelsus and an agreement could not be reached at the current time.
Other Information	• The Ministry provides coverage for subcutaneous semaglutide (Ozempic®) as a Limited Coverage benefit with criteria. • Effective January 5, 2023, Ozempic and empagliflozin (Jardiance®) coverage was changed from third-line to second-line therapy for the treatment of T2DM. The Special Authority (SA) criteria still require patients to try metformin before applying for coverage, but patients no longer need to try and fail on an insulin or a sulfonylurea (e.g., glyburide) before their prescriber can apply for SA coverage. Prescribers can re-apply for SA coverage for these drugs for patients who hadn't qualified under the old criteria. • Effective January 5, 2023, dapagliflozin (Forxiga®), a SGLT2 inhibitor drug, was changed from limited coverage to regular benefit. Prescribers no longer need to request SA coverage for this oral drug.

The Drug Review Process in B.C.

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

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

- whether the drug is safe and effective
- advice from a national group called the Canadian Agency for Drugs and Technologies in Health (CADTH) Reimbursement Reviews(CRR)
- 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

Visit The Drug Review Process in B.C. - Overview and Ministry of Health - PharmaCare for more information.

This document is intended for information only.
It does not take the place of advice from a physician or other qualified health care provider.