Drug Coverage Decision for BC PharmaCare

About PharmaCare BC PharmaCare is a publicly funded drug plan that helps B.C. residents pay for most prescription drugs and pharmacy services, and some medical devices and supplies.

Details of Drug Reviewed

Drug	nipocalimab
Brand name	Imaavy®
Dosage form(s)	300 mg/1.62 mL and 1200 mg/6.5 mL solution for intravenous infusion
Manufacturer	Janssen Inc.
Submission type	**New Submission**
Indication reviewed	As an add-on to standard therapy for the treatment of generalized myasthenia gravis (gMG) in adult and adolescent patients aged 12 years and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
Canada's Drug Agency (CDA-AMC) Reimbursement Review	The Canadian Drug Expert Committee (CDEC) recommended: **Do Not Reimburse**. Visit the CDA-AMC website for more details.
Ministry of Health (the Ministry) Review	The Ministry reviewed reports prepared by the CDA-AMC's Reimbursement Review process, including clinical and pharmacoeconomic evidence review material and the recommendations of the CDEC. The Ministry also considered patient input provided to CDEC and a budget impact assessment. The Ministry received one Your Voice patient input questionnaire response from a patient group.
Drug Coverage Decision	**Non-benefit**
Date	October 14, 2026
Reason(s)	**Drug coverage decision is consistent with the CDEC recommendation.**

	• Evidence from one clinical trial in adult patients with gMG showed that compared with placebo, treatment with nipocalimab likely improves daily function, disease severity, and may improve health-related quality of life over 22 to 24 weeks. However, the clinical importance of these improvements was deemed uncertain due to unclear meaningful benefit to patients, inconsistent improvements across outcomes, and limitations in the long-term evidence. • Evidence from one trial in eight adolescent patients with gMG was highly uncertain due to small sample size and single-arm trial design. While CDEC acknowledged that adolescents face limited treatment options, the committee was unable to conclude that nipocalimab addresses a significant unmet clinical need with enough certainty in clinical value. • CDEC was unable to draw conclusions regarding the comparative efficacy and safety of nipocalimab relative to other therapies funded by the Ministry for gMG, including rituximab, rozanolixizumab, and zilucoplan, because the submitted indirect evidence was associated with significant methodological limitations. • The pan-Canadian Pharmaceutical Alliance (pCPA) decided not to pursue negotiations with the manufacturer of nipocalimab.

The drug review process in B.C.

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

An independent national organization called Canada's Drug Agency (CDA-AMC) provides evidence-based recommendations to public drug plans across Canada through its reimbursement review process. As part of the CDA-AMC's Reimbursement Review process, the Canadian Drug Expert Committee (CDEC) makes reimbursement recommendations for non-oncology pharmaceuticals to the participating federal, provincial, and territorial publicly funded drug plans. In developing its recommendations, the CDEC considers:

- whether the drug is safe and effective
- what the drug costs and whether funding it provides good value
- ethical considerations of covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a BC PharmaCare coverage decision by considering:

- existing BC PharmaCare policies, programs and resources
- the evidence-informed advice of the CDA-AMC
- the recommendations and reimbursement conditions of the CDEC
- if a Ministry Initiated review, the advice of an independent expert group called the Drug Benefit Council (DBC)
- BC-specific patient input collected through the Your Voice website
- drugs already covered by BC PharmaCare that treat similar medical conditions
- the overall cost of covering the drug
- the outcomes of pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with manufacturers

Visit BC PharmaCare and Drug reviews for more information.

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