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	**vutrisiran**
Brand name	Amvuttra®
Dosage form(s)	25 mg/0.5 mL solution for subcutaneous injection
Manufacturer	Alnylam Netherlands B.V.
Submission type	**New Submission**
Indication reviewed	For the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin-mediated (hATTR) amyloidosis.
Canada's Drug Agency (CDA-AMC) recommendation	CDA-AMC recommended: **to Reimburse with clinical criteria and/or conditions**. Visit the CDA-AMC website for more details.
Drug Benefit Council (DBC)	The DBC decided not to review vutrisiran as it has a similar mechanism of action to patisiran (Onpattro®) which was reviewed by the DBC on August 12, 2019.
Drug Coverage Decision	**Exceptional Coverage through the Expensive Drugs for Rare Diseases (EDRD) Process**
Date	December 19, 2024
Reason(s)	**Drug coverage decision is consistent with the CDEC recommendation.** • Results from one phase III, multicentre, randomized, open-label study (HELIOS-A) with 164 adult patients with hATTR amyloidosis demonstrated that, compared to an external placebo group (from the APOLLO trial), treatment with vutrisiran resulted in added clinical benefit in adults with stage 1 or stage 2 hATTR-polyneuropathy (PN). • Compared to the external placebo group, at 18 months, treatment with vutrisiran was associated with statistically significant and clinically meaningful

	improvements in neurologic function, health-related quality of life, and disability. • Vutrisiran was non-inferior to a within-study patisiran treatment arm in the reduction of serum transthyretin (TTR). This was the only comparison between vutrisiran and patisiran in the HELIOS-A trial. The correlation between meaningful clinical outcomes and serum TTR reduction is hypothesized but remains unknown. • When compared to the current standard of care for hATTR-PN, patisiran, vutrisiran provides a more convenient and less invasive dosing regimen but similar mechanism of action, efficacy, and safety profiles. • As there is no treatment that reverses neuropathy, the primary goal of hATTR-PN therapy is to slow disease progression. • Current treatments lack comprehensive data on important outcomes such as a reduction in hospitalization and mortality, and the impact of vutrisiran on these outcomes was not evaluated. • Based on economic considerations and the submitted product price, the cost-effectiveness of vutrisiran is highly uncertain. • B.C. participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer and the pCPA was able to address some of the concerns identified by the CDA-AMC with respect to cost-effectiveness.

The drug review process in B.C.

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

An independent group called the Drug Benefit Council (DBC) gives advice to the Ministry by considering:

- whether the drug is safe and effective
- advice from a national group called Canada's Drug Agency – L'agence des médicaments du Canada (CDA-AMC)
- what the drug costs and whether funding it provides good value to the province
- ethical considerations of covering and not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a BC PharmaCare coverage decision by taking into account:

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

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.