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)	**lumasiran**
Brand name	**Oxlumo™**
Manufacturer	Alnylam Netherlands BV
Indication	Primary hyperoxaluria type 1 (PH1)
Has the drug been reviewed by the Common Drug Review (CDR)? (see the note below this table.)	Yes For more information about the CDR's review of lumasiran (Oxlumo), you can Search the CDR Reports.
Public input start date	Wednesday, August 31, 2022
Public input closing date	**Wednesday, September 28, 2022, AT MIDNIGHT**
How is the drug taken?	Lumasiran is injected subcutaneously (under the skin)
How often is the drug injected?	Lumasiran is injected once monthly for three months and then once every three months thereafter, except in patients who weigh less than 10 kg, who receive all injections once monthly.

Information about the drug	
General drug and/or drug study information	Lumasiran is used to treat primary hyperoxaluria type 1 (PH1) in adults and children. PH1 is a rare, inherited disease where the liver makes too much of a substance called oxalate. Oxalate is removed by the kidneys and is passed out in urine. In people with PH1, the oxalate accumulates in the kidneys and urinary tract and other parts of the body. Disease onset can occur any time from infancy to middle age. Symptoms of PH1 can vary in severity and type and include recurrent kidney stones, blood in the urine, and urinary tract infections (UTIs). This disease often progresses to end-stage kidney disease. As kidney function declines, oxalate may also build up in other parts of the body such as the bones, skin, eyes, heart, blood vessels, and central nervous system. This accumulation of oxalate in the later stages of PH1 can result in broken bones, irregular heartbeat, eye disease, stroke, enlarged liver, and painful nerve damage (peripheral neuropathy). The combination of end-stage kidney disease and the systemic accumulation of oxalates in the body can result in early death. Lumasiran reduces the amount of an enzyme called glycolate oxidase that the liver makes. Glycolate oxidase is one of the enzymes involved in producing oxalate. By lowering the amount of the enzyme, the liver produces less oxalate and the levels of oxalate in the urine and blood also fall. This can help to reduce the effects of PH1. Studies looked at the following: • Changes from baseline in kidney function • Kidney stone events • Health-related quality of life (HRQoL) • Changes from baseline in urine oxalate excretion • Changes from baseline in plasma oxalate • Changes from baseline in urine oxalate: creatinine ratio • Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions • Bad reactions of special interest. For example, injection site reactions, kidney problems, complications from systemic oxalosis, headaches, nasal congestion, runny nose, sneezing, and itching (rhinitis), upper respiratory infections, hypersensitivity reactions, and occurrence of antidrug antibodies[a].
Other considerations	None.

Note:

[a] Some therapies may trigger immune responses that lead to the formation of antidrug antibodies (ADAs). ADAs may negatively affect the drug's safety and effectiveness .

The Common Drug Review (CDR) 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 CDR in that process, see The Drug Review Process in B.C. - Overview.

Cost of the drug under review compared to other drugs used to treat the same indication (In this case, there are no pharmacological comparators)				
generic name (Brand Name) of Drug Comparator	**PharmaCare Status (if and how the drug is already covered)**	**Dosage Form**	**Usual Dose**	**Cost of Therapy[b]**
Lumasiran (Oxlumo)	Under Review	0.5 mL Solution for subcutaneous injection	<10 kg: loading dose of 6 mg/kg monthly for 3 doses and maintenance dose of 3 mg/kg monthly thereafter. 10 to 20 kg: loading dose of 6 mg/kg monthly for 3 doses and maintenance dose of 6 mg/kg once every 3 months thereafter. ≥20 kg: loading dose of 3 mg/kg monthly for 3 doses and maintenance dose of 3 mg/kg once every 3 months thereafter.	Pediatric Year 1: $581,131[c] Subsequent: $387,421 Adult Year 1: $1,743,395 Subsequent: $1,162,263

[b] Cost calculated assuming an average pediatric and adult weight of 26.15 kg and 82.02 kg respectively. Calculated costs include wastage, where applicable.
[c] Manufacturer's submitted price.

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 Common Drug Review (CDR)
- 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: The Drug Review Process in B.C. - 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.