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)	**burosumab**
Brand name	**Crysvita™**
Manufacturer	Kyowa Kirin Canada, Inc.
Indication	For the treatment of X-linked hypophosphatemia (XLH) in adults.
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 burosumab (Crysvita) you can Search the CADTH Reports.
Public input start date	Wednesday, April 24, 2024
Public input closing date	**Tuesday, May 21, 2024, AT 11:59 PM**
How is the drug taken?	Burosumab is administered by subcutaneous (under the skin) injection.
How often is the drug injected?	Burosumab is injected every four weeks in adult patients.

Information about the drug	
General drug and/or drug study information	Burosumab is being reviewed by PharmaCare for the treatment of X-linked hypophosphatemia (XLH) in adults. XLH is a rare genetic disease that leads to defective bone mineralization. People with XLH have higher levels of a hormone called fibroblast growth factor 23 (FGF23). FGF23 lowers the amount of phosphate in the blood. FGF23 also supresses the production of a type of vitamin D, resulting in the decreased absorption of calcium and phosphate. Low levels of phosphate in the blood may lead to bones that cannot grow properly. Adult patients with XLH experience symptoms such as bone or joint pain, fractures, the softening or weakening of bones (osteomalacia), damage to connective tissues between bones, tendons, and ligaments (enthesopathy), severe dental abnormalities, hearing loss, and fatigue. Burosumab attaches to FGF23 in the blood and stops it from working, thereby increasing phosphate levels in the blood. Studies looked at the following: • Proportion of patients attaining serum phosphorus levels above the lower limit of normal (LLN) of 81 millimoles per litre (mmol/L) at the midpoint of the dosing cycle, from baseline to week 24 • Proportion of patients achieving serum phosphorus levels over the LLN at the end of their dosing cycle, at week 48 • Changes from baseline to week 24 in Brief Pain Inventory (BPI) worst pain scores • Changes from baseline to weeks 24, 48, and 96 in BPI pain interference scores, and pain severity scores • Changes from baseline to week 24 in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) physical function and stiffness scores • Changes from baseline to weeks 24, 48, and 96 in WOMAC pain scores • Changes from baseline to weeks 24, 48, and 96 in Brief Fatigue Inventory (BFI), worst fatigue and global fatigue scores • Changes from baseline in bone-specific alkaline phosphatase (BALP)[a] at week 24, 48, and 96

[a] Bone-specific alkaline phosphatase (BALP) is an enzyme produced by bones that plays a role in bone formation and turnover. Measuring BALP levels can help to assess bone health.

Information about the drug	
	• Changes from baseline in serum 1,25 dihydroxyvitamin D, at weeks 24, 48, and 96 • Changes from baseline in tubular maximum reabsorption of phosphate per glomular filtration rate (TmP/GFR)[b] at weeks 24, 48, and 96 • Changes from baseline in tubular reabsorption of phosphate[c] (TRP) at weeks 24, 48, and 96 • Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions • Bad reactions of special interest: Injection site reactions, hypersensitivity, abnormally high serum phosphate levels (hyperphosphatemia), abnormal deposits of minerals in tissues outside of the skeleton (ectopic mineralization), and restless leg syndrome
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 The Drug Review Process in B.C. - Overview.

[b] TmP/GFR is a measure of how efficiently the kidneys reabsorb phosphate from the urine back to the bloodstream.
[c] Tubular reabsorption of phosphate is the process in the kidneys where phosphate molecules are removed from the urine and returned to the bloodstream to maintain the body's balance of minerals.

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]**
burosumab (Crysvita)	Under Review for XLH in adults; Exceptional, case-by-case coverage provided for eligible patients with XLH who initiate drug in pediatric age through the BC EDRD Process	Single-use vial	Once every 4 weeks, dosed in mg/kg of body weight[e]	$410,860 to $528,248
Phosphates				
sodium phosphates (Phoslax)	Non-Benefit, except for Plan W and Plan P beneficiaries	Oral Solution	Daily, in two or three divided doses	$1,310 to $2,795
Jamp-sodium phosphate	Regular Benefit	Oral effervescent tablet	Daily, in two or three divided doses	$1,105 to $2,209
Vitamin D				
vitamin D alfacalcidol (Generic)	Regular Benefit, Subject to LCA	Capsule	0.75 to 1.50 mcg per day	$510 to $849
calcitriol (Calcitriol-Odan)	Regular Benefit, Subject to LCA	Capsule	0.50 to 0.75 mcg per day	$147 to $239

[d] All prices as per PharmaCare Formulary, unless otherwise stated.
[e] Based on an average patient weight of 70.7 kg and assuming patients receive 13 administrations per year using 70 mg and 90 mg to calculate the range (average dose/weight to maximum dose).

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 Canada's Drug and Health Technology Agency (CADTH)
- 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.