

# **BC PharmaCare Drug Information**

The drug below is being considered for coverage under the BC PharmaCare program. PharmaCare is a government-funded drug plan that helps B.C. residents with the cost of eligible prescription drugs and medical supplies. For more information about PharmaCare, visit the PharmaCare website.

PharmaCare reviews each drug for treating a specific illness or medical condition (also called an "indication"). If PharmaCare decides to cover a drug, that coverage applies only to the indication(s) specified. In some cases, PharmaCare covers a drug only for people who have not responded to other drugs that treat the same indication.

More information about the PharmaCare drug review process is provided on the last page of this document.

Drug information			
Generic name (scientific name)	ruxolitinib cream		
Brand name	Opzelura®		
Manufacturer	Incyte Biosciences Canada Corporation		
Indication	For the topical treatment of atopic dermatitis in patients 12 years of age and older.		
Has the drug been reviewed by CDA-AMC, or will CDA-AMC be reviewing it? (See note below.)	Yes For more information about the CDA-AMC Reimbursement Review (CRR) of ruxolitinib cream (Opzelura), Search the CDA-AMC Reports.		
Public input start date	Wednesday, October 30, 2024		
Public input closing date	Tuesday, November 26, 2024, at 11:59 pm		
How is the drug taken?	Ruxolitinib cream is applied topically (to the skin).		
How often is the drug applied?	Ruxolitinib cream is applied twice daily to affected skin areas up to a maximum of 20% of body surface area for each application.		

# General drug and/or drug study information

Ruxolitinib cream is being reviewed by PharmaCare for the topical treatment of atopic dermatitis (AD) in patients 12 years of age and older whose disease is not adequately controlled with conventional topical prescription therapies (topical calcineurin inhibitors, topical corticosteroids) or when those therapies are not advisable.

AD is a type of eczema. It is a chronic, relapsing, inflammatory skin condition characterized by dry, red, severely itchy skin, blisters that may leak fluid and crust over, thickened, cracked, scaly skin, and raw, sensitive, swollen skin from scratching. AD typically involves the skin in front of the elbows and behind the knees, but may also appear on the face, neck, and hands. AD can disrupt sleep due to the itching and discomfort it causes. It is common in children but can occur at any age.

Ruxolitinib cream works by blocking certain enzymes called Janus kinases (JAKs) in the skin. These enzymes are part of a signaling pathway that leads to inflammation and itching in patients with AD. Ruxolitinib cream helps soothe irritated skin by preventing the signals that trigger inflammation and itching.

Studies looked at the following:

- Proportion of patients achieving Investigator's Global Assessment-Treatment Success (IGA-TS i.e., IGA score of 0 or 1 with at least 2 grade improvement from baseline) at week 8
- Proportion of patients achieving Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) at 52 weeks
- Proportion of patients achieving Eczema Area and Severity Index-75
  (EASI-75) (i.e., at least 75% reduction in score from baseline) at 8
  weeks
- Changes from baseline in AD afflicted percentage of body surface area (BSA) at 8 and 52 weeks
- Proportion of patients with at least 4-point improvement (i.e., reduction) from baseline in itch numeric rating scale (NRS) score at 8 weeks
- Changes from baseline in Patient-Oriented Eczema Measure (POEM) scores at 8 and 52 weeks
- Proportion of patients with at least a 6-point improvement (i.e., reduction) from baseline in Patient-Reported Outcomes
   Measurement Information System (PROMIS) Short Form – Sleep

Drug information				
	Disturbance (24-hour recall) and Sleep-Related Impairment (24-hour recall) scores at 8 weeks  Health-related quality of life (HRQoL) as measured by changes from baseline in Dermatology Life Quality Index (DLQI) and Children's			
	<ul> <li>Dermatology Life Quality Index (CDLQI) scores at weeks 8 and 52</li> <li>Bad reactions</li> <li>Serious bad reactions</li> <li>Patients leaving the trial due to bad reactions</li> <li>Bad reactions of special interest: None</li> </ul>			
Other considerations	None			

### Note:

CDA-AMC (<u>Canada's Drug Agency-L'Agence des Médicaments du Canada</u>) is a national organization that reviews drugs on behalf of Canadian public sector plans when drug manufacturers want those plans to provide coverage for the drug. For detailed information about the PharmaCare drug review process, including the role of the CDA-AMC Reimbursement Review (CRR) in that process, visit <u>How PharmaCare Decides Which Drugs to Cover</u>.

Cost of the drug 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 Therapya or Per 24-Week Course of Treatment or Cost Per Gram of Topical Treatment
ruxolitinib (Opzelura)	Under Review	Cream	Thin layer applied twice daily, up 20% of body surface area (BSA)	Year 1: \$9,297 to \$13,945 <sup>b</sup> Subsequent years: \$2,324 to \$9,297

<sup>&</sup>lt;sup>a</sup> All prices as per PharmaCare Formulary, unless otherwise specified. Weight-based dosing assumes an average weight of 85 kg for adults and 40 kg for adolescents.

<sup>&</sup>lt;sup>b</sup> Manufacturer's submitted price plus 8% markup.

Cost of the drug 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 <sup>a</sup> or Per 24-Week Course of Treatment or Cost Per Gram of Topical Treatment
Indicated for modera	ite to severe AD - Ann	ual Cost		
abrocitinib (Cibinqo)	Limited Coverage	Tablet	Once daily	\$18,651 to \$20,874
dupilumab (Dupixent)	Non-Benefit for AD for ages 12 years and older, but under review for AD ages 6 months to 12 years	Pre-filled syringe Single-use pen or syringe	Initial dose, followed by once every 2 weeks, thereafter	Year 1: \$27,746 Year 2+: \$26,719
upadacitinib (Rinvoq)	Limited Coverage	Extended release tablets	Once daily	\$19,807 to \$29,495
Immunosuppressant	s: Cost per 24-week co	ourse of treatment		
azathioprine (generic)	Regular Benefit, subject to LCA	Tablet	Once daily, dosed in mg/kg	Pediatric: \$94 to \$376 Adult: \$188 to \$470
cyclosporine (generic)	Non-Benefit for AD <sup>c</sup>	Capsule	Pediatric: Once daily, dosed in mg/kg Adult: Once daily	Pediatric: \$700 to \$1,393 Adult: \$836 to \$1,672

<sup>&</sup>lt;sup>c</sup> Special authority requests for the treatment of moderate to severe atopic dermatitis will be considered on a case-by-case basis when coverage is requested by a dermatologist, allergist, or clinical immunologist.

Cost of the drug 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 <sup>a</sup> or Per 24-Week Course of Treatment or Cost Per Gram of Topical Treatment	
methotrexate (generic)	Regular Benefit, subject to LCA	Tablet	Pediatric: Once per week, dosed in mg/kg Adult: Once per week	Pediatric: \$20 to \$72 Adult: \$20 to \$65	
mycophenolate mofetil	Non-Benefit for AD <sup>c</sup>	Capsule	Pediatric: Once daily, dosed in mg/kg Adult: Once daily	Pediatric: \$337 to \$539 Adult: \$539 to \$3,502	
Retinoids - Cost per 2	24-week course of tre	atment			
acitretin (generics)	Regular Benefit, subject to LCA	Capsule	Once daily	\$235 to \$1,239	
alitretinoin (Hanzema)	Limited Coverage <sup>d</sup>	Capsule	Once daily	\$3,082	
Topical corticosteroids – Cost per gram of product					
amcinonide (generics)	Regular Benefit, subject to LCA	0.1% Cream Ointment Lotion	Thin amount to affected area twice daily, max 5 days on face, armpits, scrotum, or scalp, 2 to 3 weeks elsewhere.	Cost per gram: Cream: \$0.49 Ointment: \$0.27 Lotion: \$0.28	

<sup>&</sup>lt;sup>d</sup> For the treatment of severe chronic hand eczema.

Cost of the drug 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 Therapya or Per 24-Week Course of Treatment or Cost Per Gram of Topical Treatment	
betamethasone dipropionate (generic)	Regular Benefit, subject to LCA	0.05% Cream Ointment Lotion	Thin film to affected area twice daily, duration of therapy varies; need should be reassessed at least every 4 weeks.	Cost per gram: Cream: \$0.22 Ointment: \$0.24 Lotion: \$0.22	
betamethasone valerate (generic)	Regular Benefit	0.05% Cream Ointment	Apply to affected area 1-3 times daily.	Cost per gram: Cream: \$0.06 Ointment: \$0.08	
	Regular Benefit	0.1% Cream Ointment Lotion		Cost per gram: Cream: \$0.11 Ointment: \$0.13 Lotion: \$0.09	
clobetasol propionate (generic)	Regular Benefit, subject to LCA	0.05% Cream Ointment Solution	Thin amount to affected area twice daily. Weekly application should not exceed 50 g, and limited to two consecutive weeks.	Cost per gram: Cream: \$0.28 Ointment: \$0.28 Solution: \$0.27	
desonide (generic)	Regular Benefit, subject to LCA	0.05% Cream Ointment	Thin amount to affected area twice daily, may be increased in stubborn cases.	Cost per gram: Cream: \$0.49 Ointment: \$0.49	

Cost of the drug 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 Therapya or Per 24-Week Course of Treatment or Cost Per Gram of Topical Treatment
desoximetasone (Topicort)	Regular Benefit, subject to LCA	0.05% Cream, Gel 0.25% Cream, Ointment	Thin amount to affected area twice daily.	Cost per gram: 0.05% Cream: \$0.71 0.05% Gel: \$0.72 0.25% Cream: \$0.93 0.25% Ointment: \$0.93
fluocinonide (Lyderm)	Regular Benefit, subject to LCA	0.05% Ointment Gel	Thin amount to affected area twice daily. Weekly application should not exceed 45 g, and limited to 2 weeks.	Cost per gram: Ointment: \$0.40 Gel: \$0.41
fluocinonide (Tiamol)	Regular Benefit, subject to LCA	0.05% Emollient Cream	Thin amount 2 to 4 times daily.	Cost per gram: \$0.26
halobetasol propionate (Ultravate)	Regular Benefit	0.05% Ointment Cream	Thin amount to affected area twice daily, limited to 50 g weekly and two weeks without re- evaluation.	Cost per gram: Ointment: \$1.34 Cream: \$1.34

Cost of the drug 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 Therapya or Per 24-Week Course of Treatment or Cost Per Gram of Topical Treatment	
hydrocortisone (generics)	Regular Benefit, subject to LCA	1.0% Cream Lotion Ointment 0.5% Ointment	Apply appropriate cream, lotion, ointment, or solution sparingly 1–4 times daily.	Cost per gram:  1% Cream:  \$0.10  1% Lotion:  \$0.20  1% Ointment:  \$0.14  0.5% Ointment:  \$0.22	
hydrocortisone acetate	Regular Benefit, subject to LCA	1% Cream	Twice-daily application is generally recommended initially; intermittent use 1 to 2 times per week on areas that commonly flare for maintenance therapy.	Cost per gram: \$0.12	
hydrocortisone valerate (Hydroval)	Regular Benefit	0.2% Ointment Cream	Small amount to affected area twice daily. Discontinue as soon as lesions heal or if no response.	Cost per gram: Ointment: \$0.20 Cream: \$0.20	

Cost of the drug 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 <sup>a</sup> or Per 24-Week Course of Treatment or Cost Per Gram of Topical Treatment	
mometasone furoate (generic)	Regular Benefit, subject to LCA	0.1% Cream Ointment Lotion	Thin film to affected areas twice daily.	Cost per gram: Cream: \$0.68 Ointment: \$0.65 Lotion: \$\$0.45	
triamcinolone acetonide (various)	Regular Benefit, subject to LCA	0.1% Cream Ointment	Small amount to affected area twice or thrice daily	Cost per gram: Cream: \$0.13 Ointment: \$0.19	
Topical calcineurin in	hibitors				
pimecrolimus (Elidel)	<u>Limited Coverage</u>	1% Cream	Thin layer to affected area twice daily, discontinue when resolved or after three weeks if no improvement or exacerbation.	Cost per gram: \$3.14	
tacrolimus	Limited Coverage	0.03% Ointment 0.10% Ointment	Thin layer to affected area twice daily. Discontinue after six weeks if no improvement or exacerbation.	Cost per gram: 0.03% Ointment: \$3.34 0.10% Ointment: \$3.58	
PDE4 inhibitor					
crisaborole (Eucrisa)	Non-Benefit	2% Ointment	Thin layer to affected area twice daily.	Cost per gram: \$2.42°	
Phototherapy					

<sup>&</sup>lt;sup>e</sup> Price as per CDA-AMC Pharmacoeconomic Review Report for ruxolitinib cream.

Cost of the drug 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 Therapya or Per 24-Week Course of Treatment or Cost Per Gram of Topical Treatment
Ultraviolet light therapy	Non-Benefit	NA	Administered 3 to 5 times per week	7.85 per treatment <sup>f</sup>

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<sup>&</sup>lt;sup>f</sup> Price as per CDA-AMC Pharmacoeconomic Review Report for ruxolitinib cream.

## The Drug Review Process in B.C.

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

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

- whether the drug is safe and effective
- advice from a national group called <u>Canada's Drug Agency-L'Agence des médicaments</u> <u>du Canada (CDA-AMC)</u>
- what the drug costs and whether it is a good value to the citizens of B.C.
- ethical considerations related to 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:

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

For more information about the drug review process in B.C., visit: the <u>How PharmaCare decides which</u> drugs to cover.

# This document provides information only.

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