

# 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)	<b>Spesolimab</b>
Brand name	<b>Spevigo®</b>
Manufacturer	<b>Boehringer Ingelheim (Canada) Ltd.</b>
Indication	For the treatment of generalized pustular psoriasis (GPP)
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 spesolimab (Spevigo), <a href="#">Search the CDA-AMC Reports</a> .
Public input start date	<b>Wednesday, September 25, 2024</b>
Public input closing date	<b>Tuesday, October 22, 2024 at 11:59 pm</b>
How is the drug administered?	Spesolimab is given by intravenous (IV) infusion for the treatment of GPP flares. An IV infusion is delivered directly into a vein through a needle. Spesolimab is given by subcutaneous (under the skin) injection for the prevention of GPP flares.
How often is the drug administered?	IV infusions for the treatment of GPP flares are administered in a single dose. If the flare persists, an additional dose may be given 1 week after the initial dose.

Drug information	
	Subcutaneous (SC) injections for the prevention of GPP flares are given as one loading dose followed by a maintenance dose every 4 weeks
General drug and/or drug study information	<p>Spesolimab is being reviewed by PharmaCare for the treatment of GPP, including both the IV treatment and SC prevention of GPP flares, in adults and pediatric patients 12 years of age and older.</p> <p>GPP is a rare, chronic, severe skin disease characterized by widespread patches of red, inflamed skin, which is covered in pus-filled blisters (pustules). It can cause itching, pain, fatigue, and fever and often appears suddenly. Severe flares may be associated with other disorders such as arthritis, inflammation of the eye (uveitis), inflammation of the bile duct system (neutrophilic cholangitis), respiratory failure (acute respiratory distress syndrome or ARDS), and serious infections which cause dangerously low blood pressure (cardiac septic shock).</p> <p>Spesolimab is a monoclonal antibody belonging to a group of medicines called interleukin (IL) inhibitors. Monoclonal antibodies are proteins that recognize and bind specifically to certain proteins in the body. Spesolimab works by blocking the activity of a protein called IL-36R, which can cause pustules, painful inflammation on the skin, and fibrosis (scarring).</p> <p>Studies looked at the following:</p> <p><i>Spesolimab versus placebo for the treatment of acute GPP flares in adults:</i></p> <ul style="list-style-type: none"> <li>• Proportion of patients with a generalized pustular psoriasis physician global assessment (GPPGA) pustulation subscore of 0 at the end of week 1</li> <li>• Proportion of patients with a GPPGA total score of 0 or 1 at the end of week 1</li> <li>• Changes from baseline in pain visual analogue scale (VAS) scores at week 4</li> </ul> <p><i>Spesolimab versus placebo for the prevention of GPP Flares in adults and pediatric patients 12 years and older</i></p> <ul style="list-style-type: none"> <li>• Time to the first GPP flare at up to week 48</li> <li>• Proportion of patients with at least 1 GPP flare at up to week 48</li> <li>• Time to first 4-point worsening of dermatology life quality index (DLQI) questionnaire results up to week 48</li> <li>• Bad reactions</li> <li>• Serious bad reactions</li> </ul>

Drug information	
	<ul style="list-style-type: none"> <li>• Patients leaving the trial due to bad reactions</li> <li>• Bad reactions of special interest: drug-induced liver injury, drug reaction with eosinophilia<sup>a</sup> and systemic symptoms, latent tuberculosis<sup>b</sup>, skin bacterial infections, and swelling under the skin (angioedema).</li> </ul>
Other considerations	None

## Note:

CDA-AMC ([Canada's Drug Agency-L'Agence des Médicaments du Canada](#)) 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 [How PharmaCare Decides Which Drugs to Cover](#).

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, or Cost Per Flare <sup>c</sup>
spesolimab (Spevigo)	Under Review	Vial for IV infusion	Treatment of flares: Single dose. If flare persists, an additional dose may be given 1 week after the first dose.	One dose: <sup>d</sup> \$22,995  Two doses: \$45,990

<sup>a</sup> Eosinophilia occurs when the body produces too many eosinophils. Eosinophils are white blood cells that support the immune system.

<sup>b</sup> Latent tuberculosis is when a person is infected with the tuberculosis bacterium, but does not have active tuberculosis. Active tuberculosis can be contagious while latent tuberculosis is not.

<sup>c</sup> All prices as per PharmaCare Formulary, unless otherwise specified. All weight-based dosing assumes an adult patient weight of 73.7 kg and an adolescent weight of 51.8 kg as well as wastage of excess medication in vials, if applicable.

<sup>d</sup> Manufacturer's submitted price plus 5% 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, or Cost Per Flare <sup>c</sup>
		Prefilled syringe for SC injection	Prevention of flares: Loading dose, followed by maintenance dose every 4 weeks.	First year: <sup>d</sup> \$107,652  Subsequent years: \$99,987
<b>Treatments Used Off-label for the Treatment of Generalized Pustular Psoriasis Flares</b>				
acitretin (Mint-Acitretin)	Regular Benefit, <a href="#">Subject to LCA</a>	Capsule	Adult: Once daily  Adolescent: Once daily, dosed in mg/kg	Cost per flare: \$69 to \$138
apremilast (Auro-Apremilast)	Non-Benefit	Tablet	Twice daily	Cost per flare: \$1,049 <sup>e</sup>
betamethasone dipropionate (generics)	Regular Benefit, <a href="#">Subject to LCA</a>	0.05% Ointment	Thin film applied to cover affected area once to twice daily	Cost per flare: \$12
calcipotriol (Dovonex)	Regular Benefit	Ointment	Applied once weekly	Cost per flare: \$373 to \$497
cyclosporine (Sandoz Cyclosporine)	<a href="#">Limited Coverage</a>	Capsule	Once daily, dosed in mg/kg of body weight	Cost per Flare: Adult: \$139 to \$349  Adolescent: \$93 to \$232
guselkumab (Tremfya)	Non-Benefit	Pre-filled syringe or autoinjector	Once at week 0 and week 4	Cost per flare: \$6,119 <sup>e</sup>
infliximab (Renflexis - biosimilar)	<a href="#">Limited Coverage</a>	Vial for IV infusion	Initial dose followed by doses at 2 and 6 weeks, dosed in mg/kg	Cost per Flare: Adult: \$6,212  Adolescent: \$4,659

<sup>e</sup> Price as per CDA-AMC Pharmacoeconomic Review Report for spesolimab.

<b>Cost of the drug compared to other drugs used to treat the same indication</b>				
<b>Generic Name (Brand Name) of Drug Comparator</b>	<b>PharmaCare Status (if and how the drug is already covered)</b>	<b>Dosage Form</b>	<b>Usual Dose</b>	<b>Annual Cost of Therapy, or Cost Per Flare<sup>c</sup></b>
ixekizumab (Taltz)	<a href="#">Limited Coverage</a> for psoriatic arthritis and plaque psoriasis	Pre-filled syringe or autoinjector	Initial dose at week 0, followed by doses at weeks 2, 4, 6, 8,10, and 12	Cost per flare: \$15,667 to \$15,774
methotrexate - PO (Apo-Methotrexate)	Regular Benefit, <a href="#">Subject to LCA</a>	Tablet	Once per week	Cost per flare: \$4 to \$11
secukinumab (Cosentyx)	<a href="#">Limited Coverage</a> for psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis	Pre-filled syringe	Once weekly at weeks 0,1,2,3, and 4	Cost per flare: Adult: \$9,807 Adolescent: \$4,904
ustekinumab (Jamteki, Wezlana and Steqeyma)	<a href="#">Limited Coverage</a> for psoriatic arthritis, plaque psoriasis, Crohn's Disease and Ulcerative Colitis	Pre-filled syringe	Once at weeks 0 and 4, by patient weight in kg	Cost per flare: \$5,787
<b>Treatments Used Off-label for the Prevention of Generalized Pustular Psoriasis Flares</b>				
acitretin (Mint-Acitretin)	Regular Benefit, <a href="#">Subject to LCA</a>	Capsule	Once daily	Annual Cost: \$898
anakinra (Kineret)	Review Pending	Pre-filled syringe	Once daily	Annual cost: \$19,949 <sup>e</sup>
apremilast (Auro-Apremilast)	Non-Benefit	Tablet	Twice daily	Annual cost: \$13,678 <sup>e</sup>
betamethasone dipropionate (generics)	Regular Benefit, <a href="#">Subject to LCA</a>	Ointment	Apply thin film to cover affected area once to twice daily	Annual cost: \$152

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, or Cost Per Flare <sup>c</sup>
cyclosporine (Sandoz Cyclosporine)	<a href="#">Limited Coverage</a>	Capsule	Daily, dosed in mg/kg	Annual cost: Adult: \$1,816 to \$4,548 Adolescent: \$1,211 to \$3,027
etanercept (Rymti)	<a href="#">Limited Coverage</a> for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, juvenile idiopathic arthritis, and plaque psoriasis	Pre-filled syringe	Adult: Once weekly Adolescent: Once weekly, dosed in mg/kg	Annual cost: \$13,264
guselkumab (Tremfya)	Non-Benefit	Pre-filled syringe or autoinjector	Once every 8 weeks	Annual cost: \$19,957 <sup>e</sup>
infliximab (Renflexis)	<a href="#">Limited Coverage</a>	Vial for IV infusion	Every 8 weeks, dosed in mg/kg	Annual cost: Adult: \$13,459 Adolescent: \$10,094
ixekizumab (Taltz)	<a href="#">Limited Coverage</a> for psoriatic arthritis and plaque psoriasis	Pre-filled syringe or autoinjector	Every 4 weeks	Annual cost: \$25,459 to \$25,633
methotrexate -PO (Apo-Methotrexate)	Regular Benefit, <a href="#">Subject to LCA</a>	Tablet	Once per week	Annual cost: \$56 to \$141
secukinumab (Cosentyx)	<a href="#">Limited Coverage</a> for psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis	Pre-filled syringe	Adults: Once every 2 to 4 weeks Adolescent: Once every 4 weeks	Annual cost: Adult: \$25,499 to \$50,999  Adolescent: \$12,450

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, or Cost Per Flare <sup>c</sup>
ustekinumab (Jamteki, Wezlana and Steqeyma)	<a href="#">Limited Coverage</a> for psoriatic arthritis, plaque psoriasis, Crohn's disease and ulcerative colitis	Pre-filled syringe	Once every 12 weeks by weight in kg	Annual cost: Adult: \$12,530 Adolescent: \$6,265

### 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 Agency-L'Agence des médicaments du Canada \(CDA-AMC\)](#)
- 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 [How PharmaCare decides which 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.

