

# 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)	<b>belimumab</b>
Brand name	<b>Benlysta</b>
Manufacturer	GlaxoSmithKline Inc.
Indication	Lupus nephritis, adults
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 belimumab (Benlysta), you can <a href="#">Search the CDR Reports</a> .
Public input start date	Wednesday, October 26, 2022
Public input closing date	<b>Tuesday, November 22, 2022 AT 11:59 PM</b>
How is the drug taken?	Belimumab can be administered intravenously (through a vein) or by subcutaneous (under the skin) injection.
How often is the drug taken?	Intravenous (IV) belimumab is given at 2-week intervals for the first 3 doses and then every 4 weeks thereafter. Subcutaneous (SC) belimumab is given as two injections once weekly for 4 weeks and then one injection once weekly thereafter.

General drug and/or drug study information	<p>Belimumab is used to treat lupus nephritis in adults. Lupus nephritis is a kidney disease caused by systemic lupus erythematosus (SLE), more commonly known as “lupus.” SLE is a disease that causes the immune system to attack the body’s tissues and organs. Lupus nephritis occurs when lupus autoantibodies damage the parts of the kidneys that filter out waste. This causes kidney inflammation and may lead to high blood pressure, impaired kidney function, and kidney failure.</p> <p>People with SLE often have high levels of a protein called B lymphocyte simulator (BLyS) in their blood. BLyS plays a role in the functioning of a type of white blood cell, called B cells. The abnormal activity of B cells is thought to play an important role in SLE and may lead to the damage of multiple organ systems, including the kidneys. Belimumab works to reduce tissue damage by inhibiting the activity of BLyS and B cells.</p> <p>Studies looked at the following:</p> <ul style="list-style-type: none"> <li>• Primary efficacy renal response (PERR)<sup>a</sup> at week 52 and week 104</li> <li>• Complete renal response (CRR)<sup>b</sup> at week 104</li> <li>• Ordinal renal response (ORR)<sup>c</sup> at week 104</li> <li>• Time to renal-related event or death</li> <li>• Changes from baseline in the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-S2K) score</li> <li>• SLEDAI-S2K score &lt; 4 at week 104</li> <li>• Prednisone use</li> <li>• Severe SLEDAI Flare Index (SFI) Flares</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 such as any post-infusion related systemic reactions, serious infections, including herpes zoster (shingles), active tuberculosis, and sepsis, malignancies, including non-melanoma skin cancer, basal cell carcinoma, papillary thyroid cancer, and thymoma (cancer of the thymus), and serious suicidal behaviour.</li> </ul>
Other considerations	None

**Note:**

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

<sup>a</sup> The primary efficacy renal response (PERR) is defined as: A ratio of urinary protein to creatinine of 0.7 or less, an estimated glomerular filtration rate (eGFR) that was no worse than 20% below the pre-flare value or at least 60 ml per minute per 1.73 m<sup>2</sup>, and no use of rescue therapy for treatment failure.

<sup>b</sup> The complete renal response (CRR) was a composite outcome that was considered achieved when all 3 of the following were met: 1) Urine protein creatinine ratio (uPCR) ≤ 0.5, 2) estimated glomerular filtration rate (eGFR) was no more than 10% below pre-flare value or within the normal range ≥ 90 mL/min/1.73m<sup>2</sup>, and 3) not a treatment failure (i.e., patients who did not take protocol prohibited or restricted medication or dose specified in the protocol).

<sup>c</sup> An ordinal response is a limited series of possible outcomes that have been placed in a ranked order. In this case, the possible ordinal responses, listed in ranked order, were 1) complete renal response, 2) partial renal response, or 3) no response.

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](#).

<b>Cost of the drug under review 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<sup>a</sup></b>
Belimumab (Benlysta)	Under Review	Single-use vials Lyophilized powder for IV infusion	Every 2 weeks for the first 3 doses, then every 4 weeks	Year 1: \$27,235 <sup>b</sup> Year 2+: \$24,426
	Non-Benefit	Solution for SC injection	Once weekly	\$21,163 <sup>b</sup>
<b>Antimalarial Drugs (Off-label Use)</b>				
Hydroxychloroquine (generics)	Regular Benefit	Oral Tablet	Once daily	\$62 to \$124
<b>Corticosteroids (Off-label Use)</b>				
Prednisone (generic)	Regular Benefit	Oral Tablet	Once daily	\$63 to \$111
<b>Immunosuppressants or Immune Modulators (Off-label Use)</b>				
Azathioprine (generic)	Regular Benefit	Oral Tablet	Once daily	\$284
Cyclophosphamide (Procytox)	Non-Benefit	Vials Powder for Injection	Every 2 weeks for 6 doses	\$587 <sup>c</sup>
Cyclosporine (generic)	<a href="#">Limited Coverage</a>	Capsules	Once daily	\$2,689 to \$4,085
	Non-Benefit	Solution for injection		\$4,190 to \$6,983 <sup>a</sup>
Mycophenolic acid (Myfortic)	Non-Benefit	Tablets	Once daily	\$4,054 to \$6,080 <sup>a</sup>
Mycophenolate mofetil (generic)	<a href="#">Limited Coverage<sup>d</sup></a> Non-Benefit for Lupus Nephritis and SLE	Oral Tablet	Once daily	\$1,170 to \$1,756
Tacrolimus (generics)	Non-Benefit	Capsules	Once daily	\$2,416 to \$4,832 <sup>a</sup>
<b>Monoclonal Antibodies (Off-label Use)</b>				

<sup>a</sup> All prices as per PharmaCare formulary, unless otherwise specified. A weight and body surface area of 70 kg and 1.8 m<sup>2</sup> was assumed.

<sup>b</sup> Price as per CDR Pharmacoeconomic Review Report for belimumab (Benlysta) plus 5% markup.

<sup>c</sup> Price as per CDR Pharmacoeconomic Review Report for belimumab (Benlysta).

<sup>d</sup> Limited coverage for the treatment of autoimmune hepatitis and/or for the treatment of bullous pemphigoid.

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 <sup>a</sup>
Rituximab (biosimilars)	<a href="#">Limited Coverage<sup>a</sup></a> Non-Benefit for lupus nephritis and SLE	Solution for IV Injection	2 doses, 2 weeks apart	\$6,415

### 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.

<sup>a</sup> Limited coverage for the treatment of rheumatoid arthritis (RA), Granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), and relapsing-remitting multiple sclerosis (RRMS).