

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)	anifrolumab
Brand name	Saphnelo™
Manufacturer	AstraZeneca Canada Inc.
Indication	Systemic lupus erythematosus (SLE)
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 anifrolumab (Saphnelo), you can Search the CDR Reports .
Public input start date	Wednesday, May 25, 2022
Public input closing date	Wednesday, June 22, 2022, AT MIDNIGHT
How is the drug given?	Anifrolumab is given by intravenous (IV) infusion. This medication is put directly into the bloodstream, through a vein.
How often is the drug given?	Anifrolumab is given every 4 weeks.

General drug and/or drug study information

Anifrolumab (Saphnelo) is used to treat systemic lupus erythematosus (SLE). SLE is a disease of the immune system. Patients with SLE can experience fatigue, joint pain, rash, issues with the heart, kidneys, and brain, and a variety of other symptoms.

Anifrolumab is a monoclonal antibody (a type of specialized protein) that blocks the action of a group of proteins called Type I Interferons (IFN). Type I Interferons are found at high levels in people with lupus and blocking them can reduce the inflammation in your body that causes the signs and symptoms of lupus. Anifrolumab may help to reduce your lupus disease activity and the number of lupus flares you are experiencing.

Studies looked at the following:

- Safety and effectiveness of anifrolumab compared to placebo (sugar pill)
- Changes from baseline in British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment (BICLA) test results. The BILAG index is tool for measuring disease activity in SLE. This test gives alphabetic scores (A-E) to disease activity in eight organ-based systems, including the skin, nervous system, heart and lungs, kidneys, blood, eyes, muscles, and digestive tract.
- Changes from baseline in SLE Responder Index (SRI) scores. The SRI score combines the results of 3 different measures of disease activity in patients with SLE. SLE has a broad range of different symptoms and the SRI acts as a tool for measuring and assessing them as a whole.
- Changes from baseline in Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) scores. This tool also measures overall disease activity, including skin rashes, hair loss, mucosal ulcers (sores), and the increased presence of proteins in the urine.
- Reductions in oral corticosteroid (OCS) use
- Changes from baseline in health-related quality of life (HRQoL) as measured by standardized tests
- Changes from baseline in Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F) scores. FACIT-F is a 40-item test that assesses self-reported fatigue and its impact upon daily activities and function.
- Changes from baseline in Cutaneous LE Disease Area and Severity Index (CLASI) activity. This test measures the impact of SLE on patients' skin, including the hair, scalp, and mucous membranes (i.e., the skin at the opening of the nose, mouth, eyes, ears, lip, vagina, urethra, and anus).
- Annual flare (worsening of symptoms) rate through week 52
- Reductions in joint inflammation
- Bad reactions
- Serious bad reactions
- Patients leaving the trial due to bad reactions

Information about the drug	
	<ul style="list-style-type: none"> Bad reactions of special interest (for example, shingles, serious infections, hypersensitivity to the treatment, reactions to the infusion, depression, thoughts of suicide, and cancers)
Other considerations	

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 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				
generic name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose ^a	Annual Cost of Therapy or Per Course of Therapy
anifrolumab (Saphnelo)	Under Review	Vial for intravenous infusion	Once every 4 weeks	\$23,689 ^b
Antimalarial drugs				
hydroxychloroquine (generic)	Regular Benefit, subject to LCA	Tablet	Once daily	\$62 to \$124
Corticosteroids				
prednisolone (generic)	Regular Benefit	Oral solution	Once daily	Up to \$372
Immunosuppressants				
azathioprine (generic)	Regular Benefit	Tablet	Once daily	\$95 to \$190
methotrexate (generic)	Regular Benefit	Tablet	Once weekly	\$152
	Non-Benefit	Vial for injection		\$231 ^c
mycophenolate mofetil (generic)	Limited Coverage^d Non-Benefit for systemic lupus erythematosus	Capsule	Once daily	\$878 to \$1170

^a Any weight-based dosing assumes a patient weight of 70 kg.

^b Price as per CDR Pharmacoeconomic Review Report for Saphnelo plus 8% markup.

^c This footnote is just acting as a placeholder for the comments. If I delete the footnote, the comments will disappear. I will delete it.

^d 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 ^a	Annual Cost of Therapy or Per Course of Therapy
Rituximab (Biosimilars)	Limited Coverage^e Non-Benefit for systemic lupus erythematosus	Vial for IV infusion	Once on day 1 and 15 of an infusion cycle	\$6,415 per infusion cycle
Cyclophosphamide (Procytox)	Non-Benefit	Vial for IV infusion	≤2.5 mg/kg daily	Up to \$25,097 per year

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.

^e Limited coverage for the treatment of rheumatoid arthritis (RA), Granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), and relapsing-remitting multiple sclerosis (RRMS).