

Reimbursement Recommendation

Anifrolumab SC (Saphnelo SC)

Indication: In addition to standard therapy for the treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus

Sponsor: AstraZeneca Canada Inc.

Final recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Saphnelo SC?

Canada's Drug Agency (CDA-AMC) recommends that Saphnelo subcutaneous (SC) be reimbursed by public drug plans in addition to standard therapy for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) if certain conditions are met.

Why Did CDA-AMC Recommend Reimbursement?

The Canadian Drug Expert Committee (CDEC) subcommittee determined that Saphnelo SC demonstrates acceptable clinical value versus placebo or Saphnelo IV in patients with SLE. This determination was enough for the CDEC subcommittee to recommend that Saphnelo SC be reimbursed. Given that Saphnelo is expected to be an alternative to placebo or Saphnelo IV, acceptable clinical value refers to at least comparable value versus placebo or Saphnelo IV.

Evidence from 1 phase III, randomized controlled trial (TULIP-SC) comparing Saphnelo SC with placebo (standard of care) in 367 patients with SLE demonstrated there were clinical benefits observed with Saphnelo, including an increased British Isles Lupus Assessment Group-based Composite Lupus Assessment (BICLA) response, which is a composite global measure of SLE disease activity. According to the clinical experts consulted for this review, the reporting of harms was as they expected and broadly consistent with the safety profile for Saphnelo IV. The SC and IV formulations were compared in bioequivalence studies that were reviewed by Health Canada; the SC formulation received its Notice of Compliance (NOC) on March 5, 2026.

The availability of a SC formulation may address an unmet need to improve the ease of administration for patients by alleviating treatment burden associated with the IV formulation. This may include travel time to an infusion centre and resources required by the health care system to support IV infusion. However, there is a lack of direct clinical evidence to inform how Saphnelo SC compares with Saphnelo IV, and the efficacy of Saphnelo SC relative to all relevant comparators available in practice is uncertain.

Which Patients Are Eligible for Coverage?

Saphnelo SC should only be reimbursed for patients with active, autoantibody-positive SLE in line with the Health Canada indication.

Summary

What Are the Conditions for Reimbursement?

Saphnelo SC should only be reimbursed similar to each public drug plan's current initiation, renewal, discontinuation, and prescribing criteria for Saphnelo IV for the treatment of adult patients with active, autoantibody-positive SLE and if the total drug acquisition cost of Saphnelo SC does not exceed the total drug acquisition cost for Saphnelo IV.

Review Background

- **Disease background:**

- Lupus is a chronic and debilitating rheumatic autoimmune disease and SLE is the most common and serious form of the disease. Diagnosing SLE is complex because the disease presents in a heterogenous fashion, with initial symptoms that are often nonspecific (e.g., fatigue, arthralgia, anorexia) and with further manifestations presenting over the course of months or years.
- Prevalence rates may vary based on case definitions or detection rates; in 2017, SLE was estimated to affect approximately 1 in every 2,000 individuals living in Canada.

- **Indication and reimbursement request:** Anifrolumab (Saphnelo) has been approved by Health Canada, in addition to standard therapy, for the treatment of adult patients with active, autoantibody-positive SLE. The sponsor is requesting the reimbursement criteria for anifrolumab SC to align with the 2023 CDA-AMC reimbursement recommendation for anifrolumab IV formulation.
- **Drug under review:** Anifrolumab is a type 1 IFN receptor antagonist. It is available as an IV infusion or SC injection. The focus of this tailored review is on the SC formulation with 120 mg per 0.8 mL autoinjector; the dosage recommended in the product monograph is 120 mg once weekly.
- **Treatment costs:** At the submitted price of \$1,736.14 per 4-pack unit, the annual cost of anifrolumab SC is expected to be \$22,647 per patient based on the Health Canada–recommended dosage.
- **Tailored review process:** This application was reviewed through the tailored review process. When submitting an application for a tailored review, the sponsor does not claim added clinical benefit with the drug under review compared with the most appropriate comparators. A subcommittee of the relevant expert committee deliberates on and, when there is unanimous agreement, issues the recommendation for tailored review applications. The focus of the subcommittee deliberations is on whether the evidence supports that the drug under review demonstrates comparable clinical benefit and harms to 1 or more appropriate comparators, and whether the evidence supports the drug being reimbursed in accordance with the existing reimbursement criteria for the most appropriate comparators.

Highlights of Input From Interested Parties

The patient groups (Arthritis Consumer Experts, Lupus Canada, The Canadian Arthritis Patient Alliance, and Lupus Ontario) noted the following regarding impacts of the disease, unmet needs, and important outcomes:

- SLE has wide-ranging impacts on their lives, including financial impacts due to work absenteeism for medical appointments; inability to participate in daily activities, particularly physical activities; and effects on emotional well-being.
- SLE impacts nearly all aspects of patients' lives to varying degrees, with many reporting long delays in diagnosis, limited access to specialists and culturally appropriate care, and reimbursement barriers.

The clinician groups (the Canadian Network for Improved Outcomes in SLE, the Canadian Rheumatology Association, and the Toronto Lupus Program) and the clinical experts consulted by CDA-AMC noted the following regarding unmet needs arising from the disease and place in therapy for the drug under review:

- Most clinicians align with the 2023 update of the European Alliance of Associations for Rheumatology (EULAR) recommendations and the 2025 American College of Rheumatology guidelines for the management of SLE. A general treatment paradigm has shifted toward earlier introduction of biologic therapies as well as rapid escalation and greater focus on achieving a lupus low disease activity state (LLDAS) as a goal of therapy.
- There is also emphasis on relying less on long-term glucocorticoid therapy as well as recognizing organ damage accrual in patients due to glucocorticoid therapy and persistent mild to moderate disease.
- Anifrolumab SC should be considered in the same place in treatment paradigms as the current IV formulation, and patients with antibody-positive, moderate (Systemic Lupus Disease Activity Index [SLEDAI] score ≥ 6) to severe (SLEDAI score ≥ 10) disease activity despite background hydroxychloroquine and glucocorticoid treatment (particularly at doses > 7.5 mg per day) would be suitable candidates for treatment.

The participating public drug programs raised potential implementation issues related to considerations for relevant comparators, initiation, renewal, and prescribing of therapy, generalizability, care provision issues, and system and economic issues.

Recommendation

The subcommittee of CDEC recommends that anifrolumab SC be reimbursed in addition to standard therapy for the treatment of adult patients with active, autoantibody-positive SLE only if the conditions listed in [Table 1](#) are met.

Table 1: Reimbursement Conditions and Reasons

Reimbursement condition	Reason	Implementation guidance
Initiation, renewal, discontinuation, and prescribing		
1. The eligibility for reimbursement of anifrolumab SC should be similar to each public drug plan's current criteria for anifrolumab IV for the following indication: in addition to standard therapy for the treatment of adult patients with active, autoantibody-positive SLE. This alignment should apply to all aspects of coverage, including initiation, renewal, discontinuation, and prescribing requirements.	Evidence from the TULIP-SC study showed that when anifrolumab SC treatment was compared to placebo (plus standard of care), there was an improved BICLA response and a reduction in the proportion of patients with an oral corticosteroid dose of 7.5 mg per day or less. The results of bioequivalence analyses comparing the SC and IV formulations of anifrolumab were reviewed by Health Canada, and the NOC for anifrolumab SC formulation was issued on March 5, 2026. Based on	Refer to the product monograph for guidance on transitioning between routes of administration.

Reimbursement condition	Reason	Implementation guidance
	this, the CDEC subcommittee anticipated the 2 routes of administration of anifrolumab would be considered acceptable by Health Canada and will be prescribed by clinicians based on patients' preferences. The CDEC subcommittee considered it appropriate to align the reimbursement conditions for anifrolumab SC with current public drug plan reimbursement criteria in Canada for anifrolumab IV.	
Pricing		
2. The cost of anifrolumab SC should be negotiated so that it does not exceed the drug acquisition costs with anifrolumab IV for the same indication.	Based on the subcommittee's assessment of the evidence, anifrolumab SC is expected to have comparable clinical benefits and harms compared with anifrolumab IV. Therefore, the total drug acquisition cost of anifrolumab SC should be no more than the total drug acquisition cost anifrolumab IV.	—

BICLA = British Isles Lupus Activity Group-based Composite Lupus Assessment; CDEC = Canadian Drug Expert Committee; NOC = Notice of Compliance; SC = subcutaneous; SLE = systemic lupus erythematosus.

Rationale for the Recommendation

Clinical Value

The subcommittee deliberated on whether the evidence supports that anifrolumab SC demonstrates comparable clinical benefit and harms to 1 or more appropriate comparators in patients with SLE. The evidence from the TULIP-SC trial demonstrated anifrolumab SC has comparable clinical benefit to placebo. The bioequivalence analyses reviewed by Health Canada also indicated the 2 formulations are comparable pharmacokinetically, and the input from clinical experts confirms the 2 formulations can be prescribed for the treatment of SLE in clinical practice. Based on the totality of the clinical evidence, the subcommittee concluded that anifrolumab SC has acceptable clinical value.

Evidence from 1 phase III randomized controlled trial (TULIP-SC) comparing anifrolumab SC with placebo in 367 patients with SLE demonstrated that there was an increased BICLA response at 52 weeks (risk difference [RD] = 19.1%; 95% confidence interval [CI], 9.0% to 29.2%; $P = 0.0002$) and a BICLA response with maintained or low oral corticosteroid use at 52 weeks (RD = 22.3%; 95% CI, 12.3% to 32.2%; $P = < 0.0001$), versus placebo, although the results are imprecise based on the minimally important difference (MID) threshold of approximately 14% provided by clinical experts. According to the clinical experts consulted for this review, the reporting of harms was as expected and broadly consistent with the safety profile for anifrolumab IV. The SC and IV formulations were considered comparable pharmacokinetically in bioequivalence studies that were reviewed by Health Canada; the SC formulation received its NOC on March 5, 2026.

The availability of a SC formulation may address an unmet need to improve the ease of administration for patients by alleviating treatment burden associated with the IV formulation, which may include travel time to an infusion centre and resources required to support IV infusion. There is a lack of direct clinical evidence to inform how anifrolumab SC compares with anifrolumab IV, and the efficacy of anifrolumab SC relative to all relevant comparators including placebo and anifrolumab IV is uncertain.

Further information on the subcommittee's discussion around clinical value is provided in the Summary of Deliberation section.

Developing the Recommendation

The determination of acceptable clinical value was sufficient for the CDEC subcommittee to recommend reimbursement of anifrolumab SC.

Because the CDEC subcommittee recommended that anifrolumab SC be reimbursed, the subcommittee also deliberated on whether reimbursement conditions should be added to address important economic considerations, health system impacts, or social and ethical considerations, or to ensure clinical value is realized. The resulting reimbursement conditions, with accompanying reasons and implementation guidance, are stated in [Table 1](#).

Summary of Deliberation

The subcommittee considered all domains of value of the deliberative framework before developing its recommendation: clinical value, unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems. For further information on the domains of value, refer to [Expert Committee Deliberation at Canada's Drug Agency](#).

The subcommittee considered the following key discussion points, organized by the 5 domains of value.



Clinical Value

- **Appropriate comparators:** The subcommittee considered both placebo and anifrolumab IV as appropriate comparators for the drug under review.
- **Efficacy versus standard of care (placebo):** Evidence from 1 phase III randomized controlled trial (TULIP-SC) comparing anifrolumab SC with placebo in 367 patients with SLE, demonstrated that there was an increased BICLA response at 52 weeks (RD = 19.1%; 95% CI, 9.0% to 29.2%; P = 0.0002) and a BICLA response with maintained or low oral corticosteroid use at 52 weeks (RD = 22.3%; 95% CI, 12.3% to 32.2%; P = < 0.0001), versus placebo, although the results were imprecise based on the threshold of approximately 14% provided by clinical experts. There was also a reduction in the proportion of patients with an oral corticosteroid dosage of 7.5 mg per day or less (RD = 21.0%; 95% CI, 7.2% to 34.8%; P = 0.0029) and an increase in the proportion of patients with the Systemic Lupus Erythematosus Responder Index (SRI) (RD = 15.7%; 95% CI, 5.7% to 25.7%;

$P = 0.0020$), although the results are imprecise based on the MID threshold of approximately 14% provided by clinical experts. Results for an annualized flare rate were not significant between study arms (rate ratio = 0.78; 95% CI, 0.57 to 1.08; $P = 0.1311$). According to the clinical experts consulted for this review, the reporting of harms was as expected and broadly consistent with the safety profile for anifrolumab IV.

- Efficacy versus anifrolumab IV:** The SC and IV formulations were compared in bioequivalence studies comprised of an exposure efficacy and exposure safety analysis of anifrolumab SC and IV and a population pharmacokinetic analysis of anifrolumab. Findings were reviewed by Health Canada, with results to support that the 2 formulations are pharmacokinetically comparable, with the NOC for the SC formulation issued on March 5, 2026. Although there was no direct clinical evidence to inform how anifrolumab SC compares with anifrolumab IV, the clinical experts consulted for this review said they considered anifrolumab SC and IV to be identical and expect the treatment to produce treatment response when administered in either the IV or SC formulation.
- Clinical importance of treatment effects:** The subcommittee considered the treatment effects to be clinically meaningful. The primary outcome of BICLA is a composite response that measures symptom improvement by the British Isles Lupus Assessment Group (BILAG-2004) disease activity index, no worsening measured by the SLEDAI-2K, and no worsening of lupus disease activity. This aligns with the clinician group input that noted a treatment response could be considered as a reduction in severity and frequency of symptoms, a reduction in daily prednisone dose, or a reduction in frequency and intensity of flares. Clinical experts consulted for this review also highlighted that a reduction in prednisone with low disease activity could be considered a treatment response. Based on input from patient groups, clinician groups, and clinical experts consulted for this review, the SC formulation of anifrolumab may address an unmet need by offering an added treatment option that is easier to administer and can potentially alleviate treatment burden typically associated with IV administration.
- Certainty of the evidence:** In the TULIP-SC trial, there were factors that contributed to the uncertainty of the evidence comparing anifrolumab SC to placebo. These included some imbalances between the 2 treatment arms in terms of concomitant medications and discontinuations during the trial, methodological limitations of the study design regarding study interim analysis and a lack of sensitivity analyses for some outcomes, and factors related to external validity, including racial and ethnic characteristics of participants and dosages of concomitant drugs. These limitations contributed to the imprecision of the results. There was also the lack of direct comparison between the SC and IV formulations of anifrolumab. Overall, the evidence is uncertain.
- Clinical value:** Based on all the preceding considerations, the subcommittee determined there was comparable or similar clinical value versus appropriate comparators (placebo or anifrolumab IV).



Unmet Clinical Need

- Input on unmet clinical need:** The subcommittee acknowledges that the availability of the SC formulation may address the unmet needs by offering a more convenient route of administration for

patients. Because the SC formulation can be taught and self-administered at home by the patient or caregiver, this option can alleviate treatment burden related to travel, resources to the health care system, and work absenteeism related to patient appointments for administration and monitoring of the IV formulation. These unmet needs were highlighted by input received from the patient groups, clinician groups, and the clinical experts consulted for this review.

- **Deliberation on significant unmet clinical need:** The subcommittee reviewed the considerations for unmet clinical need. Given that deliberations for tailored reviews have a specific focus, further deliberation on whether there was significant unmet clinical need was not required.



Distinct Social and Ethical Considerations

- **Deliberation on significant nonclinical need or health inequity:** The subcommittee reviewed the considerations for unmet nonclinical need and health inequity. Given that deliberations for tailored reviews have a specific focus, further deliberation on whether the drug under review addresses a significant unmet nonclinical need or health inequity was not required.



Economic Considerations

- **Cost of anifrolumab SC versus anifrolumab IV:** At the submitted price of \$1,736.14 per 4-pack unit, the annual cost of anifrolumab SC is expected to be \$22,647 per patient. The reimbursement of anifrolumab SC is expected to result in no additional costs to the health care system versus anifrolumab IV based on public list prices. The subcommittee noted that the sponsor currently funds a patient support program for anifrolumab IV. As a result, administration costs are not currently paid for by public drug plans or the public health system. The funding of anifrolumab SC is therefore not expected to increase health care resource use costs, contingent on the continued provision of the sponsor's patient support program for anifrolumab SC and IV.



Impacts on Health Systems

- **Anticipated budget impact:** CDA-AMC estimated that by year 3 of reimbursement, 7,181 patients would be eligible for anifrolumab SC; of these, 3,949 patients are expected to receive anifrolumab SC. The sponsor estimates that the budget impact of reimbursing anifrolumab SC for SLE will be \$0 to public drug plans over the first 3 years of reimbursement compared to the amount currently spent on anifrolumab IV, with an expected expenditure of \$14 million on anifrolumab SC over this period. CDA-AMC was unable to provide a more robust estimate of the expected budget impact owing to a lack of reliable estimates. Whether there will be budget neutrality to the public drug plans is uncertain and will depend on the negotiated price of anifrolumab SC and its comparator.

Sources of Information Used by the Subcommittee

To make its recommendation, the subcommittee considered the following information (links to the full documents for the review can be found on the [project web page](#)):

- the CDA-AMC review of the clinical and pharmacoeconomic evidence submitted by the sponsor related to anifrolumab SC (refer the Main Report and Supplemental Material document)
- the sponsor's comments on the draft report and the CDA-AMC responses
- patients' perspectives gathered by 3 patient groups (Arthritis Consumer Experts, Lupus Canada, The Canadian Arthritis Patient Alliance, and Lupus Ontario) (refer to the Patient and Clinician Group Input document)
- input from 3 clinician groups (the Canadian Network for Improved Outcomes in SLE, the Canadian Rheumatology Association, and the Toronto Lupus Program) (refer to the Patient and Clinician Group Input document)
- input from public drug programs that participate in the reimbursement review process (refer to the Supplemental Material document)
- input from 2 clinical experts with expertise in the management of SLE consulted by CDA-AMC.

All feedback received in response to the draft recommendation is available on the CDA-AMC [project web page](#).

CDEC Information

Members of the Committee

Dr. Peter Jamieson (Chair), Dr. Kerry Mansell (Vice-Chair), Sally Bean, Daryl Bell, Dan Dunskey, Dr. Ran Goldman, Dr. Trudy Huyghebaert, Dr. Dennis Ko, Dr. Christine Leong, Dr. Alicia McCallum, Dr. Srinivas Murthy, Dr. Nicholas Myers, Dr. Krishnan Ramanathan, Dr. Marco Solmi, Carla Velastegui, Dr. Edward Xie, and Dr. Peter Zed.

A subcommittee composed of 4 CDEC members was convened. None had a conflict of interest that precluded their participation.

Meeting date: May 27, 2026

Regrets: None

Conflicts of interest: None



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