Saphnelo (Anifrolumab) – Request for Reimbursement - Exceptional Access Program (EAP)

Fax the completed form and/or any additional/relevant information to (416) 327-7526 or toll-free to 1-866-811-9908; or send your request to Delivery Eligibility Review Branch, Exceptional Access Program, 3rd Floor, 5700 Yonge Street, Toronto, ON, M2M 4K5.

SECTION 1 - Prescriber Information

First Name	Initial	Last name

Street no.	Street Name

City	Postal Code

Fax Number	Telephone Number

SECTION 2- Patient Information

First Name	Initial	Last name

Healthcard Number

Date of Birth (yyyy/mm/dd)

SECTION 3 - Drug Requested

Anifrolumab (Saphnelo)
150 mg/mL (300 mL vial)
(DIN 02522845)

☐ Initial request to the EAP.

Is the patient currently on anifrolumab?
☐ Yes (Fill section 4, 5, 6): Start Date_____
☐ No (Fill section 4, 5)

☐ Renewal request with a prior EAP approval (Fill section 6)

Approved EAP request #

Dosage Requested
☐ 300 mg IV every 4 weeks Other dose:

Expected Start Date

SECTION 4 – Clinical Information

1. Does the patient have Moderate to Severe Systemic Lupus erythematosus as defined by a SLE Disease Activity Index 2000 (SLEDAI-2K) score equal to or greater than 6? ☐Yes ☐ No

   Specify the patient's SLEDAI-2K score **BEFORE** initiating anifrolumab _____ and include a copy of the SLEDAI-2K data score sheet with your application.
   (OR if the British Isles Lupus Assessment Group (BILAG)-2004 Index was used for the baseline assessment, you may provide this baseline evaluation and subsequent evaluations will be assessed case-by-case in accordance to the BILAG-2004 baseline provided.)
2. Does the patient have autoantibody positive SLE? ☐Yes ☐ No

   Submit a copy of the Antinuclear Antibody Screening test results with your application.
3. Is the patient experiencing inadequate disease control from an oral corticosteroid dose of at least 10 mg daily of prednisone (or another equivalent corticosteroid) in addition to standard of care therapy for SLE?

   ☐Yes ☐ No

In Section 5 below, complete the details of corticosteroid use below including the names, doses and responses to other standard of care therapies used to manage this patient's SLE.

4. Is the request from a prescriber with expertise in the diagnosis and management of SLE? ☐Yes ☐ No
5. **Does the patient meet any of the following exclusion criteria**?
   i) Is anifrolumab used in combination with other biologic treatments for SLE? ☐Yes ☐ No
   ii) Does the patient have severe or unstable neuropsychiatric SLE? ☐Yes ☐ No
   iii) Does the patient have severe active SLE nephritis? ☐Yes ☐ No

SECTION 5 - Current /Previous Treatment (Provide information about use of standard treatment for SLE below)

Name of Drug	Dosage	Start date	End date	Response or other Clinical details
Prednisone ☐ Current ☐Previous				
☐ Current ☐Previous				
☐ Current ☐Previous				
☐ Current ☐Previous				

Additional therapies:

SECTION 6 – Renewal information

1. After using 9 to 12 months of anifrolumab treatment, complete the following information of the response to treatment?
   - What is the current dose of prednisone or oral corticosteroid while on anifrolumab?
   - What is the patient's current SLEDAI-2K score? (Please submit the data score sheet with your application)

   If BILAG-2004 index was used at baseline, provide the BILAG-2004 evaluation of organ for case-by-case review.

Prescriber Signature (mandatory)	License number:	Date (yyyy/mm/dd)