Australian Government
Services Australia

medicare

PBS

Systemic lupus erythematosus – anifrolumab – initial authority application

When to use this form

Use this form to apply for **initial** PBS-subsidised anifrolumab for patients with systemic lupus erythematosus.

Important information

Initial applications to start PBS-subsidised treatment must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for systemic lupus erythematosus **initial** authority applications.

The information in this form is correct at the time of publishing and may be subject to change.

Continuing treatment

This form is ONLY for **initial** treatment.

After a written authority application for **initial** treatment has been approved, applications for **continuing** or **recommencement** of treatment (within 12 months of a treatment break) can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

Section 100 arrangements for anifrolumab

This item is available to a patient who is attending:

- an approved private hospital, **or**
- a public hospital

and is a:

- day admitted patient
- non-admitted patient, **or**
- patient on discharge.

This item is not available as a PBS benefit for in-patients of a public hospital.

The hospital name and provider number must be included in this authority form.

For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

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Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

6 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

7 Hospital name

This hospital is a:

☐ public hospital

☐ private hospital

8 Hospital provider number

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

9 Is the patient being treated by a specialist physician experienced in the management of systemic lupus erythematosus (SLE)?

No ☐

Yes ☐

10 Does the patient have a confirmed and documented diagnosis of SLE according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019?

No ☐

Yes ☐

11 Does the patient have persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points?

No ☐

Yes ☐ Provide details of the completed SLEDAI-2K score sheet

SLEDAI-2K score

Date of the score (DD MM YYYY)

12 Does the patient have either severe active lupus nephritis or severe active central nervous system SLE?

No ☐

Yes ☐

MCA0PB365 2502

13 The patient:

☐ is currently taking and has received at least 4 weeks of continuous treatment with prednisolone or equivalent at a dose ≥ 7.5 mg/day

Dose _____ mg/day

From (DD MM YYYY) __ __ __ __ __ __ __ __

To (DD MM YYYY) __ __ __ __ __ __ __ __

or

☐ has a contraindication/severe intolerance to prednisolone or equivalent necessitating permanent treatment withdrawal

Details	Toxicity Grade

14 The patient:

☐ is currently taking and has received at least 12 weeks of continuous treatment with hydroxychloroquine

Dose _____

From (DD MM YYYY) __ __ __ __ __ __ __ __

To (DD MM YYYY) __ __ __ __ __ __ __ __

or

☐ has a contraindication/severe intolerance to hydroxychloroquine necessitating permanent treatment withdrawal

Details	Toxicity Grade

15 The patient:

☐ is currently taking and has received at least 12 weeks of continuous immunosuppressant treatment with:

☐ methotrexate at a dose ≥ 20 mg/week

Dose _____ mg/week

From (DD MM YYYY) __ __ __ __ __ __ __ __

To (DD MM YYYY) __ __ __ __ __ __ __ __

or

☐ azathioprine at a dose ≥ 100 mg/day

Dose _____ mg/day

From (DD MM YYYY) __ __ __ __ __ __ __ __

To (DD MM YYYY) __ __ __ __ __ __ __ __

or

☐ mycophenolate at a dose ≥ 1000 mg/day

Dose _____ mg/day

From (DD MM YYYY) __ __ __ __ __ __ __ __

To (DD MM YYYY) __ __ __ __ __ __ __ __

and/or

☐ has a contraindication/severe intolerance necessitating permanent withdrawal of treatment with:

☐ methotrexate

Details	Toxicity Grade

and/or

☐ azathioprine

Details	Toxicity Grade

and/or

☐ mycophenolate

Details	Toxicity Grade

16 If applicable, provide details of prior anifrolumab use

Dose _____

From (DD MM YYYY) __ __ __ __ __ __ __ __

To (DD MM YYYY) __ __ __ __ __ __ __ __

Systemic therapy	Minimum dose	Minimum treatment period
a) prednisolone	7.5 mg/day	4 weeks
b) hydroxychloroquine	N/A	12 weeks
c) methotrexate	20 mg/week	12 weeks
d) azathioprine	100 mg/day	12 weeks
e) mycophenolate	1000 mg/day	12 weeks

- All patients must trial **a), and b), and either c), or d), or e)**.
- If treatment with a) is contraindicated or the patient is intolerant of required minimum dose for the required 4 weeks of continuous treatment, then the systemic therapy must be **b), and either c), d) or e)**.
- If treatment with a) and b) is contraindicated or the patient is intolerant at required minimum dose for the required treatment period, then the systemic therapy must be **either c), or d), or e)**.
- If any of c), d) or e) is/are contraindicated or cannot be tolerated, a remaining tolerated therapy must be trialled at the minimum dose, unless all 3 options are contraindicated or cannot be tolerated.
- If treatment with each of a), b), c), d) or e) is contraindicated or the patient is intolerant of the required minimum dose for the required treatment period, provide details for each of the contraindications/severe intolerances claimed in the authority application.
- Provide details of contraindications according to the TGA-approved Product Information or intolerances of a severity necessitating permanent withdrawal of any of the prior therapies including the drug name, the degree of toxicity and dose. For details of the toxicity criteria, go to **servicesaustralia.gov.au/healthprofessionals**

Checklist

17 The relevant attachments need to be provided with this form.

☐ Details of the proposed prescription(s).

Privacy notice

18 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application.

Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at **servicesaustralia.gov.au/privacypolicy**

Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

19 I declare that:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine.
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application.
- I have provided details of the proposed prescription(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction.
- the information I have provided in this form is complete and correct.

I understand that:

- giving false or misleading information is a serious offence.

☐ I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

Prescriber's signature (**only** required if returning by post)

If returning by post, print and sign by hand.

Returning this form

Return this form, details of the proposed prescription(s) and any relevant attachments:

- **online** (no signature required), upload through HPOS at **servicesaustralia.gov.au/hpos**

  or

- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

Reset form