Australian Government
Department of Human Services

medicare

PBS

Rheumatoid arthritis
Initial PBS authority application
Supporting information

When to use this form

This form must be completed by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis.

You must lodge this form for an adult patient:

- starting **initial PBS** subsidised treatment with a biological Disease Modifying Anti Rheumatic Drug (bDMARD), excluding rituximab
- **recommencing** PBS subsidised bDMARD treatment where they have failed fewer than five bDMARDs, for which they are eligible, and where the break in treatment is longer than 24 months. Prescribers do not need to complete another patient and prescriber acknowledgement form for these applications.
- starting **initial rituximab** treatment, provided:
  - they have failed prior treatment with a TNFα antagonist and
  - they have failed fewer than five bDMARDs for which they are eligible and
  - the break in treatment is longer than 24 months
  - Prescribers do not need to complete another patient and prescriber acknowledgement form for these applications.

Patients whose most recent course of treatment was PBS subsidised rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab as a continuing patient.

Where the term 'bDMARD' appears, it refers to abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab and tocilizumab only. Patients are eligible for PBS subsidised treatment with only one bDMARD at any time.

Where it is a requirement of the restriction that methotrexate be taken in combination with the bDMARD, the minimum dose is 7.5 mg per week.

All applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

All tests and assessments must be performed at the completion of the six month intensive DMARD trial, prior to ceasing DMARD therapy.

The lodgement of this application must be made within one month of the date of the joint assessment and Erythrocyte Sedimentation Rate (ESR)/C-Reactive Protein (CRP) blood tests.

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

Section 100 arrangements—for abatacept i.v., infliximab, rituximab and tocilizumab

These items are only available to a patient who is attending:

- an approved private hospital
- a public participating hospital

  or
- a public hospital

  and is either:
- a day admitted patient
- a non-admitted patient

  or
- a patient on discharge.

These items are not available as a PBS benefit for in-patients of the hospital. The hospital provider number must be included on the application form

Acknowledgements

The patient's and the prescriber's acknowledgements must be signed in front of a witness (over 18 years of age).

Authority prescription form

A completed authority prescription form must be attached to this form.

The medical indication section of the authority prescription form does not need to be completed when submitted with this form.

Phone approvals

Under no circumstance will phone approvals be granted for complete initial authority applications, or for treatment that would otherwise extend the treatment period.

Applications for continuing treatment

The assessment of the patient's response to an initial course of treatment must be made after a minimum of 12 weeks of treatment. Assessments before 12 weeks of treatment have been completed will not be considered.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Department of Human Services no later than one month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Department of Human Services within these time frames, the patient will be deemed to have failed to respond to treatment.

For more information

If you need assistance completing this form or need more information call **1800 700 270** (call charges apply from mobile phones) and select option 2, between 8.00 am and 5.00 pm Australian Eastern Standard time, Monday to Friday or go to **humanservices.gov.au/healthprofessionals** and search for **Rheumatoid arthritis**

Returning your form(s)

Send the completed authority application form and completed authority prescription form to:

Department of Human Services
Prior written approval of specialised drugs
Reply Paid 9826
Hobart TAS 7001

Print in **BLOCK LETTERS**

Tick where applicable ☑

Privacy notice

Centrelink, Medicare Australia, Child Support and CRS Australia are all part of the Australian Government Department of Human Services. Personal information held by Human Services is protected by law, including the *Privacy Act 1988*. The information provided on this form will be used to assess eligibility of a nominated person to receive PBS subsidised treatment. The collection of this information is authorised by the *National Health Act 1953*. This information may be disclosed to the Department of Health and Ageing, Department of Veterans' Affairs or as authorised or required by law.

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Patient's details

1 Medicare/DVA card number

– – Ref no.

2 Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name

First given name

3 Date of birth

/ /

4 Patient's current weight

kg

Patient's acknowledgement

5 I acknowledge that PBS subsidised treatment with bDMARDs for rheumatoid arthritis will stop if:

- subsequent testing demonstrates that I have failed to demonstrate or sustain a response to treatment as detailed in the criteria
- I have failed up to, and including, five bDMARD treatment courses for which I was eligible.

My prescriber has explained the nature of the ongoing monitoring and testing required to demonstrate an adequate response to therapy.

Patient's signature

Date

/ /

Prescriber's details

6 Prescriber number

7 Family name

First given name

8 Work phone number

( )

Alternative phone number

Fax number

( )

Prescriber's acknowledgement

9 **I have explained:**

- the circumstances governing PBS subsidised treatment with bDMARDs for rheumatoid arthritis
- the nature of the ongoing monitoring and testing required to demonstrate an adequate and sustained response to therapy.

I believe these to be understood and accepted by the patient.

Prescriber's signature

Date

/ /

Witness's acknowledgement

10 I have witnessed the signatures of **BOTH** the patient and the prescriber.

Witness's full name (over 18 years of age)

Witness's signature

Date

/ /

Biological agent details

11 Which bDMARD is this application for?

☐ abatacept i.v.
☐ abatacept s.c.
☐ abatacept s.c with i.v.loading
☐ adalimumab
☐ certolizumab pegol
☐ etanercept
☐ golimumab
☐ infliximab
☐ rituximab
☐ tocilizumab

For abatacept i.v., infliximab, rituximab and tocilizumab only:

Hospital name

Hospital provider number

Conditions and criteria

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

12 The patient:

☐ has severe active rheumatoid arthritis

and

☐ has signed the patient's acknowledgement

and

☐ is currently taking methotrexate at a dose of

mg per week

(minimum methotrexate requirement is 7.5 mg per week for PBS subsidised abatacept, golimumab, infliximab and rituximab)

and

☐ has failed a six month intensive DMARD treatment trial with a minimum of two agents for a minimum of three months each. Details provided below:

	DMARD	Minimum dose
a)	methotrexate	20 mg/week
b)	hydroxychloroquine	200 mg/day
c)	leflunomide	10 mg/day
d)	sulfasalazine	2 g/day
e)	azathioprine	1 mg/kg/day
f)	cyclosporin	2 mg/kg/day
g)	sodium aurothiomalate	50 mg weekly

All patients must trial

- a), **and** either b), and/or c) and/or d)

If treatment with a) is contraindicated or the patient is intolerant of the required minimum dose (this must be documented according to the approved toxicity criteria) for the required minimum three months of treatment then the intensive treatment trial must be:

- any two of b),c), or d)

If treatment with three or more of a),b),c),or d), is contraindicated or the patient is intolerant of the required minimum dose (this must be documented according to the approved toxicity criteria) for the required minimum three months of treatment then the intensive treatment trial must be completed with:

- one or more of e), f), or g)

Provide details of DMARDs trialled

a) methotrexate

Dose

mg

From / / to / /

b) hydroxychloroquine

Dose

mg

From / / to / /

c) leflunomide

Dose

mg

From / / to / /

d) sulfasalazine

Dose

mg

From / / to / /

e) azathioprine

Dose

mg

From / / to / /

f) cyclosporin

Dose

mg

From / / to / /

g) sodium aurothiomalate

Dose

mg

From / / to / /

13 Provide details of contraindications or intolerances to any of the prior therapies including the degree of toxicity.

Details of the toxicity criteria are available at **humanservices.gov.au/healthprofessionals** and search for **Rheumatoid arthritis**

Intolerance must be of a severity to necessitate permanent treatment withdrawal.

Prior therapy contraindication or toxicity and grade

methotrexate

hydroxychloroquine

leflunomide

sulfasalazine

azathioprine

cyclosporin

sodium aurothiomalate

Current assessment of patient

14 The patient can demonstrate failure to achieve an adequate response to six months of intensive prior treatment by:

☐ an elevated ESR greater than 25 mm/hr

ESR result

Date of test / /

and/or

☐ an elevated CRP greater than 15 mg/L

CRP result

Date of test / /

Note: where only one marker (ESR or CRP) has been provided at baseline, the same marker must be used for assessment for all continuing applications.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, state the reason why.

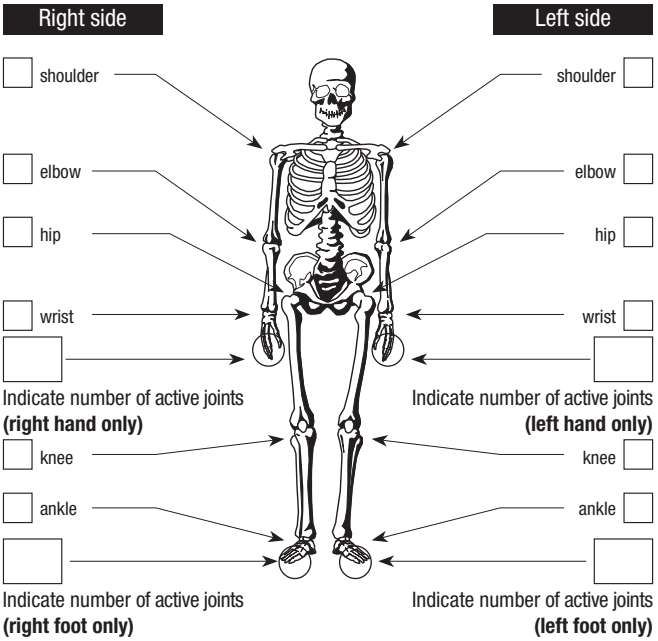
and

☐ an active joint count of at least 20 active (swollen and tender) joints

or

☐ at least four major active joints: elbow, wrist, knee, ankle, shoulder and/or hip

15 Indicate affected joints on the diagram and complete the boxes below:



Current active joint count

Date of joint assessment / /

Note: Where a patient has at least four active major joints and less than 20 total active joints at baseline, assessment of the major joints only will be used for all continuing applications.

Attachments

Attach a completed authority prescription form.

Prescriber's declaration

16 I declare that:

- the information on this form is correct.

Prescriber's signature

Date / /