



Rheumatoid arthritis

Initial PBS 'grandfather' authority application

Supporting information

Important information

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 either certolizumab pegol, golimumab or tocilizumab only. Patients must have been receiving non-PBS subsidised treatment on an ongoing and continuous basis at the time of the application for PBS subsidised treatment.

Where the term 'bDMARD' appears, it refers to abatacept, adalimumab, anakinra, 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 should be performed preferably whilst still on treatment, but no longer than one month following cessation of the most recent non PBS subsidised treatment.

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—tocilizumab only

This item is 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.

This item is 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 PBS subsidised course of treatment must be made no later than one month from the date of completion of this initial course of treatment and must be submitted to Medicare Australia. Where a response assessment is not undertaken and submitted to Medicare Australia within these time frames, the patient will be deemed to have failed to respond to treatment.

Assistance

If you need assistance completing this form or need more information call **1800 700 270** (call charges may apply) and select option 2, between 8.00 am and 5.00 pm EST, Monday to Friday or go to **www.medicareaustralia.gov.au > For health professionals > PBS > Specialised drugs (PBS) J-Z > Rheumatoid arthritis**

Lodgement

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

Medicare Australia
Prior written approval of specialised drugs
Reply Paid 9826
Hobart TAS 7001

Print in **BLOCK LETTERS**

Tick where applicable



Rheumatoid arthritis

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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 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 treatment.

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?

certolizumab pegol
 golimumab
 tocilizumab

Provide dates of prior non PBS subsidised treatment
 From / / to / /

For tocilizumab only:

Hospital name

Hospital provider number

Conditions and criteria

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

The patient named above:

has received prior treatment with a PBS subsidised bDMARD for rheumatoid arthritis
*go to 16 to supply a new baseline set, or
 go to 18 if using a previous baseline set*

or

has not received prior treatment with a PBS subsidised bDMARD and commenced treatment with:

certolizumab pegol prior to 1 March 2010,

or

golimumab prior to 1 March 2010,

or

tocilizumab prior to 1 July 2009

go to 16

or

has not received prior treatment with a PBS subsidised bDMARD and commenced treatment with:

certolizumab pegol after 1 March 2010,

or

golimumab after 1 March 2010,

or

tocilizumab after 1 July 2009

go to 13

13 To qualify for PBS authority approval the following conditions must be met. The patient:

has a documented history of 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 golimumab)

and immediately prior to the commencement of non-PBS subsidised treatment

failed to achieve an adequate response to prior DMARD treatment

go to 14

14 Prior treatment

Methotrexate, at a dose of at least 20 mg/week

from / / to / /

and for a minimum of three months,

methotrexate (at a minimum dose of 7.5 mg/week) in combination with two other approved disease modifying antirheumatic drugs (DMARDs), at approved doses,

from / / to / /

and for a minimum of three months,

at least one of the following two options

leflunomide

from / / to / / **Go to 14**

or

cyclosporin

from / / to / / **Go to 14**

or

was unable to complete prior treatment requirements

Go to 15

15 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

www.medicareaustralia.gov.au > For health professionals > PBS > Specialised drugs (PBS) J-Z > Rheumatoid arthritis

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

Methotrexate 20 mg

Maximum dose tolerated

mg

Methotrexate triple therapy

Leflunomide

Cyclosporin

Baseline patient assessment immediately prior to the start of non-PBS subsidised treatment.

16 Provide the following.

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 4 major active joints: elbow, wrist, knee, ankle, shoulder and/or hip

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

Right side	Left side
<input type="checkbox"/> shoulder <input type="checkbox"/> elbow <input type="checkbox"/> hip <input type="checkbox"/> wrist <input type="checkbox"/> Indicate number of active joints (right hand only) <input type="checkbox"/> knee <input type="checkbox"/> ankle <input type="checkbox"/> Indicate number of active joints (right foot only)	<input type="checkbox"/> shoulder <input type="checkbox"/> elbow <input type="checkbox"/> hip <input type="checkbox"/> wrist <input type="checkbox"/> Indicate number of active joints (left hand only) <input type="checkbox"/> knee <input type="checkbox"/> ankle <input type="checkbox"/> Indicate number of active joints (left foot only)

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.

Current assessment of patient

18 Provide the following.

ESR result

Date of test / /

and/or

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.

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

Right side	Left side
<input type="checkbox"/> shoulder <input type="checkbox"/> elbow <input type="checkbox"/> hip <input type="checkbox"/> wrist <input type="checkbox"/> Indicate number of active joints (right hand only) <input type="checkbox"/> knee <input type="checkbox"/> ankle <input type="checkbox"/> Indicate number of active joints (right foot only)	<input type="checkbox"/> shoulder <input type="checkbox"/> elbow <input type="checkbox"/> hip <input type="checkbox"/> wrist <input type="checkbox"/> Indicate number of active joints (left hand only) <input type="checkbox"/> knee <input type="checkbox"/> ankle <input type="checkbox"/> Indicate number of active joints (left foot only)

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

20 I declare that:

- the information on this form is correct.

Prescriber's signature

Date

 / /

Privacy note

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.