Australian Government
Medicare Australia

PBS

Juvenile idiopathic arthritis for adult patients with onset prior to age 18
Initial PBS 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 with a documented history of juvenile idiopathic arthritis with onset prior to age 18:

- starting **initial** PBS subsidised treatment with a biological Disease Modifying Anti Rheumatic Drug (bDMARD)
- **recommencing** PBS subsidised bDMARD treatment where they have failed fewer than three bDMARD treatment courses, for which they are eligible, and where the break in treatment is longer than 12 months. Prescribers do not need to complete another patient and prescriber acknowledgement form for these applications.

Where the term 'bDMARD' appears, it refers to adalimumab and etanercept only. Patients are eligible for PBS subsidised treatment with only one bDMARD at any time.

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 prior 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.

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 Medicare Australia 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 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 > Juvenile idiopathic arthritis - under and over 18 years**

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 ☑

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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

/ /

Patient's acknowledgement

4 I acknowledge that PBS subsidised treatment with bDMARDs for juvenile idiopathic arthritis with onset prior to age 18 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, three 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

5 Prescriber number

6 Family name

First given name

7 Work phone number

( )

Alternative phone number

Fax number

( )

Prescriber's acknowledgement

8 **I have explained:**

- the circumstances governing PBS subsidised treatment with bDMARDs for juvenile idiopathic arthritis with onset prior to age 18
- 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

9 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

10 Which bDMARD is this application for?

☐ adalimumab

☐ etanercept

Conditions and criteria

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

11 The patient:

☐ has a documented history of juvenile idiopathic arthritis with onset prior to the age of 18

and

☐ has signed the patient's acknowledgement

and

☐ has failed a six month intensive DMARD treatment trial with a minimum of two agents for a minimum of 3 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 3 months of treatment then the intensive treatment trial must be:

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

If treatment with 3 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 3 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 / /

12 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 > Juvenile idiopathic arthritis - under and over 18 years**

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

13 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.

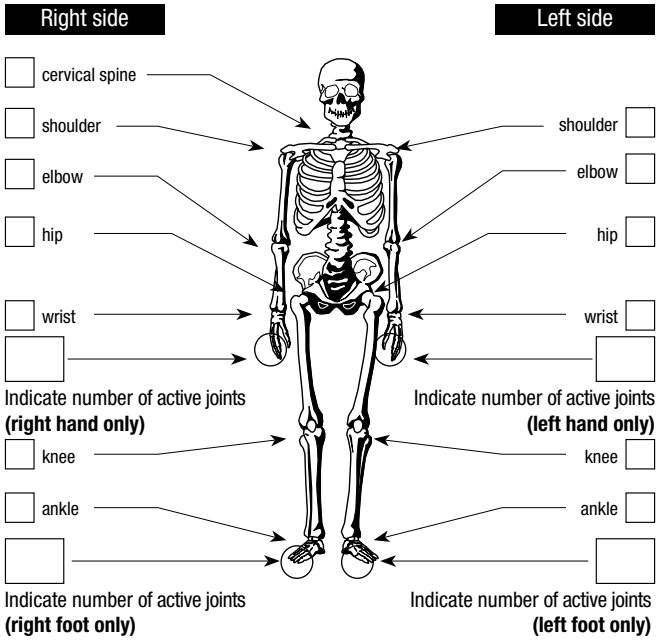
and

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

or

☐ at least 4 major active joints: elbow, wrist, knee, ankle, shoulder, hip and/or cervical spine

14 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

15 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.