

# APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER Reg No:** .....

Reg No: .....      First Names: .....      First Names: .....

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## Adalimumab

### INITIAL APPLICATION - rheumatoid arthritis

Applications only from a rheumatologist. Approvals valid for 6 months.

#### Prerequisites (tick boxes where appropriate)

- Patient has had severe and active erosive rheumatoid arthritis for six months duration or longer  
**and**  
 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance  
**and**  
 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose  
**and**  
 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with at least two of the following (triple therapy): sulphasalazine, prednisone at a dose of at least 7.5 mg per day, azathioprine, intramuscular gold, or hydroxychloroquine sulphate (at maximum tolerated doses)  
**and**
- Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of cyclosporin alone or in combination with another agent  
**or**  
 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent
- and**
- Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints  
**or**  
 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip
- and**
- Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application  
**or**  
 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

Use next page for: Initial application - Crohn's disease, Initial application - severe chronic plaque psoriasis, Initial application - ankylosing spondylitis, Initial application - psoriatic arthritis, Renewal - rheumatoid arthritis, Renewal - Crohn's disease, Renewal - severe chronic plaque psoriasis, Renewal - ankylosing spondylitis and Renewal - psoriatic arthritis

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....

Post application to Ministry of Health, Private Bag 3015, Wanganui – Fax: 0800 100 131

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**Adalimumab - continued**

**INITIAL APPLICATION - Crohn's disease**

Applications only from a gastroenterologist. Approvals valid for 3 months.

**Prerequisites** (tick boxes where appropriate)

Patient has severe active Crohn's disease

and

Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300

or

Patient has extensive small intestine disease affecting more than 50 cm of the small intestine

or

Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection

or

Patient has an ileostomy or colostomy, and has intestinal inflammation

and

Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids

and

Surgery (or further surgery) is considered to be clinically inappropriate

**INITIAL APPLICATION - severe chronic plaque psoriasis**

Applications only from a dermatologist. Approvals valid for 4 months.

**Prerequisites** (tick boxes where appropriate)

Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis

or

Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis

and

Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, cyclosporin, or acitretin

and

A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course

and

The most recent PASI assessment is no more than 1 month old at the time of application

**Note:**

"Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

**Use next page for: Initial application - ankylosing spondylitis, Initial application - psoriatic arthritis, Renewal - rheumatoid arthritis, Renewal - Crohn's disease, Renewal - severe chronic plaque psoriasis, Renewal - ankylosing spondylitis and Renewal - psoriatic arthritis**

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**Adalimumab - continued**

**INITIAL APPLICATION - ankylosing spondylitis**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites** (tick boxes where appropriate)

- Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months
- and
- Patient has low back pain and stiffness that is relieved by exercise but not by rest
- and
- Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan
- and
- Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of an exercise regimen supervised by a physiotherapist
- and
- Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI)
- or
- Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes)
- and
- A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale
- and
- An elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour
- or
- A C-reactive protein (CRP) level greater than 15 mg per litre

Note:  
The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI, ESR and CRP measures must be no more than 1 month old at the time of initial application.  
Average normal chest expansion corrected for age and gender:

- 18-24 years - Male: 7.0 cm; Female: 5.5 cm
- 25-34 years - Male: 7.5 cm; Female: 5.5 cm
- 35-44 years - Male: 6.5 cm; Female: 4.5 cm
- 45-54 years - Male: 6.0 cm; Female: 5.0 cm
- 55-64 years - Male: 5.5 cm; Female: 4.0 cm
- 65-74 years - Male: 4.0 cm; Female: 4.0 cm
- 75+ years - Male: 3.0 cm; Female: 2.5 cm

**Use next page for: Initial application - psoriatic arthritis, Renewal - rheumatoid arthritis, Renewal - Crohn's disease, Renewal - severe chronic plaque psoriasis, Renewal - ankylosing spondylitis and Renewal - psoriatic arthritis**  
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**Adalimumab - continued**

**INITIAL APPLICATION - psoriatic arthritis**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites** (tick boxes where appropriate)

- Patient has had severe active psoriatic arthritis for six months duration or longer
- and
- Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose
- and
- Patient has tried and not responded to at least three months of sulphasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses)
- and

- Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints
- or
- Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

- and
- Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application
  - or
  - Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour
  - or
  - ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

**RENEWAL - rheumatoid arthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites** (tick boxes where appropriate)

- Applicant is a rheumatologist
- or
- Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

- and
- Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
  - and
  - Following 4 months initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
  - or
  - On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

**Use next page for: Renewal - Crohn's disease, Renewal - severe chronic plaque psoriasis, Renewal - ankylosing spondylitis and Renewal - psoriatic arthritis**

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## Adalimumab - continued

### RENEWAL - Crohn's disease

Current approval Number (if known):.....

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites** (tick boxes where appropriate)

Applicant is a gastroenterologist

or

Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

and

The treatment remains appropriate and the patient is benefiting from treatment

### RENEWAL - severe chronic plaque psoriasis

Current approval Number (if known):.....

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

**Prerequisites** (tick boxes where appropriate)

Applicant is a dermatologist

or

Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

and

Patient has "whole body" severe chronic plaque psoriasis

and

Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value

or

Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot

and

Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values

or

Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value

Note:

An adalimumab treatment course is defined as a minimum of 12 weeks adalimumab treatment.

**Use next page for: Renewal - ankylosing spondylitis and Renewal - psoriatic arthritis**

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## Adalimumab - continued

### RENEWAL - ankylosing spondylitis

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites** (tick boxes where appropriate)

Applicant is a rheumatologist

or

Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

and

Following 12 weeks of adalimumab treatment, BASDAI has improved by 4 or more points from pre-adalimumab baseline on a 10 point scale, or by 50%, whichever is less

and

ESR or CRP is within the normal range

and

Physician considers that the patient has benefited from treatment and that continued treatment is appropriate

### RENEWAL - psoriatic arthritis

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites** (tick boxes where appropriate)

Applicant is a rheumatologist

or

Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

and

Following 4 months initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the treating physician

or

The patient demonstrates at least a continuing 50% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician

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