

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

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Fax Number: Fax Number:

Adalimumab

INITIAL APPLICATION - rheumatoid arthritis

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

Prerequisites (tick boxes where appropriate)

The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis

and

The patient has experienced intolerable side effects from etanercept

or

The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for rheumatoid arthritis

or

Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) 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 sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses)

and

Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin

or

Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold

or

Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate

and

Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints

or

Patient has persistent symptoms of poorly controlled and active disease in at least four 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

See also: **INITIAL APPLICATION** - Crohn's disease *p2*, **INITIAL APPLICATION** - severe chronic plaque psoriasis *p3*, **INITIAL APPLICATION** - ankylosing spondylitis *p4*, **INITIAL APPLICATION** - psoriatic arthritis *p5*, **INITIAL APPLICATION** - juvenile idiopathic arthritis *p6*, **INITIAL APPLICATION** - fistulising Crohn's disease *p7*, **INITIAL APPLICATION** - pyoderma gangrenosum *p7*, **INITIAL APPLICATION** - adult-onset Still's disease *p8*, **RENEWAL** - rheumatoid arthritis *p9*, **RENEWAL** - Crohn's disease *p10*, **RENEWAL** - severe chronic plaque psoriasis *p11*, **RENEWAL** - ankylosing spondylitis *p12*, **RENEWAL** - psoriatic arthritis *p12*, **RENEWAL** - juvenile idiopathic arthritis *p13*, **RENEWAL** - fistulising Crohn's disease *p13*, **RENEWAL** - pyoderma gangrenosum *p14* and **RENEWAL** - adult-onset Still's disease *p14*

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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

See also: **INITIAL APPLICATION** - severe chronic plaque psoriasis *p3*, **INITIAL APPLICATION** - ankylosing spondylitis *p4*, **INITIAL APPLICATION** - psoriatic arthritis *p5*, **INITIAL APPLICATION** - juvenile idiopathic arthritis *p6*, **INITIAL APPLICATION** - fistulising Crohn's disease *p7*, **INITIAL APPLICATION** - pyoderma gangrenosum *p7*, **INITIAL APPLICATION** - adult-onset Still's disease *p8*, **RENEWAL** - rheumatoid arthritis *p9*, **RENEWAL** - Crohn's disease *p10*, **RENEWAL** - severe chronic plaque psoriasis *p11*, **RENEWAL** - ankylosing spondylitis *p12*, **RENEWAL** - psoriatic arthritis *p12*, **RENEWAL** - juvenile idiopathic arthritis *p13*, **RENEWAL** - fistulising Crohn's disease *p13*, **RENEWAL** - pyoderma gangrenosum *p14* and **RENEWAL** - adult-onset Still's disease *p14*

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Adalimumab - continued

INITIAL APPLICATION - severe chronic plaque psoriasis
Applications only from a dermatologist. Approvals valid for 4 months.

Prerequisites (tick boxes where appropriate)

The patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis

and

The patient has experienced intolerable side effects from etanercept

or

The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for severe chronic plaque psoriasis

or

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, ciclosporin, 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.

See also: **INITIAL APPLICATION** - ankylosing spondylitis p4, **INITIAL APPLICATION** - psoriatic arthritis p5, **INITIAL APPLICATION** - juvenile idiopathic arthritis p6, **INITIAL APPLICATION** - fistulising Crohn's disease p7, **INITIAL APPLICATION** - pyoderma gangrenosum p7, **INITIAL APPLICATION** - adult-onset Still's disease p8, **RENEWAL** - rheumatoid arthritis p9, **RENEWAL** - Crohn's disease p10, **RENEWAL** - severe chronic plaque psoriasis p11, **RENEWAL** - ankylosing spondylitis p12, **RENEWAL** - psoriatic arthritis p12, **RENEWAL** - juvenile idiopathic arthritis p13, **RENEWAL** - fistulising Crohn's disease p13, **RENEWAL** - pyoderma gangrenosum p14 and **RENEWAL** - adult-onset Still's disease p14

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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)

The patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis

and

The patient has experienced intolerable side effects from etanercept

or

The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for ankylosing spondylitis

or

Patient has a confirmed diagnosis of ankylosing spondylitis 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 a regular exercise regimen for ankylosing spondylitis

and

Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right)

or

Patient has limitation of chest expansion by at least 2.5 cm below the following 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

Note:

The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure 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

See also: **INITIAL APPLICATION** - psoriatic arthritis *p5*, **INITIAL APPLICATION** - juvenile idiopathic arthritis *p6*, **INITIAL APPLICATION** - fistulising Crohn's disease *p7*, **INITIAL APPLICATION** - pyoderma gangrenosum *p7*, **INITIAL APPLICATION** - adult-onset Still's disease *p8*, **RENEWAL** - rheumatoid arthritis *p9*, **RENEWAL** - Crohn's disease *p10*, **RENEWAL** - severe chronic plaque psoriasis *p11*, **RENEWAL** - ankylosing spondylitis *p12*, **RENEWAL** - psoriatic arthritis *p12*, **RENEWAL** - juvenile idiopathic arthritis *p13*, **RENEWAL** - fistulising Crohn's disease *p13*, **RENEWAL** - pyoderma gangrenosum *p14* and **RENEWAL** - adult-onset Still's disease *p14*

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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)

The patient has had an initial Special Authority approval for etanercept for psoriatic arthritis

and

The patient has experienced intolerable side effects from etanercept

or

The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for psoriatic arthritis

or

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 sulfasalazine 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 15 swollen, tender joints

or

Patient has persistent symptoms of poorly controlled and active disease in at least four 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

See also: **INITIAL APPLICATION** - juvenile idiopathic arthritis p6, **INITIAL APPLICATION** - fistulising Crohn's disease p7, **INITIAL APPLICATION** - pyoderma gangrenosum p7, **INITIAL APPLICATION** - adult-onset Still's disease p8, **RENEWAL** - rheumatoid arthritis p9, **RENEWAL** - Crohn's disease p10, **RENEWAL** - severe chronic plaque psoriasis p11, **RENEWAL** - ankylosing spondylitis p12, **RENEWAL** - psoriatic arthritis p12, **RENEWAL** - juvenile idiopathic arthritis p13, **RENEWAL** - fistulising Crohn's disease p13, **RENEWAL** - pyoderma gangrenosum p14 and **RENEWAL** - adult-onset Still's disease p14

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Adalimumab - continued

INITIAL APPLICATION - juvenile idiopathic arthritis

Applications only from a named specialist or rheumatologist. Approvals valid for 6 months.

Prerequisites (tick boxes where appropriate)

The patient has had an initial Special Authority approval for etanercept for juvenile idiopathic arthritis (JIA)

and

The patient has experienced intolerable side effects from etanercept

or

The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for juvenile idiopathic arthritis

or

To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

Patient diagnosed with JIA

and

Patient has had severe active polyarticular course JIA for 6 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 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections

and

Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints

or

Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip

and

Physician's global assessment indicating severe disease

See also: **INITIAL APPLICATION** - fistulising Crohn's disease p7, **INITIAL APPLICATION** - pyoderma gangrenosum p7, **INITIAL APPLICATION** - adult-onset Still's disease p8, **RENEWAL** - rheumatoid arthritis p9, **RENEWAL** - Crohn's disease p10, **RENEWAL** - severe chronic plaque psoriasis p11, **RENEWAL** - ankylosing spondylitis p12, **RENEWAL** - psoriatic arthritis p12, **RENEWAL** - juvenile idiopathic arthritis p13, **RENEWAL** - fistulising Crohn's disease p13, **RENEWAL** - pyoderma gangrenosum p14 and **RENEWAL** - adult-onset Still's disease p14

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Adalimumab - continued

INITIAL APPLICATION - fistulising Crohn's disease

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

Prerequisites (tick boxes where appropriate)

Patient has confirmed Crohn's disease

and

Patient has one or more complex externally draining enterocutaneous fistula(e)

or

Patient has one or more rectovaginal fistula(e)

and

A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application

and

The patient will be assessed for response to treatment after 4 months' adalimumab treatment (see Note)

Note:

A maximum of 4 months' adalimumab will be subsidised on an initial Special Authority approval for fistulising Crohn's disease.

INITIAL APPLICATION - pyoderma gangrenosum

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

Prerequisites (tick boxes where appropriate)

Patient has pyoderma gangrenosum*

and

Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response

and

A maximum of 4 doses

Note:

Note: Indications marked with * are unapproved indications.

See also: **INITIAL APPLICATION** - adult-onset Still's disease *p8*, **RENEWAL** - rheumatoid arthritis *p9*, **RENEWAL** - Crohn's disease *p10*, **RENEWAL** - severe chronic plaque psoriasis *p11*, **RENEWAL** - ankylosing spondylitis *p12*, **RENEWAL** - psoriatic arthritis *p12*, **RENEWAL** - juvenile idiopathic arthritis *p13*, **RENEWAL** - fistulising Crohn's disease *p13*, **RENEWAL** - pyoderma gangrenosum *p14* and **RENEWAL** - adult-onset Still's disease *p14*

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Adalimumab - continued

INITIAL APPLICATION - adult-onset Still's disease

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

Prerequisites (tick boxes where appropriate)

The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD)

or

The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules

and

The patient has experienced intolerable side effects from etanercept and/or tocilizumab

or

The patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab such that they do not meet the renewal criteria for AOSD

or

Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430)

and

Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate

and

Patient has persistent symptoms of disabling poorly controlled and active disease

See also: **RENEWAL** - rheumatoid arthritis *p9*, **RENEWAL** - Crohn's disease *p10*, **RENEWAL** - severe chronic plaque psoriasis *p11*, **RENEWAL** - ankylosing spondylitis *p12*, **RENEWAL** - psoriatic arthritis *p12*, **RENEWAL** - juvenile idiopathic arthritis *p13*, **RENEWAL** - fistulising Crohn's disease *p13*, **RENEWAL** - pyoderma gangrenosum *p14* and **RENEWAL** - adult-onset Still's disease *p14*

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Adalimumab - continued

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 3 to 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

and

Adalimumab to be administered at doses no greater than 40 mg every 14 days

or

Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response

See also: **RENEWAL** - Crohn's disease *p10*, **RENEWAL** - severe chronic plaque psoriasis *p11*, **RENEWAL** - ankylosing spondylitis *p12*, **RENEWAL** - psoriatic arthritis *p12*, **RENEWAL** - juvenile idiopathic arthritis *p13*, **RENEWAL** - fistulising Crohn's disease *p13*, **RENEWAL** - pyoderma gangrenosum *p14* and **RENEWAL** - adult-onset Still's disease *p14*

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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, and write the data requested in the space provided 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

CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab

or

CDAI score is 150 or less

or

The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed

and

Applicant to indicate the reason that CDAI score cannot be assessed:

and

Adalimumab to be administered at doses no greater than 40 mg every 14 days

See also: **RENEWAL** - severe chronic plaque psoriasis *p11* , **RENEWAL** - ankylosing spondylitis *p12* , **RENEWAL** - psoriatic arthritis *p12* , **RENEWAL** - juvenile idiopathic arthritis *p13* , **RENEWAL** - fistulising Crohn's disease *p13* , **RENEWAL** - pyoderma gangrenosum *p14* and **RENEWAL** - adult-onset Still's disease *p14*

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Adalimumab - continued

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 had "whole body" severe chronic plaque psoriasis at the start of treatment

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 had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment

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

and

Adalimumab to be administered at doses no greater than 40 mg every 14 days

Note:

A treatment course is defined as a minimum of 12 weeks adalimumab treatment

See also: **RENEWAL** - ankylosing spondylitis p12 , **RENEWAL** - psoriatic arthritis p12 , **RENEWAL** - juvenile idiopathic arthritis p13 , **RENEWAL** - fistulising Crohn's disease p13 , **RENEWAL** - pyoderma gangrenosum p14 and **RENEWAL** - adult-onset Still's disease p14

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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' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less

and

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

and

Adalimumab to be administered at doses no greater than 40 mg every 14 days

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 3 to 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

The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician

and

Adalimumab to be administered at doses no greater than 40 mg every 14 days

See also: **RENEWAL** - juvenile idiopathic arthritis *p13*, **RENEWAL** - fistulising Crohn's disease *p13*, **RENEWAL** - pyoderma gangrenosum *p14* and **RENEWAL** - adult-onset Still's disease *p14*

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APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

Adalimumab - continued

RENEWAL - juvenile idiopathic arthritis

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

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

Prerequisites (tick boxes where appropriate)

Applicant is a named specialist or rheumatologist

or

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

and

Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

RENEWAL - fistulising 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 number of open draining fistulae have decreased from baseline by at least 50%

or

There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain

See also: **RENEWAL** - pyoderma gangrenosum p14 and **RENEWAL** - adult-onset Still's disease p14

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

Signed: Date:

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Adalimumab - continued

RENEWAL - pyoderma gangrenosum

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

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months.

Prerequisites (tick boxes where appropriate)

Patient has shown clinical improvement
and
 Patient continues to require treatment
and
 A maximum of 4 doses

RENEWAL - adult-onset Still's disease

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
 The patient has a sustained improvement in inflammatory markers and functional status

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

Signed: Date:

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