SA2157 - Adalimumab (Humira - Alternative brand)

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 (Humira - Alternative brand)

Initial application — Behcet's disease – severe
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- **or**
- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and
☐ Patient has received a maximum of 6 months treatment with Amgevita
and
☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication
and
☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

Renewal — Behcet's disease – severe

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

Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ The patient has had a good clinical response to treatment with measurably improved quality of life
and
☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

Initial application — Hidradenitis suppurativa
Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- **or**
- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and
☐ Patient has received a maximum of 6 months treatment with Amgevita
and
☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication
and
☐ Adalimumab to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered

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 (Humira - Alternative brand) *- continued*

Renewal — Hidradenitis suppurativa

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)

- ☐ The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline

and

- ☐ The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline

and

- ☐ Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered

Initial application — Psoriasis - severe chronic plaque

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

Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ☐ Patient has received a maximum of 6 months treatment with Amgevita

and

- ☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

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

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Adalimumab (Humira - Alternative brand) *- continued*

Renewal — Psoriasis - severe chronic plaque

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)

- ☐ 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**
  - ☐ Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-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

Initial application — Pyoderma gangrenosum

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

Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- **or**
- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ☐ Patient has received a maximum of 6 months treatment with Amgevita

and

- ☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ☐ A maximum of 8 doses

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Adalimumab (Humira - Alternative brand) *- continued*

Renewal — Pyoderma gangrenosum

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

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

Prerequisites(tick boxes where appropriate)

- ☐ The patient has demonstrated clinical improvement and continues to require treatment

and

- ☐ A maximum of 8 doses

Initial application — Crohn's disease - adult

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

Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevitat

or

- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

- ☐ Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment

and

- ☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

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

Renewal — Crohn's disease - adult

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)

- ☐ 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

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

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Adalimumab (Humira - Alternative brand) *- continued*

Initial application — Crohn's disease - children
Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita

or

- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

- ☐ Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment

and

☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

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

Renewal — Crohn's disease - children

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)

- ☐ PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab

or

- ☐ PCDAI score is 15 or less

or

- ☐ The patient has demonstrated an adequate response to treatment, but PCDAI score cannot be assessed

and

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

Initial application — Crohn's disease - fistulising
Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita

or

- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

- ☐ Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment

and

☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

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

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Adalimumab (Humira - Alternative brand) *- continued*

Renewal — Crohn's disease - fistulising

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)

- ☐ 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

and

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

Initial application — Ocular inflammation – chronic

Applications from any relevant practitioner. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita

or

- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

- ☐ Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment

and

- ☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

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

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Adalimumab (Humira - Alternative brand) *- continued*

Renewal — Ocular inflammation – chronic

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

Applications from any relevant practitioner. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient has had a good clinical response following 12 weeks' initial treatment

or

- ☐ Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or

- ☐ Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

and

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

Initial application — Ocular inflammation – severe

Applications from any relevant practitioner. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita

or

- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

- ☐ Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment

and

- ☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

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

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Adalimumab (Humira - Alternative brand) *- continued*

Renewal — Ocular inflammation – severe

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

Applications from any relevant practitioner. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient has had a good clinical response following 3 initial doses

or

- ☐ Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or

- ☐ Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

and

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

Initial application — ankylosing spondylitis

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

Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita)

and

- ☐ Patient has received a maximum of 6 months treatment with Amgevita

and

- ☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

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

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)

- ☐ 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

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

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Adalimumab (Humira - Alternative brand) *- continued*

Initial application — Arthritis – oligoarticular course juvenile idiopathic
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)

☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

☐ Patient has received a maximum of 6 months treatment with Amgevita

and

☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

Renewal — Arthritis – oligoarticular course juvenile idiopathic

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 box where appropriate)

☐ The patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

Initial application — Arthritis - polyarticular course juvenile idiopathic
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)

☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

☐ Patient has received a maximum of 6 months treatment with Amgevita

and

☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

Renewal — Arthritis - polyarticular course juvenile idiopathic

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 box where appropriate)

☐ The patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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Adalimumab (Humira - Alternative brand) *- continued*

Initial application — Arthritis - psoriatic
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)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- **or**
- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

☐ Patient has received a maximum of 6 months treatment with Amgevita

and

☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

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

Renewal — Arthritis - psoriatic

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)

☐ 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

Initial application — Arthritis – rheumatoid
Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- **or**
- ☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

☐ Patient has received a maximum of 6 months treatment with Amgevita

and

☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

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

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Adalimumab (Humira - Alternative brand) *- continued*

Renewal — Arthritis – rheumatoid

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)

☐ 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

or

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

Initial application — Still's disease – adult-onset (AOSD)

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

Prerequisites(tick boxes where appropriate)

☐ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

☐ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

☐ Patient has received a maximum of 6 months treatment with Amgevita

and

☐ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

Renewal — Still's disease – adult-onset (AOSD)

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 box where appropriate)

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

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