

SA2157 - Adalimumab (Humira - Alternative brand)

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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)

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

- and The patient has had a good clinical response to treatment with measurably improved quality of life
 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)

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

- and 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)

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

- and Patient had "whole body" severe chronic plaque psoriasis at the start of treatment
- or 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)

- or 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)

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

- or 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 - 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)

- or 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)

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> 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)

- | |
|---------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab |
| or |
| <input type="checkbox"/> PCDAI score is 15 or less |
| or |
| <input type="checkbox"/> 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)

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> 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)

- or The number of open draining fistulae have decreased from baseline by at least 50%
 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)

- or 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
 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)

- | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> The patient has had a good clinical response following 12 weeks' initial treatment |
| or |
| <input type="checkbox"/> Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < 1/2+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema) |
| or |
| <input type="checkbox"/> 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

- | |
|-----------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 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)

- | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment |

and

- | |
|-----------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication |
|-----------------------------------------------------------------------------------------------------------------------------------------|

and

- | |
|-----------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 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)

- or 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 < 1/2+ 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)

- or 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)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| or | <input type="checkbox"/> The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment |
| <input type="checkbox"/> 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 | <input type="checkbox"/> Patient has received a maximum of 6 months treatment with Amgevita |
| and | <input type="checkbox"/> 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)

- | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 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)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| or | <input type="checkbox"/> The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment |
| <input type="checkbox"/> 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 | <input type="checkbox"/> Patient has received a maximum of 6 months treatment with Amgevita |
| and | <input type="checkbox"/> 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)

- | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 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)

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment |
| or |
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> Patient has received a maximum of 6 months treatment with Amgevita |
| and |
| <input type="checkbox"/> Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication |
| and |
| <input type="checkbox"/> 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)

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> 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)

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment |
| or |
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> Patient has received a maximum of 6 months treatment with Amgevita |
| and |
| <input type="checkbox"/> Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication |
| and |
| <input type="checkbox"/> Adalimumab to be administered at doses no greater than 40 mg every 14 days |
| or |
| <input type="checkbox"/> 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)

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> Adalimumab to be administered at doses no greater than 40 mg every 14 days |
| or |
| <input type="checkbox"/> 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)

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment |
| or |
| <input type="checkbox"/> 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 |
| <input type="checkbox"/> Patient has received a maximum of 6 months treatment with Amgevita |
| and |
| <input type="checkbox"/> 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)

- | |
|-----------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> The patient has demonstrated a sustained improvement in inflammatory markers and functional status |
|-----------------------------------------------------------------------------------------------------------------------------|

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