SA2157 - Adalimumab (Humira - Alternative brand)

| Arthritis - polyarticular course juvenile idiopathic - Initial application | 10 |
|---|----|
| Arthritis - polyarticular course juvenile idiopathic - Renewal | |
| Arthritis - psoriatic - Initial application | |
| Arthritis - psoriatic - Renewal | 11 |
| Arthritis – oligoarticular course juvenile idiopathic - Initial application | |
| Arthritis – oligoarticular course juvenile idiopathic - Renewal | |
| Arthritis – rheumatoid - Initial application | |
| Arthritis – rheumatoid - Renewal | 12 |
| Behcet's disease – severe - Initial application | 2 |
| Behcet's disease – severe - Renewal | |
| Crohn's disease - adult - Initial application | |
| Crohn's disease - adult - Renewal | 5 |
| Crohn's disease - children - Initial application | |
| Crohn's disease - children - Renewal | 6 |
| Crohn's disease - fistulising - Initial application | |
| Crohn's disease - fistulising - Renewal | |
| Hidradenitis suppurativa - Initial application | |
| Hidradenitis suppurativa - Renewal | |
| Ocular inflammation – chronic - Initial application | |
| Ocular inflammation – chronic - Renewal | |
| Ocular inflammation – severe - Initial application | 8 |
| Ocular inflammation – severe - Renewal | 9 |
| Psoriasis - severe chronic plaque - Initial application | |
| Psoriasis - severe chronic plaque - Renewal | |
| Pyoderma gangrenosum - Initial application | 4 |
| Pyoderma gangrenosum - Renewal | 5 |
| Still's disease – adult-onset (AOSD) - Initial application | |
| Still's disease – adult-onset (AOSD) - Renewal | 12 |
| Ankylosing spondylitis - Initial application | |
| Ankylosing spondylitis - Renewal | |
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APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: | |
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| Reg No: | First Names: | First Names: | |
| Name: | Surname: | Surname: | |
| Address: | DOB: | Address: | |
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| Fax Number: | | Fax Number: | |
| Adalimumab (Humira - Alternative brar | nd) | | |
| Initial application — Behcet's disease – severe Applications from any relevant practitioner. Appro Prerequisites(tick boxes where appropriate) | vals valid for 6 months. | | |
| | I intolerable side effects from adalimumab (Amgevita) | following a minimum of 4 weeks treatment | |
| | toms of loss of disease control following a minimum of butes this loss of disease response to a change in tre | | |
| 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. Approvemental Prerequisites (tick boxes where appropriate) | als valid for 6 months. | | |
| The patient has had a good clinical response to treatment with measurably improved quality of life | | uality 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 Practitio Prerequisites(tick boxes where appropriate) | ner on the recommendation of a dermatologist. Appr | ovals valid for 6 months. | |
| | I intolerable side effects from adalimumab (Amgevita) | following a minimum of 4 weeks treatment | |
| | toms of loss of disease control following a minimum of butes this loss of disease response to a change in tre | | |
| l l . | f 6 months treatment with Amgevita | | |
| | al Authority approval for the Humira brand of adalimu | ımab for this indication | |
| Adalimumab to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered | | | |

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: | |
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| Reg No: | First Names: | First Names: | |
| Name: | Surname: | Surname: | |
| Address: | DOB: | Address: | |
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| | ad) - continued | Fax Number: | |
| Adalimumab (Humira - Alternative brand) - continued Renewal — Hidradenitis suppurativa Current approval Number (if known): | | | |
| Adalimumab is to be administered | at doses no greater than 40mg every 7 days. Fortnig | ghtly dosing has been considered | |
| Initial application — Psoriasis - severe chronic Applications only from a dermatologist or Practitic Prerequisites(tick boxes where appropriate) | plaque ner on the recommendation of a dermatologist. Appr | rovals valid for 6 months. | |
| 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 previously had a Spec | of 6 months treatment with Amgevita ial Authority approval for the Humira brand of adalimuted tooses no greater than 40 mg every 14 days | umab for this indication | |
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APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPL | -ICAN | T (sta | mp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: |
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| Fax N | lumbe | r: | | | Fax Number: |
| Adal | limur | nab | (Humira - Alternative bran | nd) - continued | |
| Ren | ewal – | – Pso | riasis - severe chronic plaque | | |
| Appl | ication | is only | Number (if known): r from a dermatologist or Practition of the company of t | ner on the recommendation of a dermatologist. Appr | ovals valid for 6 months. |
| | | | | | |
| | | | | dy" severe chronic plaque psoriasis at the start of tre | atment |
| | | | | prior adalimumab treatment course the patient has a | |
| | | | or | ained at this level, when compared with the pre-adali | |
| | | | | prior adalimumab treatment course the patient has a 5 or more, when compared with the pre-treatment ba | |
| | | or | | | |
| | | | | e 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 eryth | nema, thickness and scaling, to slight or better, or sus e baseline values | |
| | | | or Following each | prior adalimumab treatment course the patient has a | reduction of 75% or more in the skin area |
| | | | affected, or sus | tained at this level, as compared to the pre-adalimum | nab treatment baseline value |
| | and | | | | |
| | l | | Adalimumab to be administered at | doses no greater than 40 mg every 14 days | |
| App | licatio | ns onl | on — Pyoderma gangrenosum y from a dermatologist. Approvals ck boxes where appropriate) | s valid for 6 months. | |
| | | | The patient has experienced | I 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 | | | | |
| | Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication | | umab for this indication | | |
| | and [| | A maximum of 8 doses | | |
| | | | | | |

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: |
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| Reg No: | First Names: | First Names: |
| Name: | Surname: | Surname: |
| Address: | DOB: | Address: |
| | Address: | |
| | nd) - continued | Fax Number: |
| Renewal — Pyoderma gangrenosum | ia) - commueu | |
| Current approval Number (if known): | | |
| Applications only from a dermatologist. Approvals Prerequisites(tick boxes where appropriate) | | |
| The patient has demonstrated clin and A maximum of 8 doses | ical improvement and continues to require treatment | |
| Prerequisites (tick boxes where appropriate) The patient has experienced and a maximum of 6 months or Patient has developed symp 6 months treatment with Amor Patient has Crohn's and is companded and Patient has previously had a Speciand | d intolerable side effects from adalimumab (Amgevita) is treatment with Amgevitat browns of loss of disease control following a minimum of a gevita and clinician attributes this loss of disease resistant of the attributes the loss of disease resistant and clinician attributes the loss of disease resistant and clinician attributes the loss of disease resistant and the loss of disease destabilisation if the | of 4 weeks treatment, and a maximum of ponse to a change in treatment regimen ere were to be a change to current treatment |
| Renewal — Crohn's disease - adult | | |
| Current approval Number (if known): Applications only from a gastroenterologist or Prace Prerequisites(tick boxes where appropriate) | ctitioner on the recommendation of a gastroenterologi | st. Approvals valid for 6 months. |
| or CDAI score has reduced by CDAI score is 150 or less | 100 points from the CDAI score when the patient was | s initiated on adalimumab |
| | ed an adequate response to treatment, but CDAI scor | re cannot be assessed |
| and Adalimumab to be administered at | t doses no greater than 40 mg every 14 days | |

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: |
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| Reg No: | First Names: | First Names: |
| Name: | Surname: | Surname: |
| Address: | DOB: | Address: |
| | Address: | |
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| Fax Number: | | Fax Number: |
| Adalimumab (Humira - Alternative brai | nd) - continued | |
| Initial application — Crohn's disease - children Applications only from a gastroenterologist or Pra Prerequisites(tick boxes where appropriate) | ctitioner on the recommendation of a gastroenterolog | ist. Approvals valid for 6 months. |
| or and a maximum of 6 months Patient has developed symp 6 months treatment with Am or | d intolerable side effects from adalimumab (Amgevita treatment with Amgevita streatment with Amgevita streatment with Amgevita streatment with Amgevita and clinician attributes this loss of disease resonsidered to be at risk of disease destabilisation if the | of 4 weeks treatment, and a maximum of ponse to a change in treatment regimen |
| and Patient has previously had a Spec | ial Authority approval for the Humira brand of adalimed 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 Prace Prerequisites(tick boxes where appropriate) | titioner on the recommendation of a gastroenterologi | st. Approvals valid for 6 months. |
| PCDAI score has reduced b | y 10 points from the PCDAI score when the patient w | ras initiated on adalimumab |
| PCDAI score is 15 or less | | |
| | ed an adequate response to treatment, but PCDAI sc | ore cannot be assessed |
| Adalimumab to be administered at | doses no greater than 40 mg every 14 days | |
| Initial application — Crohn's disease - fistulisin Applications only from a gastroenterologist or Pra Prerequisites(tick boxes where appropriate) | ng ctitioner on the recommendation of a gastroenterolog | iist. Approvals valid for 6 months. |
| and a maximum of 6 months | d intolerable side effects from adalimumab (Amgevita s treatment with Amgevita |) following a minimum of 4 weeks treatment, |
| 6 months treatment with Am | otoms of loss of disease control following a minimum gevita and clinician attributes this loss of disease res | |
| Patient has Crohn's and is c | onsidered to be at risk of disease destabilisation if th | ere were to be a change to current treatment |
| and Patient has previously had a Spec | ial Authority approval for the Humira brand of adalim | umab for this indication |
| | doses no greater than 40 mg every 14 days | |

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: | |
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| Reg No: | First Names: | First Names: | |
| Name: | Surname: | Surname: | |
| Address: | DOB: | Address: | |
| | Address: | | |
| | | | |
| Fax Number: | | Fax Number: | |
| Adalimumab (Humira - Alternative brar | nd) - continued | | |
| Renewal — Crohn's disease - fistulising | | | |
| Prerequisites(tick boxes where appropriate) | titioner on the recommendation of a gastroenterologi | | |
| 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 | | | |
| | <u> </u> | | |
| Initial application — Ocular inflammation – chro Applications from any relevant practitioner. Appro Prerequisites(tick boxes where appropriate) | | | |
| The patient has experienced and a maximum of 6 months | l intolerable side effects from adalimumab (Amgevita treatment with Amgevita |) following a minimum of 4 weeks treatment, | |
| maximum of 6 months treatr | toms of loss of disease control following a minimum ment with Amgevita and clinician attributes this loss of | | |
| Patient has uveitis and is co | nsidered to be at risk of vision loss if they were to cha | ange treatment | |
| and | al Authority approval for the Humira brand of adalimonal doses no greater than 40 mg every 14 days | umab for this indication | |
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APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: |
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| Reg No: | First Names: | First Names: |
| Name: | Surname: | Surname: |
| Address: | DOB: | Address: |
| | Address: | |
| Fax Number: | | Fax Number: |
| Adalimumab (Humira - Alternative bran | nd) - continued | |
| Renewal — Ocular inflammation – chronic | | |
| Current approval Number (if known): | | |
| Applications from any relevant practitioner. Approx | als 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) 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 Adalimumab to be administered at doses no greater than 40 mg every 14 days Initial application — Ocular inflammation – severe | | |
| Applications from any relevant practitioner. Appro Prerequisites (tick boxes where appropriate) | vals valid for 12 months. | |
| and a maximum of 6 months Patient has developed symp maximum of 6 months treati regimen or | d intolerable side effects from adalimumab (Amgevita streatment with Amgevita stoms of loss of disease control following a minimum ment with Amgevita and clinician attributes this loss of the control following a minimum ment with Amgevita and clinician attributes this loss of the control following a minimum ment with Amgevita and clinician attributes this loss of the control following a minimum ment with Amgevita and clinician attributes this loss of the control following a minimum ment with Amgevita and clinician attributes this loss of the control following a minimum ment with Amgevita and clinician attributes the control following a minimum ment with Amgevita and clinician attributes the control following a minimum ment with Amgevita and clinician attributes the control following a minimum ment with Amgevita and clinician attributes the control following a minimum ment with Amgevita and clinician attributes the control following a minimum ment with Amgevita and clinician attributes the control following a minimum ment with Amgevita and clinician attributes the control following a minimum ment with Amgevita and clinician attributes the control following attributes the control following attributes the control following attributes and clinician attributes are control following attributes at the control following at the control following attributes attributes at the control following attributes attributes at the | of 4 weeks treatment with Amgevita, and a of disease response to a change in treatment |
| and | ial Authority approval for the Humira brand of adalimate | umab for this indication |
| Adalimumab to be administered at | doses no greater than 40 mg every 14 days | |

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp | or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: |
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| Fax Number: | | | Fax Number: |
| Adalimumab (H | lumira - Alternative bra | nd) - continued | |
| Renewal — Ocula | r inflammation – severe | | |
| Applications from a | umber (if known): Iny relevant practitioner. Approboxes where appropriate) | vals valid for 12 months. | |
| 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) | | |
| | < 10mg daily, or steroid drops less than twice daily if under 18 years old | | |
| Adalimumab to be administered at doses no greater than 40 mg every 14 days | | | |
| Applications only for | ankylosing spondylitis rom a rheumatologist or Practit boxes where appropriate) | ioner on the recommendation of a rheumatologist. Ap | oprovals valid for 6 months. |
| or | The patient has experienced | d 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 Pat | Patient has received a maximum of 6 months treatment with Amgevita | | |
| Pat | tient has previously had a Spec | ial Authority approval for the Humira brand of adalimu | ımab for this indication |
| | Adalimumab to be administered at doses no greater than 40 mg every 14 days | | |
| Renewal — ankylo | osing spondylitis | | |
| Current approval N | umber (if known): | | |
| Applications only fr | , , | oner on the recommendation of a rheumatologist. Ap | provals valid for 6 months. |
| imp | 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 | | tment baseline on a 10 point scale, or an |
| and Ada | Adalimumab to be administered at doses no greater than 40 mg every 14 days | | |

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: |
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| Address: | DOB: | Address: |
| | Address: | |
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| | | Fax Number: |
| Adalimumab (Humira - Alternative brai | | |
| Initial application — Arthritis – oligoarticular co | <u> </u> | named specialist or rheumatologist. Approvals |
| The patient has experienced | d intolerable side effects from adalimumab (Amgevita) |) following a minimum of 4 weeks treatment |
| Patient has developed symp | otoms of loss of disease control following a minimum of ibutes this loss of disease response to a change in tro | |
| and | of 6 months treatment with Amgevita | ımab for this indication |
| valid for 6 months. Prerequisites(tick box where appropriate) | • | |
| Initial application — Arthritis - polyarticular con Applications only from a named specialist, rheum- valid for 6 months. Prerequisites(tick boxes where appropriate) | urse juvenile idiopathic atologist or Practitioner on the recommendation of a r | named specialist or rheumatologist. Approvals |
| 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 juve | enile idiopathic | |
| valid for 6 months. Prerequisites(tick box where appropriate) | atologist or Practitioner on the recommendation of a n | |
| assessment from baseline | Service and control of the court of the court and court | |

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: |
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| Name: | Surname: | Surname: |
| Address: | DOB: | Address: |
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| Fax Number: | | Fax Number: |
| Adalimumab (Humira - Alternative brar | nd) - continued | |
| Initial application — Arthritis - psoriatic Applications only from a named specialist, rheuma valid for 6 months. Prerequisites(tick boxes where appropriate) | atologist or Practitioner on the recommendation of a r | named specialist or rheumatologist. Approvals |
| The patient has experienced | intolerable side effects from adalimumab (Amgevita) |) following a minimum of 4 weeks treatment |
| Patient has developed symp | toms of loss of disease control following a minimum obutes this loss of disease response to a change in tro | |
| and Patient has received a maximum o | f 6 months treatment with Amgevita | |
| Patient has previously had a Speci | al Authority approval for the Humira brand of adalimu | ımab for this indication |
| | doses no greater than 40 mg every 14 days | |
| | | |
| Renewal — Arthritis - psoriatic Current approval Number (if known): | tologist or Practitioner on the recommendation of a n | amed specialist or rheumatologist. Approvals |
| The patient demonstrates at least a to prior adalimumab treatment in the | a continuing 30% improvement in active joint count fr | om baseline and a clinically significant response |
| 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 Practiti Prerequisites(tick boxes where appropriate) | oner on the recommendation of a rheumatologist. Ap | oprovals valid for 6 months. |
| The patient has experienced or | intolerable side effects from adalimumab (Amgevita) | following a minimum of 4 weeks treatment |
| Patient has developed symp | toms of loss of disease control following a minimum obutes this loss of disease response to a change in tro | of 4 weeks treatment with adalimumab eatment regimen |
| and Patient has received a maximum o | f 6 months treatment with Amgevita | |
| | al Authority approval for the Humira brand of adalimu | umab for this indication |
| Adalimumab to be administe | red at doses no greater than 40 mg every 14 days | |
| Patient cannot take concomi an adequate response | tant methotrexate and requires doses of adalimumab | higher than 40 mg every 14 days to maintain |

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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| APPLICANT (stamp or sticker acceptable) | PATIENT NHI: | REFERRER Reg No: |
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| Reg No: | First Names: | First Names: |
| Name: | Surname: | Surname: |
| Address: | DOB: | Address: |
| | Address: | |
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| Fax Number: | | Fax Number: |
| Adalimumab (Humira - Alternative brar | nd) - continued | |
| Renewal — Arthritis – rheumatoid | | |
| Current approval Number (if known): Applications only from a rheumatologist or Practition Prerequisites(tick boxes where appropriate) | oner on the recommendation of a rheumatologist. Ap | provals valid for 6 months. |
| The patient demonstrates at least to prior adalimumab treatment in the | a continuing 30% improvement in active joint count fr ne opinion of the treating physician | om baseline and a clinically significant response |
| or | red at doses no greater than 40 mg every 14 days tant methotrexate and requires doses of adalimumab | higher than 40 mg every 14 days to maintain |
| Initial application — Still's disease – adult-onse Applications only from a rheumatologist or Practiti Prerequisites(tick boxes where appropriate) | et (AOSD) oner on the recommendation of a rheumatologist. Ap | oprovals valid for 6 months. |
| The patient has experienced or | intolerable side effects from adalimumab (Amgevita) |) following a minimum of 4 weeks treatment |
| Patient has developed symp | toms of loss of disease control following a minimum obutes this loss of disease response to a change in tro | |
| and Patient has received a maximum o | f 6 months treatment with Amgevita | |
| Patient has previously had a Speci | al Authority approval for the Humira brand of adalimu | umab for this indication |
| Renewal — Still's disease – adult-onset (AOSD | | |
| Prerequisites(tick box where appropriate) | oner on the recommendation of a rheumatologist. Ap | |
| The patient has demonstrated a sustained | d improvement in inflammatory markers and function | nal status |