SA2157 - Adalimumab (Humira - Alternative brand)

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Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Patient has developed symptonic (Amgevita) and clinician attributes	ovals valid for 6 months. d intolerable side effects from adalimumab (Amgevita otoms of loss of disease control following a minimum ributes this loss of disease response to a change in tr	of 4 weeks treatment with adalimumab
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. Appro Prerequisites (tick boxes where appropriate)	vals 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 Practition Prerequisites(tick boxes where appropriate)	oner on the recommendation of a dermatologist. App	rovals valid for 6 months.
or Patient has developed sym	d intolerable side effects from adalimumab (Amgevita otoms of loss of disease control following a minimum ributes this loss of disease response to a change in tr	of 4 weeks treatment with adalimumab
and Patient has received a maximum and	of 6 months treatment with Amgevita	
	sial Authority approval for the Humira brand of adalimu	umab for this indication
	t doses no greater than 40 mg every 7 days. Fortnigh	ntly dosing has been considered

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Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Adalimumab (Humira - Alternative brar	nd) - continued	
Renewal — Hidradenitis suppurativa		
Current approval Number (if known):		
	ner on the recommendation of a dermatologist. Appro	ovals 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 Applications only from a dermatologist or Practitio	plaque ner on the recommendation of a dermatologist. Appr	ovals valid for 6 months.
Prerequisites(tick boxes where appropriate)	3 11	
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 tre	
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
Adalimumab to be administered at	doses no greater than 40 mg every 14 days	

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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 — Psoriasis - severe chronic plaque		
Current approval Number (if known): Applications only from a dermatologist or Practition Prerequisites(tick boxes where appropriate)	ner on the recommendation of a dermatologist. Appro	ovals valid for 6 months.
or Following each more, or is sust. Following each improvement of Patient had severe ch and Following each for all 3 of eryth treatment cours Following each Following each	whole body" severe chronic plaque psoriasis at the start of treatment ling each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or or is sustained at this level, when compared with the pre-adalimumab treatment baseline value ling each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) linement of 5 or more, when compared with the pre-treatment baseline value severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment ling each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores of or erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the ent course baseline values ling each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area and or sustained at this level, as compared to the pre-adalimumab treatment baseline value	
Initial application — Pyoderma gangrenosum Applications only from a dermatologist. Approvals Prerequisites(tick boxes where appropriate)	s valid for 6 months.	
The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment or) 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 o	Patient has received a maximum of 6 months treatment with Amgevita	
Patient has previously had a Speciand	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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APPLIC	CANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No):	First Names:	First Names:
Name:		Surname:	Surname:
Addres	s:	DOB:	Address:
		Address:	
Fax Nu	mber:		Fax Number:
Adalir	mumab (Humira - Alternative brar	nd) - continued	
Renev	val — Pyoderma gangrenosum		
Currer	nt approval Number (if known):		
	ations only from a dermatologist. Approvals quisites(tick boxes where appropriate)	valid for 6 months.	
Γ	The relieve has demonstrated alia		
	and	cal improvement and continues to require treatment	
	A maximum of 8 doses		
Applic	application — Crohn's disease - adult cations only from a gastroenterologist or Praquisites(tick boxes where appropriate)	ctitioner on the recommendation of a gastroenterolog	ist. Approvals valid for 6 months.
	and a maximum of 6 months	I intolerable side effects from adalimumab (Amgevita) streatment with Amgevitat) following a minimum of 4 weeks treatment,
	6 months treatment with Am	toms of loss of disease control following a minimum of 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 the	ere were to be a change to current treatment
	and Patient has previously had a Speci	ial Authority approval for the Humira brand of adalimu	umab for this indication
	and	doses no greater than 40 mg every 14 days	
L			
Renev	wal — Crohn's disease - adult		
Currer	nt approval Number (if known):		
	ations only from a gastroenterologist or Prac quisites(tick boxes where appropriate)	titioner on the recommendation of a gastroenterologi	st. Approvals valid for 6 months.
Γ			
	or	100 points from the CDAI score when the patient was	s initiated on adalimumab
	CDAI score is 150 or less		
	The patient has demonstrate	ed an adequate response to treatment, but CDAI scor	re cannot be assessed
	and Adalimumab to be administered at	doses no greater than 40 mg every 14 days	

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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 (Humira - Alternative brai	nd) - continued	
Initial application — Crohn's disease - children Applications only from a gastroenterologist or Pra Prerequisites(tick boxes where appropriate)	titioner on the recommendation of a gastroenterolog	ist. Approvals valid for 6 months.
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, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen 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		
Adalimumab to be administered at	doses no greater than 40 mg every 14 days	
Renewal — Crohn's disease - children Current approval Number (if known):	ctitioner 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
and 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	ist. Approvals valid for 6 months.
The patient has experienced and a maximum of 6 months	d intolerable side effects from adalimumab (Amgevita s treatment with Amgevita) following a minimum of 4 weeks treatment,
Patient has developed symp 6 months treatment with Am	otoms of loss of disease control following a minimum or gevita and clinician attributes this loss of disease res	ponse to a change in treatment regimen
Patient has Crohn's and is c	considered 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 adalimu	umab for this indication
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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 (Humira - Alternative brar	nd) - continued	
Renewal — Crohn's disease - fistulising		
Current approval Number (if known):		
, ,	titioner on the recommendation of a gastroenterologi	st. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)	g.	
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 – chroapplications from any relevant practitioner. Appro		
Prerequisites(tick boxes where appropriate)		
and a maximum of 6 months	I intolerable side effects from adalimumab (Amgevita)	following a minimum of 4 weeks treatment,
or	toms of loss of disease control following a minimum	of 4 weeks treatment with Amgevita, and a
	ment with Amgevita and clinician attributes this loss o	
or	nsidered to be at risk of vision loss if they were to cha	ange treatment
and		
and Patient has previously had a Spec	ial Authority approval for the Humira brand of adalimu	imab for this indication
Adalimumab to be administered at	doses no greater than 40 mg every 14 days	

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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 (Humira - Alternative brar	nd) - continued	
Renewal — Ocular inflammation – chronic		
Current approval Number (if known):		
Applications from any relevant practitioner. Approx	vals 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 – sev Applications from any relevant practitioner. Appro Prerequisites(tick boxes where appropriate)		
or Patient has developed symp maximum of 6 months treate regimen or	otoms of loss of disease control following a minimum of ment with Amgevita and clinician attributes this loss of	of 4 weeks treatment with Amgevita, and a of disease response to a change in treatment
	nsidered to be at risk of vision loss if they were to cha	ange treatment
and Patient has previously had a Speciand and and	ial Authority approval for the Humira brand of adalimu	umab for this indication
Adalimumab to be administered at	doses no greater than 40 mg every 14 days	

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APPL	ICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg N	lo:	First Names:	First Names:
Name	:	Surname:	Surname:
Addre	ss:	DOB:	Address:
		Address:	
	umber:		
	imumab (Humira - Alternative brai	1a) - continued	
	ent approval Number (if known):		
	cations from any relevant practitioner. Approrequisites(tick boxes where appropriate)	als valid for 12 months.	
	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) 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		
Appl	I application — ankylosing spondylitis ications only from a rheumatologist or Practitequisites(tick boxes where appropriate)	oner on the recommendation of a rheumatologist. A	pprovals valid for 6 months.
Ĭ	or	I intolerable side effects from adalimumab (Amgevita toms of loss of disease control following a minimum	
	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		uniabilot tins indication
Rene	ewal — ankylosing spondylitis		
Appli	ent approval Number (if known):cations only from a rheumatologist or Practition of the propriate of the	oner on the recommendation of a rheumatologist. Ap	oprovals valid for 6 months.
	improvement in BASDAI of 50%, v	ovement in BASDAI of 4 or more points from pre-treat/hichever is less doses no greater than 40 mg every 14 days	atment baseline on a 10 point scale, or an

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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 (Humira - Alternative bra	nd) - continued		
Initial application — Arthritis – oligoarticular constant Applications only from a named specialist, rheums valid for 6 months. Prerequisites(tick boxes where appropriate)	ourse juvenile idiopathic atologist or Practitioner on the recommendation of a r	named specialist or rheumatologist. Approvals	
or Patient has developed symp	d intolerable side effects from adalimumab (Amgevita) stoms of loss of disease control following a minimum of the control	of 4 weeks treatment with adalimumab	
and	and Patient has received a maximum of 6 months treatment with Amgevita		
Renewal — Arthritis – oligoarticular course juv	renile idiopathic		
Current approval Number (if known):			
The patient demonstrates at least a cont assessment from baseline	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 con Applications only from a named specialist, rheums 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	
	d intolerable side effects from adalimumab (Amgevita)) following a minimum of 4 weeks treatment	
	otoms of loss of disease control following a minimum of ibutes this loss of disease response to a change in tro		
and Patient has received a maximum of	of 6 months treatment with Amgevita		
Patient has previously had a Spec	ial Authority approval for the Humira brand of adalimu	umab for this indication	
Renewal — Arthritis - polyarticular course juve	nile idiopathic		
Current approval Number (if known):	utologist or Practitioner on the recommendation of a n	named specialist or rheumatologist. Approvals	
The patient demonstrates at least a cont assessment from baseline	inuing 30% improvement in active joint count and cor	ntinued improvement in physician's global	

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Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
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	
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 free opinion of the treating physician	om baseline and a clinically significant response
and	doses no greater than 40 mg every 14 days	
Initial application — Arthritis – rheumatoid Applications only from a rheumatologist or Practitic Prerequisites(tick boxes where appropriate)	oner on the recommendation of a rheumatologist. Ap	oprovals valid for 6 months.
The patient has experienced	intolerable side effects from adalimumab (Amgevita)	following a minimum of 4 weeks treatment
Patient has developed symp (Amgevita) and clinician attri	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

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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 — 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 a to prior adalimumab treatment in the and	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	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 sustaine	d improvement in inflammatory markers and function	nal status