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:	
Adalimumab (Humira - Alternative brar	nd)		
) following a minimum of 4 weeks treatment	
Patient has developed symp (Amgevita) and clinician attri	toms of loss of disease control following a minimum of ibutes this loss of disease response to a change in tro	of 4 weeks treatment with adalimumab eatment 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. Approv Prerequisites (tick boxes where appropriate)	vals valid for 6 months.		
The patient has had a good clinica	I response to treatment with measurably improved qu	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	rovals valid for 6 months.	
The patient has experienced or	I 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 of ibutes this loss of disease response to a change in tro		
and Patient has received a maximum o and	of 6 months treatment with Amgevita		
	ial Authority approval for the Humira brand of adalimu	umab for this indication	
and			

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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	d) - continued		
Renewal — Hidradenitis suppurativa			
Current approval Number (if known):			
Applications only from a dermatologist or Practition Prerequisites (tick boxes where appropriate)	er on the recommendation of a dermatologist. Appre	ovals valid for 6 months.	
The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline 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 Practition Prerequisites(tick boxes where appropriate)	plaque ner on the recommendation of a dermatologist. Appr	ovals 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 received a maximum of and	Patient has received a maximum of 6 months treatment with Amgevita		
	al Authority approval for the Humira brand of adalimu	umab for this indication	
	doses no greater than 40 mg every 14 days		

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APPL	ICAN	T (sta	mp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg N	lo:			First Names:	First Names:
Name	:			Surname:	Surname:
Addre	ss:			DOB:	Address:
				Address:	
Fax N	umbe	r:			Fax Number:
Adali	imur	nab	(Humira - Alternative bran	nd) - continued	
			riasis - severe chronic plaque	•	
Appli	icatior	is only	Number (if known): r from a dermatologist or Practition ck boxes where appropriate)	ner on the recommendation of a dermatologist. Appro	ovals valid for 6 months.
			Patient had "whole boo	dy" severe chronic plaque psoriasis at the start of tre	atment
			Following each p	orior adalimumab treatment course the patient has a ained at this level, when compared with the pre-adali	
			Following each p	orior adalimumab treatment course the patient has a 5 or more, when compared with the pre-treatment ba	
		or	Patient had severe chr	ronic plaque psoriasis of the face, or palm of a hand	or sole of a foot at the start of treatment
			for all 3 of erythe treatment course	orior adalimumab treatment course the patient has a ema, thickness and scaling, to slight or better, or sus a baseline values	
			Following each paffected, or sust	orior adalimumab treatment course the patient has a ained at this level, as compared to the pre-adalimum	reduction of 75% or more in the skin area ab treatment baseline value
	and		Adalimumab to be administered at	doses no greater than 40 mg every 14 days	
Appl	licatio	ns onl	on — Pyoderma gangrenosum y from a dermatologist. Approvals ck boxes where appropriate)	valid for 6 months.	
		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	F	Patient has received a maximum o	f 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		
	and and	F	Patient has previously had a Speci-	-	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 bra	and) - continued	
Renewal — Pyoderma gangrenosum		
Current approval Number (if known):		
Applications only from a dermatologist. Approval	s valid for 6 months.	
Prerequisites(tick boxes where appropriate)		
· · · · ·	nical improvement and continues to require treatment	
A maximum of 8 doses		
Initial application — Crohn's disease - adult Applications only from a gastroenterologist or Pr	actitioner on the recommendation of a gastroenterolog	gist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)	· ·	
	distribution of the state of th) following a significant of the state of th
and a maximum of 6 month	ed intolerable side effects from adalimumab (Amgevitans treatment with Amgevitat	i) following a minimum of 4 weeks treatment,
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 Spe	cial Authority approval for the Humira brand of adalim	umab for this indication
and Adalimumab to be administered a	at doses no greater than 40 mg every 14 days	
Adaintimable be administered at doses no greater than 40 mg every 14 days		
Renewal — Crohn's disease - adult		
Current approval Number (if known):		
	actitioner on the recommendation of a gastroenterolog	ist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)		
CDAI score has reduced b	y 100 points from the CDAI score when the patient wa	s 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	an adequate response to treatment, but CDAI SCO	TO CANTIOL DE ASSESSEU
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 bra	nd) - continued	
Initial application — Crohn's disease - children Applications only from a gastroenterologist or Pra Prerequisites(tick boxes where appropriate)	national cititioner on the recommendation of a gastroenterolog	ist. Approvals valid for 6 months.
or and a maximum of 6 month	d intolerable side effects from adalimumab (Amgevita s treatment with Amgevita otoms of loss of disease control following a minimum	
or 6 months treatment with Am	ngevita and clinician attributes this loss of disease res considered to be at risk of disease destabilisation if the	ponse to a change in treatment regimen
and Patient has previously had a Spec	cial Authority approval for the Humira brand of adalimu	umab for this indication
and Adalimumab to be administered a	t 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)	ctitioner on the recommendation of a gastroenterologi	st. Approvals valid for 6 months.
PCDAI score has reduced b	by 10 points from the PCDAI score when the patient w	as initiated on adalimumab
or PCDAI score is 15 or less		
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 - fistulisi Applications only from a gastroenterologist or Pra Prerequisites(tick boxes where appropriate)	ng actitioner on the recommendation of a gastroenterolog	ist. Approvals valid for 6 months.
and a maximum of 6 month	d intolerable side effects from adalimumab (Amgevita s treatment with Amgevita) following a minimum of 4 weeks treatment,
	otoms of loss of disease control following a minimum on gevita and clinician attributes this loss of disease res	
	considered to be at risk of disease destabilisation if the	ere were to be a change to current treatment
and Patient has previously had a Spec	cial Authority approval for the Humira brand of adalimu	umab for this indication
	t 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:Adalimumab (Humira - Alternative bra	nd) - continued	Fax Number:
Renewal — Crohn's disease - fistulising		
Current approval Number (if known):	ctitioner on the recommendation of a gastroenterologi	st. Approvals valid for 6 months.
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		
Adalimumab to be administered a	t doses no greater than 40 mg every 14 days	
Initial application — Ocular inflammation – che Applications from any relevant practitioner. Appro Prerequisites(tick boxes where appropriate)		
The patient has experience and a maximum of 6 month	d intolerable side effects from adalimumab (Amgevita) s treatment with Amgevita) following a minimum of 4 weeks treatment,
Patient has developed sym	otoms of loss of disease control following a minimum of ment with Amgevita and clinician attributes this loss of	
	ensidered to be at risk of vision loss if they were to cha	ange treatment
and Patient has previously had a Spec	ial Authority approval for the Humira brand of adalimu	umab for this indication
Adalimumab to be administered a	t 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:
Adalimumab (Humira - Alternative brain Renewal — Ocular inflammation – chronic Current approval Number (if known):		
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 treat regimen	d intolerable side effects from adalimumab (Amgevita streatment with Amgevita otoms 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 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 at the con	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 adalimated doses no greater than 40 mg every 14 days	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 bra	nd) - continued		
Renewal — Ocular inflammation – severe			
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 3 initial doses		
or Following each 12-month tre	eatment period, the patient has had a sustained reduc	ction in inflammation (Standardisation of Uveitis	
	$a < \frac{1}{2}$ + anterior chamber or vitreous cells, absence of		
or	eatment period, the patient has a sustained steroid sp	paring effect, allowing reduction in prednisone to	
	os less than twice daily if under 18 years old	aming onest, anothing reduction in predimente to	
and Adalimumah to be administered at	doses no greater than 40 mg every 14 days		
	about to greater than 40 mg every 14 days		
Initial application — ankylosing spondylitis	ioner on the recommendation of a rheumatologist. Ap	anyovala valid for 6 months	
Prerequisites(tick boxes where appropriate)	ioner on the recommendation of a medinatologist. A	oprovais valid for 6 months.	
The patient has experienced 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 o	Patient has received a maximum of 6 months treatment with Amgevita		
Patient has previously had a Spec	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 — ankylosing spondylitis			
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.	
	PAODAL CO.		
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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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 — Arthritis – oligoarticular confidence of Applications only from a named specialist, rheumvalid 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	
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 ial Authority approval for the Humira brand of adalimu	umab for this indication	
Renewal — Arthritis – oligoarticular course juv	ranila idionathia		
	-		
Current approval Number (if known):	atologist or Practitioner on the recommendation of a n	ramed specialist or rhaumatologist. Approvals	
valid for 6 months.	actions of the resonance of the resonance and the resonance of the re-	amed specialist of meaniatologist. Approvals	
Prerequisites(tick box where appropriate)			
assessment from baseline	inuing 30% improvement in active joint count and cor	ntinued improvement in pnysician's global	
Initial application — Arthritis - polyarticular con Applications only from a named specialist, rheumvalid for 6 months.	urse juvenile idiopathic atologist or Practitioner on the recommendation of a r	named specialist or rheumatologist. Approvals	
Prerequisites(tick boxes where appropriate)			
The patient has experienced	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			
Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication			
Renewal — Arthritis - polyarticular course juve	nile idiopathic		
Current approval Number (if known):	atologist or Practitioner on the recommendation of a n	named specialist or rheumatologist. Approvals	
valid for 6 months. Prerequisites(tick box where appropriate)			
	inuing 30% improvement in active joint count and cor	ntinued improvement in physician's global	

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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 — Arthritis - psoriatic Applications only from a named specialist, rheumvalid for 6 months. Prerequisites(tick boxes where appropriate)	atologist or Practitioner on the recommendation of a r	named specialist or rheumatologist. Approvals	
or	I intolerable side effects from adalimumab (Amgevita)	-	
	ibutes this loss of disease response to a change in tri		
and Patient has received a maximum of and	of 6 months treatment with Amgevita		
Patient 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		
Paramet Authorities and activities			
Renewal — Arthritis - psoriatic			
Current approval Number (if known):	itologist or Practitioner on the recommendation of a n	amed specialist or rheumatologist. Approvals	
to prior adalimumab treatment in t	a continuing 30% improvement in active joint count fr ne opinion of the treating physician	om baseline and a clinically significant response	
	Adalimumab to be administered at doses no greater than 40 mg every 14 days		
Initial application — Arthritis – rheumatoid Applications only from a rheumatologist or Practit Prerequisites(tick boxes where appropriate)	oner on the recommendation of a rheumatologist. Ap	oprovals valid for 6 months.	
The patient has experienced or	I intolerable side effects from adalimumab (Amgevita	following a minimum of 4 weeks treatment	
	toms of loss of disease control following a minimum of ibutes this loss of disease response to a change in tro		
Patient has received a maximum of and	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	
	ered at doses no greater than 40 mg every 14 days		
Patient cannot take concom an adequate response	itant methotrexate and requires doses of adalimumab	higher than 40 mg every 14 days to maintain	

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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 — 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
Adalimumab to be administe	ered at doses no greater than 40 mg every 14 days	
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-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.
	I 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		
	ial Authority approval for the Humira brand of adalimu	imab for this indication
Renewal — Still's disease – adult-onset (AOSD)	
Current approval Number (if known):	oner on the recommendation of a rheumatologist. Ap	provals valid for 6 months.
The patient has demonstrated a sustained	ed improvement in inflammatory markers and function	al status