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	

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 2 Form SA2157 January 2025

APPL	ICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg N	0:	First Names:	First Names:
Name	:	Surname:	Surname:
Addre	SS:	DOB:	Address:
		Address:	
Fax N	umber:		Fax Number:
Adali	mumab (Humira - Alternative brai	nd)	
Appl	I application — Behcet's disease – severe ications from any relevant practitioner. Approequisites(tick boxes where appropriate) The patient has experienced) 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 tre	
	Patient has previously had a Spec	of 6 months treatment with Amgevita ial Authority approval for the Humira brand of adalimu doses no greater than 40 mg every 14 days	umab for this indication
Curre Appli	ent approval Number (if known): cations from any relevant practitioner. Approve		
	The patient has had a good clinica	al response to treatment with measurably improved qu	uality of life
	Adalimumad to be administered at	doses no greater than 40 mg every 14 days	
Appl	I application — Hidradenitis suppurativa ications only from a dermatologist or Practitio equisites (tick boxes where appropriate)	ner on the recommendation of a dermatologist. Appr	rovals valid for 6 months.
	or Patient has developed symp	d intolerable side effects from adalimumab (Amgevita) stoms of loss of disease control following a minimum of ibutes this loss of disease response to a change in tree	of 4 weeks treatment with adalimumab
	and Patient has received a maximum of and	of 6 months treatment with Amgevita	
		ial Authority approval for the Humira brand of adalimu	umab for this indication
		doses no greater than 40 mg every 7 days. Fortnigh	atly dosing has been considered

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 3 Form SA2157 January 2025

APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:	
Reg No:	First Names:	First Names:	
Name:	Surname:	Surname:	
Address:	DOB:	Address:	
	Address:		
For North and		For Northern	
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. Appro	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 plaque Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months. Prerequisites(tick boxes where appropriate)			
The patient has experienced or	intolerable side effects from adalimumab (Amgevita)) following a minimum of 4 weeks treatment	
	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 or and	f 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		

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 4 Form SA2157 January 2025

APPL	-ICAN	T (sta	mp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg N	No:			First Names:	First Names:
Name	e:			Surname:	Surname:
Addre	ess:			DOB:	Address:
				Address:	
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 ck boxes where appropriate)	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			
	and Following each price for all 3 of erythem			ronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment	
				n prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores thema, thickness and scaling, to slight or better, or sustained at this level, as compared to the se baseline values	
			for all 3 of eryth		
			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		toms of loss of disease control following a minimum	
				ibutes this loss of disease response to a change in tr	
		Patient has received a maximum o	of 6 months treatment with Amgevita		
Patient has previously had a Special Authority approval for the Humira brand of ad		ial Authority approval for the Humira brand of adalimo	umab for this indication		
	and [A maximum of 8 doses		

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 5 Form SA2157 January 2025

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 — Pyoderma gangrenosum		
Current approval Number (if known):		
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)		
and a maximum of 6 months Patient has developed symp 6 months treatment with Am Patient has Crohn's and is c and Patient has previously had a Speciand	I intolerable side effects from adalimumab (Amgevita) is treatment with Amgevitat stoms of loss of disease control following a minimum of gevita and clinician attributes this loss of disease results on the side of the state of	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):		
or CDAI score is 150 or less or The patient has demonstrate	100 points from the CDAI score when the patient was	
Adalimumab to be administered at	doses no greater than 40 mg every 14 days	

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 6 Form SA2157 January 2025

APPLICANT (stamp or sticker acceptable)		PATIENT NHI:	REFERRER Reg No:
Reg N	No:	First Names:	First Names:
Name	·	Surname:	Surname:
Addre	SS:	DOB:	Address:
		Address:	
Fax N	umber:		Fax Number:
Adal	imumab (Humira - Alternative brar	nd) - continued	
Appl	al application — Crohn's disease - children lications only from a gastroenterologist or Prace equisites(tick boxes where appropriate)	ctitioner on the recommendation of a gastroenterolog	ist. Approvals valid for 6 months.
	and a maximum of 6 months Patient has developed symp 6 months treatment with Am Patient has Crohn's and is co and Patient has previously had a Speci	intolerable side effects from adalimumab (Amgevita) treatment with Amgevita toms of loss of disease control following a minimum of gevita and clinician attributes this loss of disease responsidered to be at risk of disease destabilisation if the all Authority approval for the Humira brand of adalimut doses no greater than 40 mg every 14 days	of 4 weeks treatment, and a maximum of ponse to a change in treatment regimen ere were to be a change to current treatment
Appli	equisites(tick boxes where appropriate)	titioner on the recommendation of a gastroenterologition of a gastroenterologity of the recommendation of a gastroenterologic of the recommendation of a gastroenterologic of the recommendation of a gastroenterologic	
	or PCDAI score is 15 or less		
	The patient has demonstrate	ed an adequate response to treatment, but PCDAI sco	ore cannot be assessed
	and Adalimumab to be administered at	doses no greater than 40 mg every 14 days	
Appl	al application — Crohn's disease - fistulisin lications only from a gastroenterologist or Prace equisites(tick boxes where appropriate)	g titioner on the recommendation of a gastroenterolog	ist. Approvals valid for 6 months.
	or Patient has developed symp 6 months treatment with Am or Patient has Crohn's and is co	intolerable side effects from adalimumab (Amgevita) treatment with Amgevita toms of loss of disease control following a minimum of gevita and clinician attributes this loss of disease responsidered 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	al Authority approval for the Humira brand of adalimudoses no greater than 40 mg every 14 days	umab for this indication

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 7 Form SA2157 January 2025

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 bran	nd) - continued	
Renewal — Crohn's disease - fistulising		
Prerequisites(tick boxes where appropriate) The number of open draining or	titioner on the recommendation of a gastroenterological stress of the st	0%
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 at	doses no greater than 40 mg every 14 days	
Initial application — Ocular inflammation – chro Applications from any relevant practitioner. Approx Prerequisites(tick boxes where appropriate)		
The patient has experienced and a maximum of 6 months	intolerable side effects from adalimumab (Amgevita) treatment with Amgevita	following a minimum of 4 weeks treatment,
	toms of loss of disease control following a minimum on ment with Amgevita and clinician attributes this loss of	
	nsidered to be at risk of vision loss if they were to cha	ange treatment
and Patient has previously had a Speciand	al 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	

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 8 Form SA2157 January 2025

PATIENT NHI:	REFERRER Reg No:	
First Names:	First Names:	
Surname:	Surname:	
DOB:	Address:	
Address:		
	Fax Number:	
nd) - continued		
vals valid for 12 months.		
The patient has had a good clinical response following 12 weeks' initial treatment 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		
vere evals valid for 12 months.		
d intolerable side effects from adalimumab (Amgevita streatment with Amgevita streatment with Amgevita streatment with Amgevita streatment with Amgevita and clinician attributes this loss of the streatment with Amgevita and clinician attributes and clinician attributes are streatment.	of 4 weeks treatment with Amgevita, and a of disease response to a change in treatment	
ial Authority approval for the Humira brand of adalimonal doses no greater than 40 mg every 14 days	umab for this indication	
	Surname: DOB: Address: Address: Clinical response following 12 weeks' initial treatment period, the patient has had a sustained reduct to be at mixed and the patient has a sustained steroid spacetiment period, the patient has a sustained reduction spacetiment period, the patient has a sustained reduction spacetiment period, the patient has a sustained steroid spacetiment period, the patient has a sustained reduction spacetiment period, the patient has a su	

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 9 Form SA2157 January 2025

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 – severe			
Current approval Number (if known):			
Applications from any relevant practitioner. Approvemental Prerequisites (tick boxes where appropriate)	als valid for 12 months.		
The patient has had a good	clinical response following 3 initial doses		
Nomenclature (SUN) criteria of uveitic cystoid macular oe	eatment period, the patient has had a sustained reduct $< \frac{1}{2}$ + anterior chamber or vitreous cells, absence of dema)		
Following each 12-month tre	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 Practiti Prerequisites(tick boxes where appropriate)	oner on the recommendation of a rheumatologist. Ap	oprovals valid for 6 months.	
The patient has experienced	l intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment	
	toms of loss of disease control following a minimum	of 4 weeks treatment with adalimumab	
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 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.	
improvement in BASDAI of 50%, w	ovement in BASDAI of 4 or more points from pre-treathchever is less	tment baseline on a 10 point scale, or an	
Adalimumab to be administered at	doses no greater than 40 mg every 14 days		

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 10 Form SA2157 January 2025

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 — 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
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	
and	of 6 months treatment with Amgevita	umab for this indication
Renewal — Arthritis – oligoarticular course juv	enile idiopathic	
Current approval Number (if known):		
Applications only from a named specialist, rheuma valid for 6 months. Prerequisites(tick box where appropriate)	tologist or Practitioner on the recommendation of a n	amed specialist or rheumatologist. Approvals
	inuing 30% improvement in active joint count and cor	ntinued improvement in physician's global
valid 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 or	I 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 Patient has received a maximum of	of 6 months treatment with Amgevita	
	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):		
Applications only from a named specialist, rheuma valid for 6 months. Prerequisites(tick box where appropriate)	tologist or Practitioner on the recommendation of a n	amed 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

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Page 11 Form SA2157 January 2025

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	
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	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

Page 12 Form SA2157 January 2025

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	
Renewal — Arthritis – rheumatoid		
Current approval Number (if known):		
, ,	oner on the recommendation of a rheumatologist. Ap	provals valid for 6 months.
Prerequisites(tick boxes where appropriate)		
to prior adalimumab treatment in the	a continuing 30% improvement in active joint count fr	om baseline and a clinically significant response
Adalimumah to be administe	ered at doses no greater than 40 mg every 14 days	
or		
Patient cannot take concom an adequate response	itant 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) ioner on the recommendation of a rheumatologist. Ap	oprovals valid for 6 months.
	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	
and Patient has proviously had a Spec	ial Authority approval for the Humira brand of adalimu	umab for this indication
Fatient has previously had a Spec	iai Authority approval for the Humila brand of adailing	illiab loi tilis iliulcation
Renewal — Still's disease – adult-onset (AOSD)	
Current approval Number (if known):		
Applications only from a rheumatologist or Practition Prerequisites (tick box where appropriate)	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	nal status