## SA2400 - Adalimumab (Amgevita)

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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 (Amgevita)					
Initial application — Behcet's disease - severe Applications from any relevant practitioner. Approvals valid without further renewal unless notified.  Prerequisites(tick boxes where appropriate)  The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life  and  The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s)  The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s)  Note: Indications marked with * are unapproved indications.					
Patient has tried, but had an inade has contraindications for systemic	va Hurley Stage II or Hurley Stage III lesions in distinct				
Patient has 3 or more active lesion and  The patient has a DLQI of 10 or m	ore and the assessment is no more than 1 month old	at time of application			
Renewal — Hidradenitis suppurativa					
Current approval Number (if known):					
The patient has a reduction in acti	ve lesions (e.g. inflammatory nodules, abscesses, does of 4 or more from baseline	raining fistulae) of 25% or more from baseline			

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APPLICANT (stamp or sticker acceptable)			r sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No: First Names: First Names: First Names:					
Name:				Surname:	Surname:
Address:				DOB:	Address:
				Address:	
Fax Numbe	er:				Fax Number:
Initial app Applicatio	olicatio	n —	Plaque psoriasis - severe	chronic vant practitioner on the recommendation of a dermate	ologist. Approvals valid for 4 months.
and Patient has experience or		Patient has experienc	ecial Authority approval for etanercept for severe chro ed intolerable side effects nsufficient benefit to meet the renewal criteria for etar		
or	Patient has "whole body" severe chronic plaque psoriasis with a PASI score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis  Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaque have been present for at least 6 months from the time of initial diagnosis  Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10  and  Patient has tried, but had an inadequate response to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin  A PASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course but no long than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application				

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Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number:		Fax Number:
Renewal — Plaque psoriasis - severe chronic  Current approval Number (if known):		
or  The patient has experiment base or  The patient has a DL or  Patient had severe chronic pand  The patient has experiment has experiment base or  The patient has experiment has experiment base or  The patient has experiment base or  The patient has experiment base or  The patient has experiment base or or  The patient has experiment base or or  The patient has experiment base or	QI improvement of 5 or more, when compared with the plaque psoriasis of the face, or palm of a hand or sole rienced reduction in the PASI symptom subscores for tained at this level, as compared to the treatment courienced reduction of 75% or more in the skin area affectaseline value	e pre-treatment baseline value  e of a foot at the start of treatment all 3 of erythema, thickness and scaling, to use baseline values ected, or sustained at this level, as compared art of treatment ffected, or sustained at this level, as compared
Initial application — pyoderma gangrenosum Applications only from a dermatologist. Approvale Prerequisites(tick boxes where appropriate)	s valid without further renewal unless notified.	
	s of conventional therapy including a minimum of three d has not received an adequate response	e pharmaceuticals (e.g. prednisone, ciclosporin,

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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 (Amgevita) - continued			
Initial application — Crohn's disease - adults Applications from any relevant practitioner. Appro Prerequisites(tick boxes where appropriate)	vals valid for 6 months.		
Patient has active Crohn's disease			
or	greater than or equal to 300, or HBI score of greater ntestine disease affecting more than 50 cm of the sm		
or Patient has evidence of shore	t gut syndrome or would be at risk of short gut syndr	ome with further bowel resection	
	colostomy and has intestinal inflammation		
Patient has tried but had an inaded and corticosteroids	quate response to, or has experienced intolerable sid	e effects from, prior therapy with immunomodulators	
Renewal — Crohn's disease - adults			
Current approval Number (if known):			
Applications from any relevant practitioner. Approx <b>Prerequisites</b> (tick boxes where appropriate)			
CDAI score has reduced by 100 po on adalimumab	oints from the CDAI score, or HBI score has reduced	by 3 points, from when the patient was initiated	
CDAI score is 150 or less, or HBI is	s 4 or less		
The patient has demonstrated an a	adequate response to treatment, but CDAI score and	or HBI score cannot be assessed	
Initial application — Crohn's disease - children Applications from any relevant practitioner. Appro Prerequisites(tick boxes where appropriate)			
Paediatric patient has active Crohr	n's disease		
Patient has a PCDAI score of	of greater than or equal to 30		
Patient has extensive small i	ntestine disease		
Patient has tried but had an inaded and corticosteroids	quate response to, or has experienced intolerable sid	e effects from, prior therapy with immunomodulators	

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APPLICANT (stamp or sticker acceptable)		PATIENT NHI:	REFERRER Reg No:
Reg No:		First Names:	First Names:
Name	:	Surname:	Surname:
Addre	ss:	DOB:	Address:
		Address:	
	umber:		Fax Number:
Adal	imumab (Amgevita) - continued		
Rene	ewal — Crohn's disease - children		
Appli	or PCDAI score is 15 or less		
Appl	al application — Crohn's disease - fistulising ications from any relevant practitioner. Appropriates (tick boxes where appropriate)	vals valid for 6 months.	
	Patient has confirmed Crohn's disc	ease	
	Patient has one or more con	nplex externally draining enterocutaneous fistula(e)	
	Patient has one or more rec	tovaginal fistula(e)	
	Patient has complex peri-an	al fistula	
	A Baseline Fistula Assessment ha	s been completed and is no more than 1 month old a	at the time of application
Rene	ewal — Crohn's disease - fistulising		
Appli	ent approval Number (if known):cations from any relevant practitioner. Approvequisites(tick boxes where appropriate)		
	The number of open draining fistul	ae have decreased from baseline by at least 50%	
		n in drainage of all fistula(e) from baseline as demon n and patient-reported pain	nstrated by a reduction in the Fistula Assessment

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APPLICANT (stamp or sticker acceptable)		IT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:			First Names:	First Names:
Name:			Surname:	Surname:
Addre	ess:		DOB:	Address:
			Address:	
Fax N	lumbe	er:		Fax Number:
Adal	imu	mab (Amgevita) - continued		
App	licatio	olication — Ocular inflammation - chroons from any relevant practitioner. Approxites(tick boxes where appropriate)		
	or	The patient has had an initial Spec	ial Authority approval for infliximab for chronic ocular	inflammation
		Patient has severe uveitis un	controlled with treatment of steroids and other immu	nosuppressants with a severe risk of vision loss
		Patient is 18 years or c	older and treatment with at least two other immunom	odulatory agents has proven ineffective
		Patient is under 18 year	ars and treatment with methotrexate has proven ineff	ective or is not tolerated at a therapeutic dose
		Patient is under 8 yea	rs and treatment with steroids or methotrexate has p sease requires control to prevent irreversible vision l	
				-1
Rene	ewal -	— Ocular inflammation - chronic		
Curre	ent ap	oproval Number (if known):		
		ns from any relevant practitioner. Approv sites(tick boxes where appropriate)	als valid for 2 years.	
	or	The patient has had a good clinical	response following 12 weeks' initial treatment	
	0.		eriod, the patient has had a sustained reduction in in anterior chamber or vitreous cells, absence of active	
	or	Following each 2 year treatment pedaily, or steroid drops less than twice	eriod, the patient has a sustained steroid sparing effece daily if under 18 years old	ect, allowing reduction in prednisone to < 10mg
App	licatio	olication — Ocular inflammation - seve ons from any relevant practitioner. Approv sites(tick boxes where appropriate)		
	or	Patient has had an initial Special A	uthority approval for infliximab for severe ocular infla	mmation
	OI	Patient has severe, vision-the	reatening ocular inflammation requiring rapid control	
			ose steroids (intravenous methylprednisolone) followers	ed by high dose oral steroids has proven
		Patient developed new	inflammatory symptoms while receiving high dose s	steroids
		Patient is aged under to ineffective at controlling	8 years and treatment with high dose oral steroids and g symptoms	nd other immunosuppressants has proven

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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 (Amgevita) - continued			
Renewal — Ocular inflammation - severe			
Current approval Number (if known):			
Applications from any relevant practitioner. Appro <b>Prerequisites</b> (tick boxes where appropriate)			
The patient has had a good clinical	al response following 3 initial doses		
Following each 2 year treatment	period, the patient has had a sustained reduction in ir - anterior chamber or vitreous cells, absence of active		
or	period, the patient has a sustained steroid sparing effe	ect, allowing reduction in prednisone to < 10mg	
daily, or steroid drops less than tw	nce daily il under 16 years old		
Initial application — ankylosing spondylitis Applications only from a rheumatologist. Approva Prerequisites(tick boxes where appropriate)	als valid for 6 months.		
Patient has had an initial Sp	pecial Authority approval for etanercept for ankylosing	spondylitis	
	rienced intolerable side effects		
or The patient has recei	red insufficient benefit to meet the renewal criteria for ankylosing spondylitis		
or			
Patient has a confirmed diag	gnosis of ankylosing spondylitis for more than six more	nths	
	nd stiffness that is relieved by exercise but not by rest	t	
	itis demonstrated by radiology imaging		
Patient has not responded a a regular exercise regimen	adequately to treatment with two or more NSAIDs, wh for ankylosing spondylitis	ile patient was undergoing at least 3 months of	
BASMI measures: a	of motion of the lumbar spine in the sagittal and the fi modified Schober's test of less than or equal to 4 cm n (mean of left and right)		
	of chest expansion by at least 2.5 cm below the aver	age normal values corrected for age and	
	0-10 scale completed after the 3 month exercise trial, an 1 month old at the time of application	but prior to ceasing any previous pharmacological	

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APPLICANT (stamp or sticker acceptable)			PATIENT NHI:	REFERRER Reg No:
Reg No:			First Names:	First Names:
Name:			Surname:	Surname:
Addre	ss:		DOB:	Address:
			Address:	
Fax N	umbei	r		Fax Number:
Adal	imun	nab (Amgevita) - continued		
Rene	ewal –	– ankylosing spondylitis		
Curre	ent api	oroval Number (if known):		
Appli	cation	s from any relevant practitioner. Approv		
Prer	equisi —	tes(tick box where appropriate)		
Ĺ		reatment has resulted in an improvement ASDAI of 50%, whichever is less	nt in BASDAI of 4 or more points from pre-treatment	baseline on a 10 point scale, or an improvement in
App	lication	ication — Arthritis - oligoarticular cons only from a named specialist or rheurtes(tick boxes where appropriate)	ourse juvenile idiopathic matologist. Approvals valid for 6 months.	
		The potient has had an initia	l Special Authority approval for etanercept for oligoar	tigular aguras invanila idianathia arthritia ( IIA)
		and	ii Speciai Authority approval for etariercept for oligoar	ticulai course juverille idiopatriic artifitis (JIA)
		Patient has experience	ed intolerable side effects	
			nsufficient benefit to meet the renewal criteria for oligo	oarticular course JIA
	or			
		l . <del> </del>	methotrexate therapy or monotherapy where use of r	nethotrexate is limited by toxicity or intolerance
		and Patient has had oligoarticula	r course JIA for 6 months duration or longer	
		and		
		maximum tolerated do	with limited range of motion, pain or tenderness aftense)	er a 3-month trial of methotrexate (at the
			ase activity (cJADAS10 score greater than 1.5) with p	poor prognostic features after a 3-month trial of
		methotrexate (at the n	naximum tolerated dose)	
Rene	ewal –	– Arthritis - oligoarticular course juv	enile idiopathic	
Curre	ent app	proval Number (if known):		
		s from any relevant practitioner. Approvites(tick boxes where appropriate)	als valid for 2 years.	
	,			
	ااا	Following initial treatment, the pati assessment from baseline	ent has at least a 50% decrease in active joint count	and an improvement in physician's global
	or [		patient demonstrates at least a continuing 30% impr	ovement in active joint count and continued
		improvement in physician's global	assessment from daseline	

# APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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APPLICANT (stamp or sticker acceptable)			le) PATIENT NHI:	REFERRER Reg No:
Reg No:			First Names:	First Names:
Name:	:		Surname:	Surname:
Addres	ss:		DOB:	Address:
			Address:	
Fax N	umber	······································		Fax Number:
Adali	mun	nab (Amgevita) - contin	nued	
Appli	ication	Patient has had a and  Patient has had a and  Patient has had a Patient has  Or  Patient has  At least 5 a methotrexa  Or  Moderate of tolerated do	an initial Special Authority approval for etanercep sexperienced intolerable side effects areceived insufficient benefit to meet the renewal adjunct to methotrexate therapy or monotherapy polyarticular course JIA for 6 months duration or lactive joints and at least 3 joints with limited rangulate (at the maximum tolerated dose) or high disease activity (cJADAS10 score of at least	t for polyarticular course juvenile idiopathic arthritis (JIA)  I criteria for polyarticular course JIA  where use of methotrexate is limited by toxicity or intolerance longer  ge of motion, pain or tenderness after a 3-month trial of  ast 2.5) after a 3-month trial of methotrexate (at the maximum
Rene	wal –	– Arthritis - polyarticular c	ourse juvenile idiopathic	
Applic	cations	s from any relevant practition  tes(tick boxes where approp  Following initial treatme assessment from baseli  On subsequent reapplic	ent, the patient has at least a 50% decrease in ac ine	ctive joint count and an improvement in physician's global nuing 30% improvement in active joint count and continued

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APPLICANT (stamp or sticker acceptable)			r stick	ker acceptable)	PATIENT NHI:	REFERRER Reg No:	
Reg No:					First Names:	First Names:	
Name:					Surname:	Surname:	
Addre	ss:					DOB:	Address:
						Address:	
	umbe	r:			ita) - continued		Fax Number:
Appl	licatio	ns onl	y fro	m a rh	ritis - psoriatic neumatologist. Approv here appropriate)	als valid for 6 months.	
		and		Patie	ent has had an initial S	pecial Authority approval for etanercept or secukinum	ab for psoriatic arthritis
		unu			The patient has expe	rienced intolerable side effects	
			or		The patient has rece	ived insufficient benefit from to meet the renewal crite	ria for psoriatic arthritis
	or						
Patient has tried and not re			Patie Patie	ent has tried and not re	riatic arthritis for six months duration or longer sponded to at least three months of methotrexate at a sponded to at least three months of sulfasalazine or least three mont	·	
		and		contr	raindicated)		
			or		Patient has persisten	t symptoms of poorly controlled and active disease in	at least 15 swollen joints
						nt symptoms of poorly controlled and active disease in and either shoulder or hip	at least four joints from the following: wrist,
		and					_
			or		Patient has a CRP le	vel greater than 15 mg/L measured no more than one	e month prior to the date of this application
			or		Patient has an ESR	greater than 25 mm per hour	
						easured as patient is currently receiving prednisone tl more than three months	herapy at a dose of greater than 5 mg per day
Rene	ewal –	– Art	hritis	- psc	oriatic		
Appli	cation	ns fror	n any	relev	if known): ant practitioner. Appro here appropriate)	ovals valid for 2 years.	
	0"				nitial treatment, the pa	tient has at least a 50% decrease in swollen joint cour ysician	nt from baseline and a clinically significant
	or  Patient demonstrates at least a continuing 30% improvement in swollen joint count from baseline and a clinically significant response the opinion of the treating physician						m baseline and a clinically significant response in

# APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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APPLICANT (stamp or sticker acceptable)			o or	sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:					First Names:	First Names:
Name:					Surname:	Surname:
Addre	ss:				DOB:	Address:
					Address:	
Fax N	umbei	r:				Fax Number:
Adali	imun	nab (A	m	gevita) - continued		
Appl	lication	ns only f	rom	Arthritis - rheumatoid  a rheumatologist. Approva  ses where appropriate)	lls valid for 6 months.	
		and	] ·	The patient has had an initia	al Special Authority approval for etanercept for rheum	atoid arthritis
			or		rienced intolerable side effects  ved insufficient benefit from etanercept to meet the re	newal criteria for rheumatoid arthritis
	or					
months duration or longer  and  Treatment is to be used as a intolerance  and  Patient has tried and not res sulphate at maximum tolerate and dose of ciclosporin  Patient has tried and rest an			or	months duration or longer  Treatment is to be used as a intolerance  Patient has tried and not resulphate at maximum tolerates  Patient has tried and dose of ciclosporin  Patient has tried and alone or in combination  Patient has persistent  Patient has persistent	arthritis (either confirmed by radiology imaging, or the an adjunct to methotrexate therapy or monotherapy where ponded to at least three months of methotrexate at a sponded to at least three months of methotrexate in content doses (unless contraindicated)  not responded to at least three months of methotrexate and responded to at least three months of therapy at the provided mot methotrexate and responded to at least three months of therapy at the provided mother poorly controlled and active disease in symptoms of poorly controlled and active disease in and either shoulder or hip	here use of methotrexate is limited by toxicity or maximum tolerated dose (unless contraindicated) ombination with sulfasalazine and hydroxychloroquir te in combination with the maximum tolerated the maximum tolerated dose of leflunomide at least 15 swollen joints
Rene	ewal –	– Arthri	tis	- rheumatoid		
Current approval Number (if known):			ıny	relevant practitioner. Appro-		
	or [			ing initial treatment, the pati	ent has at least a 50% decrease in active joint count on of the physician	from baseline and a clinically significant
	[				patient demonstrates at least a continuing 30% impresatment in the opinion of the physician	ovement in active joint count from baseline and a

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Reg No:			First Names:	First Names:					
Name:			Surname:	Surname:					
Address:			DOB:	Address:					
			Address:						
Fax Number:				Fax Number:					
Adal	Adalimumab (Amgevita) - continued								
Initial application — Still's disease - adult-onset (AOSD) Applications only from a rheumatologist. Approvals valid without further renewal unless notified.  Prerequisites(tick boxes where appropriate)									
		The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD  Patient has experienced intolerable side effects from etanercept and/or tocilizumab  or							
	or	Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab							
		Patient diagnosed with AOSD according to the Yamaguchi criteria  Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate  Patient has persistent symptoms of disabling poorly controlled and active disease							
Initial application — ulcerative colitis Applications from any relevant practitioner. Approvals valid for 3 months.  Prerequisites(tick boxes where appropriate)									
	and	Patient has active ulcerative colitis							
		Patient's SCCAI score is gre	eater than or equal to 4						
		Patient's PUCAI score is gre	Patient's PUCAI score is greater than or equal to 20						
	and	Patient has tried but had an inadequate response to, or has experienced intolerable side effects from prior therapy with immunomodulators and systemic corticosteroids  Surgery (or further surgery) is considered to be clinically inappropriate							
		Surgery (or further surgery) is con	sidered to be clinically mappropriate						
Rene	Renewal — ulcerative colitis								
Appli	Current approval Number (if known):								
		The SCCAI score has reduced by	2 points or more from the SCCAI score when the pat	ient was initiated on biologic therapy					
	or 	The PUCAI score has reduced by	10 points or more from the PUCAI score when the pa	tient was initiation on biologic therapy					

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Name:	Surname:	Surname:						
Address:	DOB:	Address:						
	Address:							
Fax Number:		Fax Number:						
Adalimumab (Amgevita) - continued								
Initial application — undifferentiated spondyloarthritis Applications only from a rheumatologist. Approvals valid for 6 months.  Prerequisites(tick boxes where appropriate)								
Patient has undifferentiated periph wrist, elbow, knee, ankle, and either	eral spondyloarthritis* with active peripheral joint arther shoulder or hip	nritis in at least four joints from the following:						
Patient has tried and not responde tolerated doses (unless contraindic	ed to at least three months of each of methotrexate, so cated)	ulfasalazine and leflunomide, at maximum						
Patient has a CRP level grea	Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application							
Patient has an ESR greater	nt has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application							
ESR and CRP not measured done so for more than three	d as patient is currently receiving prednisone therapy months	at a dose of greater than 5 mg per day and has						
Note: Indications marked with * are unapproved in	dications							
Renewal — undifferentiated spondyloarthritis								
Current approval Number (if known):								
Prerequisites(tick boxes where appropriate)	rate valid for 2 years.							
response to treatment in the opinion	t, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant the opinion of the physician							
The patient demonstrates at least in the opinion of the treating physic	a continuing 30% improvement in active joint count fr cian	rom baseline and a clinically significant response						
Initial application — inflammatory bowel arthritis – axial Applications only from a rheumatologist. Approvals valid for 6 months.  Prerequisites(tick boxes where appropriate)								
Patient has a diagnosis of active u	lcerative colitis or active Crohn's disease							
Patient has axial inflammatory pair	n for six months or more							
Patient is unable to take NSAIDs								
Patient has unequivocal sacroiliitis	tis demonstrated by radiological imaging or MRI							
physiotherapist	ately to prior treatment consisting of at least 3 months	s of an exercise regime supervised by a						
A BASDAI of at least 6 on a 0-10 streatment	scale completed after the 3 month exercise trial, but p	prior to ceasing any previous pharmacological						

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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 (Amgevita) - continued								
Renewal — inflammatory bowel arthritis – axial								
Current approval Number (if known):								
and Patient has active arthritis in at least sternoclavicular  and Patient has tried and not experience (unless contraindicated)  and Patient has tried and not experience contraindicated)  and Patient has a CRP level greator tor Patient has an ESR greater tor	cerative colitis or active Crohn's disease st four joints from the following: hip, knee, ankle, subsed a response to at least three months of methotrexacted a response to at least three months of sulfasalazing the subsection of the sulfasalazing that the subsection of the subsection o	ne at a maximum tolerated dose  ne at a maximum tolerated dose (unless  prior to the date of this application  onth prior to the date of this application						
Renewal — inflammatory bowel arthritis – peripheral  Current approval Number (if known):								