SA2178 - Adalimumab (Amgevita)

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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			
or 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.			
Initial application — Hidradenitis suppurativa Applications only from a dermatologist. Approvals valid for 4 months. Prerequisites(tick boxes where appropriate)			
 Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas and Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or has demonstrated intolerance to or has contraindications for systemic antibiotics and Patient has 3 or more active lesions and The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application 			
Renewal — Hidradenitis suppurativa			
Current approval Number (if known): Applications from any relevant practitioner. Approvals valid for 2 years. 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 The patient has a DLQI improvement of 4 or more from baseline			

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Adalimumab (Amgevita) - continued

Appl	lication	ns only	y froi	Plaque psoriasis - severe chronic m a dermatologist. Approvals valid for 4 months. exes where appropriate)
		and		Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis
			or	Patient has experienced intolerable side effects
			0.	Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis
	or			
			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 plaques have been present for at least 6 months from the time of initial diagnosis
		and 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 longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application

Renewal — Plaque psoriasis - severe chronic				
Application	ns from	any	nber (if known): relevant practitioner. Approvals valid for 2 years. xes where appropriate)	
	and	or	Patient had "whole body" severe chronic plaque psoriasis at the start of treatment The patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre treatment baseline value The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value	
or	and	or	Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment The patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values The patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre treatment baseline value	

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Adalimumab (Amgevita) - continued

Initial application — pyoderma gangrenosum Applications only from a dermatologist. Approvals valid without further renewal unless notified. Prerequisites(tick boxes where appropriate)
Patient has pyoderma gangrenosum* And Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and has not received an adequate response
Note: Indications marked with * are unapproved indications.
Initial application — Crohn's disease - adults Applications from any relevant practitioner. Approvals valid for 6 months. Prerequisites(tick boxes where appropriate)
Patient has active Crohn's disease
Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10 or Patient has extensive small intestine disease affecting more than 50 cm of the small intestine
or Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection or
Patient has an ileostomy or colostomy and has intestinal inflammation
and Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids
Renewal — Crohn's disease - adults

Current a	approval Number (if known):
	ions from any relevant practitioner. Approvals valid for 2 years. I isites (tick boxes where appropriate)
or	CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on adalimumab

CDAI score is 150 or less, or HBI is 4 or less

or

The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed

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Adalimumab (Amgevita) - continued

Initial application — Crohn's disease - children Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)
Paediatric patient has active Crohn's disease
Patient has a PCDAI score of greater than or equal to 30
Patient has extensive small intestine disease
and Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids
Renewal — Crohn's disease - children
Current approval Number (if known):
Applications from any relevant practitioner. Approvals valid for 2 years. Prerequisites(tick boxes where appropriate)
PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab or
PCDAI score is 15 or less
or The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed
Initial application — Crohn's disease - fistulising Applications from any relevant practitioner. Approvals valid for 6 months. Prerequisites(tick boxes where appropriate)
Patient has confirmed Crohn's disease and
Patient has one or more complex externally draining enterocutaneous fistula(e)
Patient has one or more rectovaginal fistula(e)
or Patient has complex peri-anal fistula
and A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application

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Adalimumab (Amgevita) - continued		

Renewal — Crohn's disease - fistulising			
Current approval Number (if known):			
Applications from any relevant practitioner. Approvals valid for 2 years. Prerequisites (tick boxes where appropriate)			
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			
Initial application — Ocular inflammation - chronic Applications from any relevant practitioner. Approvals valid for 4 months. Prerequisites(tick boxes where appropriate)			
The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation or			
Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss and			
Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective or			
Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose			
Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate			
Renewal — Ocular inflammation - chronic			
Current approval Number (if known):			
Applications from any relevant practitioner. Approvals valid for 2 years.			
Prerequisites(tick boxes where appropriate)			

	The patient has had a good clinical response following 12 weeks' initial treatment
or	Following each 2 year 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)
or	Following each 2 year 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

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Adalimumab (Amgevita) - continued

Арр	Initial application — Ocular inflammation - severe Applications from any relevant practitioner. Approvals valid for 4 months. Prerequisites(tick boxes where appropriate)		
	or	Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation	
		Patient has severe, vision-threatening ocular inflammation requiring rapid control and	
		Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms	
		Patient developed new inflammatory symptoms while receiving high dose steroids	
		or Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms	
Renewal — Ocular inflammation - severe			
Current approval Number (if known):			
Applications from any relevant practitioner. Approvals valid for 2 years.			
Prer	equi	sites(tick boxes where appropriate)	
	or	The patient has had a good clinical response following 3 initial doses	
	or	Following each 2 year 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 2 year 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	

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Adalimumab (Amgevita) - continued

	and	Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis
		The patient has experienced intolerable side effects
		The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis
or		
	and	Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months
		Patient has low back pain and stiffness that is relieved by exercise but not by rest
	and	Patient has bilateral sacroiliitis demonstrated by radiology imaging
	and	Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 month a regular exercise regimen for ankylosing spondylitis
		Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of le than or equal to 10 cm (mean of left and right)
		Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender

Renewal — ankylosing spondylitis

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick box where appropriate)

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

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Adalimumab (Amgevita) - continued

Applicati	ons only	y fror	Arthritis - oligoarticular course juvenile idiopathic n a named specialist or rheumatologist. Approvals valid for 6 months. xes where appropriate)
	and		The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA)
			Patient has experienced intolerable side effects
		or	Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA
or			
	and		To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
	and		Patient has had oligoarticular course JIA for 6 months duration or longer
		or	At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)
			Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose)

Renewal — Arthritis - oligoarticular course juvenile idiopathic

Current approval Number (if known):
Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

I confirm the above details are correct and that in signing this form I understand I may be audited.

L

or

..... Date:

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Adalimumab (Amgevita) - continued

Applicatio	ons only	on — Arthritis - polyarticular course juvenile idiopathic y from a named specialist or rheumatologist. Approvals valid for 6 months. ck boxes where appropriate)
	and	 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA) Patient has experienced intolerable side effects Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA
or	and [To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance Patient has had polyarticular course JIA for 6 months duration or longer
		 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose) Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose) or
		Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate

Renewal — Arthritis - polyarticular course juvenile idiopathic				
Curre	ent a	pproval Number (if known):		
	Applications from any relevant practitioner. Approvals valid for 2 years. Prerequisites (tick boxes where appropriate)			
	or	Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline		
		On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline		

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Adalimumab (Amgevita) - continued

Applicatio	ns only	n — Arthritis - psoriatic / from a rheumatologist. Approvals valid for 6 months. /k boxes where appropriate)
	and	Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis
		The patient has experienced intolerable side effects
		The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis
or		
	and	Patient has had active psoriatic arthritis for six months duration or longer
		Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicate
	and Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unles contraindicated)	
	and Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints	
		or Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip
	and	
		Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application or
		Patient has an ESR greater than 25 mm per hour
		ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

Renewal — Arthritis - psoriatic

Current approval Number (if known):..... Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick boxes where appropriate)

Following initial treatment, the patient has at least a 50% decrease in swollen joint count from baseline and a clinically significant response in the opinion of the physician

Patient demonstrates at least a continuing 30% improvement in swollen joint count from baseline and a clinically significant response in the opinion of the treating physician

I confirm the above details are correct and that in signing this form I understand I may be audited.

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Adalimumab (Amgevita) - continued

	and		The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis
		or	The patient has experienced intolerable side effects
		UI	The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis
or			
			Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is CCP antibody positive) for six months duration or longer
	and		
	and		Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
	and		Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated
	and		Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloro sulphate at maximum tolerated doses (unless contraindicated)
	anu		Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin
		or	Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate
	and		
			Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints
		or	Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist,

Renewal — Arthritis - rheumatoid

Current approval Number (if known):				
Applications from any relevant practitioner. Approvals valid for 2 years. Prerequisites(tick boxes where appropriate)				
	Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinica response to treatment in the opinion of the physician or	Ily significant		
	On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint cou clinically significant response to treatment in the opinion of the physician	nt from baseline and a		

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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 and				
Patient has experienced intolerable side effects from etanercept and/or tocilizumab				
Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab				
or	_			
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 and				
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)				
Patient has active ulcerative colitis				
Patient's SCCAI score is greater than or equal to 4				
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 immunomodula and systemic corticosteroids and 	tors			
Surgery (or further surgery) is considered to be clinically inappropriate				
Renewal — ulcerative colitis				
Current approval Number (if known):				
Applications from any relevant practitioner. Approvals valid for 2 years.				

Prerequisites(tick boxes where appropriate)

or

The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on biologic therapy

The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiation on biologic therapy

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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 peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip and				
Patient has tried and not responded to at least three months of each of methotrexate, sulfasalazine and leflunomide, at maximum tolerated doses (unless contraindicated) and				
Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application or				
Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application or				
ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months				
Note: Indications marked with * are unapproved indications				
Renewal — undifferentiated spondyloarthritis				
Current approval Number (if known): Applications from any relevant practitioner. Approvals valid for 2 years. Prerequisites (tick boxes where appropriate)				
Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician or				
The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician				
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 ulcerative colitis or active Crohn's disease and				
Patient has axial inflammatory pain for six months or more and				
And Patient is unable to take NSAIDs				
Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI and				
Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist and				
A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment				

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Renewal — inflammatory bowel arthritis – axial				
Current approval Number (if known):				
Applications from any relevant practitioner. Approvals valid for 2 years. Prerequisites (tick box where appropriate)				
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				

Initial application — inflammatory bowel arthritis – peripheral

Applications only from a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

and		Patient has a diagnosis of active ulcerative colitis or active Crohn's disease
and		Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular
and		Patient has tried and not experienced a response to at least three months of methotrexate, or azathioprine at a maximum tolerated dose (unless contraindicated)
and		Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated)
and	11	
		Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application
	or	Patient 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 as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months
enewal — inflammatory bowel arthritis – peripheral		

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick boxes where appropriate)

Following initial treatment, patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

Patient has experienced at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician

I confirm the above details are correct and that in signing this form I understand I may be audited.

or

Signed: Date: