SA2402 - Infliximab

Crohn's disease (adults) - Initial application
Crohn's disease (adults) - Renewal
Crohn's disease (children) - Initial application
Crohn's disease (children) - Renewal
Graft vs host disease - Initial application
Pulmonary sarcoidosis - Initial application
Acute fulminant ulcerative colitis - Initial application
Ankylosing spondylitis - Initial application
Ankylosing spondylitis - Renewal
Chronic ocular inflammation - Initial application
Chronic ocular inflammation - Renewal
Fistulising Crohn's disease - Initial application
Fistulising Crohn's disease - Renewal
Fulminant ulcerative colitis - Renewal
Inflammatory bowel arthritis – axial - Initial application
Inflammatory bowel arthritis – axial - Renewal
Inflammatory bowel arthritis – peripheral - Initial application
Inflammatory bowel arthritis - peripheral - Renewal
Neurosarcoidosis - Initial application
Neurosarcoidosis - Renewal
Plaque psoriasis - Initial application
Plaque psoriasis - Renewal
Previous use - Initial application
Psoriatic arthritis - Initial application
Psoriatic arthritis - Renewal
Pyoderma gangrenosum - Initial application
Pyoderma gangrenosum - Renewal
Rheumatoid arthritis - Initial application11
Rheumatoid arthritis - Renewal
Severe Behcet's disease - Initial application
Severe Behcet's disease - Renewal
Severe ocular inflammation - Initial application
Severe ocular inflammation - Renewal
Ulcerative colitis - Initial application
Ulcerative colitis - Renewal

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:

Infliximab

Appli	catior	i on — Crohn's disease (adults) om any relevant practitioner. Approvals valid for 6 months. tick boxes where appropriate)	
	and	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	
		Patient has extensive small intestine disease affecting more than 50 cm of the small intestine	
		Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection	
		Patient has an ileostomy or colostomy, and has intestinal inflammation	
	and [Patient has tried but has experienced an inadequate response to, or intolerable side effects from, prior therapy with imm and corticosteroids	unomodulators
Rene	wal –	ohn's disease (adults)	
		al Number (if known):	
		m any relevant practitioner. Approvals valid for 2 years. tick boxes where appropriate)	
		CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the initiated on infliximab	e patient was
		CDAI score is 150 or less, or HBI is 4 or less	
		The patient has demonstrated an adequate response to treatment but CDAI score and/or HBI score cannot be as	sessed
	and [Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treat prior to 1 February 2019	d sixteen weeks

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0800 855	066	

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Infliximab - 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 experienced an inadequate response to, or 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 infliximab			
PCDAI score is 15 or less			
or The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed			
and	1		
Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up			
to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose	;		
prior to 1 February 2019			
Initial application — Graft vs host disease Applications from any relevant practitioner. Approvals valid without further renewal unless notified. Prerequisites(tick box where appropriate)			
Patient has steroid-refractory acute graft vs. host disease of the gut			
Initial application — Pulmonary sarcoidosis Applications from any relevant practitioner. Approvals valid without further renewal unless notified. Prerequisites(tick box where appropriate)			
Patient has life-threatening pulmonary sarcoidosis diagnosed by a multidisciplinary team that is refractory to other treatments			

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	Fax Number:
	First Names:

Infliximab - continued

Applicat	oplication — acute fulminant ulcerative colitis tions only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks. iisites(tick boxes where appropriate)
an	Patient has acute, fulminant ulcerative colitis
Applicat	pplication — ankylosing spondylitis tions only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months. iisites(tick boxes where appropriate)
an	The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis
	The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept or
	Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis

Renewal — ankylosing spondylitis

and

and

Current approval Number	í (if	known):
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Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months. **Prerequisites**(tick boxes where appropriate)

> Following 12 weeks of infliximab treatment, BASDAI has improved by 4 or more points from pre-infliximab baseline on a 10 point scale, or by 50%, whichever is less

Physician considers that the patient has benefited from treatment and that continued treatment is appropriate

Infliximab to be administered at doses no greater than 5 mg/kg every 6-8 weeks

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	Address:	
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Infliximab - continued

Applicatio	ons fror	on — chronic ocular inflammation m any relevant practitioner. Approvals valid for 4 months. ck boxes where appropriate)
	and	The patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation
		The patient has experienced intolerable side effects from adalimumab
		or The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for chronic ocular inflammation
or		
	and	Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss
		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 or
		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 — chronic ocular inflammation

Current approval Number (if known): Applications from any relevant practitioner. Approvals valid for 12 months. Prerequisites (tick boxes where appropriate)
or Following each 12 month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis
or 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 Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

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Infliximab - continued

Applications	ration — fistulising Crohn's disease from any relevant practitioner. Approvals valid for 6 months. rs(tick boxes where appropriate)
and	Patient has confirmed Crohn's disease
	Patient has one or more complex externally draining enterocutaneous fistula(e)
	Patient has one or more rectovaginal fistula(e)
	Patent has complex peri-anal fistula
Renewal —	fistulising Crohn's disease
Applications	oval Number (if known): only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 2 years. se(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 (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain
and	Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019
Applications	ration — neurosarcoidosis only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months. es(tick boxes where appropriate)
and	Patient has been diagnosed with neurosarcoiosis by a multidisciplinary team
and	Patient has CNS involvement
and	Patient has steroid-refractory disease
	IV cyclophosphamide has been tried
	Treatment with IV cyclophosphamide is clinically inappropriate

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APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

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Infliximab - continued		
Renewal — neurosarcoidosis		
Current approval Number (if known):		
	on the recommendation of a neurologist. Approvals	valid for 18 months.
Prerequisites(tick boxes where appropriate)		
A withdrawal period has been tried	and the patient has relapsed	
A withdrawal period has bee	n considered but would not be clinically appropriate	
and There has been a marked re	duction in prednisone dose	
and There has been an im	provement in MRI appearances	
or	in other symptomology	
	n oner symptomology	

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Fax Number:		Fax Number:

Infliximab - continued

App	lication	ns only	on — plaque psoriasis y from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 3 months. ck boxes where appropriate)	
		and	The patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis	
			Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab	
			Patient has received insufficient benefit from adalimumab, etanercept or secukinumab to meet the renewal criteria for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis	
	or			_
			 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (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 	
			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		
		and	Patient has tried, but had an inadequate response (see Note) 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	
		and	A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course	
		[The most recent PASI assessment is no more than 1 month old at the time of initiation	
while face seve	e still o , hand, re, and	n treat foot, g d for th	te response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably tment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the genital or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very ne face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed still on treatment but no longer than 1 month following cessation of the most recent prior treatment.	b

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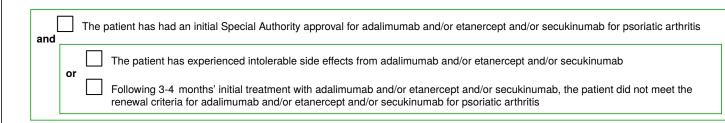
APPLICAN	T (star	np or sticke	er acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:				First Names:	First Names:
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Fax Numbe					Fax Number:
Infliximat	b - co	ntinued			
Application	proval ns from	Number (if any releva	í known):	vals valid for 6 months.	
	or	and	Following each prior i sustained at this level Patient had severe ch Group Following each all 3 of erythem course baseline Following each affected, or sus	dy" severe chronic plaque psoriasis at the start of tre infliximab treatment course the patient has a PASI sco , when compared with the pre-infliximab treatment ba ronic plaque psoriasis of the face, or palm of a hand of prior infliximab treatment course the patient has a rec a, thickness and scaling, to slight or better, or sustain values prior infliximab treatment course the patient has a rec tained at this level, as compared to the pre-infliximab ronic localised genital or flexural plaque psoriasis at t	ore which is reduced by 75% or more, or is seline value or sole of a foot at the start of treatment duction in the PASI symptom subscores for ed at this level, as compared to the treatment duction of 75% or more in the skin area treatment baseline value
		or	compared to the	experienced a reduction of 75% or more in the skin a e pre-treatment baseline value ermatology Quality of Life Index (DLQI) improvement ncing infliximab	
and	<u> </u>	nfliximab to	be administered at do	oses no greater than 5 mg/kg every 8 weeks	

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Infliximab - continued

and	Patient was being treated with infliximab prior to 1 February 2019
	Rheumatoid arthritis
	Ankylosing spondylitis
	Psoriatic arthritis
	Severe ocular inflammation
	Chronic ocular inflammation
	or Crohn's disease (adults)
	or Crohn's disease (children)
	Fistulising Crohn's disease
	or Severe fulminant ulcerative colitis
	Severe ulcerative colitis
	Plaque psoriasis
	or Neurosarcoidosis
C	Severe Behcet's disease



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	nab - continued
Renew	al — psoriatic arthritis
Current	approval Number (if known):
	tions only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months. uisites(tick boxes where appropriate)
	 Following 3 to 4 months' 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 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician
a	nd Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks
Applica	application — rheumatoid arthritis ations only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months. uisites(tick boxes where appropriate)
a	The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis nd
a	The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept or
	Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept
а	nd Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
Renew	al — rheumatoid arthritis
Current	approval Number (if known):
	tions only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months. uisites(tick boxes where appropriate)
a	Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
	Following 3 to 4 months' 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
	The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
a	nd Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks

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Fax Number:		Fax Number:

Infliximab - continued

Initial application — severe Behcet's disease Applications from any relevant practitioner. Approvals valid for 4 months.			
Prerequisites (tick boxes where appropriate)			
The patient has severe Behcet's disease which is significantly impacting the patient's quality of life (see Notes)			
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) (see Notes)			
The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes)			
and The patient is experiencing significant loss of quality of life			
Note: Behcet's disease diagnosed according to the International Study Group for Behcet's Disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al J Rheumatol. 2004;31:931-7. Treatments appropriate for the particular symptoms are those that are considered standard conventional treatments for these symptoms, for example intravenous/oral steroids and other immunosuppressants for ocular symptoms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for mucocutaneous symptoms; and colchicine, steroids and methotrexate for rheumatological symptoms.			
Renewal — severe Behcet's disease			
Current approval Number (if known):			
Applications from any relevant practitioner. Approvals valid for 6 months. Prerequisites (tick boxes where appropriate)			
Patient has had a good clinical response to initial treatment with measurably improved quality of life and Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks			
Renewal — fulminant ulcerative colitis			
Current approval Number (if known):			
Applications from any relevant practitioner. Approvals valid for 2 years. Prerequisites(tick boxes where appropriate)			
Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months and			
Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019			

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Infliximab - continued

	application — severe ocular inflammation ations from any relevant practitioner. Approvals valid for 4 months.
Prerec	uisites(tick boxes where appropriate)
	The patient has had an initial Special Authority approval for adalimumab for severe o

	The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation and			
	The patient has experienced intolerable side effects from adalimumab			
	The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe ocular inflammation			
or				
	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 			
		Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms		

Rene	ewal	— severe ocular inflammation			
Curre	Current approval Number (if known):				
		ons from any relevant practitioner. Approvals valid for 12 months. sites(tick boxes where appropriate)			
	or	The patient has had a good clinical response following 3 initial doses			
	or	Following each 12 month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)			
	01	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			
		rial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible s if infliximab is withdrawn.			

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Fax Number:		Fax Number:

Infliximab - continued

Initial application — ulcerative colitis Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)
Patient has active ulcerative colitis and
Patients SCCAI is greater than or equal to 4
Patients PUCAI score is greater than or equal to 20
and Patient has tried but has experienced an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids
Renewal — ulcerative colitis
Current approval Number (if known):
Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)
The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab
The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiated on infliximab
and Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019
Initial application — pyoderma gangrenosum
Applications only from a dermatologist. Approvals valid for 4 months. Prerequisites (tick boxes where appropriate)
and
Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response
A maximum of 8 doses
Note: Indications marked with * are unapproved indications.

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Infliximab - continued		
Renewal — pyoderma gangrenosum		
Current approval Number (if known):		
	ner on the recommendation of a dermatologist. Appr	ovals valid for 4 months.
Prerequisites(tick boxes where appropriate)		
Patient has shown clinical improve	ment	
Patient continues to require treatm	lent	
A maximum of 8 doses		
Initial application — inflammatory bowel arthri Applications from any relevant practitioner. Appro		
Prerequisites(tick boxes where appropriate)		
Patient has a diagnosis of active u	Icerative colitis or active Crohn's disease	
Patient has had axial inflammatory	pain for six months or more	
Patient is unable to take NSAIDs		
and Patient has unequivocal sacroiliitis	demonstrated by radiological imaging or MRI	
	ed adequately to prior treatment consisting of at least	3 months of an exercise regime supervised by a
and		
Patient has a BASDAI of at least 6 pharmacological treatment	on a 0 - 10 scale completed after the 3 month exe	rcise trial, but prior to ceasing any previous
Renewal — inflammatory bowel arthritis – axia		
Current approval Number (if known): Applications from any relevant practitioner. Approv		

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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Infliximab - continued

	ation — inflammatory bowel arthritis – peripheral from any relevant practitioner. Approvals valid for 6 months. s(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 do (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)
C	Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application r
a	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 h done so for more than three months
ewal — i	nflammatory bowel arthritis – peripheral
ent appro	oval Number (if known):

Following initial treatment, patient has experienced 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