# SA2179 - 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:
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Fax Number:		Fax Number:

# Infliximab

Арр	lication	ns fr	t <b>ion — Crohn's disease (adults)</b> om any relevant practitioner. Approvals valid for 6 months. (tick boxes where appropriate)
	and		Patient has active Crohn's disease
		or	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
			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 immunomodulators and corticosteroids
Ren	ewal –	– Cı	rohn's disease (adults)
		•	al Number (if known):
			om any relevant practitioner. Approvals valid for 2 years. (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 infliximab
		or	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 assessed
	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

Enquiries	to Ministry	of Health
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 are corticosteroids	nd
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 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 u to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen wee 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 d prior to 1 February 2019	ks
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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## Infliximab - continued

Initial application — acute fulminant ulcerative colitis Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks. Prerequisites(tick boxes where appropriate)
Patient has acute, fulminant ulcerative colitis         and         Treatment with intravenous or high dose oral corticosteroids has not been successful
Initial application — ankylosing spondylitis Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months. Prerequisites(tick boxes where appropriate)
The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis and
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 (if known):.....

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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### Infliximab - continued

oplicatio	ns fron	n — chronic ocular inflammation n any relevant practitioner. Approvals valid for 4 months. k 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

# $\label{eq:Renewal} \textbf{Renewal} - \textbf{chronic ocular inflammation}$

Current approval Number (if known): Applications from any relevant practitioner. Approvals valid for 12 months. <b>Prerequisites</b> (tick boxes where appropriate)
The patient has had a good clinical response following 3 initial doses
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 uveiti cystoid macular oedema)
Following each 12 month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10m 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.

Enquiries to Ministry of	Health
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Infliximab - continued

Appli	ication	ns fro	ion — fistulising Crohn's disease om any relevant practitioner. Approvals valid for 6 months. tick boxes where appropriate)
	and		Patient has confirmed Crohn's disease
		or	Patient has one or more complex externally draining enterocutaneous fistula(e)
		or	Patient has one or more rectovaginal fistula(e)
			Patent has complex peri-anal fistula
Rene	wal –	– fis	tulising Crohn's disease
Applic	cation	Is on	al Number (if known): ly from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 2 years. tick boxes where appropriate)
		or	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
Appli	ication	ns or	ion — neurosarcoidosis nly from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months. 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
		or	IV cyclophosphamide has been tried
		<u> </u>	Treatment with IV cyclophosphamide is clinically inappropriate

Enquiries to Ministry of Health 0800 855 066

# APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

PATIENT NHI:	REFERRER Reg No:			
First Names:	First Names:			
Surname:	Surname:			
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Address:				
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Current approval Number (if known): Applications only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months. <b>Prerequisites</b> (tick boxes where appropriate)				
l and the patient has relapsed				
A withdrawal period has been considered but would not be clinically appropriate				
There has been a marked reduction in prednisone dose				
provement in MRI appearances				
in other symptomology				
	First Names:			

APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
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## Infliximab - continued

Appl	icatior	ns only	/ fror	<b>plaque psoriasis</b> n a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 3 months. exes 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
			or	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			
			or	<ul> <li>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</li> <li>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</li> </ul>
		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
				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
		and		The most recent PASI assessment is no more than 1 month old at the time of initiation
while hand affect	still o or foc ted is	n trea ot, at le 30% c	tmen east : or mc	sponse" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably it but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area ore of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following recent prior treatment.

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nfliximab - continued		
Prerequisites(tick boxes where appropriate)	ner on the recommendation of a dermatologist. Appr ody" severe chronic plaque psoriasis at the start of tre infliximab treatment course the patient has a PASI sco I, when compared with the pre-infliximab treatment ba	eatment pre which is reduced by 75% or more, or is
and Following each all 3 of erythem course baseline Following each	prior infliximab treatment course the patient has a re a, thickness and scaling, to slight or better, or sustair e values prior infliximab treatment course the patient has a re stained at this level, as compared to the pre-infliximab	duction in the PASI symptom subscores for ned at this level, as compared to the treatment duction of 75% or more in the skin area

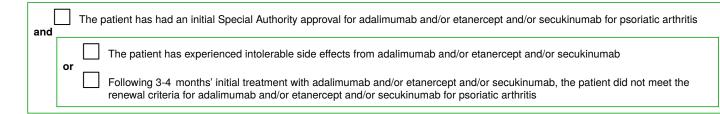
Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

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### Infliximab - continued

itial application — previous use applications from any relevant practitioner. Approvals valid for 6 months. rerequisites(tick boxes where appropriate)				
and	Patient was being treated with infliximab prior to 1 February 2019			
0	Rheumatoid arthritis			
0	Ankylosing spondylitis			
0	Psoriatic arthritis			
0	Severe ocular inflammation			
0	Chronic ocular inflammation			
0	Crohn's disease (adults)			
0	Crohn's disease (children)			
0	Fistulising Crohn's disease			
0	Severe fulminant ulcerative colitis			
0	Severe ulcerative colitis			
0	Plaque psoriasis			
0	Neurosarcoidosis			
	Severe Behcet's disease			
olications of	Ition — psoriatic arthritis only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months. (tick boxes where appropriate)			



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Infliximab - continued
Renewal — psoriatic arthritis
Current approval Number (if known):
Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.  Prerequisites(tick boxes where appropriate)
<ul> <li>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</li> <li>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</li> </ul>
and Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks
Initial application — rheumatoid arthritis Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months. Prerequisites(tick boxes where appropriate)
The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis and
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
and Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
Renewal — rheumatoid arthritis
Current approval Number (if known):
Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months. <b>Prerequisites</b> (tick boxes where appropriate)
Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance and
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
and Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks

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# 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. <b>Prerequisites</b> (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

App	licatio	ns fror	n an	- <b>severe ocular inflammation</b> y relevant practitioner. Approvals valid for 4 months. oxes where appropriate)	
		and		The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation	
			or	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	
			or	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 — severe ocular inflammation				
Current approval Number (if known):				
Applications from any relevant practitioner. Approvals valid for 12 months. <b>Prerequisites</b> (tick boxes where appropriate)				
The patient has had a good clinical response following 3 initial doses				
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)				
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

Initial application — ulcerative colitis Applications from any relevant practitioner. Approvals valid for 6 months. Prerequisites(tick boxes where appropriate)	
Patient has active ulcerative colitis	
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 dos prior to 1 February 2019	3
Initial application — pyoderma gangrenosum Applications only from a dermatologist. Approvals valid for 4 months. Prerequisites(tick boxes where appropriate)	
Patient has pyoderma gangrenosum*	
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	ə,
A maximum of 8 doses	

Note: 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		
and Patient continues to require treatment			
A maximum of 8 doses			
Initial application — inflammatory bowel arthrit 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		
and Patient has had axial inflammatory	pain for six months or more		
and Patient is unable to take NSAIDs			
and Patient has unequivocal sacroiliitis	demonstrated by radiological imaging or MRI		
and	ed adequately to prior treatment consisting of at least	3 months of an exercise regime supervised by a	
physiotherapist and			
	on a 0 - 10 scale completed after the 3 month exer	rcise trial, but prior to ceasing any previous	
Renewal — inflammatory bowel arthritis – axia	l		
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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### Infliximab - continued

plications	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 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)
	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 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
newal — i	inflammatory bowel arthritis – peripheral
rrent appro	oval Number (if known):
	from any relevant practitioner. Approvals valid for 2 years. s(tick boxes where appropriate)

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