RS1941 - Infliximab

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Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

July 2024

PRESCRIBER				PATIENT:
Name	:			
Ward				NHI:
Inflix	ima	ab		
		sites	(tick b	ox host disease ox where appropriate) steroid-refractory acute graft vs. host disease of the gut
Re-a	sses	ssmen	t requ	atoid arthritis ired after 4 months oxes where appropriate)
and	Э —	Preso Hosp		by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ
	and	\circ	The p	patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis
		or	O O	The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept 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			ment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or rance
Re-a	sses	smen sites	t requ (tick b cribed	neumatoid arthritis ired after 6 months oxes where appropriate) by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ
unu	and			ment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or rance
		or	0	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
			0	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	O	Inflixi	mab to be administered at doses no greater than 3 mg/kg every 8 weeks
Re-a	sses	ssmen sites	t requ (tick b cribed	osing spondylitis ired after 3 months oxes where appropriate) by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ
anu	and	O	The p	patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis
		or	0	The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept 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

July 2024

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:
Infliximab - continued	
Hospital.	oved by 4 or more points from pre-infliximab baseline on a 10 point scale,
Physician considers that the patient has benefited from treatm and Infliximab to be administered at doses no greater than 5 mg/kg	
Hospital.	ce with a protocol or guideline that has been endorsed by the Health NZ
The patient has experienced intolerable side effects from or	dalimumab and/or etanercept and/or secukinumab for psoriatic arthritis m a reasonable trial of adalimumab and/or etanercept and/or secukinumab and/or etanercept and/or secukinumab, the patient did not meet the or secukinumab for psoriatic arthritis.
	ce with a protocol or guideline that has been endorsed by the Health NZ
clinically significant response to treatment in the opinion	provement in active joint count from baseline and a clinically significant
Infliximab to be administered at doses no greater than 5 mg/kg	g every 8 weeks

RESCR	IBER		PATIENT:
lame: .			Name:
lard:			NHI:
ıflixim	ab - c	ontinued	
Re-asse	ssment	evere ocular inflammation required after 4 months tick boxes where appropriate)	
	and		Authority approval for adalimumab for severe ocular inflammation
		O The patient has experienced into	colerable side effects from adalimumab cient benefit from adalimumab to meet the renewal criteria for adalimumab for severe
or			
	and	Treatment with high-dose steroic ineffective at controlling symptor or Patient developed new inflamma	atory symptoms while receiving high dose steroids nd treatment with high dose oral steroids and other immunosuppressants has proven
le-asse	ssment	N – severe ocular inflammation required after 12 months tick boxes where appropriate)	
or	0		the patient has had a sustained reduction in inflammation (Standardisation of Uveitis
or		uveitic cystoid macular oedema)	chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of
		Following each 12-month treatment period, t 10mg daily, or steroid drops less than twice	the patient has a sustained steroid sparing effect, allowing reduction in prednisone to be daily if under 18 years old
		hdrawal should be considered after every 24 iximab is withdrawn.	4 months of stability, unless the patient is deemed to have extremely high risk of irreversible

I confirm that the above details are correct:	
Signed:	Date:

July 2024

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRES	CRIE	BER			PATIENT:
Name:					
Ward:					NHI:
Inflixi	ma	b - c	ontin	ued	
Re-as	sess	ment	requ	ired a	ular inflammation (fter 4 months where appropriate)
		and	O	The	patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation
			or	0	The patient has experienced intolerable side effects from adalimumab
				0	The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for chronic ocular inflammation
	or	and		Patie loss	ent has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision
			or	0	Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at therapeutic dose
			or	0	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
Re-as	sess	ment	requ	ired a	ic ocular inflammation Ifter 12 months where appropriate)
	0"	0	The	oatien	t has had a good clinical response following 3 initial doses
	or or		Nom	encla	each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis ture (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of toid macular oedema)
	(each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to illy, or steroid drops less than twice daily if under 18 years old
					hould be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vithdrawn.
				-	sarcoidosis where appropriate)
	and	0	Patie	nt ha	s life-threatening pulmonary sarcoidosis that is refractory to other treatments
	anu	0	Treat	ment	is to be prescribed by, or has been recommended by, a physician with expertise in the treatment of pulmonary sarcoidosis

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

PRES	SCRII	BER		PATIENT:
Name	e:			
Ward	:			NHI:
Inflix	cima	ıb -	contin	ued
Re-a	sses	smen	t requ	's disease (adults) ired after 6 months oxes where appropriate)
and			ribed ospita	by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health I.
	and	0	Patie	nt has active Crohn's disease
		or	0	Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10
		or	\circ	Patient has extensive small intestine disease affecting more than 50 cm of the small intestine
		or	0	Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection
			0	Patient has an ileostomy or colostomy, and has intestinal inflammation
	and			nt has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators corticosteroids
1	equis	sites Preso	(tick b	ired after 2 years oxes where appropriate) by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health I.
		or	\circ	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	\circ	CDAI score is 150 or less, or HBI is 4 or less
			\cup	The patient has demonstrated an adequate response to treatment but CDAI score and/or HBI score cannot be assessed
	and	0	up to	mab 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 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen s after completing the last re-induction cycle
Re-a	sses	smen	t requ	's disease (children) ired after 6 months oxes where appropriate)
(C	Preso		by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health
and	and	0	Paed	iatric patient has active Crohn's disease
		or	0	Patient has a PCDAI score of greater than or equal to 30
			\cup	Patient has extensive small intestine disease
	and	0		nt has tried but experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators corticosteroids

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:
Infliximab - continued	
CONTINUATION – Crohn's disease (children) Re-assessment required after 2 years Prerequisites (tick boxes where appropriate) O Prescribed by, or recommended by any relevant practitioner, or in a NZ Hospital. and	accordance with a protocol or guideline that has been endorsed by the Health
INITIATION – fistulising Crohn's disease Re-assessment required after 6 months Prerequisites (tick boxes where appropriate) Prescribed by, or recommended by a gastroenterologist, or in acco Hospital. and Patient has confirmed Crohn's disease and Patient has one or more complex externally draining er or Patient has one or more rectovaginal fistula(e) or Patient has complete peri-anal fistula	rdance with a protocol or guideline that has been endorsed by the Health NZ
NZ Hospital. Or The number of open draining fistulae have decreased to or There has been a marked reduction in drainage of all find a reduction in the Fistula Assessment score), together and Infliximab to be administered at doses up to 5 mg/kg every 8	istula(e) from baseline (in the case of adult patients, as demonstrated by

PRESCRIBER	PATIENT:		
Name:	Name:		
Ward:	NHI:		
Infliximab - continued			
INITIATION – acute fulminant ulcerative colitis Re-assessment required after 6 weeks Prerequisites (tick boxes where appropriate)			
Prescribed by, or recommended by a gastroenterologist, or in accord Hospital.	dance with a protocol or guideline that has been endorsed by the Health NZ		
O Patient has acute, fulminant ulcerative colitis and C Treatment with intravenous or high dose oral corticosteroids h	nas not been successful		
CONTINUATION – fulminant ulcerative colitis Re-assessment required after 2 years Prerequisites (tick boxes where appropriate) Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorso NZ Hospital.			
reassessed every 6 months and Infliximab to be administered at doses up to 5 mg/kg every 8	ximab should be used in combination with immunomodulators and weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used forment for re-induction. Another re-induction may be considered sixteen		
INITIATION – ulcerative colitis Re-assessment required after 6 months Prerequisites (tick boxes where appropriate) Prescribed by, or recommended by any relevant practitioner, or in activity to the property of the prescribed by any relevant practitioner, or in activity and the prescribed by the pres	ccordance with a protocol or guideline that has been endorsed by the Health		
Patient has active ulcerative colitis O Patients SCCAI is greater than or equal to 4 O Patients PUCAI score is greater than or equal to 20			
Patient has experienced an inadequate response to, or intoler systemic corticosteroids	rable side effects from, prior therapy with immunomodulators and		

I confirm that the above details are correct:	
Signed:	Date:

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

July 2024

PRES	CRIB	ER		PATIENT:	
Name:				Name:	
Ward:				NHI:	
Inflixi	mak) - co	ontini	j	
Re-as	sessr quisi) P	nent tes (t	requick b	erative colitis In dafter 2 years The ses where appropriate) or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health	h
	and (ι	ıp to	ne SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab ne PUCAI score has reduced by 30 points or more from the PUCAI score when the patient was initiated on 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 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen fiter completing the last re-induction cycle	
Re-as	sessr quisi) P	ment tes (t	requick b	d after 3 doses es where appropriate) or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ eatient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque soriasis	
			or	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	
Note: while hand affecte	still or or foo ed is 3	n trea t, at l 30% (itmer east or mo	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 atient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, cyclosporin, or acitretin PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment burses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course me most recent PASI assessment is no more than 1 month old at the time of initiation Tonse" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area 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	
cessa			11108	cent prior treatment.	_

PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:
Infliximab - continued	
CONTINUATION – plaque psoriasis Re-assessment required after 3 doses	
Prerequisites (tick boxes where appropriate) O Prescribed by, or recommended by a dermatologist, or in accordance Hospital.	ee with a protocol or guideline that has been endorsed by the Health NZ
allu	
Patient had "whole body" severe chronic plaque p	osoriasis at the start of treatment
Following each prior infliximab treatment course the sustained at this level, when compared with the p	he patient has a PASI score which is reduced by 75% or more, or is re-infliximab treatment baseline value
or	
Patient had severe chronic plaque psoriasis of the	e face, or palm of a hand or sole of a foot at the start of treatment
Following each prior infliximab treatment co for all 3 of erythema, thickness and scaling treatment course baseline values	ourse the patient has a reduction in the PASI symptom subscores , to slight or better, or sustained at this level, as compared to the
	ared to the pre-infliximab treatment baseline value
and	
Infliximab to be administered at doses no greater than 5 mg/kg	g every 8 weeks
INITIATION – neurosarcoidosis Re-assessment required after 18 months	
Prerequisites (tick boxes where appropriate)	
O Prescribed by, or recommended by a neurologist, or in accordance Hospital.	with a protocol or guideline that has been endorsed by the Health NZ
Biopsy consistent with diagnosis of neurosarcoidosis	
Patient has CNS involvement	
O Patient has steroid-refractory disease and	
O IV cyclophosphamide has been tried	
Treatment with IV cyclophosphamide is clinically inappro	opriate

I confirm that the above details are correct:	
Signed:	Date:

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PRESCRIBER	PATIENT:			
Name:	Name:			
Ward:	NHI:			
Infliximab - continued				
CONTINUATION – neurosarcoidosis Re-assessment required after 18 months Prerequisites (tick boxes where appropriate) O Prescribed by, or recommended by a neurologist, or in accordance of Hospital. and O A withdrawal period has been tried and the patient has relaps or O A withdrawal period has been considered but would not and O There has been a marked reduction in prednisone dose and O There has been an improvement in MRI appearance or O Marked improvement in other symptomology	be clinically appropriate			
or treatment(s) appropriate for the particular symptom(s) (s	ulitic symptoms and has not responded adequately to one or more			
two or more treatment appropriate for the particular symptom(s) (see Notes) The patient is experiencing significant loss of quality of life Note: a) 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. b) 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.				
CONTINUATION – severe Behcet's disease Re-assessment required after 6 months Prerequisites (tick boxes where appropriate) O Patient has had a good clinical response to initial treatment w and O Infliximab to be administered at doses no greater than 5 mg/kg				

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

PRESCRIBER	PATIENT:		
Name:	Name:		
Ward:	NHI:		
Infliximab - continued			
INITIATION – pyoderma gangrenosum Prerequisites (tick boxes where appropriate) O Prescribed by, or recommended by a dermatologist, or in accordance	e with a protocol or guideline that has been endorsed by the Health NZ		
Hospital.			
Patient has pyoderma gangrenosum* Patient has received three months of conventional therapy included azathioprine, or methotrexate) and not received an adequate rand A maximum of 8 doses	luding a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, esponse		
Note: Indications marked with * are unapproved indications.			
CONTINUATION – pyoderma gangrenosum Prerequisites (tick boxes where appropriate) O Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.			
Patient has shown clinical improvement and Patient continues to require treatment and A maximum of 8 doses			
INITIATION – Inflammatory bowel arthritis (axial) Re-assessment required after 6 months Prerequisites (tick boxes where appropriate)			
by a physiotherapist And Patient has a BASDAI of at least 6 on a 0-10 scale complete pharmacological treatment CONTINUATION – Inflammatory bowel arthritis (axial) Re-assessment required after 2 years Prerequisites (tick box where appropriate) Where treatment has resulted in an improvement in BASDAI of 4 or	eal imaging or MRI reatment consisting of at least 3 months of an exercise regime supervised d after the 3 month exercise trial, but prior to ceasing any previous		
improvement in BASDAI of 50%, whichever is less			

PRES	CRII	BER		PATIENT:
Name	:			Name:
Ward:				NHI:
Inflix	ima	ıb -	continued	
			Inflammatory bowel arthritis (peripheral) nt required after 6 months	
Prere	equis	sites	(tick boxes where appropriate)	
	and	O	Patient has a diagnosis of active ulcerative colitis or active Crol	hn's disease
		0	Patient has active arthritis in at least four joints from the following sternoclavicular	ng: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder,
	and		Patient has tried and not experienced a response to at least thr dose (unless contraindicated)	ree months of methotrexate or azathioprine at a maximum tolerated
	and	O Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated d contraindicated)		
and		or	O Patient has a CRP level greater than 15 mg/L measured	no more than one month prior to the date of this application
			O Patient has an ESR greater than 25 mm per hour measur	red no more than one month prior to the date of this application
		or	O ESR and CRP not measured as patient is currently received has done so for more than three months	ving prednisone therapy at a dose of greater than 5 mg per day and
CONTINUATION – Inflammatory bowel arthritis (peripheral) Re-assessment required after 2 years Prerequisites (tick boxes where appropriate)				
	or	0	Following initial treatment, patient has experienced at least a 50 significant response to treatment in the opinion of the physician	
	JI	0	Patient has experienced at least a continuing 30% improvement physician	nt in active joint count from baseline in the opinion of the treating

I confirm that the above details are correct:		
Cianad:	Doto	