### RS2065 - Infliximab

1			
	Crohn's disease (adults) - INITIATION	6	
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	Pulmonary sarcoidosis - INITIATION	5	
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	Ulcerative colitis - CONTINUATION	9	
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Signed: ...... Date: .....

# HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

May 2025

PRES	CRI	BER		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

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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	
CONTINUATION – ankylosing spondylitis Re-assessment required after 6 months Prerequisites (tick boxes where appropriate)  Prescribed by, or recommended by a rheumatologist, or in accordan Hospital.	ce with a protocol or guideline that has been endorsed by the Health NZ
and	
Hospital.  The patient has had an initial Special Authority approval for ad and  The patient has experienced intolerable side effects from or	ce with a protocol or guideline that has been endorsed by the Health NZ dalimumab and/or etanercept and/or secukinumab for psoriatic arthritis in a reasonable trial of adalimumab and/or etanercept and/or secukinumab and/or etanercept and/or secukinumab, the patient did not meet the
renewal criteria for adalimumab and/or etanercept and/o	
CONTINUATION – psoriatic arthritis Re-assessment required after 6 months Prerequisites (tick boxes where appropriate)  O Prescribed by, or recommended by a rheumatologist, or in accordan Hospital.  and	ce with a protocol or guideline that has been endorsed by the Health NZ
clinically significant response to treatment in the opinion	rovement 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

May 2025

PRES	CRIE	BER			PATIENT:
Name	e:				Name:
Ward	:				NHI:
nflix	cima	<b>b</b> - c	ontin	ued	
Re-a	ssess	sment	requ	ired a	ar inflammation fter 4 months where appropriate)
	or	and	O or	The O	Datient has had an initial Special Authority approval for adalimumab for severe ocular inflammation  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
		and	0	Patie	Int has severe, vision-threatening ocular inflammation requiring rapid control  Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms
			or or	0	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
Re-a	ssess	sment	requ	ired a	ocular inflammation fter 12 months where appropriate)
	or or	0	Follo Nome	wing e enclat c cys	t has had a good clinical response following 3 initial doses each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis ure (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of oid macular oedema) each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to
		rial wit	< 10r hdrav	ng da val sh	ould be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible ithdrawn.
			4		

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.

PRESCRIE	BER	PATIENT:	
Name:		Name:	
Ward:		NHI:	
nflixima	<b>b</b> - c	ntinued	
Re-assess	sment	conic ocular inflammation equired after 4 months ek boxes where appropriate)	
	and	The patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation	
		O The patient has experienced intolerable side effects from adalimumab or	
		O 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	
		O Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective or	
		O Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at therapeutic dose	
		O 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-assess	sment	- chronic ocular inflammation equired after 12 months ck boxes where appropriate)	
or	0	ne patient has had a good clinical response following 3 initial doses	
		ollowing each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis omenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of veitic cystoid macular oedema)	
or		ollowing 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	
		drawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible imab is withdrawn.	le
		Imonary sarcoidosis sk boxes where appropriate)	
and		atient has life-threatening pulmonary sarcoidosis that is refractory to other treatments	
unu		eatment is to be prescribed by, or has been recommended by, a physician with expertise in the treatment of pulmonary sarcoidosis	

I confirm that the above details are correct:

Signed: Date:

Signed: ...... Date: .....

## HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

May 2025

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	<b>sites</b> 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

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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	CRII	BER		PATIENT:
Name	:			
Ward:				NHI:
Inflix	ima	ıb -	contir	nued
Re-as	ssess equis	smer sites Pres NZ F or or	trequitive (tick I	Crohn's disease (children) uired after 2 years boxes where appropriate)  d by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health al.  PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab  PCDAI score is 15 or less  The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed  kimab 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 a 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen
INITIATION – fistulising Crohn's disease Re-assessment required after 6 months Prerequisites (tick boxes where appropriate)  O Prescribed by, or recommended by a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health Hospital.			ising Crohn's disease uired after 6 months boxes where appropriate)	
and	and	O or or	Patie	Patient has one or more complex externally draining enterocutaneous fistula(e)  Patient has one or more rectovaginal fistula(e)  Patient has complete peri-anal fistula
Re-as	ssess equis	smer sites Pres NZ F	t required (tick I	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
			up to	kimab 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 o 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen ks after completing the last re-induction cycle

May 2025

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	CRIBE	R	PATIENT:			
Name	e:		Name:			
Ward	:		NHI:			
Inflix	kimab	- continued				
Re-a	ssessm equisite	- acute fulminant ulcerative colitis ent required after 6 weeks es (tick boxes where appropriate) escribed by, or recommended by a gastroenterologist, or in accordispital.	lance with a protocol or guideline that has been endorsed by the Health NZ			
and	and	Patient has acute, fulminant ulcerative colitis  Treatment with intravenous or high dose oral corticosteroids has not been successful				
Re-a	ssessm	FION – fulminant ulcerative colitis ent required after 2 years es (tick boxes where appropriate)				
and		escribed by, or recommended by any relevant practitioner, or in ac Hospital.	cordance with a protocol or guideline that has been endorsed by the Health			
	and	Where maintenance treatment is considered appropriate, inflix reassessed every 6 months	imab should be used in combination with immunomodulators and			
			weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for nent for re-induction. Another re-induction may be considered sixteen			
Re-a	ssessm	- ulcerative colitis ent required after 6 months es (tick boxes where appropriate)				
and		escribed by, or recommended by any relevant practitioner, or in ac Hospital.	cordance with a protocol or guideline that has been endorsed by the Health			
Patient has active ulcerative colitis		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				
	and	Patient has experienced an inadequate response to, or intoleral systemic corticosteroids	able side effects from, prior therapy with immunomodulators and			

Signed: ...... Date: .....

# HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

PRESCRIBER	PATIENT:		
Name:	Name:		
Ward:	NHI:		
Infliximab - conti	ntinued		
O Prescribed NZ Hospit	equired after 2 years k boxes where appropriate) ed by, or recommended by any relevant practitioner, or in accordance with a pr	otocol or guideline that has been endorsed by the Health	
up to	The SCCAI score has reduced by 2 points or more from the SCCAI score volume.  The PUCAI score has reduced by 30 points or more from the PUCAI score fliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg to 3 doses if required for secondary non-response to treatment for re-induction tecks after completing the last re-induction cycle	when the patient was initiated on infliximab  g/kg every 8 weeks (or equivalent) can be used for	
Prerequisites (tick	ed by, or recommended by a dermatologist, or in accordance with a protocol or	guideline that has been endorsed by the Health NZ	
and or	Patient has had an initial Special Authority approval for adalimumab, etane psoriasis  Patient has experienced intolerable side effects from adalimumab, et  O Patient has received insufficient benefit from adalimumab, etanercep adalimumab, etanercept or secukinumab for severe chronic plaque p	anercept or secukinumab t or secukinumab to meet the renewal criteria for	
O	Patient has "whole body" severe chronic plaque psoriasis with a Psoriaria greater than 10, where lesions have been present for at least 6 months.  Patient has severe chronic plaque psoriasis of the face, or palm of a have been present for at least 6 months from the time of initial diagnosis.  Patient has severe chronic localised genital or flexural plaque psorias for at least 6 months from the time of initial diagnosis, and with a Der than 10  Patient has tried, but had an inadequate response (see Note) to, or has exported the following (at maximum tolerated doses unless contraindicated): photon A PASI assessment has been completed for at least the most recent prior to courses), preferably while still on treatment but no longer than 1 month folions.	hand or sole of a foot, where the plaque or plaques osis sis where the plaques or lesions have been present matology Life Quality Index (DLQI) score greater  perienced intolerable side effects from, at least three otherapy, methotrexate, cyclosporin, or acitretin reatment course (but preferably all prior treatment	

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PRESCRIBER	PATIENT:				
Name:					
Ward: NHI:					
Infliximab -	continued				
Re-assessmer	ON – plaque psoriasis  It required after 3 doses (tick boxes where appropriate)				
	O Patient had "whole body" severe chronic plaque psoriasis at the start of treatment  O Following each prior infliximab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab treatment baseline value				
or	O Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment and				
	Following each prior infliximab treatment course 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  Following each prior infliximab treatment course the patient has a reduction of 75% or more in the skin area				
or	affected, or sustained at this level, as compared to the pre-infliximab treatment baseline value  O Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment and				
	The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value  Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing infliximab				
and	Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks				
Re-assessmer Prerequisites	neurosarcoidosis  It required after 18 months (tick boxes where appropriate)				
Hosp and					
and	Biopsy consistent with diagnosis of neurosarcoidosis  Patient has CNS involvement				
and and	Patient has steroid-refractory disease				
or	O IV cyclophosphamide has been tried				
	Treatment with IV cyclophosphamide is clinically inappropriate				
-					

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 will Hospital.  and  O A withdrawal period has been tried and the patient has relapsed 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 appearant 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 see Notes) and/or mucocutaneous symptoms and has not responded adequately to		
Note:			
<ul><li>a) Behcet's disease diagnosed according to the International Study Group for measured using an appropriate quality of life scale such as that published</li><li>b) Treatments appropriate for the particular symptoms are those that are constant.</li></ul>	in Gilworth et al J Rheumatol. 2004;31:931-7. sidered standard conventional treatments for these symptoms, for example oms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for		
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 wind and Infliximab to be administered at doses no greater than 5 mg/kg			

Signed: ...... Date: .....

## HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

May 2025

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 with a protocol or guideline that has been endorsed by the Health N Hospital.  and		
Patient has pyoderma gangrenosum*  Patient has received three months of conventional therapy incleazathioprine, or methotrexate) and not received an adequate read A maximum of 8 doses  Note: Indications marked with * are unapproved indications.	uding a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, esponse	
CONTINUATION myodormo gongrenooum		
CONTINUATION – pyoderma gangrenosum  Prerequisites (tick boxes where appropriate)  Prescribed by, or recommended by a dermatologist, or in accordance Hospital.  and	e with a protocol or guideline that has been endorsed by the Health NZ	
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 completed pharmacological treatment  CONTINUATION – Inflammatory bowel arthritis (axial)  Re-assessment required after 2 years  Prerequisites (tick box where appropriate)	al imaging or MRI atment consisting of at least 3 months of an exercise regime supervised I after the 3 month exercise trial, but prior to ceasing any previous	
O Where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10-point scale, or an		

May 2025

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PRES	CRI	BER	PATIENT:				
Name	:						
Ward:			NHI:				
Inflix	ima	ab -	continued				
Re-a	sses	smen	nflammatory bowel arthritis (peripheral) t required after 6 months				
Prere	equi	sites	(tick boxes where appropriate)				
	anc	O	Patient has a diagnosis of active ulcerative colitis or active Crohn's disease				
	and	0	Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular				
	and	0	Patient has tried and not experienced a response to at least three months of methotrexate or azathioprine at a maximum tolerated dose (unless contraindicated)				
		0	Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated)				
		or	Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application				
		or	O Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application				
			O 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				
CONTINUATION – Inflammatory bowel arthritis (peripheral) Re-assessment required after 2 years Prerequisites (tick boxes where appropriate)							
	or	O	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				
		0	Patient has experienced at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician				

I confirm that the above details are correct:

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Signed.	Date:	
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