RS2124 - Infliximab

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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	CRI	BER			PATIENT:
Name:					Name:
Ward:					NHI:
Inflix	ima	ab			
				vs host disease	
Prere	`			box where appropriate) s steroid-refractory acute graft vs. host disease of the gr	
	_	Palle	ni nas	s steroid-refractory acute graft vs. Host disease of the gr	11
				natoid arthritis uired after 4 months	
Prere	qui	sites	(tick t	boxes where appropriate)	
and		Preso Hosp		by, or recommended by a rheumatologist, or in accorda	ance with a protocol or guideline that has been endorsed by the Health NZ
	and	O	The	patient has had an initial Special Authority approval for a	adalimumab and/or etanercept for rheumatoid arthritis
		or	0	The patient has experienced intolerable side effects from	om a reasonable trial of adalimumab and/or etanercept
			0	Following at least a four month trial of adalimumab and adalimumab and/or etanercept	d/or etanercept, the patient did not meet the renewal criteria for
	and			tment is to be used as an adjunct to methotrexate theraperance	by or monotherapy where use of methotrexate is limited by toxicity or
Prere	equi	sites	tick b	uired after 6 months boxes where appropriate) I by, or recommended by a rheumatologist, or in accorda	ance with a protocol or guideline that has been endorsed by the Health NZ
and	and	d		tment is to be used as an adjunct to methotrexate theraperance	by or monotherapy where use of methotrexate is limited by toxicity or
		or	0	Following 3 to 4 months' initial treatment, the patient h clinically significant response to treatment in the opinion	has at least a 50% decrease in active joint count from baseline and a on of the physician
			0	The patient demonstrates at least a continuing 30% in response to treatment in the opinion of the physician	provement in active joint count from baseline and a clinically significant
	and		Inflix	rimab to be administered at doses no greater than 3 mg/	kg every 8 weeks
Re-as	sses equi	ssmen sites	t requestick to the cribed ital.		ance with a protocol or guideline that has been endorsed by the Health NZ
	and		ne		adalimumab and/or etanercept for ankylosing spondylitis
		or	0		om a reasonable trial of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab

I confirm that the above details are correct:

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Signed	Dale	

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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 accordance Hospital. and Following 12 weeks of infliximab treatment, BASDAI has improof by 50%, whichever is less and	ce with a protocol or guideline that has been endorsed by the Health NZ eved by 4 or more points from pre-infliximab baseline on a 10 point scale,
Physician considers that the patient has benefited from treatment and Infliximab to be administered at doses no greater than 5 mg/kg	
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 alimumab 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 r secukinumab for psoriatic arthritis.
Hospital. O Following 3 to 4 months' initial treatment, the patient has clinically significant response to treatment in the opinion or	rovement in active joint count from baseline and a clinically significant te treating physician

PRES	CRII	BER			PATI	ENT:
Name:					Nam	e:
Ward:					NHI:	
Inflixi	ima	ıb -	contin	ued		
Re-as	ses	smen	t requ	ired	ular inflammation after 4 months s where appropriate)	
	or	and	or	C	ocular inflammation tient has severe, vision-threatening ocular inflammation req Treatment with high-dose steroids (intravenous methylpr ineffective at controlling symptoms Patient developed new inflammatory symptoms while re-	umab to meet the renewal criteria for adalimumab for severe uiring rapid control ednisolone) followed by high dose oral steroids has proven ceiving high dose steroids
Re-as	ses	smen	t requ	ired	re ocular inflammation after 12 months s where appropriate)	ose oral steroids and other immunosuppressants has proven
	or or	О О	Follo Nom uveit	wing encla c cy wing	ature (SUN) criteria < ½+ anterior chamber or vitreous cells vistoid macular oedema)	stained reduction in inflammation (Standardisation of Uveitis s, absence of active vitreous or retinal lesions, or resolution of ed steroid sparing effect, allowing reduction in prednisone to
			thdrav	val s		ess the patient is deemed to have extremely high risk of irreversible

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

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PRESCRIB	BER	PATIENT:
Name:		
Ward:		NHI:
nfliximal	b - cor	tinued
Re-assess	ment re	onic ocular inflammation equired after 4 months k 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 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
Re-assess	ment re	- chronic ocular inflammation quired after 12 months k boxes where appropriate)
or (От	e patient has had a good clinical response following 3 initial doses
(No	llowing each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis menclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of eitic cystoid macular oedema)
or (O Fo	llowing 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
		rawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible mab is withdrawn.
		monary sarcoidosis k boxes where appropriate)
and	ОРа	tient has life-threatening pulmonary sarcoidosis that is refractory to other treatments
and (O Tr	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:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

PRES	CRIE	BER		PATIENT:
Name	e:			
Ward	:			NHI:
Inflix	cima	b -	contin	ued
Re-a	ssess equis	smen sites	t requ (tick b	's disease (adults) ired after 6 months ioxes where appropriate)
and			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	\circ	Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection
			\circ	Patient has an ileostomy or colostomy, and has intestinal inflammation
	and	0		nt has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators corticosteroids
Re-a	ssess equis	Preson NZ H	t requi(tick beribed ospital) Inflixiup to	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 II. 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 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 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 is after completing the last re-induction cycle
Re-a	sses	smen	t requ	's disease (children) 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	Paed	iatric patient has active Crohn's disease
		or	0	Patient has a PCDAI score of greater than or equal to 30 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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PRES	CRII	BER		PATIENT:
Name:				
Ward:				NHI:
Inflixi	ima	ıb -	contin	nued
Re-as	ses quis	smer sites Pres	t required tick to the cribed ospita	
	and	or or	0	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
	a 110	0	up to	imab 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 as after completing the last re-induction cycle
Re-as	ses qui	smer sites	t requestick to the control of the c	sing Crohn's disease uired after 6 months poxes where appropriate) by, or recommended by a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ ent has confirmed Crohn's disease
	and	or or	O O	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	ses qui	smer sites Pres	t requ (tick t	
	and	or O	up to	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 imab 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 as after completing the last re-induction cycle

PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:
Infliximab - continued	
	dance with a protocol or guideline that has been endorsed by the Health NZ
Hospital. O Patient has acute, fulminant ulcerative colitis and O Treatment with intravenous or high dose oral corticosteroids has	as 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 ac NZ Hospital.	ecordance with a protocol or guideline that has been endorsed by the Health
reassessed every 6 months and Infliximab to be administered at doses up to 5 mg/kg every 8 v	weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for ment 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 act NZ Hospital.	ecordance 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 and	
	able side effects from, prior therapy with immunomodulators and

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

I confirm that the above details are correct:

Signed: Date:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

PRES	SCRII	BER		PATIENT:
Name	e:			
Ward	:			NHI:
Inflix	kima	ab - c	ontini	ued
Re-a	equis	sment sites (requi tick b	Icerative colitis ired after 2 years oxes where appropriate)
and		NZ Ho		by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health I.
		or	0	The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab
			\bigcup	The PUCAI score has reduced by 30 points or more from the PUCAI score when the patient was initiated on infliximab
	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	issesi equis	sment sites (requitick b	e psoriasis irred after 3 doses oxes where appropriate) by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ
		and	O	Patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis O 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			
		and	or 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 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, cyclosporin, or actiretin
		and	0	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 , hand re, ar	on tread, foot not for t	atmer geni the fa	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 tall or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very ce, 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 on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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PRESCRIBER	PATIENT:				
Name:	Name:				
Ward:	NHI:				
Infliximab - continued					
CONTINUATION – plaque psoriasis Re-assessment required after 3 doses Prerequisites (tick boxes where appropriate)					
Patient had severe chronic plaque psoriasis of the and Patient had severe chronic plaque psoriasis of the for all 3 of erythema, thickness and scaling treatment course baseline values Pollowing each prior infliximab treatment or treatment course baseline values Pollowing each prior infliximab treatment or affected, or sustained at this level, as compand or patient had severe chronic localised genital or flee and	the patient has a PASI score which is reduced by 75% or more, or is pre-infliximab treatment baseline value e face, or palm of a hand or sole of a foot at the start of treatment purse the patient has a reduction in the PASI symptom subscores go, to slight or better, or sustained at this level, as compared to the purse the patient has a reduction of 75% or more in the skin area pared to the pre-infliximab treatment baseline value				
or compared to the pre-treatment baseline va	ndex (DLQI) improvement of 5 or more, as compared to baseline DLQI				
INITIATION – neurosarcoidosis Re-assessment required after 18 months Prerequisites (tick boxes where appropriate)					
Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.					
Biopsy consistent with diagnosis of neurosarcoidosis and Patient has CNS involvement and Patient has steroid-refractory disease and IV cyclophosphamide has been tried or Treatment with IV cyclophosphamide is clinically inapp	ropriate				
C Troumon Marry Gyolophicophiamide to difficulty inapp	<u></u>				

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Signed: Date:

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PRES	CRIE	BER PATIENT:			
Name):				
Ward:	:	NHI:			
Inflix	Infliximab - continued				
Re-a	ssess equis	DATION – neurosarcoidosis sment required after 18 months sites (tick boxes where appropriate) Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital. O A withdrawal period has been tried and the patient has relapsed A withdrawal period has been considered but would not be clinically appropriate and There has been a marked reduction in prednisone dose O There has been an improvement in MRI appearances or O Marked improvement in other symptomology			
INITIATION – severe Behcet's disease Re-assessment required after 4 months Prerequisites (tick boxes where appropriate) Or 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 material 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 one or material treatment appropriate for the particular symptom(s) (see Notes)					
Note	and				
 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)					
	and	Patient has had a good clinical response to initial treatment with measurably improved quality of life Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks			

I confirm that the above details are correct:

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.	Hospital.			
Patient has pyoderma gangrenosum* Patient has received three months of conventional therapy incl azathioprine, or methotrexate) and not received an adequate read A maximum of 8 doses	uding 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) 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)				
O Patient has a diagnosis of active ulcerative colitis or active Cro	hn's disease			
Patient has had axial inflammatory pain for six months or more				
Patient is unable to take NSAIDs				
Patient has unequivocal sacroiliitis demonstrated by radiologic and	al imaging or MRI			
	atment consisting of at least 3 months of an exercise regime supervised			
Patient has a BASDAI of at least 6 on a 0-10 scale completed pharmacological treatment	after the 3 month exercise trial, but prior to ceasing any previous			
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 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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PRESCRIBER		R	PATIENT:			
Name:			Name:			
Ward:			NHI:			
Inflix	imab	- continued				
Re-a	INITIATION – Inflammatory bowel arthritis (peripheral) Re-assessment required after 6 months Prerequisites (tick boxes where appropriate)					
		Patient has tried and not experienced a response to at least thredose (unless contraindicated) Patient has tried and not experienced a response to at least threcontraindicated) Patient has a CRP level greater than 15 mg/L measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm per hour measured or Patient has an ESR greater than 25 mm pe	nn's disease ng: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, ee months of methotrexate or azathioprine at a maximum tolerated ee months of sulfasalazine at a maximum tolerated dose (unless no more than one month prior to the date of this application red no more than one month prior to the date of this application 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 C	Following initial treatment, patient has experienced at least a 50 significant response to treatment in the opinion of the physician Patient has experienced at least a continuing 30% improvement physician				
INITIATION – immune checkpoint inhibitor toxicity in malignancy* Re-assessment required after 4 months Prerequisites (tick boxes where appropriate) Orescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Heal NZ Hospital.						
and	and and	The individual requires treatment for moderate to severe autoin malignancy The individual has received insufficient benefit from use of corti Infliximab is to be administered at up to 5mg/kg for up to four do				

PRESCRIBER	PATIENT:				
Name:	Name:				
Ward:	NHI:				
Infliximab - continued					
CONTINUATION – immune checkpoint inhibitor toxicity in malignancy* Re-assessment required after 4 months Prerequisites (tick boxes where appropriate)					
O Prescribed by, or recommended by any relevant practitioner, or in a NZ Hospital.	ccordance with a protocol or guideline that has been endorsed by the Health				
O The individual has shown clinical improvement and ongoing treatment is required					
O Infliximab is to be administered at up to 5mg/kg for up to a tot	al of 8 doses				
Note: Indications marked with * are unapproved indications.					