RS2062 - Etanercept

Arthritis - rheumatoid - INITIATION	4
Arthritis - rheumatoid - CONTINUATION	4
Adult-onset Still's disease - INITIATION	10
Adult-onset Still's disease - CONTINUATION	10
Ankylosing spondylitis - INITIATION	5
Ankylosing spondylitis - CONTINUATION	6
Oligoarticular course juvenile idiopathic arthritis - INITIATION	
Oligoarticular course juvenile idiopathic arthritis - CONTINUATION	3
Polyarticular course juvenile idiopathic arthritis - INITIATION	2
Polyarticular course juvenile idiopathic arthritis - CONTINUATION	2
Psoriatic arthritis - INITIATION	6
Psoriatic arthritis - CONTINUATION	7
Pyoderma gangrenosum - INITIATION	9
Pyoderma gangrenosum - CONTINUATION	10
Severe chronic plaque psoriasis - CONTINUATION	9
Severe chronic plaque psoriasis, prior TNF use - INITIATION	
Severe chronic plaque psoriasis, treatment-naive - INITIATION	8
Undifferentiated spondyloarthritis - INITIATION	11
Undifferentiated spondyloarthritis - CONTINUATION	11

PRES	SCRIE	BER	PATIENT:
Name	ə:		Name:
Ward	:		NHI:
Etan	erce	ept	
Re-a	equis	sment sites (Presc	olyarticular course juvenile idiopathic arthritis required after 6 months tick boxes where appropriate) ribed by, or recommended by a rheumatologist or named specialist, or in accordance with a protocol or guideline that has been endorsed Health NZ Hospital.
		and	The patient has had an initial Special Authority approval for adalimumab for polyarticular course juvenile idiopathic arthritis (JIA)
			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 polyarticular course JIA
	or	and	O Patient has had polyarticular course JIA for 6 months duration or longer
Re-a	assess	sment	N – polyarticular course juvenile idiopathic arthritis required after 6 months tick boxes where appropriate)
and			ribed by, or recommended by a rheumatologist or named specialist, or in accordance with a protocol or guideline that has been endorsed Health NZ Hospital.
	and		Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
		or	Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

I confirm that the above details are correct:

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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	CRIB	BER		PATIENT:
Name	e:			
Ward	:			NHI:
Etan	erce	pt -	conti	nued
Re-a	ssess equis	ment ites (Presci	requitick b	rticular course juvenile idiopathic arthritis red after 6 months oxes where appropriate) by, or recommended by a rheumatologist or named specialist, or in accordance with a protocol or guideline that has been endorsed th NZ Hospital.
		and		The patient has had an initial Special Authority approval for adalimumab for oligoarticular course juvenile idiopathic arthritis (JIA) The patient has experienced intolerable side effects from adalimumab
			or	The patient has experienced intolerable side elects from adalimumab The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for oligoarticular course JIA
	or	and	\circ	To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance Patient has had oligoarticular course JIA for 6 months duration or longer O At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose) O Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose) O High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate
Re-a	ssess equis	ment i tes (Presci	requitick b	ligoarticular course juvenile idiopathic arthritis red after 6 months oxes where appropriate) by, or recommended by a rheumatologist or named specialist, or in accordance with a protocol or guideline that has been endorsed th NZ Hospital.
	and	0	Subs	dised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
		or	0	Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baselinee On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

I confirm that the above details are correct:

Signed: Date:

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	CRIB	BER			PATIENT:
Name:	:				Name:
Ward:					NHI:
Etane	erce	pt -	conti	nued	
				s - rheumatoid	
				red after 6 months expectations are series of the series	
(`				de constate de la constante de
		rescr Hospit		by, or recommended by a	rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ
and			$\overline{\bigcirc}$	The constant has been been as to	
		and		The patient has had an ir	nitial Special Authority approval for adalimumab for rheumatoid arthritis
			۵.	O The patient has exp	perienced intolerable side effects
			or	O The patient has red	ceived insufficient benefit to meet the renewal criteria for rheumatoid arthritis
	or				
			O		oid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP)
		and		antibody positive) for six	months duration or longer
			\bigcirc	Treatment is to be used a or intolerance	as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity
		and	\bigcirc		responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated)
		and	\bigcirc		
					responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquinerated doses (unless contraindicated)
		and		O Patient has tried an	nd not responded to at least three months of methotrexate in combination with the maximum tolerated
			or	dose of ciclosporin	in not responded to at least time months of methodexate in combination with the maximum tolerated
					nd not responded to at least three months of therapy at the maximum tolerated dose of leflunomide ation with methotrexate
		and		aione or in combina	anon with methodexate
				O Patient has persiste	ent symptoms of poorly controlled and active disease in at least 15 swollen joints
			or	O Patient has persiste	ent symptoms of poorly controlled and active disease in at least four joints from the following: wrist,
					, and either shoulder or hip
				rthritis - rheumatoid red after 2 years	
				exes where appropriate)	
(and		Prescr NZ Ho			ny relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health
	and			nent is to be used as an a	adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or
		or	0		t, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant the opinion of the physician
			0		tions, the patient demonstrates at least a continuing 30% improvement in active joint count from significant response to treatment in the opinion of the physician
	and	\bigcirc	E+o∽-	roopt to be administered	at desce no greater than 50 mg every 7 deve
			Liane	rcept to be administered	at doses no greater than 50 mg every 7 days
			_		

ard: NHI: Intercept - continued	RESCRIB	ER		PATIENT:
ANTIATION — ankylosing spondylitis e-assessment required after 6 months rerequilates (tick boxes where appropriate) Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital. The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis and Patient has low back pain and stiffness that is relieved by exercise but not by rest and Patient has low back pain and stiffness that is relieved by exercise but not by rest and Patient has bilateral sacrolilitis demonstrated by plain radiographs, CT or MRI scan Patient has bilateral sacrolilitis demonstrated by plain radiographs, CT or MRI scan Patient has bilateral sacrolilitis demonstrated by plain radiographs, CT or MRI scan and Patient has bilateral sacrolilitis demonstrated by plain radiographs, CT or MRI scan and Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology index (BASDAI) measures: a medified Schober's test of less than or equal to 4 cm and unbar's side flexion measurement of less than or equal to 10 or Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender: Age Male Fermi Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale block: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI exercise normal chest expansion corrected for age and gender: Age Male Fermi 5.5 cm 4.0 cm 6.5 cm 6.5 cm 4.0 cm 6.5 cm 6.5 cm 6.5 cm 6.5 cm 6.5 cm 6.5 cm 6	ıme:			Name:
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HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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	SCRIE	BER		PATIENT:
Name	e:			Name:
Ward	:			NHI:
Etan	erce	ept - d	contin	nued
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and		Prescri Hospita		by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ
	and	I F	oints	wing 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more is from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less cian considers that the patient has benefited from treatment and that continued treatment is appropriate
		O E	Etane	ercept to be administered at doses no greater than 50 mg every 7 days
Re-a	ssess equis	sment sites (t	requir ick bo bed b	tic arthritis red 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
		and	or	The patient has had an initial Special Authority approval for adalimumab or secukinumab for psoriatic arthritis The patient has experienced intolerable side effects from adalimumab or secukinumab The patient has received insufficient benefit from adalimumab or secukinumab to meet the renewal criteria for adalimumab or secukinumab for psoriatic arthritis
	or		_	
		and		Patient has had severe active psoriatic arthritis for six months duration or longer Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses)
			or	O Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints O Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip
		and	or or	Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour 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

HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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	CRIB	ER			PATIENT:
Name	e:				Name:
Ward:	:				NHI:
Etan	erce	pt -	- contii	nued	
Re-a	ssessi	ment	t requi	soriatic arthritis red after 6 months oxes where appropriate)	
(and		resc lospi		by, or recommended by a rheumatologist, or in accordance	ce with a protocol or guideline that has been endorsed by the Health NZ
		or	O O	clinically significant response to treatment in the opinion	ovement in active joint count from baseline and a clinically significant
	and	<u>С</u>	Etane	ercept to be administered at doses no greater than 50 mg	every 7 days
Re-a	ssessi	ment	t requi	chronic plaque psoriasis, prior TNF use red after 4 months oxes where appropriate)	
(Эр		` cribed	,	with a protocol or guideline that has been endorsed by the Health NZ
	and	С	The p	patient has had an initial Special Authority approval for ad	alimumab for severe chronic plaque psoriasis
		or	0	The patient has experienced intolerable side effects from	adalimumab
		OI	0	The patient has received insufficient benefit from adalimuplaque psoriasis	umab to meet the renewal criteria for adalimumab for severe chronic
	and (C	Patier	nt must be reassessed for continuation after 3 doses	

SCRIBER	R		PATIENT:
e:			Name:
l:			NHI:
nercept	t - con	tinued	
		e chronic plaque psoriasis, treatment-naive	
		uired after 4 months boxes where appropriate)	
	escribed spital.	d by, or recommended by a dermatologist, or in accorda	ance with a protocol or guideline that has been endorsed by the Health NZ
		Delication has been been been been as a second	in the Basis Annual Court India (BACI)
		10, where lesions have been present for at least 6 m	iasis with a Psoriasis Area and Severity Index (PASI) score of greater than onths from the time of initial diagnosis
	or O	Patient has severe chronic plaque psoriasis of the factories been present for at least 6 months from the time of ir	ce, or palm of a hand or sole of a foot, where the plaque or plaques have itial diagnosis
C	or O		al plaque psoriasis where the plaques or lesions have been present for at with a Dermatology Life Quality Index (DLQI) score greater than 10
and			te) to, or has experienced intolerable side effects from, at least three of the ted): phototherapy, methotrexate, ciclosporin, or acitretin
and	trea		DLQI) assessment has been completed for at least the most recent prior s), preferably while still on treatment but no longer than 1 month following
and) The	most recent PASI or DLQI assessment is no more than	n 1 month old at the time of initiation
e still on t , hand, fo ere, and f	treatme oot, ger for the f	ent but no longer than 1 month following cessation of the bit but no longer than 1 month following cessation of the services at least 2 of the 3 PASI symptom	plaque psoriasis, a PASI score of greater than 10, as assessed preferably ne most recent prior treatment; for severe chronic plaque psoriasis of the subscores for erythema, thickness and scaling are rated as severe or very cted is 30% or more of the face, palm of a hand or sole of a foot, as assess sation of the most recent prior treatment.

I confirm that the above details are correct:

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Schedule. For community funding, see the Special Authority Criteria.

RESTRICTIONS CHECKLIST

PRESCRIBER PATIENT: Name: Name: NHI: Etanercept - continued CONTINUATION - severe chronic plaque psoriasis Re-assessment required after 6 months Prerequisites (tick boxes where appropriate) Patient had "whole body" severe chronic plaque psoriasis at the start of treatment and Following each prior etanercept 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-etanercept treatment baseline value or Following each prior etanercept treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value or 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 etanercept 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 or Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-etanercept treatment baseline value or 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 or Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing etanercept and Etanercept to be administered at doses no greater than 50 mg every 7 days INITIATION - 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. and Patient has pyoderma gangrenosum* and Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response and A maximum of 8 doses Note: Indications marked with * are unapproved indications.

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

I confirm that the above details are correct:

Signed: Date:

PRES	CRIB	ER	PATIENT:
Name	:		
Ward:			NHI:
Etan	erce	pt -	ntinued
	equisi	rescr	pyoderma gangrenosum boxes where appropriate) d by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ ient has shown clinical improvement
	and (and	C	ient continues to require treatment naximum of 8 doses
Re-a Prero (and	or TINU/ ssesss equisi F	and and and ard ites (t	thonset Still's disease quired after 6 months boxes where appropriate) d by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD) The patient has been started on tocilizumab for AOSD in a Health NZ Hospital The patient has experienced intolerable side effects from etanercept and/or tocilizumab The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or tocilizumab such that they do not meet the renewal criteria for AOSD Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430) Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate Patient has persistent symptoms of disabling poorly controlled and active disease adult-onset Still's disease quired after 6 months box where appropriate) d by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ
allu (тС	he pa	nt has a sustained improvement in inflammatory markers and functional status

I confirm that the above details are correct:

SCRIB	BER		PATIENT:
ne:			Name:
d:			NHI:
nerce	pt -	- continu	ued
assess erequis	men ites Presc	t require (tick box cribed by	rentiated spondyloarthritis ed after 6 months exes where appropriate) y, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ
and (Hospi O	Patient wrist, e	has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: elbow, knee, ankle, and either shoulder or hip has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a um tolerated dose
and	\circ	Patient dose)	has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day (or maximum tolerated has tried and not responded to at least three months of leflunomide at a dose of up to 20 mg daily (or maximum tolerated dose)
and	or or		Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour measured no more than one month prior to the date of this application ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and last done so for more than three months
te: Indi	catio		xed with * are unapproved indications.
-assess	men	t require	differentiated spondyloarthritis ed after 6 months xes where appropriate)
	or	O A	Applicant is a rheumatologist Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment
and	or	От	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 esponse to prior etanercept treatment in the opinion of the treating physician
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I confirm that the above details are correct: