SA2489 - Tocilizumab

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Reg No:	First Names:	First Names:	
Name:	Surname:	Surname:	
Address:	DOB:	Address:	
	Address:		
Fax Number:		Fax Number:	
Tocilizumab			
Initial application — cytokine release syndrome Applications from any relevant practitioner. Approvals valid without further renewal unless notified. Prerequisites(tick boxes where appropriate) The patient has developed grade 3 or 4 cytokine release syndrome associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses (if less than 30kg, maximum of 12 mg/kg) or The patient is enrolled in the Malaghan Institute of Medical Research ENABLE trial programme The patient has developed CRS or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) following CAR T-cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma Tocilizumab is to be administered according to the consensus guidelines for CRS or ICANS for CAR T-cell therapy at doses no greater than 8 mg/kg IV for a maximum of 3 doses			
Initial application — previous use Applications from any relevant practitioner. Approvals valid for 6 months. Prerequisites(tick boxes where appropriate)			
Patient was being treated with toc	ilizumab prior to 1 February 2019		
Rheumatoid arthritis			
Systemic juvenile idiopathic	arthritis		
Adult-onset Still's disease			
Polyarticular juvenile idiopa			
Idiopathic multicentric Castl	eman's disease		

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	Address:	
Fax Number:		Fax Number:
Tocilizumab - continued		
The patient has had an initial Speciand The patient has experienced or The patient has experienced instruction in the patient has received instruction in the patient has received instruction and The patient is seronegative for The patient has been sand The patient has been sand At four months for	ial Authority approval for adalimumab and/or etanero intolerable side effects from adalimumab and/or etanero ufficient benefit from at least a three-month trial of ad for rheumatoid arthritis or both anti-cyclic citrullinated peptide (CCP) antibod started on rituximab for rheumatoid arthritis in a Heali experienced intolerable side effects from rituximab ollowing the initial course of rituximab the patient has renewal criteria for rheumatoid arthritis	ept for rheumatoid arthritis hercept alimumab and/or etanercept such that they do lies and rheumatoid factor

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Reg No:		First Names:	. First Names:
Name: Surname: Surname:		. Surname:	
Address:		DOB:	. Address:
		Address:	
Fax Numb	er:		. Fax Number:
Tocilizu	mab - continued		
Applicati	plication — Rheumatoid Arthritis ons only from a rheumatologist or Pra sites(tick boxes where appropriate)	ctitioner on the recommendation of a rheumatologist.	Approvals valid for 6 months.
and	peptide (CCP) antibody positive Tocilizumab is to be used as m	ive erosive rheumatoid arthritis (either confirmed by ra e) for six months duration or longer onotherapy	diology imaging, or the patient is cyclic citrullinated
and	and Treatment with methotrexate is contraindicated or Patient has tried and did not tolerate oral and/or parenteral methotrexate		
and	d		
	Patient has tried and not combination with anothe	responded to at least three months therapy at the max agent	kimum tolerated dose of ciclosporin alone or in
		responded to at least three months therapy at the max agent	kimum tolerated dose of leflunomide alone or in
and	d		
	Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints or		
	Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip		
and	d		
	or	protein level greater than 15 mg/L measured no more to more the measured as patient is currently receiving prednisor	
	day and has done so for		one therapy at a dose of greater than 3 mg per
Initial application — systemic juvenile idiopathic arthritis			
Applicati		ctitioner on the recommendation of a rheumatologist.	Approvals valid for 6 months.
	Patient diagnosed with system	c juvenile idiopathic arthritis	
and	Patient has tried and not responded to a reasonable trial of all of the following, either alone or in combination: oral or parenteral methotroyate; non-storoidal anti-inflammatory drugs (NSAIDs); and systemic continuous transitions.		

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Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
	Address:	
Fax Number: Tocilizumab - continued		Fax Number:
Initial application — adult-onset Still's disease Applications only from a rheumatologist or Practiti Prerequisites(tick boxes where appropriate)	oner on the recommendation of a rheumatologist. A	pprovals valid for 6 months.
or (AOSD)	n initial Special Authority approval for adalimumab an	
or The patient has received.	ienced intolerable side effects from adalimumab and red insufficient benefit from at least a three-month trial enewal criteria for AOSD	.
Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430) and 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		
Initial application — polyarticular juvenile idiop Applications only from a rheumatologist or Practiti Prerequisites(tick boxes where appropriate)	oathic arthritis oner on the recommendation of a rheumatologist. A	pprovals valid for 4 months.
idiopathic arthritis (JIA)	Il Special Authority approval for both etanercept and	
and Patient has had polyarticular and To be used as an adjunct to	crosis factor alpha inhibitor is contraindicated r course JIA for 6 months duration or longer methotrexate therapy or monotherapy where use of the contract of	methotrexate is limited by toxicity or intolerance
	s and at least 3 joints with limited range of motion, panaximum tolerated dose)	ain or tenderness after a 3-month trial of
Moderate or high dise tolerated dose)	ase activity (cJADAS10 score of at least 2.5) after a	3-month trial of methotrexate (at the maximum
	cJADAS10 score between 1.1 and 2.5) after a 6-mon	th trial of methotrexate

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	Address:	
Fax Number:		Fax Number:
Tocilizumab - continued		
Initial application — idiopathic multicentric Ca Applications only from a haematologist, rheumato 6 months. Prerequisites(tick boxes where appropriate)	stleman's disease plogist or Practitioner on the recommendation of a hae	ematologist or rheumatologist. Approvals valid for
Delicat has source IVIV 0 massing	idia adhia mulaisandria Castlana ale dia sa	
and	e idiopathic multicentric Castleman's disease	
and	f corticosteroids has proven ineffective	
Tocilizumab to be administered at	doses no greater than 8 mg/kg IV every 3-4 weeks	
Initial application — moderate to severe COVID Applications from any relevant practitioner. Appropriete (tick boxes where appropriate)		
Patient has confirmed (or probable	e) COVID-19	
Oxygen saturation of < 92% on ro	om air, or requiring supplemental oxygen	
and Patient is receiving adjunct systemic corticosteroids, or systemic corticosteroids are contraindicated		
and Tocilizumab is to be administered at doses no greater than 8mg/kg IV for a maximum of one dose		
and Tocilizumab is not to be administered in combination with barcitinib		
Renewal — Rheumatoid Arthritis		
Current approval Number (if known):	oner on the recommendation of a rheumatologist. Ap	provals valid for 6 months
Prerequisites(tick boxes where appropriate)	oner on the recommendation of a medinatologist. Ap	provais valid for 6 months.
Following 6 months' initial treatment is significant response to treatment in	ent, the patient has at least a 50% decrease in active	joint count from baseline and a clinically
or	e patient demonstrates at least a continuing 30% impr	ovement in active joint count from baseline and a
	eatment in the opinion of the physician	,
Renewal — systemic juvenile idiopathic arthritis		
Current approval Number (if known):		
Prerequisites(tick boxes where appropriate)	<u> </u>	
improvement criteria (ACR Pedi 30	eatment, the patient has achieved at least an America 0) response from baseline	an College of Rheumatology paediatric 30%
On subsequent reapplications, the	e patient demonstrates at least a continuing ACR Pedi	30 response from baseline

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	Address:	
		Fax Number:
Tocilizumab - continued		
Renewal — adult-onset Still's disease		
Current approval Number (if known):		
Applications only from a rheumatologist or Practit Prerequisites (tick box where appropriate)	ioner on the recommendation of a rheumatologist. Ap	provals valid for 6 months.
The patient has a sustained improveme	nt in inflammatory markers and functional status	
Renewal — polyarticular juvenile idiopathic ar	thritic	
Current approval Number (if known):		
Applications only from a rheumatologist or Practit Prerequisites (tick boxes where appropriate)	ioner on the recommendation of a rheumatologist. Ap	provals valid for 6 months.
Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance		
and		
Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline		
On subsequent reapplication	ons, the patient demonstrates at least a continuing 30°	% improvement in active joint count and
continued improvement in physician's global assessment from baseline		
Renewal — idiopathic multicentric Castleman	s disease	
Current approval Number (if known):		
, , ,	logist or Practitioner on the recommendation of a hae	matologist or rheumatologist. Approvals valid for
Prerequisites(tick box where appropriate)		
The treatment remains appropriate and	the patient has a sustained improvement in inflammat	tory markers and functional status
Initial application — immune checkpoint inhib	itor toxicity in malignancy*	
Applications from any relevant practitioner. Apprepriates (tick boxes where appropriate)	ovals valid for 4 months.	
Trerequisites (tient poxes where appropriate)		
malignancy	for moderate to severe autoimmune toxicity following	immune checkpoint inhibitor treatment for
	icient benefit from use of corticosteroids	
and Tocilizumab is to be administered	at a maximum dose of 8 mg/kg fortnightly	

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	Address:			
Fax Number:		Fax Number:		
Tocilizumab - continued	Tocilizumab - continued			
Renewal — immune checkpoint inhibitor toxicity in malignancy*				
Current approval Number (if known):				
Applications from any relevant practitioner. Approx Prerequisites (tick boxes where appropriate)	als valid for 4 months.			
l .——	mprovement and ongoing treatment is required			
Tocilizumab is to be administered a	at a maximum dose of 8 mg/kg fortnightly			
Note: Indications marked with * are unapproved indications.				