## \*\*Other indications for particular drugs may be included on completion of further specialist lists\*\*

For information on use of unlicensed medicines or medicines used 'off-label' - click here

## The following specialist medicines are approved for prescribing by or on the recommendation of a prescribing rheumatology specialist:

In the event of a broken link please forward details to <u>carol.walkinshaw@nhs.scot</u> Please include the location and full title of the link

MEDICINE	SUMMARY OF RESTRICTED INDICATION	CATEGORY	PROTOCOL
Adalimumab (Yuflyma <sup>®</sup> ) for subcutaneous injection	<ul> <li>1<sup>st</sup> choice: Sero-negative and sero-positive RA (with or without methotrexate) when response to DMARDs inadequate.</li> <li>1<sup>st</sup> choice: Active and progressive psoriatic arthritis.1<sup>st</sup> choice: severe active ankylosing spondylitis when response to DMARDs inadequate.</li> <li>1<sup>st</sup> choice: Severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis but with objective signs of inflammation by elevated CRP and/or MRI evidence of active inflammation despite NSAID therapy, or when there is an intolerance to NSAIDs</li> </ul>	Red	<ul> <li><u>Shared Care Agreement – Biologic Therapies</u> <u>for Rheumatic Disease</u> (NHS Tayside Staffnet intranet link only)</li> <li>Brand name must be stated on prescriptions for adalimumab</li> </ul>
Etanercept (Benepali <sup>®</sup> ) solution for subcutaneous injection	<ul> <li>Alternative TNF-alpha antagonist for sero-negative and sero-positive RA (with or without methotrexate) in patients who have had an inadequate response or intolerance to another TNF-alpha inhibitor.</li> <li>Alternative TNF-alpha inhibitor for severe active ankylosing spondylitis (AS) in patients who have had an inadequate response to, or intolerance to another TNF-alpha inhibitor.</li> <li>First choice for severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or intolerance to another TNF-alpha inhibitor.</li> <li>Alternative TNF-alpha inhibitor.</li> <li>Alternative TNF-alpha inhibitor.</li> </ul>	Red	<ul> <li><u>Shared Care Agreement – Biologic Therapies</u> <u>for Rheumatic Disease</u> (NHS Tayside Staffnet intranet link only)</li> <li>Brand name must be stated on prescriptions for etanercept</li> </ul>

Tocilizumab (RoActemra <sup>®</sup> ) solution for subcutaneous injection (pre-filled syringe and pre-filled pen)	Pre-filled syringe for subcutaneous administration is now preferred to intravenous infusion where possible. RA in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, when response inadequate/intolerance to previous therapy with one or more DMARDs or TNF- alpha antagonists. RA in combination with methotrexate when response to at least one DMARD or TNF-alpha inhibitor has been inadequate. First choice biologic agent for giant cell arteritis (GCA) in patients with newly diagnosed GCA or relapsed disease – treatment subject to 12 month clinical stopping rule.	Red	
Filgotinib (Jyseleca <sup>®</sup> ▼) tablets	2 <sup>nd</sup> choice: Sero-negative moderate or severe RA (with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs and in patients with severe disease inadequately controlled by a TNF-alpha inhibitor or where a TNF-alpha inhibitor is unsuitable. 2 <sup>nd</sup> choice: Sero-positive moderate RA (with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs and in patients who have not responded to intensive therapy with a combination of conventional DMARDs and in patients with severe disease inadequately controlled by a TNF-alpha inhibitor or where a TNF-alpha inhibitor is unsuitable. 3 <sup>rd</sup> choice: Sero-positive severe RA (with methotrexate) in patients with severe disease inadequately controlled by a TNF-alpha inhibitor or where a TNF-alpha inhibitor is unsuitable. 3 <sup>rd</sup> choice: Sero-positive severe RA (with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs or in patients with severe disease inadequately controlled by a TNF-alpha inhibitor is unsuitable.	Amber	<u>Shared Care Agreement – Biologic Therapies</u> <u>for Rheumatic Disease</u> (NHS Tayside Staffnet intranet link only)
Upadacitinib (Rinvoq®▼) prolonged- release tablets	<ul> <li>Alternative JAK inhibitor for sero-negative severe RA (with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs and in patients with severe disease inadequately controlled by a TNF-alpha inhibitor or where a TNF-alpha inhibitor is unsuitable.</li> <li>Alternative JAK inhibitor for sero-positive severe RA (with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs or in patients with severe disease inadequately controlled by a TNF-alpha inhibitor for sero-positive severe RA (with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs or in patients with severe disease inadequately controlled by a TNF-alpha inhibitor or rituximab.</li> </ul>	Amber	<u>Shared Care Agreement – Biologic Therapies</u> <u>for Rheumatic Disease</u> <u>Rheumatology GP letter</u>

	2 nd choice: Active PsA (with or without methotrexate) when response to at least 2 standard DMARDs (individually or in combination) has been inadequate and when TNF-alpha inhibitor therapy has failed or is unsuitable.		
Tocilizumab (RoActemra <sup>®</sup> ) concentrate for intravenous infusion	Pre-filled syringe for subcutaneous administration is now preferred to intravenous infusion where possible. RA in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, when response inadequate/intolerance to previous therapy with one or more DMARDs or TNF- alpha antagonists. RA in combination with methotrexate when response to at least one DMARD or TNF-alpha inhibitor has been inadequate.	Red	<u>Shared Care Agreement – Biologic Therapies</u> <u>for Rheumatic Disease</u> <u>Tocilizumab protocol</u> (NHS Tayside Staffnet intranet links only)
Baricitinib (Olumiant®) tablets	Sero-negative severe RA (with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs or in patients with severe disease inadequately controlled by a TNF antagonist.	Amber	<u>Shared Care Agreement – Biologic Therapies</u> <u>for Rheumatic Disease</u> (NHS Tayside Staffnet intranet link only)
	Sero-positive severe RA (with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs or in patients with severe disease inadequately controlled by a TNF antagonist. Can be given as monotherapy in accordance with above resitrictions in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate.		
Rituximab (Ruxience <sup>®</sup> ▼) concentrate for intravenous infusion	2 <sup>nd</sup> choice: Sero-positive severe RA (with methotrexate) when response to DMARDs (including at least one TNF-alpha inhibitor) inadequate.	Red	<u>Shared Care Agreement – Biologic Therapies</u> <u>for Rheumatic Disease</u> <u>Rituximab protocol</u> (NHS Tayside Staffnet
			<ul><li>intranet links only)</li><li>Brand name must be stated on prescriptions for rituximab</li></ul>
Rituximab (Ruxience <sup>®</sup> ▼) concentrate for intravenous infusion	In combination with glucocorticoids for induction of remission in severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA) in patients who have relapsed following cyclophosphamide or who are intolerant to or	Red	<ul> <li>Brand name must be stated on prescriptions for rituximab</li> </ul>

	unable to receive cyclophosphamide.		
Tofacitinib (Xeljanz®) tablets	Active PsA (with or without methotrexate) when response to at least 2 standard DMARDs (individually or in combination) has been inadequate and when TNF-alpha- inhibitor therapy is contraindicated.	Red	
Secukinumab (Cosentyx <sup>®</sup> ) solution for subcutaneous injection	<ul> <li>2nd choice for severe active AS in patients who have had an inadequate response to conventional therapy (adequate trial of at least 2 NSAIDs).</li> <li>2nd choice for active PsA (with or without methotrexate) when response to at least 2 standard DMARDs (individually or in combination) has been inadequate and when TNF-alpha inhibitor therapy is contraindicated or in patients in whom the 150mg dose of secukinumab is indicated.</li> <li>May also be used in active PsA in patients who have had failure or an inadequate response to TNF-alpha inhibitor therapy as an alternative to tofacitinib.</li> </ul>	Red	<u>Shared Care Agreement – Biologic Therapies</u> <u>for Rheumatic Disease</u> (NHS Tayside Staffnet intranet link only)
Certolizumab pegol (Cimzia <sup>®</sup> ) for subcutaneous injection	RA (with or without methotrexate) when response to DMARDs inadequate. Active and progressive psoriatic arthritis and severe active ankylosing spondylitis when response to DMARDs inadequate. Severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, despite NSAID therapy, or when intolerance to NSAIDs	Red	Shared Care Agreement – Biologic Therapies for Rheumatic Disease (NHS Tayside Staffnet intranet link only)
Golimumab (Simponi <sup>®</sup> ) injection	RA (with methotrexate) when response to DMARDs inadequate. Restricted to use at a dose of 50mg only. Active and progressive psoriatic arthritis and severe active ankylosing spondylitis in patients who have responded inadequately to conventional therapy/when response to DMARDs inadequate. Restricted to use at a dose of 50mg only.	Red	Shared Care Agreement – Biologic Therapies for Rheumatic Disease (NHS Tayside Staffnet intranet link only)
Infliximab (Remsima <sup>®</sup> ) intravenous infusion	RA (with methotrexate) when response to DMARDs inadequate. Active and progressive PsA (alone or in combination with methotrexate) when response to DMARDs inadequate. Severe active AS in those who have had an inadequate	Red	<ul> <li><u>Shared Care Agreement – Biologic Therapies</u> <u>for Rheumatic Disease</u> (NHS Tayside Staffnet intranet link only)</li> <li>Brand name must be stated on prescriptions for infliximab</li> </ul>

	response to, or are intolerant to NSAIDs.		
Sarilumab (Keyzara®) subcutaneous injection (pre-filled syringe, pre-filled pen)	Severe RA (with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs or in patients with severe disease inadequately controlled by a TNF antagonist. Can be given as monotherapy in accordance with above resitrictions in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate.	Red	Shared Care Agreement – Biologic Therapies for Rheumatic Disease (NHS Tayside Staffnet intranet link only)
Abatacept (Orencia <sup>®</sup> ) concentrate for intravenous infusion	RA (with methotrexate) when response to DMARDs (including at least one TNF-alpha inhibitor) inadequate.	Red	Abatacept protocol (NHS Tayside Staffnet intranet link only)
Abatacept (Orencia <sup>®</sup> ) 125mg/mL solution for subcutaneous injection (pre- filled syringe)	Must have DAS 28 score >5.1 confirmed on two occasions, one month apart. Fourth line agent.	Red	<u>Shared Care Agreement – Biologic Therap</u> <u>for Rheumatic Disease</u> (NHS Tayside Staffnet intranet link only)
Guselkumab (Tremfya <sup>®</sup> ▼) injection	Active psoriatic arthritis alone or in combination with methotrexate in patients who have responded inadequately to, or are unsuitable for, treatment with an anti-TNF.	Red	
Ustekinumab (Stelara <sup>®</sup> ) injection	Active psoriatic arthritis alone or in combination with methotrexate in patients who have responded inadequately to, or are unsuitable for, treatment with an anti-TNF.	Red	
Celecoxib capsules 100mg	Alternative to standard NSAIDs under the direction of Rheumatology for patients who cannot tolerate or have had no benefit from standard NSAID treatments	Amber	
Etoricoxib Tablets 60mg, 90mg	Alternative to standard NSAIDs under the direction of Rheumatology for patients who cannot tolerate or have had no benefit from standard NSAID treatments	Amber	
Methotrexate (oral) - 2.5mg tablets ONCE WEEKLY	Rheumatoid arthritis (RA). Commonly used (unlicensed 'off-label') in other rheumatic disorders.	Amber	Methotrexate Shared Care Agreement Rheumatology GP letter - methotrexate Rheumatology GP letter- methotrexate dose change (NHS Tayside Staffnet intranet links

			only)
Methotrexate (subcutaneous) - injection (Metoject <sup>®</sup> ) ONCE WEEKLY	Rheumatoid arthritis (RA), severe psoriatic arthritis (PsA). Commonly used (unlicensed 'off-label') in other rheumatic disorders.	Amber	Methotrexate Shared Care Agreement
Sulphasalazine e/c tablets	RA. Sero-negative spondyloarthropathy including psoriatic arthritis (PsA) (unlicensed use 'off-label').	Amber	Rheumatology GP letter - sulfasalazine (NHS Tayside Staffnet intranet link only)
Azathioprine tablets	RA. Commonly used (unlicensed 'off-label') in other rheumatic disorders.	Amber	Rheumatology GP letter - azathioprine (NHS Tayside Staffnet intranet link only).
Ciclosporin capsules (Capimune®)	RA.	Amber	Rheumatology GP letter - ciclosporin (NHS Tayside Staffnet intranet link only)
Cyclophosphamide injection	Induction therapy for severe systemic vasculitis, (including ANCA associated vasculitis (active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA)), severe RA, systemic lupus erythematosus (SLE).	Red	<u>Cyclophosphamide protocol</u> (NHS Tayside Staffnet intranet link only)
Cyclophosphamide tablets	Induction therapy for severe systemic vasculitis, (including ANCA associated vasculitis (active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA)), severe RA, systemic lupus erythematosus (SLE).	Amber	<u>Cyclophosphamide protocol</u> (NHS Tayside Staffnet intranet link only)
Hydroxychloroquine sulphate tablets	RA, connective tissue diseases.	Amber	Rheumatology GP letter - hydroxychloroquine (NHS Tayside Staffnet intranet link only)
Leflunomide tablets	RA and psoriatic arthritis (PsA).	Amber	Rheumatology GP letter - leflunomide (NHS Tayside Staffnet intranet link only)
Mycophenolate mofetil tablets	RA, SLE and inflammatory myopathy such as dermatomyositis and polymyositis (unlicensed use 'off-label').	Amber	Rheumatology GP letter - mycophenolate (NHS Tayside Staffnet intranet link only)
Penicillamine tablets	RA.	Amber	Rheumatology GP letter - penicillamine (NHS Tayside Staffnet intranet link only)

Hydroxychloroquine sulphate tablets	RA, connective tissue diseases.	Amber	Rheumatology GP letter - hydroxychloroquine (NHS Tayside Staffnet intranet link only)
Febuxostat tablets (Adenuric <sup>®</sup> )	Restricted to patients where allopurinol is inadequate, not tolerated or contraindicated.	Amber	Local protocol on the Management of gout
Sildenafil tablets	To be prescribed only by Vascular or Rheumatology specialists for digital vasculopathy (including Raynaud's phenomenon) [off-label] in accordance with local pathway.	Red	NHS Tayside Raynaud's Management Pathway
Sodium fluoride 0.619% (2800ppm) toothpaste	Prevention of dental caries in patients with Sjögren's syndrome	Amber	

For further information on Tayside Rheumatology Services, including referral guidance and links to local, national and international guidance see the <u>NHS Tayside</u> <u>Rheumatology website</u> (NHS Tayside Staffnet intranet link only).

Traffic light status information			
Red Red	To be prescribed by Hospital Specialists Only.		
Amber Can be prescribed in General Practice under the direction of a Specialist.			

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