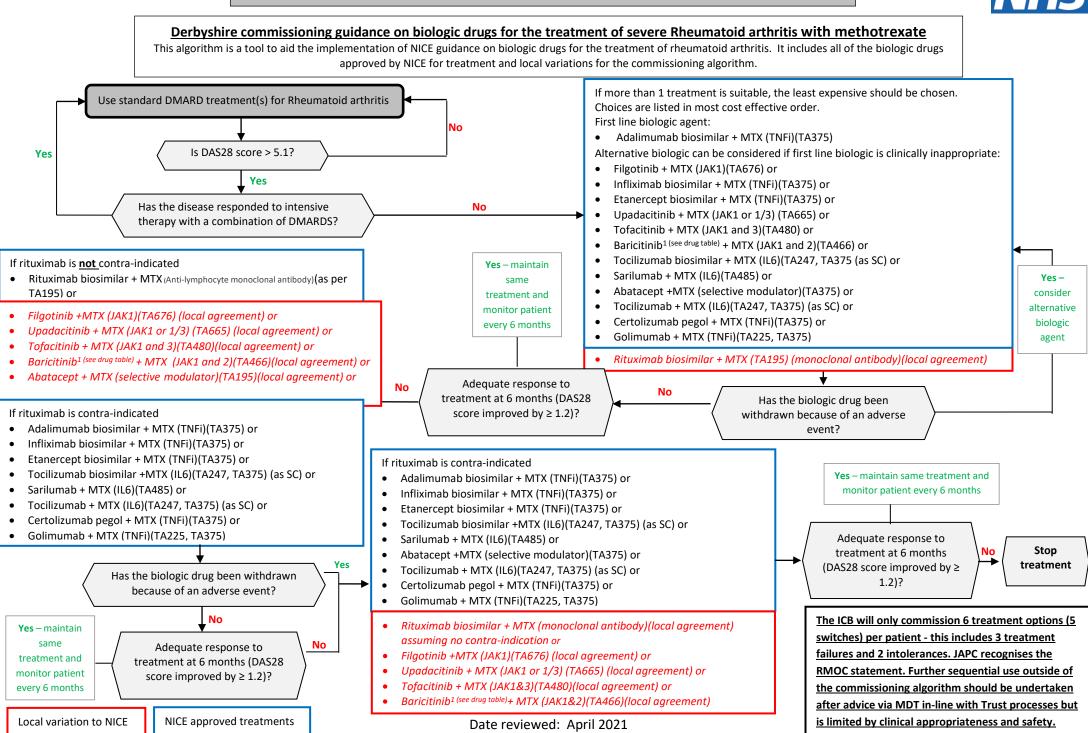
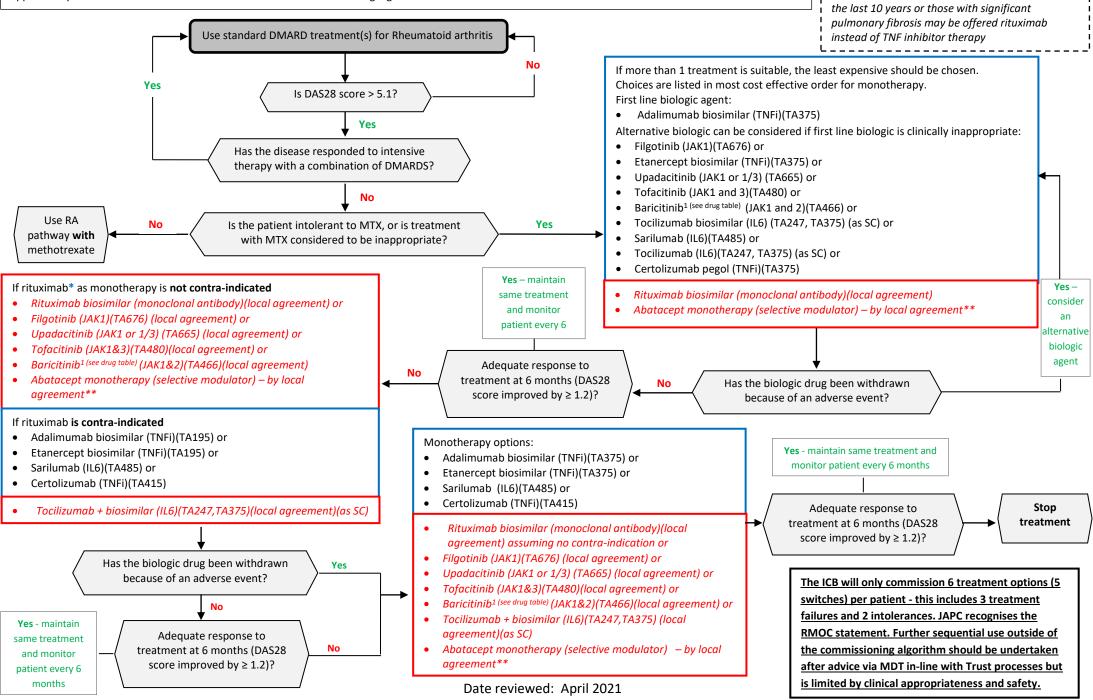
## DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)



## Derbyshire commissioning guidance on biologic drugs for the treatment of severe Rheumatoid arthritis without methotrexate

This algorithm is a tool to aid the implementation of NICE guidance on biologic drugs for the treatment of rheumatoid arthritis. It includes all of the biologic drugs approved by NICE for treatment and local variations for the commissioning algorithm.



Patients who have had a proven malignancy in



Drug Intravenous the	rapies	NICE TA	TA details	Route	Dose
Abatacept (+MTX)	Selective T-cell stimulation modulator	NICE TA195 NICE TA375	Disease has not responded to conventional DMARDS – 1 <sup>st</sup> line <b>and</b> May also be used if disease has not responded to a previous TNF inhibitor.	SC or IV	SC – 125mg once weekly IV for pts: <60kg – 500mg dose 60-100kg - 750mg dose >100kg - 1000mg dose Given initially at week 0, 2, and 4 and then every 4 weeks thereafter.
**Abatacept monotherapy	abatacept mor	notherapy for p	atients with RA and interstitial lung disease – outside o	of NICE g	uidance – by local agreement
Adalimumab (±MTX)	Monoclonal antibody that specifically binds to TNF	NICE TA195 NICE TA375	Disease has not responded to conventional DMARDS - 1 <sup>st</sup> line <b>and</b> Inadequate response/ intolerance to TNF inhibitor and CI/intolerance to rituximab therapy	SC	40mg every other week For monotherapy – dose may increase to 40mg per week, if patient experiences a decrease in response.
Certolizumab (±MTX)	Recombinant humanised antibody Fab' fragment against TNF alpha	NICE TA415 NICE TA375	Disease has not responded to conventional DMARDS - 1 <sup>st</sup> line <b>and</b> Inadequate response/ intolerance to TNF inhibitor and CI/intolerance to rituximab therapy	SC	Initially 400mg given at Week 0, 2 and 4 and then 200mg every 2 weeks thereafter Or 400mg every 4 weeks, once clinical response confirmed.
Etanercept Biosimilar (±MTX)	Recombinant human TNF receptor fusion protein.	NICE TA195 NICE TA375	Disease has not responded to conventional DMARDS - 1 <sup>st</sup> line <b>and</b> Inadequate response/ intolerance to TNF inhibitor and CI/intolerance to rituximab therapy	SC	50mg every week Or 25mg twice weekly
Golimumab (+MTX)	Monoclonal antibody that prevents the binding of TNF to its receptors.	NICE TA225 NICE TA375	Disease has not responded to conventional DMARDS - 1 <sup>st</sup> line <b>and</b> May also be used if disease has not responded to a previous TNF inhibitor.	SC	For pts < 100kg - 50mg every month For pts >100kg - 100mg every month, if inadequate clinical response after 3-4 doses.)
Infliximab	Chimeric monoclonal	NICE TA195	Disease has not responded to conventional	IV	3mg/kg IV dose, given at week 0, 2, 6 and then every 8 weeks



biosimilar (±MTX)	antibody, with high affinity to TNF.	NICE TA375	DMARDS - 1 <sup>st</sup> line and Inadequate response/ intolerance to TNF inhibitor and CI/intolerance to rituximab therapy		thereafter. If there is an inadequate response or loss of response after 12 weeks of treatment, consider increasing dose step-wise by approximately 1.5mg/kg up to a maximum of 7.5mg/kg every 8 weeks or 3mg/kg every 4 weeks
Rituximab Biosimilar (+MTX)	Chimeric monoclonal antibody – depletes B- cell population.	NICE TA195	If pt has had an inadequate response or intolerant of DMARDS and at least one TNF inhibitor.	IV	2x 1000mg given 2 weeks apart, repeated no less than 16 weeks.
Sarilumab (±MTX)	Human monoclonal antibody selective for the IL-6 receptor	NICE TA485	Active RA for pts who have had an inadequate response to DMARDs and/or 1 biological DMARD , only if they cannot have rituximab <b>and</b> Disease responded inadequately to rituximab and at least 1 biological DMARD	SC	200mg once every 2 weeks. Reduce the dose to 150mg once every 2 weeks for patients with neutropenia, thrombocytopenia and increased LFTS.
Tocilizumab Biosimilar (±MTX)	Monoclonal antibody – inhibits interleukin-6 (IL-6) receptor	NICE TA375 NICE TA247	Disease has not responded to conventional DMARDS - 1 <sup>st</sup> line <b>and</b> May also be used if disease has not responded to a previous TNF inhibitor and the pt cannot receive rituximab because of CI or adverse event to rituximab	SC or IV	<ul> <li>SC - 162mg once weekly (as per SPC) or</li> <li>IV - 8mg/kg every 4 weeks</li> <li>For patients &gt;100kg, doses exceeding 800mg are not recommended</li> </ul>
Oral therapies Baricitinib (±MTX)	Selective JAK1 and JAK2 inhibitor	NICE TA466	Active RA for pts who have had an inadequate response to DMARDs and/or 1 biological DMARD (only if they cannot have rituximab)	PO	<ul> <li>4mg once daily.</li> <li>2mg once daily is appropriate for pts ≥75 years and over</li> <li><sup>1</sup>MHRA Drug Safety Update August 2020 - Use baricitinib with caution in patients with diverticular disease and in those concomitantly treated with medications associated with an increased risk of diverticulitis</li> </ul>
Filgotinib (±MTX)	Selective JAK1 inhibitor	NICE TA676	Active RA for pts who have had an inadequate response to DMARDs and/or 1 biological DMARD (only if they cannot have rituximab)	PO	200mg once daily for adult 18-74 yrs 100mg once daily increasing to 200mg daily if necessary for adult 75 years and over



Tofacitinib (±MTX)	Inhibitor of JAK1 and JAK3.	NICE TA480	Active RA for pts who have had an inadequate response to DMARDs and/or 1 biological DMARD (if they cannot have rituximab)	PO	5mg taken twice daily
			<u>MHRA Oct 2021</u> - Tofacitinib should not be used in patients older than 65 years of age, people who are current or past smokers, or individuals with other cardiovascular (such as diabetes or coronary artery disease) or malignancy risk factors unless there are no suitable treatment alternatives		
Upadacitinib	selective and reversible inhibitor of the Janus-associated tyrosine kinase JAK1 or JAK 1/3	NICE TA665	For treating severe rheumatoid arthritis	PO	15mg taken once daily