

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Derbyshire commissioning guidance for the treatment of radiographic ankylosing spondylitis and non-radiographic axial spondyloarthritis (nrAS)

Does the patient have radiographic ankylosing spondylitis or non-radiographic axial spondyloarthritis?

Non-radiographic axSPA

Offer physical therapy

Non-steroidal anti-inflammatory drugs

Is there confirmation of sustained active spinal disease, demonstrated by:

- score of ≥ 4 units on BASDAI **and**
- ≥ 4 cm on 0-10 cm spinal pain VAS

Radiographic axSPA

Non-pharmacological interventions (exercise and physiotherapy)

Inadequate response or intolerance to NSAIDs

Is there confirmation of sustained active spinal disease, demonstrated by:

- score of ≥ 4 units on BASDAI **and**
- ≥ 4 cm on 0-10 cm spinal pain VAS

If more than 1 treatment is suitable, the least expensive should be chosen. Choices are listed in most cost effective order by category.

First line TNFi biologic agent:

- **Adalimumab biosimilar** (TNFi) (TA383)

An alternative TNFi biologic can be considered if first line biologic is clinically inappropriate:

- Etanercept biosimilar (TNFi) (TA383) or
- Certolizumab (TNFi) (TA383) or
- Golimumab (TNFi) (TA497 + TA383)

Biologics are only recommended if TNFi are not suitable for treatment with or whose condition is not controlled well enough:

- Secukinumab (IL17A) (TA719) or
- Ixekizumab (IL17A) (TA718)
- Upadacitinib (JAK1) (TA861)

If more than 1 treatment is suitable, the least expensive should be chosen. Choices are listed in most cost effective order by category.

First line biologic agent:

- **Adalimumab biosimilar** (TNFi) (TA383)

Alternative biologic can be considered if first line biologic is clinically inappropriate:

- Etanercept biosimilar (TNFi) (TA383) or
- Infliximab biosimilar (TNFi) (TA383) or
- Certolizumab (TNFi) (TA383) or
- Golimumab (TNFi) (TA497 + TA383)

Biologics are only recommended if TNFi are not suitable for treatment with or whose condition is not controlled well enough:

- Secukinumab (IL17A) (TA407) or
- Ixekizumab (IL17A) (TA718) or
- Upadacitinib (JAK1) (TA829)

Yes – maintain treatment and monitor patient at appropriate intervals

Is the patient assessed to have an adequate response to the **TNF inhibitor**, defined as:

- Reduction of BASDAI to 50% of the pre-treatment value or by $>$ two units **and**
- Reduction of spinal pain VAS by $>$ 2 cm?

See dosing table for when to measure the response to each TNF inhibitor

Yes – maintain treatment and monitor patient at appropriate intervals

No

Switching treatment to a biologic with a different mechanism of action is recommended for people who cannot tolerate, or whose disease has not responded to treatment, or whose disease has stopped responding after an initial response.

Consider an alternative biologic agent

The CCG's will only commission 4 treatment options (3 switches) per patient - this includes 2 treatment failures and 1 intolerance. JAPC recognises the RMOC statement. Further sequential use outside of the commissioning algorithm should be undertaken after advice via MDT in-line with Trust processes but is limited by clinical appropriateness and safety

Dosing schedule

Biologic		Radiographic ankylosing spondylitis (AS)			Non radiographic axial spondyloarthritis (nrAS)			Response measured
		NICE TA	Loading dose	Maintenance dose	NICE TA	Loading dose	Maintenance dose	
Subcutaneous preparations								
Adalimumab (SC)	Monoclonal antibodies	TA383	40mg every 2 weeks	NA	TA383	40mg every 2 weeks	NA	12 Weeks
Etanercept (SC)	Recombinant human TNF receptor fusion protein	TA383	50mg once weekly Or 25mg twice weekly	NA	TA383	50mg once weekly	NA	12 weeks
Certolizumab (SC)	Monoclonal antibody	TA383	400mg (2x 200mg) given at Week 0, 2 & 4	200mg every 2 weeks or 400mg every 4 weeks	TA383	400mg (2x 200mg) given at Week 0, 2 & 4	200mg every 2 weeks or 400mg every 4 weeks	12 weeks
Golimumab (SC)	Monoclonal antibody	TA475	50mg every month >100kg in body weight, (& disease does not respond after 4x50mg doses), increase dose to 100mg every month	NA	TA497	50mg every month >100kg in body weight, (& disease does not respond after 4x50mg doses), increase dose to 100mg every month	NA	12-14 weeks
Secukinumab (SC)	Human monoclonal antibody selective for IL-17A	TA407	Week 0,1,2 & 3 – 150mg	Week 4 – 150mg & then continue every month	TA719	Week 0,1,2 & 3 – 150mg	Week 4 – 150mg & then continue every month	16 weeks
Ixekizumab (SC)	Human monoclonal antibody selective for IL-17A	TA718	160mg (2x 80mg) given at Week 0	80mg every 4 weeks	TA718	160mg (2x 80mg) given at Week 0	80mg every 4 weeks	16-20 weeks
Intravenous infusion								
Infliximab (IV)	Monoclonal antibodies	TA383	5mg/kg IV at week 0, 2 & 6	5mg/kg IV every 6-8 weeks thereafter	--	--	--	6 weeks
Oral therapies								
Upadacitinib (PO)	Selective and reversible inhibitor of the Janus-associated tyrosine kinase JAK1	TA829	15mg taken once daily	NA	TA861	15mg taken once daily	NA	16 weeks Some patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks.