South West London
Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis Drug Pathway
Version 6.0

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Approved by: SWL Integrated Medicines Optimisation Committee
Date: 18th Oct 2023

SWL Drug Pathway – Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis: High-Cost Drug Pathway

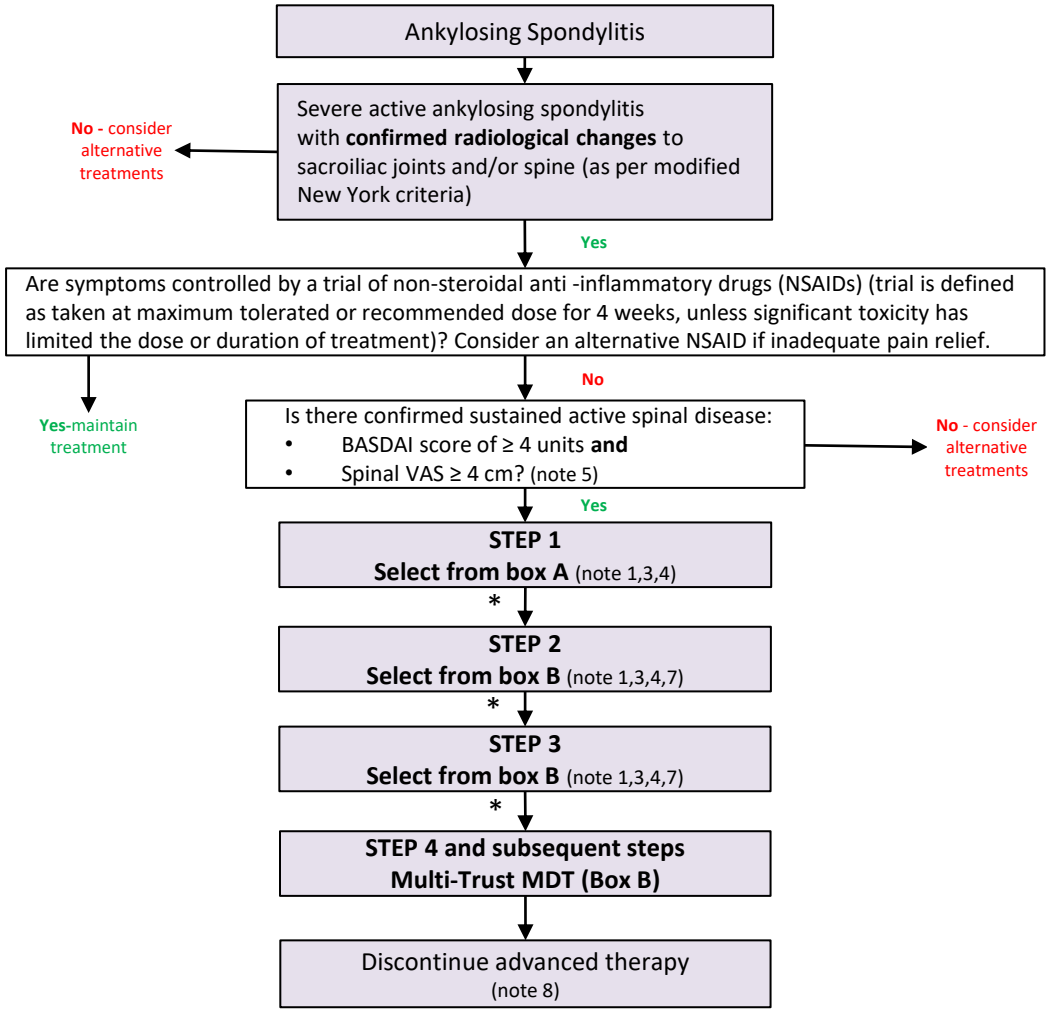
Version 6.0 – (based on NICE NG65 with local adaptation)

Box A: Ankylosing spondylitis
For 1st treatment only (note 1,2,7)
1st choice: Adalimumab biosimilar (especially if IBD or uveitis) (TA383)
2nd choice: Etanercept biosimilar (TA383) **or** Infliximab IV/SC biosimilar (TA383)
3rd choice: Certolizumab (TA383)
4th choice: Golimumab (if >100kg) (note 6) (TA383)

If TNF-alpha inhibitor contraindicated or not suitable:
1st choice: Upadacitinib (TA829) **or** Secukinumab (TA407)
2nd choice: Tofacitinib (TA920)
3rd choice: Bimekizumab (TA918)
4th choice: Ixekizumab (TA718)

Box B: Ankylosing spondylitis
For subsequent treatment (note 1,2,7)
1st choice: Adalimumab biosimilar (especially if IBD or uveitis) (TA383)
2nd choice: Etanercept biosimilar (TA383) **or** Infliximab IV/SC biosimilar (TA383) **or** Upadacitinib (TA829) **or** Secukinumab (TA407)
3rd choice: Tofacitinib (TA920)
4th choice: Bimekizumab (TA918)
5th choice: Certolizumab (TA383) **or** Ixekizumab (TA718)
6th choice: Golimumab (if >100kg) (note 6) (TA383)

Refer to the relevant technology appraisal for each drug for further information about their eligibility and prescription.



***AFTER EACH STEP**
Is there an adequate response to treatment defined as:
- Reduction in BASDAI to 50% of the pre-treatment value **or** by ≥ 2 units **and**
- Reduction of spinal pain VAS by ≥ 2cm?

Response to be first measured at 12 (TNF-alpha inhibitor) or 16 (IL-17 inhibitors, upadacitinib) weeks (note 5,6)
Yes - maintain same treatment and monitor at 12 week intervals (note 3)
No- move to next step (note 4)

SWL Drug Pathway – Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis: High-Cost Drug Pathway

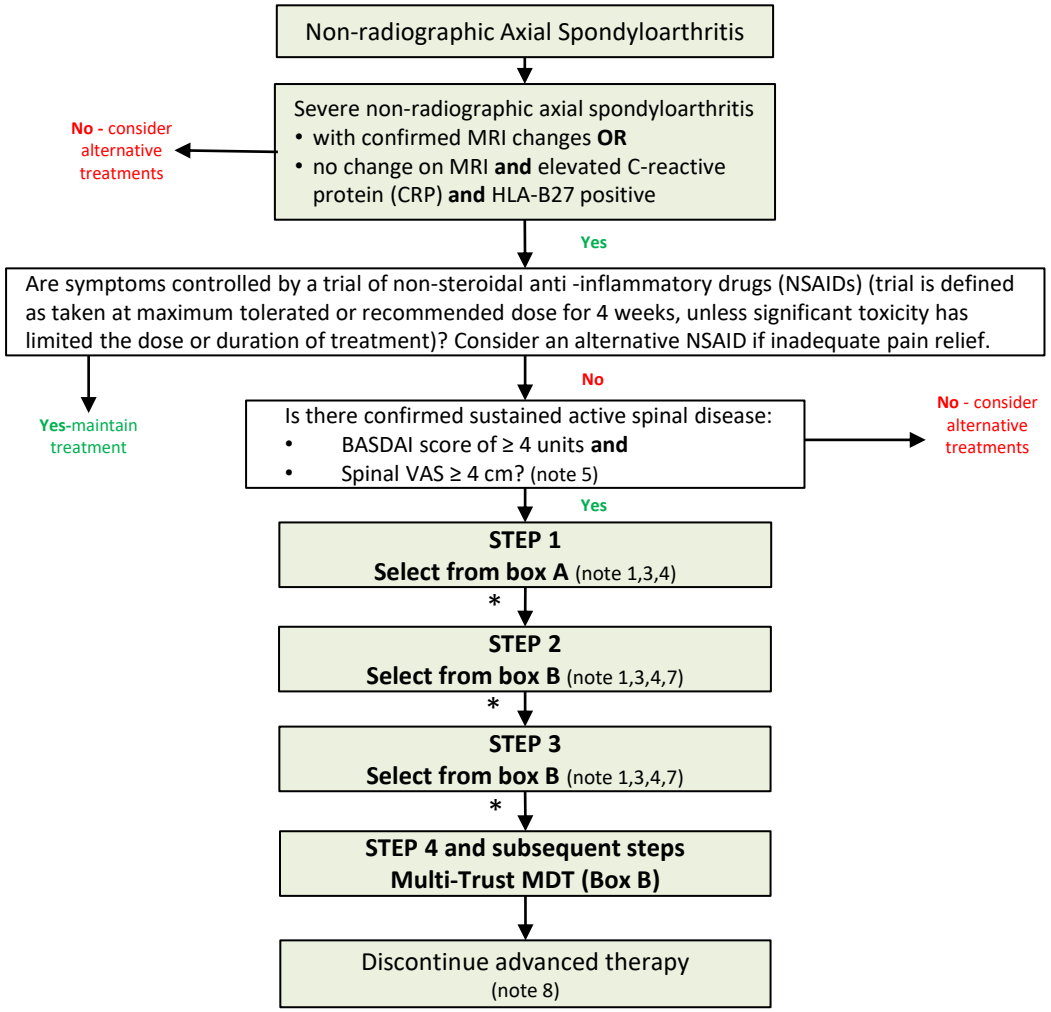
Version 6.0 – (based on NICE NG65 with local adaptation)

Box A: Nr-axial spondyloarthritis
For 1st treatment only (note 1,2,7)
1st choice: Adalimumab biosimilar (especially if IBD or uveitis) (TA383)
2nd choice: Etanercept biosimilar (TA383) **or**
3rd choice: Certolizumab (TA383)
4th choice: Golimumab (if >100kg) (note 6) (TA383)

If TNF-alpha inhibitor contra-indicated or not suitable:
1st choice: Upadacitinib (TA861) **or** Secukinumab (TA719)
2nd choice: Bimekizumab (TA918)
3rd choice: Ixekizumab (TA718)

Box B: Nr-axial spondyloarthritis
For subsequent treatment (note 1,2,7)
1st choice: Adalimumab biosimilar (especially if IBD or uveitis) (TA383)
2nd choice: Etanercept biosimilar (TA383) **or** Upadacitinib (TA861) **or** Secukinumab (TA719)
3rd choice: Bimekizumab (TA918)
4th choice: Certolizumab (TA383) **or** Ixekizumab (TA718)
5th choice: Golimumab (if >100kg) (note 6) (TA383)

Refer to the relevant technology appraisal for each drug for further information about their eligibility and prescription.



***AFTER EACH STEP**
Is there an adequate response to treatment defined as:
- Reduction in BASDAI to 50% of the pre-treatment value **or** by ≥ 2 units **and**
- Reduction of spinal pain VAS by ≥ 2cm?

Response to be first measured at 12 (TNF-alpha inhibitor) or 16 (IL-17 inhibitors, upadacitinib) weeks (note 5,6)
Yes - maintain same treatment and monitor at 12 week intervals (note 3)
No- move to next step (note 4)

SWL Drug Pathway – Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis: Notes

Version 6.0 (based on NICE NG65 with local adaptation)

Note 1 – Moving Steps: Choose **ONE** option per step before moving onto the next step due to primary or secondary treatment failure. If more than one NICE approved treatment is available, NICE recommends discussion between responsible clinician and patient about advantages and disadvantages of each treatment (considering therapeutic need and likely adherence). This may include considering associated conditions such as extra articular manifestations. If more than one treatment is suitable, the least expensive will be chosen (taking into account administration costs, dosage and price per dose) unless an order of preference is stated in the TAs. The SWL drug choices in this algorithm are based on cost (including relevant administration costs, list price or national (NICE) / local (LPP) agreed contract price).

Note 2 – Commercial agreement: Bimekizumab, certolizumab, golimumab, ixekizumab, secukinumab tofacitinib and upadacitinib are recommended only if provided according to commercial agreement (i.e. certolizumab: 1st 12 weeks (10 x 200mg) free of charge; golimumab: 100mg dose at the same cost as 50mg dose).

Note 3 – Adverse event or new contra-indication: Consider alternative from same step (in step 1, 2 and 3 only) if treatment had to be stopped due to adverse event or new contra-indication **AND**:

- patient was responding to the drug **OR**
- response was not yet assessed i.e. within 12 (TNF-alpha inhibitor) or 16 (bimekizumab, ixekizumab, secukinumab, tofacitinib, upadacitinib) weeks of initiating treatment.

Note 4 – Primary / secondary treatment failure with TNF-alpha inhibitor: An alternative TNF-alpha inhibitor may be chosen from the same step (in step 1 and 2 only), if considered clinically appropriate. Restricted to ONE switch within the TNF-alpha inhibitor class only (does not apply to other drug classes).

Note 5 – BASDAI and spinal pain VAS score assessment: Healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the questionnaires and make any adjustments they consider appropriate.

Note 6 – Dose adjustment:
Golimumab: Consider increasing to 100mg/month if weight >100kg and inadequate clinical response after 3 or 4 x 50mg doses; consider increased risk of serious adverse drug reactions. Continued therapy should be reconsidered if no therapeutic benefit after 3 to 4 additional doses of 100mg.

Note 7 – Pregnancy: If, following careful consideration of expected benefits/risks of options, drug therapy is changed due to (planning) pregnancy, consider switch back to previous most cost-effective therapy post-partum (and move back to the previous step).

Note 8 – IFR: Requests for treatment outside this commissioned pathway can be made via the Individual Funding Request (IFR) process (swlimo.southwestlondon.icb.nhs.uk for IFR policy and application form).

SWL Drug Pathway – Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis: Non-Pharmacological Management

Version 6.0 (based on NG65[1])

Physiotherapy

Refer people with axial spondyloarthritis to a specialist physiotherapist to start an individualised, structured exercise programme, which should include:

- stretching, strengthening and postural exercises
- deep breathing
- spinal extension
- range of motion exercises for the lumbar, thoracic and cervical sections of the spine
- aerobic exercise

Hydrotherapy

Consider as an adjunctive therapy for people with axial spondyloarthritis:

- to manage pain
- maintain or improve function

Specialist therapy

Consider a referral to a specialist therapist (such as a physiotherapist, occupational therapist, hand therapist, orthotist or podiatrist) for people with spondyloarthritis who have difficulties with any of their everyday activities. The specialist therapist should:

- assess people's needs
- provide advice about physical aids
- arrange periodic reviews to assess people's changing needs

SWL Drug Pathway – Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis: Drug Information for Advanced Therapies

Version 6.0 (this list is not exhaustive; see summary of product characteristics (SPC) for full information)

Drug Class	Drug Name	Administration	Contra-indications	Special warnings and precautions	
Tumour necrosis factor (TNF) alpha inhibitors	Adalimumab biosimilar	SC – alternate weeks	• Hypersensitivity to active substance or excipients • Active, severe infections (e.g. TB, sepsis, abscesses) and opportunistic infections • Moderate to severe heart failure (NYHA class III/IV)	• >65 years of age • Autoimmune processes (Lupus) • More susceptible to serious infections (e.g. TB) • Viral reactivation (e.g. hepatitis B) • Malignancy and lymphoproliferative disorder • Congestive heart failure Neurological events	• Immunosuppression • Haematologic reactions • Infusion-related reactions (infliximab) • COPD (certolizumab) • Latex sensitivity (adalimumab, certolizumab, golimumab) • Diabetes (etanercept)
	Certolizumab pegol	SC – alternate weeks or 4 weekly			
	Etanercept	SC – weekly			
	Golimumab	SC – monthly			
	Infliximab biosimilar	SC – 2 weekly IV – 8 weekly			
Interleukin inhibitor (IL) 17	Ixekizumab	SC – 4 weekly	• Hypersensitivity to the active substance or excipients • Active, severe infections (e.g. TB)	• More susceptible to serious infections (e.g. TB) • Hypersensitivity • Inflammatory bowel disease	• Latex sensitivity (secukinumab 150mg PFS and PFP only) • Contraception
	Secukinumab 150mg	SC – week 0, 1, 2, 3 and 4, then monthly			
	Bimekizumab	SC – 4 weekly			

Janus Kinase (JAK) inhibitors	Upadacitinib	PO – once daily	• Hypersensitivity to the active substance or excipients
			• Age 65 years or older
			• Current or past long-time smoking
			• Known risk factors for cardiovascular disease or malignancy
			• Active, severe infections (e.g. TB, sepsis, abscesses) and opportunistic infections
			• Severe hepatic impairment
			• Pregnancy
				• Major adverse cardiovascular event
				• More susceptible to serious infections (e.g. TB)
				• Viral reactivation (e.g. hepatitis B)
				• Malignancy and lymphoproliferative disorder
				• Interstitial lung disease
				• GI perforation
				• Liver enzyme elevation
				• Derangement of neutrophils, haemoglobin, lipids, glycaemic control
					MHRA update (26/4/23):
					• **Do not use** in patients with the following risk factors unless there is no suitable alternative:
					  • age 65 years or older
					  • current or past long-time smokers
					  • other risk factors for cardiovascular disease or malignancy
					• **Use with caution** in patients with risk factors for VTE other than those listed above
					• Where no suitable alternative, use lower doses
					• Carry out periodic skin examinations to check for signs of skin malignancy

	Tofacitinib	PO – twice daily			

SWL Drug Pathway – Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis: References

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2. NICE TA383: TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis. 1 February 2016
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4. NICE TA829: Upadacitinib for treating active ankylosing spondylitis. 30 Sept 2022
5. NICE TA718: Ixekizumab for treating axial spondyloarthritis. 21 July 2021
6. NICE TA497: Golimumab for treating non-radiographic axial spondyloarthritis. 10 Jan 2018
7. NICE TA719: Secukinumab for treating non-radiographic axial spondyloarthritis. 21 July 2021
8. NICE TA861: Upadacitinib for treating active non-radiographic axial spondyloarthritis. 1 Feb 2023
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16. Rinvoq® (upadacitinib) Summary of Product Characteristics (SPC) https://www.medicines.org.uk/emc/product/10972/ Accessed 17/01/23; last updated 30/08/22
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19. NICE TA920: Tofacitinib for treating active ankylosing spondylitis. 18 Oct 2023
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SWL Drug Pathway – Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis: Version Control

Version 6.0

Version number	Previous version label	Main amendments	Date of approval
0		NICE TA383	Feb 2016
1.0	final v1- 21/07/16	Include approved recommendations from South West London Rheumatology network meeting (9th March 2016): • Include preferred drug choices and clinical criteria that may influence choice • Update notes and add note 5	21st Jul 2016
2.0	final v2- 24/11/16	Interim amendment: • Update diagnostic criteria and degree of severity in line with BSR guidelines and expert consultation • Add secukinumab (NICE TA407) to step 1 and 2 (1st choice option - local agreement)	24th Nov 2016
3.0	final v3- 10/05/17	Include approved recommendations from South West London Rheumatology network meeting (10th May 2017): • Update title, pathway presentation and notes • Update preferred drug choices	01st Aug 2017
4.0	final v1- 04/10/17	Include approved recommendations from South West London Rheumatology network meeting (4th October 2017): • Update title • Add golimumab (NICE TA497) to nr-axial spondyloarthritis step 1 (3rd choice - local agreement)	07th Feb 2018
5.0		Include recommendation from virtual South West London Rheumatology network (7th January 2019): • Update preferred drug choices in step 1 and 2	11th Mar 2019
6.0		• Add ixekizumab (TA718) and upatacitiib (TA829), bimekizumab (TA918), tofacitinib (TA920) to ankylosing spondyloarthritis pathway • Add ixekizumab (TA718), upadacitinib (TA861), secukinumab (TA719), bimekizumab (TA918) to non-radiographic axial spondyloarthritis pathway • Update preferred drug choices • Introduce multi-trust MDT step for 3rd line treatment • Add non-pharmacological management • Add drug information for advanced therapies and MHRA update for JAK inhibitors (26/4/23)	18th Oct 2023
Date of next review: Oct 2026 (or earlier if indicated)			