NHS Greater Glasgow and Clyde

CLINICAL GUIDELINE

Axial Spondyloarthritis (SpA) Biologic Guideline

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Approval Group:	Medicines Utilisation Subcommittee of ADTC

Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Greater Glasgow and Clyde (GGC) Biologics Guideline: Axial Spondyloarthritis (SpA)

1. Eligibility

The British Society for Rheumatology (BSR) has established eligibility criteria for the use of biologic medicines in SpA. This is the standard used in GGC and is accessible via: https://academic.oup.com/view-large/figure/371023401/keac295f1.tif

2. Choice of therapy

Three mechanisms of action are available as outlined in table 1.

	TNF blockade	IL-17A Blockade	JAK inhibitor
Most cost effective agent	Amgevita - Adalimumab*	Secukinumab	Tofacitinib
Alternatives	Etanercept*		
	Infliximab IV*		
	Golimumab		
	Certolizumab		
	Infliximab s/c*		

- *Biosimilar agents are licensed for these originator products. Infliximab is 'off label'.
- **TNF Blockade is the preferred initiation therapy unless clinical contraindications are present**
- Where no clinical requirement for a specific TNF blocker exists, the most cost-effective subcutaneous agent (originator or biosimilar) should be used.
- Medicine costs, inclusive of impact of any patient access schemes or discounts, are made available to the service in strict confidence to assist in identifying preferred treatment options

3. BSR : Assessing Response

i. Initial efficacy response should be assessed following 3–6 months of therapy and responders should then be reassessed every 6 months

ii. Response is defined as a reduction in the BASDAI and spinal pain VAS of ⩾2 U from baseline

iii. If, because of cognitive or communication difficulties, the BASDAI cannot be used to monitor disease activity, the decision to initiate and continue therapy should be based on the treating clinician's assessment of disease activity

4. BSR : Withdrawal of Therapy

i. In the absence of an initial clinical response by 6 months, or failure to maintain response at two consecutive assessments, withdrawal should be considered

ii. There is no evidence to support the withdrawal (of anti-TNF therapy) in treatment responders

5. Off-label dosing and drug monitoring

A decision to prescribe a biologic drug for an approved condition but using doses that are lower than licenced doses or frequency (e.g. tapering), is a decision for the rheumatologist and patient, but may be implemented by other members of the MDT.

i. Increasing the interval of dosing or dose reduction at same frequency could be considered when:

1. Patients have maintained remission/LDA for a sustained period
2. Infection concerns have developed
3. Tolerability/patient request

ii. Use of biologic drug level monitoring (for infliximab and adalimumab) could be considered when adjusting dose, or where secondary failure has occurred to inform choice of subsequent therapy. Advice can be found at https://www.nhsggc.org.uk/about-us/professional-support-sites/laboratory-medicine/laboratory-disciplines/biochemistry/biological-therapy-monitoring/

iii. All bDMARDS and tsDMARDS are not included in near patient testing arrangements. Responsibility for any blood monitoring remains with the prescriber.