Systemic Biological Therapy for Rheumatoid Arthritis

(To be used in conjunction with the relevant NICE TA)

Methotrexate: Switch to S.C. if oral not tolerated/ lack of efficacy before initiation of biologics

DAS28 >5.1 *and* disease has not responded to intensive therapy with a combination of conventional DMARDs, including methotrexate
[Do not meet NICE criteria: do not initiate bDMARD, monitor and consider alternatives]

Yes

1

Choose from **Biosimilar** agents:
Etanercept (Benepali) or **Adalimumab (Amgevita)**

Adequate response at 3-6 months?
(DAS28 reduction ≥ 1.2)

Yes → **Maintain treatment and re-assess every 3-6 months**

No

2

Choose alternate from **INFLIXIMAB biosimilar (Remsima)** or **TNFi** or **ABATACEPT** or **JAK inhibitor** or **RITUXIMAB (Truxima)** or **SARILUMAB*** or **TOCILIZUMAB*** **(*only for those patients who are intolerant to RTX)**

Secondary non-response or intolerance

Adequate response at 3-6 months?
(DAS28 reduction ≥ 1.2)

Yes → **Maintain treatment and re-assess every 3-6 months**

No

3

Alternative INFb/TNFi/RTX/ABT/TCZ/JAK/SAR

Secondary non-response or intolerance

Adequate response at 3-6 months?
(DAS28 reduction ≥ 1.2)

Yes → **Maintain treatment and re-assess every 3-6 months**

No

4

Alternative INFb/TNFi/RTX/ABT/TCZ/JAK/SAR

Secondary non-response or intolerance

Adequate response at 3-6 months?
(DAS28 reduction ≥ 1.2)

Yes → **Maintain treatment and re-assess every 3-6 months**

No

If DAS28 score has not improved by 1.2 stop bDMARD
(Requests for further bDMARD are subject to IFR process)

Secondary non-response or intolerance

Review Patients at 3/12 or 6/12 as per relevant NICE TAGS for disease severity improvement and quality of life improvement as per EULAR criteria

Choice of Biologic then dependent upon:

- Cost effectiveness: where the option of a biosimilar agent is available, the most cost-effective product should be utilised when that particular bDMARD option is clinically indicated
- Proven efficacy and safety profile in long term use
- Patient co-morbidities
- Ease vs complexity of monitoring and administration
- Dosing schedule as per patient needs, patient device preference

Consider:

- Disease characteristics
- Serological status, acute phase
- Concomitant IMD
- Concomitant MTX (if not CI/tolerated)
- Concomitant medication
- Absolute / relative contra-indications
- IgG level

Key:

- bDMARD = biologic disease modifying anti-rheumatic drug
- INFb = Biosimilar Infliximab (Remsima)
- ABT = Abatacept
- MTX = Methotrexate
- RTX = Rituximab
- TCZ = Tocilizumab
- SAR = Sarilumab
- TNFi = Tumour Necrosis Factor inhibitor (Infliximab, Etanercept, Adalimumab, Certolizumab, Golimumab)
- JAK inhibitor = baricitinib, tofacitinib

- The above pathway is applicable to newly diagnosed patients and those whose disease is not responding to current therapy.
- Patients should not be initiated on a biologic agent unless prior treatment with standard disease modifying anti-rheumatic drugs at optimum dose has been trialled and patient has failed to respond or not tolerated.
- Clinicians are able to choose the most appropriate treatment for each patient's disease characteristics, within the confines of the pathway.
- The pathway reflects current NICE guidance for the treatment of RA (see below), and recognises several sub-cohorts of patients where evidence suggests an alternative therapy may be more appropriate.
- The CCG will currently only support 4 lines of funding in line with the above pathway. Evidence for sequential use beyond this has not demonstrated cost-effectiveness.
- For exceptional *INDIVIDUAL* patients, an IFR submission will be considered.
- Further cohorts of patients will not be considered through the IFR panel.

Prepared by Emily Hardaker. Senior Pharmacist Approved by Rheumatology on February 2018. Review: March 2021