Pathway for use of biologic monotherapy for Rheumatoid Arthritis. February 2020

Trial of conventional DMARD; escalate dose as tolerated. If treatment target has not been achieved despite dose escalation, offer additional cDMARD with at least 2 months at standard dose, unless significant toxicity limits dose or duration; to include methotrexate (NICE NG100).

Yes

Severe disease with a DAS28 score > 5.1

No → Does not qualify for a biologic

Yes

Is the patient unable to take methotrexate?

No → Follow biologic with methotrexate pathway

Yes

Have pre-treatment clinical checks been completed

Key to terms:

DAS28: Disease Activity Score
DMARD: Disease-Modifying anti-rheumatic drug
TA: NICE Technology appraisal
TNFi: Tumour Necrosis Factor inhibitor
EULAR - European League Against Rheumatism
Etanercept- includes etanercept biosimilar
JAKi - Janus kinase
IL-6i - interleukin-6

Does patient have significant ILD/pulmonary fibrosis, multiple sclerosis, SLE or proven malignancy in the past 10 years such that TNFi is not considered clinically appropriate?

No

BOX 1. First line biologic monotherapy without MTX TA 375, 466, 480 or 485:

Adalimumab biosimilar is the best value biologic in line with NHSE guidance and 1st line preferred biologic.

1. TNFi: Adalimumab biosimilar, Etanercept biosimilar, Certolizumab (may be considered before/during pregnancy)
2. JAKi: Tofacitinib, Baricitinib
3. 1L-6i: ^^Sarilumab, *Tocilizumab

Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). For each target pathway, drugs are listed in order of maintenance dose price left to right.

BOX 2.

Adequate response is defined as moderate response measured using EULAR criteria at 6 months after starting therapy (DAS improvement of ≥1.2).

No

Second line Biologic options (monotherapy)
Consider changing to an alternative biologic from a different class (from **BOX 1**).
An alternative TNFi can be considered.
Assess as per **BOX 2.**

Yes

No

Subsequent Biologic options (monotherapy)
Consider changing to an alternative biologic from a different class (from **BOX 1**).
Assess as per **BOX 2.**

Yes

Yes

For patients with an adequate response, continue treatment with 6 monthly monitoring. Stop treatment where adequate response is not maintained, and consider next step in pathway.

Yes

First and subsequent line option if multiple sclerosis, SLE, previous malignancy, ILD/pulmonary fibrosis Local agreement MOPB Feb 2020

^Rituximab biosimilar

Response assessed by 6 months. Treatment to be continued only if there is an adequate response (improvement in DAS28 of 1.2 points or more). Treatment should be given no more frequently than every 6 months

Locally agreed commissioning position:

^ Rituximab monotherapy (without MTX) first or subsequent line biologic option if multiple sclerosis, SLE, previous malignancy, ILD/pulmonary fibrosis MOPB Feb 2020

^^ A second IL-6i would not be routinely funded following inadequate response to a first IL-6i. MOPB Mar 2018

*Tocilizumab

- Tocilizumab sc may be used in place of tocilizumab IV. APC July 2014
- Tocilizumab may be used in patients whose rheumatoid arthritis has responded inadequately, or who has not tolerated TWO TNFi, each given as monotherapy. APC July 2014

Maximum 4 biologics routinely commissioned per patient MOPB Mar 2018

With thanks and acknowledgement to Hertfordshire Pharmacy and Medicines Optimisation Team.
Produced by West Essex CCG Medicines Optimisation Team. Update approved MOPB February 2020; Review February 2022