NHS Bedfordshire Clinical Commissioning Group

NHS Luton Clinical Commissioning Group

Bedfordshire and Luton Joint Prescribing Committee

ALGORITHM B: Treatment algorithm for the treatment of severe Rheumatoid Arthritis (ie. DAS 28 > 5.1) in a select group of patients∇ who are not suitable to have a TNF inhibitor as a first line agent due to the presence of specified comorbidities.

(NB: This algorithm (starting at second line treatment option section stage can also be applied for patients who subsequently develop one of the specified co-morbidities and who can no longer have a TNF inhibitor.)

Select Patient Group ∇: Patients with the following co-morbidities are not suitable for treatment with a TNF inhibitor agent:

- **Patient has had a proven malignancy in the last 10 years**
- **malignant melanoma at any point**
- **bronchiectasis**
- **pulmonary fibrosis**
- **multiple sclerosis**
- **SLE**

Prescribing notes:

- The initial choice of biologic will be influenced by the exact nature of the co-morbidity.
- Biologics should be prescribed in combination with methotrexate unless methotrexate is contraindicated or not tolerated.
- Biologics should be prescribed by brand name (due to the availability of biosimilar products).
- Where a biosimilar exists, all new patients should be started on the biosimilar preparation and existing patients should be reviewed for consideration of switching from originator to biosimilar product. (To date, biosimilars exist for etanercept, infliximab and rituximab. (Contact pharmacy for relevant brand names)).

First line treatment option in combination with methotrexate:
The initial choice of biologic will be influenced by the exact nature of the co-morbidity.

- **Rituximab** (biosimilar) **IV or abatacept s/c or tocilizumab s/c**
- **Abatacept IV or tocilizumab IV** can be considered for use in patients where the s/c route is not suitable (e.g. problems with self-injection).
- If using rituximab, treatment should be given no more frequently than every 6 months.

First line treatment option If methotrexate is contraindicated or not tolerated: The initial choice of biologic will be influenced by the exact nature of the co-morbidity

- **Rituximab** (biosimilar) **IV** in combination with another DMARD **e.g. leflunomide or tocilizumab s/c monotherapy**
- **Rituximab IV monotherapy** is an option if the use of another DMARDs is not suitable.
- If using rituximab, treatment should be given no more frequently than every 6 months.
- **Tocilizumab IV** can be considered for use in patients where the s/c route is not suitable (e.g. problems with self-injection)

Assess response after 6 months:

- If a moderate response* or more is achieved, continue treatment and monitor every 6-12 months.
- If a moderate response is **not** achieved after the initial 6 months, withdraw treatment and consider a second line biologic agent.
- If a moderate response is **not** maintained in the longer term, withdraw treatment and consider a second line biologic agent.
- If intolerance develops, withdraw treatment and consider a second line biologic agent.

*moderate response: as measured using the European League against Rheumatism (EULAR) i.e.an improvement in DAS28 of 1.2 points

Second line Treatment option (in combination with methotrexate)

Choice of biologic depends on exact nature of comorbidity and also on which agent was used first line.

- **Choose from either rituximab** (biosimilar) **IV or abatacept s/c or tocilizumab s/c**
- **IV abatacept or IV tocilizumab can be used if s/c route not suitable**

If none of the above agents are suitable as a second line choice, a TNF inhibitor can be considered based on a risk v's benefit decision.

Second line Treatment option (if methotrexate is contraindicated or not tolerated)

Choice of biologic depends on exact nature of comorbidity and also on which agent was used first line.

- **Choose from either rituximab** (biosimilar) **IV monotherapy or tocilizumab s/c monotherapy**
- **IV tocilizumab can be used if s/c route not suitable**

If none of the above agents are suitable as a second line choice, a TNF inhibitor monotherapy option can be considered based on a risk v's benefit decision.

Assess response after 6 months:

- If a moderate response* or more is achieved, continue treatment and monitor every 6 -12 months.
- If not achieved after the initial 6 months, withdraw treatment
- If a moderate response* is not maintained in the longer term **or** if intolerance develops, withdraw treatment and **submit an IFR request** (as no local or NICE guidance available for the use of a further biologic agent beyond this stage in this select patient group∇.

*moderate response: as measured using the European League against Rheumatism (EULAR) i.e.an improvement in DAS28 of 1.2 points