NHS
Coventry and Warwickshire
Integrated Care Board

Rituximab in Rheumatoid Arthritis for Patients with a Contraindication to anti-TNF Therapy Policy

Reference Number:	This will be applied to all new ICB-wide PPSs by the Governance and Corporate Affairs Team and will be retained throughout its life span.
Version:	Version 1.0
Name of responsible Committee and date approved or recommended to Integrated Care Board Board:	Audit Committee
Date approved by the Integrated Care Board (if applicable):	1 July 2022
Next Review Date:	1 April 2024
Expiry Date:	1 October 2024
Name of author and title:	Altaz Dhanani, ICB
Name of reviewer and title:	Angela Brady, Chief Medical Officer, ICB
Department:	Corporate Office

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.

Date:	April 2020
Requested Intervention:	Rituximab in rheumatoid arthritis for patients with a contraindication (absolute or relative) to anti-TNF therapy
ICB decision:	Rituximab is recommended as an option for the treatment of adults with severe active rheumatoid arthritis as a first line biologic drug **IF** the patient has an absolute or relative contra-indication to anti-TNF therapy (including previous cancer or a history of interstitial lung disease). Rituximab can be used as monotherapy or in combination with methotrexate or leflunomide. Treatment with rituximab should be given no more frequently than every 6 months.
Evidence Summary:	As per British Society of Rheumatology (BSR): Link to an Executive summary: Guidelines on the Use of Rituximab in Rheumatoid Arthritis
Criteria for Use (if applicable):	Patient has: • Active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 • Undergone trials of two disease-modifying antirheumatic drugs (DMARDs), including methotrexate (unless contraindicated). A trial of a DMARD is defined as being normally of 6 months, with 2 months at standard dose, unless significant toxicity has limited the dose or duration of treatment. • Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. • After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. • Since rituximab is unlicensed in this setting and is being used off label, patient consent must be sought and documented within the patient's clinical notes prior to treatment. Patients must be informed that the product is being used off label and ideally sign a consent form before treatment is initiated.
Discontinuation:	• Adverse event due to rituximab **or** • If at an interval of not <16 weeks and ideally at 24 weeks, patient does not show at least a moderate EULAR response to the first treatment course, discontinue treatment. • After initial response, treatment should be monitored no less frequently than 6-monthly intervals with assessment of the EULAR response. Treatment should be withdrawn if an adequate response is not maintained.

Further Information	This policy will be updated for a year, during which an audit should take place. An audit will take place prior to the policy review date to ensure compliance with this policy and to assess patient response. This policy will be reviewed in light of new evidence or guidance. **Prior approval from the Integrated Care Board will be required before any treatment proceeds in secondary care unless an alternative contract arrangement has been agreed with the ICB that does not necessitate the requirement of prior approval before treatment.**

Equality Impact Assessment

AGEM CSU	Department	Medicines Optimisation	Name of lead person	Jas Sagoo

Organisation

Rituximab in rheumatoid arthritis for patients with a contraindication (absolute or relative) to anti-TNF therapy

Piece of work being assessed

To provide a policy and criteria for patients requiring Rituximab in the above circumstances Aims of this piece of work

April 2020	Other partners/stakeholders involved	Secondary care clinicians, Trust MO Pharmacist

Date of EIA

Patients requiring treatment with Rituximab in the above circumstances Who will be affected by this piece of work?

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	All clinical decisions are based on extensive research and apply to all patients regardless of gender, race, disability, age, religion or belief, sexual orientation, gender identity, social deprivation or caring responsibility	No
Race		
Disability		
Religion/ belief		
Sexual orientation		
Age		
Social deprivation		
Carers		
Human rights	Will this piece of work adversely impact on anyone's human rights?	No