NHS
Warwickshire North
Clinical Commissioning Group

Drug Policy: Rituximab in Rheumatoid Arthritis

Quality & Equality First

Version Control

Version	2.0
Ratified by	NHS Warwickshire North CCG Governing Body
Date ratified	12th January 2017
Name of originator/author	Suzy Heafield, Medicine Optimisation team Arden Clinical Commissioning Policy Development Group
Responsible committee	Commissioning, Finance and Performance Committee
Date issued	01 April 2017
Review date	April 2020

Version History

Date	Version	Comment / Update
27 / 03 / 2013	V1	Approved by CCG CDG
12 / 01 / 2017	V2	Version drafted by Arden Clinical Policy Development Group

Treatment	**Drug Policy: Rituximab in Rheumatoid Arthritis**
Indication	Rheumatoid Arthritis
Funding Status	Treatment restricted

OPCS Codes	Not applicable
Treatment (1)	***For Patients with a contraindication to Methotrexate*** Rituximab monotherapy or in combination with leflunomide is recommended as an option for the treatment of adults with severe active rheumatoid arthritis who have had an inadequate response to, or are intolerant of, other disease-modifying anti-rheumatic drugs (DMARDs), including at least one tumour necrosis factor (TNF) inhibitor **AND** the patient is methotrexate intolerant or treatment with methotrexate is considered to be inappropriate. Treatment with rituximab should be given no more frequently than every 6 months. **Criteria for Use (if applicable):** • Inadequate response to anti-TNF therapy (DAS28 score not improved by ≥ 1.2 during the 6 months following treatment). • As rituximab is unlicensed in this setting patients must be informed that the product is being used off label and sign a consent form before treatment is initiated. **Discontinuation** • Adverse event due to rituximab **or** • DAS28 score not improved by ≥ 1.2 after 6 months of treatment 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. *Reference: As per British Society of Rheumatology (BSR) Guidelines on the Use of Rituximab in Rheumatoid Arthritis*
Treatment (2)	***For Patients with a contraindication (absolute or relative) to anti-TNF therapy*** 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. **Criteria for Use (if applicable):** Patient has: • Active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart. • Undergone trials of two disease-modifying anti-rheumatic 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 • Treatment with TNF-α inhibitors should be continued only if there is an adequate response at 6 months following initiation of therapy. An adequate response is defined as an improvement in DAS28 of 1.2 points or more. • As rituximab is unlicensed in this setting patients must be informed that the product is being used off label and sign a consent form before treatment is initiated. **Discontinuation** • Adverse event due to rituximab **or** • DAS28 score not improved by ≥ 1.2 after 6 months of treatment After initial response, treatment should be monitored no less frequently than 6-monthly intervals with assessment of DAS28. Treatment should be withdrawn if an adequate response is not maintained. *Reference: As per British Society of Rheumatology (BSR) Guidelines on the Use of Rituximab in Rheumatoid Arthritis*
Equality Impact	See EIA attached
Quality Impact	See QIA attached

Equality Impact Assessment

Policy	**Rituximab in Rheumatoid Arthritis**	**Person completing EIA**	Suman Ghaiwal, Equality and Human Rights Manager, CSU
Date of EIA	9 October 2016	**Accountable CCG Lead**	Jenni Northcote, Director of Partnerships and Engagement

Aim of Work	The Public Sector Equality duty requires us to eliminate discrimination, advance equality of opportunity, and foster good relations with protected groups. This EIA assesses the impact of the policy on protected groups.
Who Affected	Warwickshire North registered patients

Protected Group	Likely to be a differential impact?	Protected Group	Likely to be a differential impact?
Sex	No	**Age**	No
Race	No	**Gender Reassignment**	No
Disability	No	**Marriage and Civil Partnership**	No
Religion / belief	No	**Pregnancy and Maternity**	No
Sexual orientation	No		

Describe any potential or known adverse impacts or barriers for protected/vulnerable groups and what actions will be taken (if any) to mitigate. If there are no known adverse impacts, please explain.

Since CCGs operate within finite budgetary constraints the policy detailed in this document make explicit the need for the CCG to prioritise resources and provide interventions with the greatest proven health gain. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.

The impact of this policy has been considered against all protected groups and human rights principles.

Rheumatoid arthritis affects around 400,000 people in the UK. It can affect adults at any age, but most commonly starts between the ages of 40 and 50. About three times as many women as men are affected. It is more common in people who smoke and in people who are above a healthy weight.

The policy provides a consistent clinically based criteria for decision making, benefitting patients within the CCG area by providing consistency and equity of service provision. The policy provides an avenue through the 'Individual Funding Requests' policy to seek funding in exceptional clinical circumstances.

No potential or known adverse impacts or barriers for protected and/or vulnerable groups were identified.

Quality Impact Assessment

QIA Completed By: Mary Mansfield, Deputy Chief Quality Officer (CCG)						Completed: 9 October 2016			
Rituximab in rheumatoid arthritis for patients unable to take other medication **AREA OF ASSESSMENT**		**OUTCOME ASSESSMENT**			**Evidence/Comments for answers**	**Risk rating** (For negative outcomes)			**Mitigating actions**
		Positive	**Negative**	**Neutral**		**Risk impact (I)**	**Risk likelihood (L)**	**Risk Score (IxL)**	
Duty of Quality Could the scheme impact positively or negatively on any of the following	Effectiveness – clinical outcome			X	There has been no change to the policy.				
	Patient experience			X					
	Patient safety			X					
	Parity of esteem			X					
	Safeguarding children or adults			X					
NHS Outcomes Framework Could the scheme impact positively or negatively on the delivery of the five domains:	Enhancing quality of life			X					
	Ensuring people have a positive experience of care			X					
	Preventing people from dying prematurely			X					
	Helping people recover from episodes of ill health or following injury			X					
	Treating and caring for people in a safe environment and protecting them from avoidable harm			X					
Patient services Could the proposal impact positively or negatively on any of the following:	A modern model of integrated care, with key focus on multiple long-term conditions and clinical risk factors			X					
	Access to the highest quality urgent and emergency care			X					
	Convenient access for everyone			X					
	Ensuring that citizens are fully included in all aspects of service design and change			X					
	Patient Choice			X					
	Patients are fully empowered in their care			X					
	Wider primary care, provided at scale								