NHS
Warwickshire North
Clinical Commissioning Group

Drug Policy: Tocilizumab Subcutaneous Injection (monotherapy) for 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	Ann Hutton: High Cost Drugs Pharmacist, UHCW Beverley Bazant-Hegemark: MO Lead Pharmacist, Arden & GEM Commissioning Support Unit
Responsible committee	Commissioning, Finance and Performance Committee
Date issued	01 April 2017
Review date	April 2020

Version History

Date	**Version**	**Comment / Update**
01 / 11 / 2013	V1	Approved by CCG
12 / 01 / 2017	V2	Version drafted by Arden Clinical Policy Development Group

Treatment	**Drug Policy: Tocilizumab Subcutaneous Injection (monotherapy) for Rheumatoid Arthritis**
Indication	Moderate to Severe Rheumatoid Arthritis
Funding Status	Treatment restricted

OPCS Code	Not applicable
Treatment	This policy is for patients who have moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists, including when biologic combination with methotrexate (MTX) is inappropriate [e.g. due to intolerance to MTX]. **Criteria for Use** As per NICE TAs 130, 195 and 247 • DAS28 score > 5.1, on 2 occasions, 1 month apart **and** the patient has undergone two x DMARD trials including MTX. (A trial of 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). AND • Intolerance/contraindication to MTX, or where continued treatment with MTX is inappropriate. NB as per NICE TA 195: "*1.6 When using DAS28, healthcare professionals should take into account any physical, sensory or learning disabilities, communication difficulties, or disease characteristics that could adversely affect patient assessment and make any adjustments they consider appropriate*." i.e. for patients with ankle or foot RA, who do not meet the DAS28 criteria (due to disease characteristics in these joints); clinicians must outline to the CCG the proposed method of determining a successful outcome prior to commencing therapy. **Stopping criteria** • Adequate response (as per NICE TAs 130, 195 and 247) to treatment at 6 months **not** achieved (i.e. DAS28 score not improved by ≥ 1.2) OR • Intolerance/allergy to therapy OR • For patients with foot or ankle RA, agreed outcome measure not achieved at 6 months. **Evidence summary** • Trial data (ADACTA) supports clinical effectiveness (and superiority) of SC tocilizumab vs. SC adalimumab comparator1,2. • Trial data (SUMMACTA) supports clinical equivalence (non-inferiority) of SC vs IV tocilizumab3.

	• The SMC have approved the use of SC tocilizumab in monotherapy, where there is methotrexate intolerance or it is inappropriate to continue: it notes an economic case has been demonstrated4. NICE will not be considering this as a new TA as: "*New formulations or routes of delivery (such as subcutaneous) are looked at on a case by case basis by NICE. If the indication (target population) for the subcutaneous (sc) formulation is exactly the same as for the iv preparation, and if NICE has already had a positive appraisal (of the iv preparation) on all of the target groups covered by the planned sc indications, then the cost-savings would support a switch (assuming clinical equivalence of the iv and sc preparations) to the sc formulation. Therefore, NICE guidance is unlikely to add value for patients and the NHS*."5 **References** 1. *C. Gabay, P. Emery et. al. TOCILIZUMAB (TCZ) MONOTHERAPY IS SUPERIOR TO ADALIMUMAB (ADA) MONOTHERAPY IN REDUCING DISEASE ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA): 24-WEEK DATA FROM THE PHASE 4 ADACTA TRIAL. Ann Rheum Dis 2012;71(Suppl3):152. Accessed via http://www.ncbi.nlm.nih.gov/pubmed/23515142* 2. *Maxime Dougados, Karsten Kissel et. al. Adding tocilizumab or switching to tocilizumab monotherapy in methotrexate inadequate responders: 24-week symptomatic and structural results of a 2-year randomised controlled strategy trial in rheumatoid arthritis (ACT-RAY) ACT-RAY study. Ann Rheum Dis 2013;72:43–50. Accessed via http://ard.bmj.com/content/72/1/43.abstract Full text: http://ard.bmj.com/content/72/1/43.full.pdf+html* 3. *Burmester GR, Rubbert-Roth A, Cantagrel A et al. A randomised, double-blind, parallel-group study of the safety and efficacy of subcutaneous tocilizumab versus intravenous tocilizumab in combination with traditional disease-modifying antirheumatic drugs in patients with moderate to severe rheumatoid arthritis (SUMMACTA study). Ann. Rheum Dis 2014; 73 (1): 69 to 74. Accessed via http://ard.bmj.com/content/73/1/69.full.pdf+html* 4. *Scottish Medicines Consortium. tocilizumab, 162mg, solution for injection in pre-filled syringe (RoActemra®) SMC No. (982/14) (published 11th August 2014). Accessed via https://www.scottishmedicines.org.uk/files/advice/tocilizumab__RoActemra__FINAL_July_2014_for_website.pdf* 5. *Letter to Roche from NICE: Tocilizumab SC for moderate-to-severe rheumatoid arthritis in combination with disease-modifying antirheumatic drugs (TS ID 5689). Dated 6.6.2014.*
Equality Impact	See EIA attached
Quality Impact	See QIA attached

Equality Impact Assessment

Policy	Tocilizumab subcutaneous injection (monotherapy)	**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			
Tocilizumab subcutaneous injection (monotherapy) **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			X					