NHS
Staffordshire and Stoke-on-Trent
Integrated Care Board

Policy for the use of abatacept without methotrexate for the treatment of rheumatoid arthritis outside the scope of NICE (TA195 and TA375)

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Ratified by:	Staffordshire & Stoke-on-Trent Integrated Care Board (ICB)
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Name of originator/author:	Hardip Kalirai – Senior Medicine Optimisation Pharmacist Katie Burns – Senior High-Cost Drugs Technician
Name of responsible committee/individual:	Staffordshire and Stoke-on-Trent ICB Finance and Performance Committee
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Target audience:	Organisation wide

CONSULTATION SCHEDULE

Name and Title of Individual	Groups consulted	Date Consulted
Jon Packham Consultant Rheumatologist, Midlands Partnership NHS Foundation Trust (MPFT)		V0.1: 11.04.2023 V0.2: 26.06.2023 V0.3: 20.09.2023 V0.4: 08.11.2023
Samantha Bostock RSM UK Risk Assurance Services LLP V1		12/12/2023
	Staffordshire and Stoke-on-Trent Integrated Medicines Optimisation Group (IMOG) V1	06/12/2024
	Staffordshire and Stoke-on-Trent Health and Care Senate V1	08/02/2024

APPROVALS & RATIFICATION SCHEDULE

Name of Committee approving Policy	Date
Staffordshire and Stoke-on-Trent ICB Finance and Performance Committee V1	05/03/2024

VERSION CONTROL

Version	Version/Description of amendments	Date	Author/amended by
1	First draft	August 2023	Hardip Kalirai – Senior Medicine Optimisation Pharmacy Lead Katie Burns – Senior High-Cost Drugs Technician

IMPACT ASSESSMENTS – available on request

	Stage	Complete	Comments
Equality Impact Assessment	Stage 1	02/06/2023	
Quality Impact Assessment	Screening Template	28/12/2023	
Privacy Impact Assessment			Not applicable

Contents

This policy applies to the Staffordshire & Stoke-on-Trent Integrated Care Board.

1.0 Introduction

1.1 Abatacept selectively modulates a key costimulatory signal required for full activation of T lymphocytes expressing CD28. Full activation of T lymphocytes requires two signals provided by antigen presenting cells: recognition of a specific antigen by a T cell receptor (signal 1) and a second, costimulatory signal. A major costimulatory pathway involves the binding of CD80 and CD86 molecules on the surface of antigen presenting cells to the CD28 receptor on T lymphocytes (signal 2). Abatacept selectively inhibits this costimulatory pathway by specifically binding to CD80 and CD86. Studies indicate that naive T lymphocyte responses are more affected by abatacept than memory T lymphocyte responses.[1,2.]

1.2 Abatacept has a marketing authorisation for use in combination with methotrexate for the treatment of adults with severe active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to other DMARDs including one or more TNFα inhibitor therapies.[1,2.]

1.3 Abatacept with methotrexate appears in the locally agreed RA pathway for the prescribing of biological medicines.

1.4 Evidence has been submitted to consider the clinical benefit of abatacept without methotrexate or with an alternative disease-modifying anti-rheumatic drug (DMARD) for a patient who is unable to tolerate methotrexate or where methotrexate is contraindicated, after failure of other approved biological therapies.

1.5 Current National Institute for Health and Care Excellence (NICE) Guidance

1.5.1 As per NICE guidance Technology Appraisal (TA) TA 375 [3] and the locally agreed RA pathway, if a patient meets the NICE criteria, the least expensive biological agent (biosimilar TNF α inhibitor) is chosen as the preferred option.

1.5.2 NICE TA 195 sets out alternative options after initial failure of a TNF α-inhibitor. For patients able to tolerate methotrexate, rituximab is the next option for the majority of patients. Should the patient display an inadequate response to therapy with rituximab, the use of abatacept is a next treatment option. An adequate response is defined as an improvement in the Disease Activity Score 28 (DAS28) following 6 months of treatment by at least 1.2 points. [4]

2.0 Aim and objectives.

2.1 The policy aims to define Staffordshire and Stoke-on-Trent ICB's commissioning position with respect to the use of abatacept where methotrexate is contra-indicated or not tolerated, as part of the treatment pathway for adults with rheumatoid arthritis

2.2 The objective is to ensure evidence-based commissioning with the aim of improving outcomes for adults with rheumatoid arthritis.

3.0 Clinical and Cost Effectiveness.

3.1 Clinical Effectiveness

3.1.1 Rheumatoid arthritis is a long-term autoimmune disease that causes pain, swelling and stiffness in the joints. It can vary in its severity and the periods where symptoms become worse are known as flare-ups. During the flare-ups the immune system attacks the cells that line the joints and over time can damage the cartilage and bone. The condition is most likely to occur in the hands, feet, and wrists. Methotrexate, Leflunomide, Hydroxychloroquine and Sulfasalazine are examples of disease-modifying anti-rheumatic drugs (DMARDS) that are offered as initial treatment after diagnosis and are designed to control symptoms and slow disease progression. These can be combined with other DMARDs and also can be combined with biological treatments, such as abatacept. When used for the treatment of rheumatoid arthritis, abatacept is licensed for use only in combination with methotrexate, rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDS only have failed. The use of abatacept as proposed in this case would therefore be off-label.

3.2 Cost Effectiveness

3.2.1 Abatacept has a commercial in confidence patient access scheme price which reduces the cost of the treatment within the NHS. [3,4]

3.2.2 This commercial price is comparable to alternative treatment options also recommended by NICE and falls within the ICER value that NICE deems as acceptable. Using abatacept without methotrexate should therefore not increase the overall costs. [3,4]

4.0 Criteria for Commissioning

4.1 Abatacept can be used without methotrexate provided NICE recommendations NICE TA 195 and NICE TA 375 are otherwise met, in patients that have a contraindication or a previous intolerance to methotrexate.

4.2 Discontinuation criteria as per NICE TA 195 and NICE TA 375 should be adhered to. Clinicians should:[3,4]

- 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.

4.3 Prescribers have the responsibility to ensure any use of abatacept without methotrexate should follow the strict criteria as detailed in this policy, a Blueteq form will be required to be completed for all patients commencing on treatment.

4.4 Use of abatacept without methotrexate should be a shared decision between the prescriber and patient with the patient being fully informed that this is an ‘off-label’ use and outside of NICE recommendations.

5.0 Patient Pathway

5.1 Prescriptions for abatacept will be provided by specialist rheumatology services within the Staffordshire and Stoke on Trent Integrated Care System (ICS). Prescribers have the responsibility to adhere to NICE guidance and the locally agreed RA pathway for the prescribing of biological medicines.

5.2 Abatacept will be used as an additional option only within the context of the clinical pathway provided the patient meets the criteria for commissioning. The most current approved and ratified iteration of the rheumatoid arthritis pathway

6.0 Equality Impact Assessment

6.1 This policy has been assessed in relation to having due regard to (1) the public sector equality duty (PSED) three aims, dropping down from the Equality Act 2010 to: eliminate discrimination, harassment victimisation; advance equality of opportunity; and foster good relations", (2) The Health & Social Care Act 2012 re evidencing showing due regard to reducing health inequalities between the people of England.

6.2 Staffordshire and Stoke-on-Trent (SSOT) ICB has completed an internal Equality Impact Assessment when developing this policy.

7.0 Monitoring and Evaluation

7.1 The Staffordshire and Stoke-on-Trent (SSOT) ICB Medicine Optimisation Team will review and monitor uptake of the policy against completed Blueteq forms.

8.0 Policy development and review

The SSOT ICB policies will be reviewed no less than every three years from the date of approval. The lead person for the policy will be responsible for ensuring that the review is undertaken and where changes are required that the process of consultation on the revised arrangements is completed.

9.0 References

1. Summary of Product Characteristics Abatacept (Orencia) 250mg powder for concentrate for solution for infusion Updated 19 July 2021 https://www.medicines.org.uk/emc/product/334/smpc#gref Accessed August 2023.
2. Summary of Product Characteristics Abatacept (Orencia) 125mg solution for injection (pre-filled syringe) Updated 19 July 2021 https://www.medicines.org.uk/emc/product/2877/smpc#gref Accessed August 2023
3. National Institute of Health and Care Excellence (NICE) Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed Technology appraisal guidance [TA375] Published: 26 January 2016 https://www.nice.org.uk/guidance/ta375 Accessed August 2023.
4. National Institute of Health and Care Excellence (NICE) Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor Technology appraisal guidance [TA195] Published: 25 August 2010 https://www.nice.org.uk/guidance/ta195 Accessed August 2023