



Berkshire West Area Prescribing Committee Policy Statement

Drug Name	Biosimilar infliximab
Indication under review	Rheumatoid Arthritis, Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis
Policy No:	APC 099
Date of Issue:	March 2015
Review Date:	March 2018
Policy Statement: Biosimilar infliximab is indicated for use in patients with Rheumatoid Arthritis, Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis who are infliximab naive	
Traffic Light Status	RED
Key Points considered: <ul style="list-style-type: none"> • Trials in rheumatoid arthritis and ankylosing spondylitis have demonstrated equivalence of biosimilar infliximab with originator infliximab. • The committee were satisfied with the EMA's process of extrapolating the data to other indications of currently marketed infliximab. 	
References: <ol style="list-style-type: none"> 1. European Medicines Agency. Remsima assessment report. [Accessed October 2014]. http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002576/WC500151486.pdf. 2. Park W, Hrycaj P, Jeka S, et al. A randomised, double-blind, multicentre, parallel-group, prospective study comparing the pharmacokinetics, safety, and efficacy of CT-P13 and innovator infliximab in patients with ankylosing spondylitis: the PLANETAS study. <i>Ann Rheum Dis</i> 2013;72:1605-12 (and suppl appendix). 3. Yoo DH, Hrycaj P, Miranda P, et al. A randomised, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when coadministered with methotrexate in patients with active rheumatoid arthritis: the PLANETRA study. <i>Ann Rheum Dis</i> 2013;72:1613-20. 4. Park W, Miranda P, Brzosko M, et al. Efficacy and safety of CT-P13 (infliximab biosimilar) over two years in patients with ankylosing spondylitis: comparison between continuing with CT-P13 and switching from infliximab to CT-P13. Late breaking abstract presented at the American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting; 2013 Oct 25-30; San Diego, USA. 5. Yoo DH, Prodanovic N, Jaworski J, et al. Efficacy and safety of CT-P13 (infliximab biosimilar) over two years in patients with rheumatoid arthritis: comparison between continued CT-P13 and switching from infliximab to CTP13. Late breaking abstract presented at the American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting; 2013 Oct 25-30; San Diego, USA. 6. Kwan Jung S, Lee K, Won Jeon J, et al. Physicochemical characterization of Remsima. <i>mAbs</i> 2014;6. [Accessed October 2014]. http://dx.doi.org/10.4161/mabs.32221 7. Kurki P, Bielsky M-C. ECCO position challenged by European drug regulators. <i>J Crohn's Colitis</i> 2014;8:258. 8. Park W, Jaworski J, Brzezicki J, et al. A randomised, double-blind, parallel-group, phase 1 study comparing the pharmacokinetics, safety and efficacy of CT-P13 and infliximab in patients with active ankylosing spondylitis: 54 week results from the PLANETAS study. <i>Ann Rheum Dis</i> 2013;72(Suppl 3):516. 9. Yoo DH, Racewicz A, Brzezicki J, et al. A phase 3 randomised controlled trial to compare CT-P13 with infliximab in patients with active rheumatoid arthritis: 54 week results from the PLANETRA study. <i>Ann Rheum Dis</i> 2013;72(Suppl 3):73. 10. Remsima 100 mg powder for concentrate for solution for infusion summary of product characteristics 	
Date taken to APC:	4 th March 2015
Date Ratified by MMC on Behalf of the Board:	18 th March 2015

Berkshire West Area Prescribing Policies serve as a guide to clinicians. This does not overrule the clinical or budgetary responsibility of clinicians when considering treatment for individual patients.

Brown	Green	Amber	Red
These drugs have been reviewed and are not considered a cost effective use of scarce NHS resources	Medicines suitable for routine use. Primary care prescribers take full responsibility for prescribing	Medicines that should be initiated by a specialist and can be continued in primary care under a shared care agreement.	Medicines which should be prescribed by specialists only