

Berkshire West Area Prescribing Committee Policy Statement

Drug Name	Certolizumab (Cimzia®)
Indication under review	Treatment of active psoriatic arthritis in adults, when the response to previous disease modifying anti-rheumatic drug (DMARD) therapy has been inadequate
Policy No:	APC 093
Date of Issue:	January 2015
Review Date:	January 2018
Policy Statement: Certolizumab (Cimzia®) is indicated for the treatment of active psoriatic arthritis in adults, when the response to previous disease modifying anti-rheumatic drug (DMARD) therapy has been inadequate. Treatment is to be carried out within a specialist setting such as a rheumatology clinic within secondary care.	
Traffic Light Status	Red
Key Points considered:	
<ul style="list-style-type: none"> • In the 24-week, double-blind, placebo-controlled part of the RAPID-PsA study (n=409), certolizumab pegol compared with placebo: <ul style="list-style-type: none"> ○ statistically significantly increased the number of people achieving an American College of Rheumatology 20% (ACR20) response at week 12 (primary clinical end point) ○ statistically significantly increased physical function from baseline at week 24 ○ was associated with improvements in enthesitis, dactylitis, psoriatic skin involvement, and nail disease, in people with evidence of these at baseline 	
References:	
<p>Bykerk VP, Cush J, Winthrop K et al. (2013) Update on the safety profile of certolizumab pegol in rheumatoid arthritis: an integrated analysis from clinical trials. <i>Annals of the Rheumatic Diseases</i> online first doi:10.1136/annrheumdis-2013-203660</p> <p>European Medicines Agency (2013) European public assessment report for Cimzia [online, accessed 20 March 2014]</p> <p>Mease PJ (2011) Measures of psoriatic arthritis: Tender and Swollen Joint Assessment, Psoriasis Area and Severity Index (PASI), Nail Psoriasis Severity Index (NAPSI), Modified Nail Psoriasis Severity Index (mNAPSI), Mander/Newcastle Enthesitis Index (MEI), Leeds Enthesitis Index (LEI), Spondyloarthritis Research Consortium of Canada (SPARCC), Maastricht Ankylosing Spondylitis Enthesis Score (MASES), Leeds Dactylitis Index (LDI), Patient Global for Psoriatic Arthritis, Dermatology Life Quality Index (DLQI), Psoriatic Arthritis Quality of Life (PsAQOL), Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F), Psoriatic Arthritis Response Criteria (PsARC), Psoriatic Arthritis Joint Activity Index (PsAJAI), Disease Activity in Psoriatic Arthritis (DAPSA), and Composite Psoriatic Disease Activity Index (CPDAI). <i>Arthritis Care Research</i> 63: S64–S85 doi: 10.1002/acr.20577</p> <p>Mease PJ, Fleischmann R, Deodhar AA et al. (2014) Effect of certolizumab pegol on signs and symptoms in patients with psoriatic arthritis: 24-week results of a phase 3 double-blind randomised placebo-controlled study (RAPID-PsA). <i>Annals of the Rheumatic Diseases</i> 73: 48–55 doi:10.1136/annrheumdis-2013-203696</p> <p>Medicines and Healthcare products Regulatory Agency (April 2014) Tumour necrosis factor alpha inhibitors: risk of tuberculosis—screen all patients before starting treatment and monitor them closely. <i>Drug Safety Update</i>. Volume 7 issue 9, A1 [online, accessed 8 May 2014]</p> <p>National Institute for Health and Care Excellence (2013) Psoriatic arthritis (active) – ustekinumab: final scope</p> <p>National Institute for Health and Clinical Excellence (2010) Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis. NICE technology appraisal guidance 199</p> <p>National Institute for Health and Clinical Excellence (2011) Golimumab for the treatment of psoriatic arthritis. NICE technology appraisal guidance 220</p> <p>Singh JA, Wells GA, Christensen R et al. (2011) Adverse effects of biologics: a network meta-analysis and Cochrane overview. <i>Cochrane Database of Systematic Reviews</i> issue 2: CD008794 doi:10.1002/14651858.CD008794.pub2</p> <p>UCB Pharma Limited (2014) Cimzia 200 mg solution for injection summary of product characteristics [online; accessed 9 June 2014]</p> <p>van der Heijde D, Fleischmann R, Wollenhaupt J et al. (2014) Effect of different imputation approaches on the evaluation of radiographic progression in patients with psoriatic arthritis: results of the RAPID-PsA 24-week phase III double-blind randomised placebo-controlled study of certolizumab pegol. <i>Annals of the Rheumatic Diseases</i> 73: 233–37 doi:10.1136/annrheumdis-2013-203697</p>	
Date taken to APC:	8 th January 2015
Date Ratified by MMC on Behalf of the Board:	21 st January 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