

Rheumatology Advisory Committee - Clinical advice received from members via email regarding certolizumab pegol for rheumatoid arthritis in November 2023

1. Certolizumab pegol

1.1. Responding members noted that in October 2011, Pharmac received an application for certolizumab pegol as a first-line tumour necrosis factor (TNF) inhibitor for rheumatoid arthritis (RA). PTAC recommended this for Decline at its [February 2012 meeting](#), citing the lack of long-term evidence, little clinical need, and limited benefit to be gained from funding a third TNF inhibitor. Pharmac included certolizumab pegol in a [Consultation to Decline](#) a number of funding applications in December 2019. Following consultation, the application was not progressed to decline due to the consultation feedback received on the application, which highlighted:

- the long-term evidence for certolizumab pegol, through the open-label extensions to the RAPID 1 and RAPID 2 trials. The feedback referenced the following journal articles in relation to this:

Strand V, Mease P, Burmester GR, Nikaï E, Coteur G, van Vollenhoven R, Combe B, Keystone EC, Kavanaugh A. [Rapid and sustained improvements in health-related quality of life, fatigue, and other patient-reported outcomes in rheumatoid arthritis patients treated with certolizumab pegol plus methotrexate over 1 year: results from the RAPID 1 randomized controlled trial](#). Arthritis Res Ther. 2009;11(6):R170. doi: 10.1186/ar2859. Epub 2009 Nov 12.

Keystone E, Landewé R, van Vollenhoven R, Combe B, Strand V, Mease P, Shaughnessy, VanLunen B, van der Heijde D. [Long-term safety and efficacy of certolizumab pegol in combination with methotrexate in the treatment of rheumatoid arthritis: 5-year results from the RAPID 1 trial and open-label extension](#). Ann Rheum Dis. 2014 Dec;73(12):2094-100. doi: 10.1136/annrheumdis-2013-203695. Epub 2013 Aug 5.

Smolen JS, van Vollenhoven R, Kavanaugh A, Strand V, Vencovsky J, Schiff M, Landewé R, Haraoui B, Arendt C, Mountian I, Carter D, van der Heijde D. [Certolizumab pegol plus methotrexate 5-year results from the rheumatoid arthritis prevention of structural damage \(RAPID\) 2 randomized controlled trial and long-term extension in rheumatoid arthritis patients](#). Arthritis Res Ther. 2015 Sep 10;17:245. doi: 10.1186/s13075-015-0767-2.

- the potential need and benefit of certolizumab pegol in people with rheumatoid arthritis (RA) who are pregnant. The feedback referenced the following journal articles:

Cheent K, Nolan J, Shariq S, Kiho L, Pal A, Arnold J. [Case Report: Fatal case of disseminated BCG infection in an infant born to a mother taking infliximab for Crohn's disease](#). J Crohns Colitis. 2010 Nov; 4(5):603-5.

Cæcilie Bachdal Johansen, Espen Jimenez-Solem, Ann Haerskjold, Freja Lærke Sand, and Simon Francis Thomsen. [The Use and Safety of TNF Inhibitors during Pregnancy in Women with Psoriasis: A Review](#). Int J Mol Sci. 2018 May; 19(5): 1349.

1.2. Pharmac staff sought advice from PTAC on this consultation feedback at its [November 2022 meeting](#). PTAC considered that that it was unclear whether there was a need for certolizumab for the treatment of RA and where this might fit into the treatment paradigm. The Committee therefore considered that the

Rheumatology Advisory Committee should review the PTAC record regarding certolizumab pegol and provide comments and/or recommendations.

- 1.3. Responding members of the Rheumatology Advisory Committee reviewed the additional information provided in consultation feedback, along with the relevant record of the PTAC discussion and considered that the information provided does not significantly change the advice on certolizumab pegol for RA.
- 1.4. Responding members considered that it may be useful to have another advanced therapy for RA that is self-administered. However, the Committee considered that other potential self-administered options, such as subcutaneous tocilizumab, that would better address the unmet health need for people with RA.
- 1.5. Responding members considered that there may be benefits to certolizumab over currently funded anti-TNFs during pregnancy and breastfeeding for some. However, the Committee considered that, for the most part, there is clinician comfort with use of the current anti-TNFs during pregnancy, and therefore there is no significant unmet health need.
- 1.6. Responding members noted that there is currently a trial of certolizumab for use in juvenile idiopathic arthritis (JIA). Members noted that there are only 2 advanced therapies for JIA that do not require hospital admission (etanercept and adalimumab) and that it is important to consider the JIA patient population, who may benefit from an additional self-administered treatment option such as subcutaneous tocilizumab and tofacitinib.