



19 November 2015
EMA/CHMP/752205/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Cimzia

certolizumab pegol

On 19 November the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Cimzia. The marketing authorisation holder for this medicinal product is UCB Pharma SA.

The CHMP adopted a new indication as follows:

“treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX or other DMARDs.”

For information, the full indications for Cimzia will be as follows²:

Rheumatoid arthritis

Cimzia, in combination with methotrexate (MTX), is indicated for:

- the treatment of moderate to severe, active rheumatoid arthritis (RA) in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including MTX, has been inadequate. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate
- **the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs.**

Cimzia has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX.

Axial spondyloarthritis

Cimzia is indicated for the treatment of adult patients with severe active axial spondyloarthritis, comprising:

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold



Ankylosing spondylitis (AS)

Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

Axial spondyloarthritis without radiographic evidence of AS

Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated C-reactive protein (CRP) and /or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to NSAIDs.

Psoriatic arthritis

Cimzia, in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate.

Cimzia can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.