



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 September 2013  
EMA/CHMP/569182/2013  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Cimzia

#### certolizumab pegol

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Cimzia. The marketing authorisation holder for this medicinal product is UCB Pharma SA. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:

#### Axial spondyloarthritis

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

#### 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 CRP and /or MRI, who have had an inadequate response to, or are intolerant to NSAIDs.

Detailed conditions 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 the variation to the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.



For information, the full indications for Cimzia will be as follows<sup>2</sup>:

### **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 methotrexate, has been inadequate.

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

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 methotrexate.

### **Axial spondyloarthritis**

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

#### **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 CRP and /or MRI, who have had an inadequate response to, or are intolerant to NSAIDs.**

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<sup>2</sup> The text in bold represents the new or the amended indication.