BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

**SIMPONI**, (golimumab), TNF inhibitor

No clinical benefit demonstrated by comparison with other TNF inhibitors in the management of patients with severe non-radiographic axial spondyloarthritis with objective signs of inflammation and who failed NSAIDs.

**Main points**

- SIMPONI now has Marketing Authorisation in the treatment of severe non-radiographic axial spondyloarthritis in adults with objective signs of inflammation, taking the form of an elevated level of C-reactive protein (CRP) and/or signs visible in magnetic resonance imaging (MRI), in patients with an inadequate response to non-steroidal antiinflammatories (NSAIDs).
- Since no comparison is available with other TNF inhibitors indicated in non-radiographic axial spondyloarthritis, it is not possible to rank SIMPONI relative to other TNF inhibitors.

**Pre-existing indications**

SIMPONI already has Marketing Authorisation in adults in the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and active moderate to severe ulcerative colitis.

**Therapeutic use**

- The aim of management is to reduce spinal pain and stiffness and thus to maintain or improve functional capacity and quality of life. Drug treatment mainly involves the use of NSAIDs as first-line symptomatic therapy during episodes. If one NSAID fails or is not effective enough at the maximum tolerated dose, the NSAID used can be changed. Adjuvant treatments such as analgesics may be combined with NSAIDs during episodes.
- Disease-modifying anti-rheumatic treatments (e.g. sulfasalazine, methotrexate) seem to be effective only in forms involving the peripheral joints. Their efficacy in purely axial forms has not been demonstrated.
- In severe forms of axial spondyloarthritis that are not confirmed by radiographic examinations but show objective signs of inflammation in MRI and/or an elevated level of CRP, four TNF inhibitors, adalimumab, certolizumab, etanercept and now golimumab, have Marketing Authorisation in cases where there is an inadequate response or intolerance to NSAIDs.
- In patients with spondyloarthritis who experience a loss of response, primary inefficacy or intolerance to a first TNF inhibitor, changing to a second TNF inhibitor may be beneficial.

**Role of the medicinal product in the therapeutic strategy**

SIMPONI is an alternative to etanercept (ENBREL), adalimumab (HUMIRA) and certolizumab pegol (CIMZIA), other TNF inhibitors that have Marketing Authorisation in this indication. In the context of the rotating treatment strategy recommended in case of failure of one TNF inhibitor, SIMPONI is a therapeutic option. Since there are no data that compared it to other TNF inhibitors, it is not possible to rank it relative to these treatments.

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1 This summary does not cover these indications.

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Clinical data

- The efficacy and safety of golimumab in axial non-radiographic spondyloarthritis (defined according to ASAS classification criteria), active (BASDAI, and back pain VAS ≥ 4) despite optimal NSAID treatment and never treated by TNF inhibitors or other biologic treatments were evaluated in a randomised, double-blind, placebo-controlled study. A total of 197 patients were randomised to be treated for 16 weeks with golimumab at a dosage of 50 mg administered every 4 weeks (97 patients) or placebo (100 patients). Of these, 81% received concomitant NSAID treatment.

- The proportion of ASAS 20 responder patients at week 16 (primary efficacy endpoint) was 71.1% in the golimumab group and 40% in the placebo group, or a difference of 31.2%, p<0.0001. In the subpopulation of patients with objective signs of inflammation, the difference was 39.6% (95% CI: [24.6%; 52.6%]) p<0.0001

- No new safety signals were observed in this study. Long-term safety data in this remain limited for golimumab.

Special prescribing conditions

- Medicine requiring initial annual hospital prescription.
- Initial prescription and renewal restricted to specialists in rheumatology, internal medicine or gastroenterology and hepatology.
- Exception drug status.

Benefit of the medicinal product

- The actual clinical benefit* of SIMPONI is substantial.
- SIMPONI does not provide clinical added value ** (CAV V) by comparison with other TNF inhibitors (adalimumab, certolizumab, etanercept) in management.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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* The actual clinical benefit (ACB) of a medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. HAS Transparency Committee assesses the ACB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".

This document was created on the basis of the Transparency Committee Opinion of 25 May 2016 (CT-14930) available at www.has-sante.fr