HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
6 OCTOBER 2021

The legally binding text is the original French opinion version

golimumab
SIMPONI 50 and 100 mg solution for injection in pre-filled syringe and pen

Re-evaluation

Key points

Favourable opinion for maintenance of reimbursement in the treatment of:

- moderate to severe, active rheumatoid arthritis in adults, only in combination with methotrexate (MTX), when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate
- active and progressive psoriatic arthritis in adult patients, alone or in combination with MTX, when the response to previous DMARD therapy has been inadequate
- severe, active ankylosing spondylitis in adults who have responded inadequately to conventional therapy
- severe, active non-radiographic axial spondyloarthritis in adults with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

Rheumatoid arthritis

◗ Rheumatoid arthritis is a serious, chronic disabling condition.
◗ The medicinal product SIMPONI (golimumab) is a symptomatic medicinal product.
◗ The efficacy/adverse effects ratio remains high.
◗ There are therapeutic alternatives (see section 04 of this opinion).
◗ SIMPONI (golimumab) is a second-line treatment, i.e. in patients in whom conventional DMARD therapy, including methotrexate, has failed. It is an alternative to the other TNF inhibitors available in this indication (see section 07 of this opinion).

Public health impact:
SIMPONI (golimumab) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of SIMPONI (golimumab)

- **remains substantial, in combination with methotrexate (MTX), in the treatment of moderate to severe, active rheumatoid arthritis in adults, when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate.**

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the treatment of moderate to severe, active rheumatoid arthritis in adults, in combination with methotrexate (MTX), when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate, and at the MA dosages.

Psoriatic arthritis

◗ Psoriatic arthritis is a chronic disease, which can be serious and disabling in certain cases.
◗ The medicinal product SIMPONI (golimumab) is a symptomatic medicinal product.
◗ The efficacy/adverse effects ratio remains high.
◗ There are reported therapeutic alternatives (see section 04 of this opinion).
◗ Role in the care pathway: SIMPONI (golimumab) is a second-line treatment. It is an alternative to the other TNF inhibitors available in the treatment of psoriatic arthritis.

Public health impact:
SIMPONI (golimumab) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of SIMPONI (golimumab), alone or in combination with MTX, remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the marketing authorisation indication and at the MA dosages.

Ankylosing spondylitis

◗ Ankylosing spondylitis is a chronic condition that can be serious and disabling.
◗ The medicinal product SIMPONI (golimumab) is a symptomatic medicinal product.
◗ The efficacy/adverse effects ratio remains high.
◗ There are therapeutic alternatives (see section 04 of this opinion).
◗ SIMPONI (golimumab) is a second-line treatment. It is an alternative to the other TNF inhibitors available in the treatment of ankylosing spondylitis.

Public health impact:
SIMPONI (golimumab) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of SIMPONI (golimumab) remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the marketing authorisation indication and at the MA dosages.

Non-radiographic axial spondyloarthritis

◗ Non-radiographic axial spondyloarthritis is a chronic disease which, in its severe form with an inadequate response or intolerance to NSAIDs, is painful and affects spinal mobility and functional capacities.
◗ The medicinal product SIMPONI (golimumab) is a symptomatic medicinal product.
◗ The efficacy/adverse effects ratio remains high.
◗ There are therapeutic alternatives (see section 4 of this opinion).
◗ SIMPONI (golimumab) is a second-line treatment, in the event of an inadequate response or intolerance to NSAIDs. It is an alternative to the other TNF inhibitors available in the treatment of non-radiographic axial spondyloarthritis.

Public health impact:
SIMPONI (golimumab) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of SIMPONI (golimumab) remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the marketing authorisation indication and at the MA dosages.

◗ **Recommended reimbursement rate: 65%**

Clinical Added Value

The Committee considers that the new data available is not of a nature to modify the assessment of the clinical added value formulated in its previous opinions of 1 February 2012 and 22 June 2016 (CAV V, no clinical added value) in these four indications.