

# Pharmacotherapeutic Report on Golimumab (Simponi®) for the Indications Moderate to Severe Rheumatoid Arthritis (RA), Active Psoriatic Arthritis (PsA), and Active Ankylosing Spondylitis (AS)

## Summary

### Positive Effects.

I. Based on an indirect comparison the efficacy of golimumab combined with methotrexate in *rheumatoid arthritis* is within the same range as the de other TNF $\alpha$  blockers when combined with methotrexate. Moreover, golimumab is effective after insufficient response to one or more TNF $\alpha$  blockers.

II. Monotherapy of golimumab or combined with methotrexate will give an effect which is comparable to etanercept, adalimumab, and infliximab on the endpoint ARC20 for *psoriatic arthritis*. This conclusion is based on an indirect comparison between golimumab and other TNF $\alpha$  blockers.

III. Treatment with golimumab combined with treatment of methotrexate, corticosteroids and NSAIDs yields a similar effect to etanercept, adalimumab, and infliximab on the end point ASAS20 for *ankylosing spondylitis*. This conclusion is based on an indirect comparison between golimumab and other TNF $\alpha$  blockers.

**Negative Effects.** The profile of side effects for golimumab is consistent with the profiles of the other TNF- $\alpha$  blocking agents. The most frequent side effects are infections and a potential risk of malignancies.

**Experience.** The experience with golimumab is limited and less in comparison to the other treatments.

**Therapeutic Limitations.** Overall, golimumab is as broadly applicable as the treatments it is compared to.

**Userfriendliness.** Golimumab is more userfriendly, as it is administered less frequently than adalimumab en etanercept.

**In Conclusion.** The therapeutic value of golimumab in the treatment of *rheumatoid arthritis*, *psoriatic arthritis* en *ankylosing spondylitis* is comparable to that of the other TNF $\alpha$  blockers.

## Recommendations by the CFH

First choice for patients  $\geq 18$  years with active *rheumatoid arthritis* is the DMARD methotrexate, possibly with prednisone. When the response to optimally dosed methotrexate is inadequate, another DMARD or TNF-alpha-blocker may be chosen. This may also be done in case of contraindications for methotrexate or intolerance occurred.

For *psoriatic arthritis* the response to optimally dosed DMARD's needs to be insufficient, before treatment with a TNF-alpha blocker may be considered.

For *ankylosing spondylitis* treatment with a TNF- $\alpha$  blocker can be considered for serious, active spondylitis ankylopoetica and when at least two maximally dosed prostaglandinesynthase inhibitors and other conservative treatment does not yield a sufficient response; in case of periferal artritis sulfasalazine needs to be tried out first.

From an indirect comparison it appears that the efficacy and side effects for golimumab are comparable to that of other TNF-alpha blockers. Golimumab had no proven advantages, except for the less frequent administration in comparison to etanercept and adalimumab. If treatment with a TNF- $\alpha$  blocker is considered, the CFH recommends treatment with adalimumab, etanercept or infliximab, due to the limited experience with golimumab.