

Golimumab for psoriatic arthritis

Product:

GOLIMUMAB (Simponi®)

Class of drugs:

biologic response modifiers; tumor necrosis factor (TNF) alpha inhibitors

Indication:

psoriatic arthritis

Manufacturer:

Schering Plough Inc.

Highlights of Recommendation:

- ◆ Golimumab belongs to a class of drugs called tumor necrosis factor (TNF) inhibitors. Golimumab is licensed for use in several different indications. This review considered the use of golimumab in the treatment of psoriatic arthritis.
- ◆ Clinical study evidence supports that golimumab improves the signs and symptoms of psoriatic arthritis, including disease activity and physical function.
- ◆ Two different doses of golimumab, 50mg and 100mg every four weeks, were evaluated. The higher 100mg dose was not shown to be significantly more effective than the 50mg dose.
- ◆ There are no direct comparison studies evaluating the efficacy and safety of golimumab versus other TNF inhibitors. The Ontario Public Drug Programs currently fund two other TNF inhibitors for psoriatic arthritis; there is no evidence that golimumab is therapeutically superior to these alternatives.
- ◆ Golimumab costs approximately \$17,300 per patient per year when administered at the Health Canada recommended dose of 50mg once a month. At this dosing regimen, it may provide some cost savings relative to comparator products. However, the cost advantage is small and would not be realized if the drug was administered every four weeks (the dosing regimen used in the key clinical study).
- ◆ **Overall, the Committee noted that while golimumab is efficacious in the treatment of psoriatic arthritis, other TNF inhibitors are already funded for this indication. Golimumab has not demonstrated clinical superiority to available treatment options and the suggested cost savings may not be realized.**

Background:

Psoriatic arthritis is a chronic condition characterized by inflammation of the skin (psoriasis) as well as the joints (arthritis). Psoriasis is a common skin condition. Approximately 10% of patients who have psoriasis also develop an associated inflammation of their joints. Patients who have inflammatory arthritis and psoriasis are diagnosed as having psoriatic arthritis.

People with psoriatic arthritis experience pain, swelling and stiffness in the knees, elbows, spine, shoulders, fingers and toes. Some cases of psoriatic arthritis are mild and short-term, but many cases can be serious, causing severe pain, loss of ability to bend or walk, and permanent damage to joints.

Drug treatments for psoriatic arthritis include non-steroidal anti-inflammatory drugs (NSAIDs) to reduce pain and inflammation of the joints. Corticosteroids such as prednisone may be prescribed for short-term use to control inflammation. More severe disease requires treatment with disease-modifying antirheumatic drugs (DMARDs), such as leflunomide, methotrexate and sulfasalazine. Biologic response modifiers are a newer class of drugs that can be used to treat psoriatic arthritis and are thought to work by blocking a protein involved in inflammation.

Golimumab (Simponi®) is a biologic agent that belongs to a subclass of drugs called tumor necrosis factor (TNF) alpha inhibitor. It is indicated for moderate to severe psoriatic arthritis and can be used alone or in combination with methotrexate.

CED Recommendation

The CED recommended that golimumab (Simponi®) not be funded, on the basis that this drug has not been shown to provide added clinical benefits compared with available treatment alternatives and it is uncertain whether it offers an economic advantage.

Executive Officer Decision

Taking into consideration the CED's recommendation and based on a cost agreement with the manufacturer, the Executive Officer decided to fund golimumab (Simponi®) for the treatment of psoriatic arthritis through the Exceptional Access Program according to specific criteria.

Status

Funded through the Exceptional Access Program.

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Detailed Discussion:

- ◆ A single randomized controlled trial was identified for this review. This is a 24-week study comparing the efficacy of golimumab to placebo in 405 patients with moderate to severe psoriatic arthritis. Patients enrolled had active disease despite therapy with DMARDs and/or NSAIDs.
- ◆ At week 14 of the study, 51% of patients receiving golimumab 50mg every four weeks, compared with 9% of patients receiving placebo, experienced at least 20% improvement in arthritis signs and symptoms, as measured by the American College of Rheumatology (ACR) criteria. (The ACR criteria consist of swollen and tender joint counts, patient and physician assessment of disease activity, pain, physical function, as well as other markers of disease activity.)
- ◆ Other measures of arthritis and psoriasis symptoms were also found to be generally improved with the use of golimumab.
- ◆ The study reported no difference between patients treated with golimumab and those on placebo with respect to time lost from work.
- ◆ Two dosing regimens of golimumab were evaluated in the study. Efficacy appeared similar between patients who received golimumab 50mg and those who received 100mg every four weeks. Among patients who had their golimumab dose escalated from 50mg to 100mg due to lack of treatment response, limited benefit was observed from this dose escalation strategy.
- ◆ No significant differences were noted in the clinical trial between golimumab and placebo with respect to serious adverse events, infections, cancer, and withdrawals due to adverse events. However, the trial duration was short. Given that psoriatic arthritis is a chronic condition and long-term therapy would be required, the ability to generalize these safety results is limited.
- ◆ Patients who had previously tried other TNF inhibitors were excluded from the study. As such, the efficacy of golimumab in this patient population is unknown.
- ◆ Direct head-to-head studies comparing golimumab to other TNF inhibitors have not been conducted. There is no evidence that golimumab offers any therapeutic advantage compared to available alternatives.
- ◆ If administered at the Health Canada recommended dose of 50mg monthly (i.e. 12 doses per year), golimumab costs slightly less than other TNF inhibitors. However, if golimumab was given at 50mg every four weeks (the dosing regimen used in the clinical trial), its treatment cost would be similar to that of comparator products.
- ◆ **Overall, the CED noted that while golimumab is efficacious in the treatment of psoriatic arthritis, this drug has not been proven to provide clinical superiority or clear value for money relative to existing treatment options.**

EAP Funding:

Taking into consideration the CED's recommendation and based on a cost agreement with the manufacturer, the Executive Officer decided to fund golimumab (Simponi®) for the treatment of psoriatic arthritis through the Exceptional Access Program (EAP).

The EAP reimbursement criteria can be found at:

http://www.health.gov.on.ca/english/providers/program/drugs/pdf/frequently_requested_drugs.pdf



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

For more information, please contact:

**Ministry of Health and Long-Term
Care**

Ontario Public Drug Programs
Hepburn Block, 9th Floor
80 Grosvenor Street, Queen's Park
Toronto, Ontario M7A 1R3

or click: <http://www.health.gov.on.ca/english/providers/program/drugs/>