

Golimumab for ankylosing spondylitis

Product:

GOLIMUMAB (Simponi®)

Class of drugs:

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

Indication:

ankylosing spondylitis

Manufacturer:

Schering Plough Inc.

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 ankylosing spondylitis through the Exceptional Access Program according to specific criteria.

Status

Funded through the Exceptional Access Program.

Highlights of Recommendation:

- ♦ Golimumab belongs to a class of drugs called tumor necrosis factor (TNF) inhibitors. It is licensed for use in several different indications. This review considered the use of golimumab for the treatment of ankylosing spondylitis.
- ♦ Clinical study evidence supports that golimumab improves the symptoms of ankylosing spondylitis, such as physical function and pain. Golimumab has also been shown to improve a patient's quality of life.
- ♦ 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 three other TNF inhibitors for ankylosing spondylitis. 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 schedule used in the key clinical study).
- ♦ **Overall, the Committee noted that while golimumab is efficacious in improving the symptoms of ankylosing spondylitis, other TNF inhibitors are already funded for this indication. Golimumab has not demonstrated clinical superiority to comparator products and the suggested cost savings may not be realized.**

Background:

Ankylosing spondylitis is a chronic, inflammatory disease that mainly affects the joints between the spinal bones and the joints between the spine and the pelvis. Early symptoms include back pain and stiffness. Over time, ankylosing spondylitis causes the affected spinal bones to fuse together, causing significant pain and limiting movement. The disease can also cause inflammation in other joints away from the spine and in other organs (e.g. the eyes, heart, lungs, and kidneys).

There is no known cure for ankylosing spondylitis. The disease is managed with physical therapy, medications and surgery. No drug therapy has been shown to alter the progression of this disease. The primary drug treatment consists of non-steroidal anti-inflammatory drugs (NSAIDs), which help to reduce pain, swelling and stiffness. In some patients, the addition of corticosteroids and disease modifying anti-rheumatic drugs (DMARDs) may also be considered. Biologic response modifiers are a newer class of drugs that can be used to treat ankylosing spondylitis 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. Golimumab is indicated for reducing the signs and symptoms of ankylosing spondylitis in adults who have had an inadequate response to conventional therapies.

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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 356 patients with active ankylosing spondylitis despite having received maximal doses of NSAIDs or could not use NSAIDs due to intolerance or contraindications.
- ♦ At week 14 of the study, 59% of patients receiving golimumab 50mg every four weeks, compared with 22% of patients receiving placebo, experienced at least 20% improvement in their signs and symptoms, as measured by the Ankylosing Spondylitis Assessment (ASAS) criteria. (The ASAS criteria take into consideration physical function, inflammation, patient's assessment of the disease, and back pain.) Patients who were treated with golimumab also experienced greater improvements in various other measures of disease activity and in their quality of life.
- ♦ The study reported no significant difference between patients treated with golimumab and those on placebo with respect to time lost from work and spinal mobility.
- ♦ 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.
- ♦ 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 ankylosing spondylitis 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 or those with complete ankylosis of the spine were excluded from the clinical study. As such, the efficacy of golimumab in these patient populations 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.
- ♦ Similar to other treatments for ankylosing spondylitis, golimumab has not been shown in clinical studies to slow disease progression.
- ♦ 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 alternative TNF inhibitors.
- ♦ **Overall, the CED noted that while golimumab has been shown to improve the symptoms of ankylosing spondylitis, this drug has not been proven to provide therapeutic 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 ankylosing spondylitis 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



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