

Adalimumab (for psoriatic arthritis)

Product:

ADALIMUMAB (Humira), 40mg/0.8mL prefilled syringe injection

Class of drugs:

Biological response modifier

Indication:

Treatment of psoriatic arthritis

Manufacturer:

Abbott Laboratories Limited

CED Recommendation

The CED recommended that adalimumab (Humira) be funded through the Exceptional Access Program (EAP) for the treatment of severe psoriatic arthritis in adults, according to specific criteria.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer has decided to provide public funding for adalimumab (Humira) for the treatment of psoriatic arthritis through the EAP, according to specific criteria.

Status

Funding available through the Ontario Public Drug Programs under the EAP.

Highlights of Recommendation:

- ◆ Adalimumab (Humira) is a drug consisting of a genetically modified protein that blocks the effects of a natural protein, called tumour necrosis factor-alpha. The drug is used to treat adult patients with severe psoriatic arthritis. Psoriatic arthritis is a form of arthritis that only affects people who have psoriasis, a life-long skin condition.
- ◆ Drug treatment options for patients with psoriatic arthritis include pain relievers such as anti-inflammatory drugs, disease modifying anti-rheumatic drugs (DMARDs) that treat the underlying disease as well as the pain, and biologic response modifiers, such as adalimumab (Humira).
- ◆ Studies have shown that adalimumab (Humira) helps to relieve patients' pain and improve their ability to function, when compared to placebo. The benefits lasted for up to 48 weeks, for those patients who did improve while taking the drug. There was no significant difference in the rate of side effects for patients taking adalimumab (Humira) and those taking placebo.
- ◆ DMARDs include methotrexate, leflunomide and sulfasalazine. These drugs are available on the Ontario Drug Benefit (ODB) Formulary and cost up to \$4.79 per day. Adalimumab (Humira) costs approximately \$50 per day.
- ◆ Biologic drugs similar to adalimumab (Humira) include etanercept. Patients can receive funding for etanercept through the Exceptional Access Program (EAP) for the treatment of severe psoriatic arthritis. The cost of treatment with adalimumab (Humira) is similar to that of etanercept.

- ◆ Overall, the CED noted that the available evidence supports **adalimumab (Humira) as a reasonable treatment alternative for patients with psoriatic arthritis who have failed DMARD therapy**. The Committee made a positive recommendation that Humira (adalimumab) 40mg/0.8mL prefilled syringe be considered for reimbursement through the EAP for the treatment of psoriatic arthritis, according to specific criteria. Please refer to the "Detailed Discussion" section for details of the criteria.

Background:

Psoriatic arthritis is a disease of the joints that can affect up to 30 percent of people who have psoriasis. Psoriasis is a life-long skin condition that causes flare-ups of red and white scaly areas/patches on the skin.

People with psoriatic arthritis experience pain, swelling and stiffness in the knees, elbows, spine, shoulders, fingers and toes. Symptoms range from mild joint pain and swelling in a single-joint area to severe joint pain, inflammation and disfigurement in many joints. Both men and women are affected by this disease, and young children may develop it. 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.

Once diagnosed, treatments include specific exercises for the affected joints, the use of anti-inflammatory drugs including ibuprofen and naproxen and DMARDs.

Anti-inflammatory drugs are considered standard treatment for the pain associated with psoriatic arthritis.

Corticosteroids such as prednisone may be prescribed for short-term use to control inflammation, but there are side effects associated with long-term use. DMARDs are considered second-line treatment because of the more serious side effects associated with them.

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Detailed Discussion:

- ◆ The Committee reviewed three studies on the use of adalimumab (Humira) to treat psoriatic arthritis in adults.
- ◆ One study (Mease PJ, et al. *Arthritis Rheum* 2005; 52:3279-89) enrolled patients with psoriatic arthritis who had not responded adequately to treatment with non-steroidal anti-inflammatory drugs. Patients in the adalimumab (Humira) group showed statistically significant higher response rate, compared with placebo. The skin lesions of psoriasis, as indicated by the psoriasis area and severity index score, also showed greater improvement in the adalimumab (Humira) group versus placebo. Patients treated with adalimumab (Humira) also experienced less progression of joint damage and improved functional capacity and quality of life.
- ◆ The Committee noted that there are no head-to-head studies evaluating adalimumab (Humira) against DMARDs or other tumour necrosis factor (TNF) antagonists for the treatment of psoriatic arthritis.
- ◆ The Committee also noted that in the adalimumab (Humira) randomized controlled studies for psoriatic arthritis, no significant difference in the incidence of serious adverse events or withdrawals due to adverse events was observed between patients on adalimumab (Humira) and those on placebo. Potential serious adverse events with adalimumab (Humira) include life-threatening or serious infections, demyelinating disease, reactivation of tuberculosis, hepatitis B reactivation, and worsening of congestive heart failure.
- ◆ Common side effects include injection site reactions (redness, rash and swelling), headache and nausea.
- ◆ The results of the cost-effective analysis indicate that using adalimumab (Humira) as a treatment for psoriatic arthritis appears to be cost-effective.

- ◆ Overall, the Committee noted that adalimumab (Humira) represents a reasonable treatment alternative in patients with psoriatic arthritis who have failed DMARD therapy. The Committee recommended that adalimumab (Humira) be considered through the Exceptional Access Program under the following criteria:
 - For the treatment of psoriatic arthritis in patients who have had an inadequate response to consecutive trials of the following:
 - (1) Methotrexate 20mg/week for three months AND
 - (2) Leflunomide 20mg daily for three months
- If contraindications/intolerances to one of the above, then Sulfasalazine 1g bid for three months
- Patients must have a minimum of 5 swollen joints and have radiographic evidence of joint erosion.
- Duration: 1 year
- Renewals: Reviewed Externally

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee recommended that adalimumab (Humira) be listed with criteria/condition.



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