

## Recommendations and Reasons

Committee to Evaluate Drugs (CED)

### Abatacept

**Product:**  
ABATACEPT (Orencia®)

**Class of drugs:**  
selective co-stimulation modulator

**Indication:**  
rheumatoid arthritis

**Manufacturer:**  
Bristol-Myers Squibb Canada

### CED Recommendation

The CED recommended that abatacept (Orencia®) not be funded, on the basis that multiple alternative agents for the treatment of rheumatoid arthritis are already available and there is no good evidence that this drug provides added therapeutic or economic value compared to current treatment options.

### Executive Officer Decision

Taking into consideration the CED's recommendation and based on a subsequent cost agreement with the manufacturer, the Executive Officer decided to fund abatacept (Orencia®) through the Exceptional Access Program according to specific criteria.

### Status

Funded through the Exceptional Access Program.

### Highlights of Recommendation:

- ◆ Abatacept belongs to a group of drugs called biologic response modifiers or biologics. It is indicated for the treatment of rheumatoid arthritis.
- ◆ Studies versus placebo in patient with rheumatoid arthritis have shown that abatacept improves measures of disease activity, physical function and quality of life.
- ◆ There is insufficient evidence that abatacept is therapeutically superior to other biologic therapies for rheumatoid arthritis.
- ◆ Abatacept costs approximately \$17,000 to \$23,000 per year. The drug cost is similar to those of other biologic agents for treating rheumatoid arthritis.
- ◆ **Overall, the Committee noted that while abatacept is efficacious in the treatment of rheumatoid arthritis, multiple alternative therapies are already funded for this indication and abatacept does not offer significant therapeutic or economic advantages over available comparators.**

### Background:

Rheumatoid arthritis is a disease in which the body's immune system inappropriately attacks the joints and surrounding tissues. This leads to swelling, pain, and stiffness in the joints. Left untreated, patients develop permanent joint damage and deformity. The disease can also affect other organs, such as the skin, heart, lungs, blood vessels, and muscles.

The cause of rheumatoid arthritis is unknown. The disease usually requires lifelong treatment, including medications, physical therapy, exercise, education, and possibly surgery. Anti-inflammatory medications are typically used to help with symptoms of pain and swelling. Standard therapies consist of disease modifying anti-rheumatic drugs (DMARDs). Methotrexate, leflunomide and sulfasalazine are traditional DMARDs that are usually effective as first-line treatment. Biologic response modifiers are a group of drugs designed to target specific components of the immune system that play an important role in rheumatoid arthritis. Due to safety and cost-effectiveness reasons, biologic therapies are considered only after traditional DMARDs have failed. There is no good evidence that any drug therapy significantly alters the progression of rheumatoid arthritis.

Abatacept is a biologic agent that belongs to a subclass of drugs called selective co-stimulation modulators.

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## Detailed Discussion:

- ◆ The Committee considered the funding of abatacept on several occasions, most recently in July 2010.
- ◆ Several randomized controlled studies were reviewed. In studies that evaluated abatacept in patients who had failed either DMARDs or other biologic therapies, the use of abatacept, compared with placebo, resulted in more patients achieving disease response, as measured by improvements in the American College of Rheumatology (ACR) response 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.)*
- ◆ Quality of life improvements were also found to be associated with the use of abatacept.
- ◆ There are no studies that have assessed the efficacy of abatacept in patients who have failed both DMARDs and biologic therapies.
- ◆ Data comparing abatacept to other biologic treatments are lacking. Results from one study that compared abatacept to infliximab suggest that the two treatments provide similar efficacy. There is no evidence that abatacept offers any significant efficacy or safety advantage over alternative biologic treatments.
- ◆ Abatacept costs approximately \$17,000 to \$23,000 per year. The treatment cost is comparable to those of other biologic therapies. Abatacept has not been demonstrated to provide value for money.
- ◆ **Overall, the Committee acknowledged that abatacept has been shown to provide clinical efficacy in the treatment of rheumatoid arthritis. However, multiple therapies are already funded for this disease, and abatacept does not offer significant therapeutic or economic advantages over existing alternatives.**

## EAP Funding:

Taking into consideration the CED's recommendation and based on a subsequent cost agreement with the manufacturer, the Executive Officer decided to fund abatacept through the Exceptional Access Program (EAP) according to specific criteria:

The EAP reimbursement criteria can be found at:

[http://www.health.gov.on.ca/english/providers/program/drugs/eap\\_criteria.html](http://www.health.gov.on.ca/english/providers/program/drugs/eap_criteria.html)



Ministry of  
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Ontario Public Drug Programs

**For more information, please contact:**

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