# CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION Plain Language Version

## HUMIRA®

### (Adalimumab – Abbott Laboratories Ltd.)

*The information contained within this plain language version of the Canadian Expert Drug Advisory Committee (CEDAC) Final Recommendation and Reasons for Recommendation about this drug is based on the information found within the corresponding technical version of the CEDAC Final Recommendation and Reasons for Recommendation. Health care professionals and those requiring more detailed information are advised to refer to the technical version.*

**Drug**

Humira® is approved by Health Canada for reducing the signs and symptoms of Crohn's disease as well as stopping and preventing disease activity (bringing about and maintaining remission of Crohn's disease) in adult patients, with moderate to severely active Crohn's disease who are not responding well to other therapies including steroids (for example, prednisone) and drugs that block the immune system (immunosuppressants such as methotrexate and cyclosporine). Humira may also be used in patients for whom infliximab is no longer working or who cannot take it. (Infliximab, also known by its trade name Remicade®, is a drug that is similar to Humira and is also used to treat Crohn's disease.)

CEDAC previously reviewed Humira for the treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis.

**Dose**

Humira is injected under the skin. A recommended first dose for adults with Crohn's disease is 160 mg, followed by 80 mg two weeks later (when considered together, these two doses are known as "induction therapy"). After the induction therapy, the recommended ongoing (or maintenance dose) is 40 mg every other week, beginning four weeks after the first dose.

**CEDAC Recommendation**

CEDAC recommended that Humira be listed for coverage by Canada's publicly funded drug plans for certain patients with moderate to severely active Crohn's disease. This includes

patients who are not responding well to, or are unable to take other medications for their Crohn's disease, including 5-aminosalicylic acid, steroids, and medications that block the immune system. Such patients should use an initial Humira dose of 160 mg, followed by a dose of 80 mg two weeks later (induction therapy). Only patients who respond to their induction therapy should be covered for ongoing (maintenance) therapy at a maximum dose of 40 mg every two weeks.

### Reasons for the Recommendation

- When compared with commonly used medications for Crohn's disease, Humira has been shown to be better at stopping and preventing disease activity (inducing and maintaining remission). It has also been shown to improve some measures of quality of life.
- If patients do not respond to initial treatment (induction therapy) with Humira, there appears to be little benefit from further therapy with Humira.
- Treatment with Humira costs $20,700 in the first year and $18,000 each year after that. This cost is more than that for other commonly used treatments for Crohn's disease, but less expensive than the cost of Remicade®. Remicade costs $29,000 in the first year and $22,000 each year after that.
- There is limited information about using doses of Humira higher than 40 mg every two weeks; and the safety of these types of drugs is also a concern, so CEDAC does not support using more than 40 mg every two weeks.

### Summary of CEDAC Considerations

- CEDAC considered four studies of Humira in the treatment of patients with Crohn's disease. Two of the studies looked at starting patients on Humira, and two of the studies looked at the maintenance or ongoing treatment of the disease with Humira.
- The studies that looked at starting patients on Humira included 624 patients with Crohn's disease. These studies found that patients treated with Humira showed improvements in their quality of life and had higher rates of remission of their Crohn's disease than those taking no active medication (called a placebo medication).
- In one of the studies that looked at ongoing treatment with Humira compared to placebo, patients who responded to initial therapy showed improvements in their quality of life and had higher rates of remission after one year, if they continued to take Humira. Patients who did not respond to the initial therapy had no improvements in their quality of life or their rates of remission after one year with continued Humira treatment.
- A second smaller study (55 patients) of ongoing treatment with Humira found few differences between patients taking Humira for 56 weeks and those taking placebo.
- According to the information supplied in the Product Monograph, serious harmful side effects, including cancer or serious infections are possible, especially when Humira or other similar types of medication are taken for a long period of time.

### Background

The Canadian Expert Drug Advisory Committee (CEDAC) is a committee of the Canadian Agency for Drugs and Technologies in Health (CADTH). The Committee is made up of drug evaluation experts and public members. CEDAC provides recommendations about whether or

not drugs should be listed for coverage through the participating publicly funded drug plans; however, the individual drug plans make their own decision about whether or not to cover a drug.

In making its recommendations, CEDAC decides if the drug under review ought to be covered by the participating public drug plans based on an evidence-informed review of the medication's effectiveness and safety, and based on an assessment of its cost-effectiveness in comparison with other available treatment options.

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The manufacturer has reviewed this document and has not requested the deletion of any confidential information.