



SUMMARY OF AMENDMENTS

Report Title: *Therapeutic Review — CLINICAL AND ECONOMIC OVERVIEW
Biological Response Modifier Agents for Adults with Rheumatoid Arthritis*

Version to be updated: 0.0 (July 2010)

Version following completion of updates: 1.0 (November 2010)

This is a revised version of the Clinical and Economic Overview on *Biological Response Modifier Agents for Adults with Rheumatoid Arthritis*, originally published in July 2010. Revisions were made in response to concerns raised subsequent to the posting of the final report.

Modifications to the Overview were made to provide additional clarity to certain portions of the report; these changes were made by CADTH employees not involved in the conduct of the original therapeutic review. The updated version improves clarity surrounding the information that was presented to the expert committee (the Therapeutic Review Panel) for their deliberations. The changes to the original Clinical and Economic Overview are as follows:

1. Findings from ACR 50 efficacy meta-regressions and other sensitivity analyses for mixed treatment comparison (MTC) meta-analyses that were provided to the Therapeutic Review Panel for their deliberations are now presented in Table 2. These findings are discussed on pages 2-3 and 16-17.
2. The sentence, “meta-regressions conducted in the methotrexate-experienced population on variables such as baseline disease duration and control group response rates did not alter MTC conclusions considerably,” has been replaced with a more fulsome discussion (pages 16-17).
3. Cost-effectiveness analyses are presented in Appendix 6 (page 91). Although such analyses were conducted, the clinical inputs for the analyses were based on the results of the MTC meta-analyses, in which clinically meaningful differences in ACR responses were not observed. Consequently, the Therapeutic Review Panel focused their deliberations on the cost of biologics rather than the cost-effectiveness estimates.
4. A summary table, describing the studies that met the inclusion criteria for the therapeutic review, has been added to Appendix 1 (pages 27-29). This summary table, presented in an earlier (draft) version of the therapeutic review, provides details (see footnotes) as to how prior treatment experience (e.g., methotrexate-experienced) was categorized.
5. The modifications made to this Clinical and Economic Overview provide further clarity around information that was considered by the Panel in their deliberations; the recommendations made by the Therapeutic Review Panel remain unchanged.