# How Plan Sponsors May Start Restructuring Prior Authorization Criteria for Specialty Drugs

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As the first tangible piece of evidence focusing on the cost-effectiveness and clinical differences between the biologic agents used in the management of Rheumatoid arthritis (RA), the final recommendations from a recent study completed by the Canadian Agency for Drugs and Technologies in Health (CADTH), an independent government-funded agency, may transform the way plan sponsors handle expensive specialty drugs within their plans.

Specialty drugs (the catch-all category for the new expensive therapies entering the market today which includes biologic drugs) comprise the fastest growing segment of drug plan spending. By 2009, spending in this area increased to just over 14% of a plan's overall experience in the average working-age population. In the case of many plan sponsors, RA is, and continues to be, a significant cost-driver in this area. With the use of biologicals in the treatment of RA on the rise, it is important for plan sponsors to take a proactive approach to optimize the return on health investment for these products. Plan sponsors are encouraged, without delay, to ensure that the necessary Prior Authorization (PA) protocols, and stringent PA criteria, are in place to ensure the safe and effective use of these agents. This CADTH report is further evidence of how this is becoming a more mature area that will need to be looked at with a different lens moving forward.

Although there was a cost-effectiveness component in the CADTH study, the conclusions remain extremely controversial and may require further review. For plan sponsors, the value of the findings from this study lies in the insight it provides for structuring, or improving, existing PA programs for expensive specialty drugs.

| **TABLE 1.** Biologic agents available in Canada included in the CADTH Therapeutic Review |
|---|
| TNF-alpha inhibitors |
| Remicade® *(Infliximab)* |
| Enbrel® *(Etanercept)* |
| Humira® *(Adalimumab)* |
| Simponi® *(Golimumab)* |
| Cimzia® *(Certolizumab pegol)* |
| T-cell (CD28) co-stimulatory modulators |
| Orencia® *(Abatacept)* |
| IL-1 antagonists |
| Kineret® *(Anakinra)* |
| CD20+B-lymphocyte inhibitors |
| Rituxan® *(Rituximab)* |

Of all the biologics considered in this review, there were no significant differences in the efficacy, side effect or cost profiles between the following five biological agents: Orencia®, Humira®, Enbrel®, Simponi®, and Remicade®. Some of the key findings that can help plan sponsors establish or improve existing PA criteria include:

**Plan sponsors need to consider whether provisions surrounding dose escalations have been worked into their PA program.**

- Among the TNF-alpha inhibitors, the study found no significant evidence of increased benefit with increasing doses above the lowest dose recommended by Health Canada.
- Thus, the greater costs associated with higher doses cannot be justified by the lack of additional clinical benefit.
- The review panel noted that in practice, dose increases may be encountered most commonly with Remicade®.

**Since biologics are not first-line therapies in RA management, plan sponsors need to consider whether their PA program includes clear criteria that must be met prior to initiating therapy with a biologic.**

- Current evidence supporting the use of biologics in RA is only for patients who have failed to manage their disease state with traditional therapies. There is insufficient evidence to recommend the use of biologics in patients as first-line agents at this time.

**Is any follow-up evaluation done to ensure that plan members receiving these specialty agents are achieving the desired response to therapy in order to determine continuation of coverage?**

- The Canadian Expert Drug Advisory Committee (CEDAC) at CADTH recommends that response to treatment be evaluated after 14-16 weeks and that treatment with any biologic agent should be discontinued if there is no observed response to therapy. How many plans have criteria around initiation of therapy as well as continuation of therapy?

**Have plan sponsors considered tailoring their PA programs to include a stepwise approach used to optimize health return on investment with respect to the different classes of biological RA treatments?**

- There is some evidence to suggest that patients who fail on one biologic agent may achieve a better response from switching to another class of agents. However, it is important to note that this recommendation is based on a small number of studies and requires further investigation.
- Switching between biologics in the same class may be considered for patients who do not tolerate a given agent, but there is no good evidence to support that a different biologic from the same class would be any more effective.
- Observational studies do exist which suggest that switching patients to a different agent within the same drug class (i.e. TNF-alpha inhibitors) may offer some benefit to patients; however, the degree of benefit gained from this practice remains unknown.

The bottom line is that plan sponsors need to take initiative in managing their PA programs to ensure the right people are getting the right drugs when they are needed, and that they are in fact benefiting from their therapies. Without an effectively structured PA program with stringent criteria, there may be significant implications in terms of plan spending for RA in the future, including off-label use in some patients for non-Health Canada approved indications.