Feedback concerning the CADTH project scope for csDMARDs for Rheumatoid Arthritis

1. Do you think that the project as proposed in the project scope document will be useful to those making policy or clinical practice decisions? Why or why not?

The project scope places emphasis on standard economic and clinical outcomes. As we have also witnessed for many years in the rheumatoid arthritis space, there is a goal to seek evidence that can be applied across a population for the purpose of saving money on treatments, which is at odds with our idea as patients of being treated as individuals. We fundamentally understand the need for cost-savings, however caution that for some patients, this will come at a cost that has no monetary value – it will cost them their daily quality of living.

As organizations that represent people living with arthritis and/or who have vast first-hand experience living with the disease, we have taken most of the medication cited in the csDMARD list. The project scope does not sufficiently address patient preferences and important patient-reported outcomes, such as workplace participation, and the ability to carry out social roles such as parenting, as well as activities of daily living. These are important considerations when assessing the impact of a treatment regime that ultimately targets the quality of one's health status. It is imperative that health economists also realize the burden that conventional synthetic DMARDs (csDMARDs) have on people living with rheumatoid arthritis, in the form of daily nausea, vomiting, and a general malaise for days after treatment. Due to these experiences, many patients may not wish to take the medicine in question because the medication(s) are too difficult to take. This would ultimately impact adherence to treatment, increase health care costs (e.g. more visits to the doctor) and make it difficult for people living with rheumatoid arthritis to work, carry out social roles and participate in other activities of daily living.

Also worthy of mention is that some of these medications are contraindicated during pregnancy and breastfeeding, such as Methotrexate. As a result, this limits the usefulness of the information generated from this review in a real world setting particularly since many people with rheumatoid arthritis are women of reproductive age.

2. Are there policy, practice or research questions not considered in the project scope that are required to change or influence practice? If so, what would these be?

Given the side effect profiles of csDMARDs, it is valuable to consider measuring other important outcomes of interest to patients, such as workplace participation (e.g. absenteeism, reduced productivity), side effects (not just serious ones), and the impact on a patient's daily activities such as parenting children, running errands, etc. The ill effects of these medications can at times be felt for days after taking the medication.

3. Do you have any suggestions for improving the project as proposed in the project scope document?

It is recommended that the project scope emphasize that while findings will be population-based, it is important that each treatment needs to be tailored to unique patient circumstances. There are some situations where a patient may be willing to take csDMARDs particularly from a cost perspective. The recommendations made need to allow sufficient flexibility so that patients and physicians can make medication decisions suitable to their situation. Triple therapy should not become a barrier to access other available treatments if patient and physician decide it's the recommended treatment option.

Also, any changes to the guidelines for the treatment of RA must not be applied retroactively. This means that patients should not be required to try triple therapy if they haven't tried the csDMARD's before.

There are some medications missing from the proposed list including Azathioprine and Gold salts. Though they are not currently used extensively, there are some situations where they may still be used such as before or following surgery and even during pregnancy (Azathioprine).

We strongly recommend that you also engage organizations such as the Canadian Rheumatology Association or the Ontario Rheumatology Association in the review. The Canadian Rheumatology Association is currently updating its Rheumatoid Arthritis Guidelines, and two leaders from CAPA, Laurie Proulx and Dawn Richards (Vice-Presidents) are on that Guideline Committee. These professional associations represent world-class rheumatologists and clinicians who have been involved in treating hundreds of thousands of patients in Canada, developing and running national RA cohorts (one of which is one of the largest in the world, running for over 10 years and with over 3,000 participants in it – the Early RA Cohort led by Dr. Vivian Bykerk) as well as in developing and executing fundamental clinical trials globally. We strongly urge you to include these organizations in your work/discussions about the proposed project scope. It is unlikely they will reach out to you to provide input and we would be happy to make these connections for you in order to best advise the project scope.

4. Please provide any additional comments you may have about this document or the project itself, including any studies you think should be included in our review. (A list of included studies and the final project protocol will be posted at a later date.)

We appreciate the opportunity to be consulted on the draft project scope and hope to be kept updated as the project progresses. A CAPA Board member in the Ottawa area (Laurie Proulx) and Arthritis Society staff are available to discuss the findings, or even contribute to the project in some way (e.g. interpretation of outcomes important to people living with rheumatoid arthritis, connecting with the Canadian Rheumatology Association).