

Patient Group Input to Drugs for Management of Rheumatoid Arthritis

Name of patient group	The Canadian Arthritis Patient Alliance
Patient group's website	www.arthritispatient.ca
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Section 1 — General Information

1. Submitting Organization

CAPA is a grass-roots, patient-driven, independent, national education and advocacy organization with members and supporters across Canada. CAPA creates links between Canadians with arthritis to assist them in becoming more effective advocates and to improve their quality of life. We assist members to become advocates not only for themselves but for all people with arthritis. CAPA believes the first expert on arthritis is the person who lives with arthritis - ours is a unique perspective. CAPA welcomes all Canadians with arthritis and those who support CAPA's goals to become members.

2. Conflict of Interest Declarations

Sources of grants and support received by CAPA in the last year include: AbbVie Canada, Amgen Canada, Hoffman-La Roche, Eli Lilly Canada, Janssen, Novartis, Pfizer/Hospira, and UCB Pharma. Additionally, CAPA has received support in the past from: Arthritis Alliance of Canada, The Arthritis Society, Canadian Institutes for Health Research (Institute for Musculoskeletal Health& Arthritis), Canadian Rheumatology Association, Ontario Rheumatology Association, PfizerCanada, Rx&D, Schering Canada, the Scleroderma Society, and STA Communications.

We have the following **declaration(s) of conflict of interest** with regard to those playing a significant role in compiling this submission: None

3. Information-Gathering

The information was obtained through CAPA's Board which consists of Canadians living with various forms of inflammatory joint disease, including five board members with Rheumatoid Arthritis (RA) who live across the country. CAPA also has a wide network that frequently engages in dialogues around treatment for RA.

Section 2 — Treatment Outcomes

1. What would adult patients, their families, and caregivers like drug therapies for moderate to severe rheumatoid arthritis to achieve?

Patients, their families and caregivers would like drug therapies to achieve total disease remission without significant joint damage and impact on their lives. This would enable patients to have meaningful employment, have relationships and families, and a “normal” life that other Canadians without RA enjoy and potentially take for granted.

For patients with long term disease, for whom total remission may be unrealistic, they would like to have as low disease activity as possible to be able to live a life that is as productive and as pain free as possible.

2. If treatment were able to achieve these outcomes, what would it mean for patients', their families', and caregivers' daily activities and quality of life?

As alluded to in question 1, total remission would enable patients to live a “normal” life; be employed, raise a family, participate in social activities, which are all things Canadians who do not live with RA take for granted. If this outcome were achieved, disability would be prevented as well as significant health care system costs. This scenario sees people remaining employed, going to school, and able to live like they would without RA.

For patients with long term disease, low disease activity with pain levels that are managed, this they can conduct the necessary activities of daily life; dressing, bathing, sleeping and eating, avoiding or significantly delaying long term care facility placement and additional strain on the health care system. It may even allow them to participate in social activities and lead to a better state of mental health. Many patients in Canada are living with long term, established disease. It can be financially draining as some prescribed medications and necessary supplements are over the counter products thus patients must pay out of pocket for these prescribed treatments.

Patients often have to navigate the complex health care system on their own and frequently they do not receive optimal care. Simply receiving a diagnosis of RA and then being put on appropriate therapy is a years-long process.

Having a partner with severe, unmanaged RA is very difficult and can place severe strain on a relationship. They require assistance with the simplest of tasks; putting on socks, tying shoes, zippers, buttons, grocery shopping, child care, as well as all the psycho-social aspects of living with a serious, long term disabling condition. To have their partners pain controlled and achieve low disease activity takes a huge burden off of everyone in the household including children of a parent with RA who worry about how their mom or dad are able to cope with a disease that can mean hospitalizations and time away from the family.

Section 3 — Lived Experience

1. From patients' experiences outside of clinical trials, are there any notable harms or safety concerns with any of the drugs included in this project?

All drugs used for RA have the potential for harms and safety concerns. Drugs like methotrexate, while generally well tolerated, for some patients they can cause liver damage or severe, persistent nausea which greatly impacts ones quality of life and adherence to a treatment regime. The negative effects of the drugs can persist for several days. There is also a lack of research and information regarding the safety of taking some medications while trying to get pregnant, during pregnancy and while breastfeeding.

In 2016 CAPA launched a survey to identify patient information needs relating to pregnancy and parenting needs. The survey results indicated that:

- 88% of respondents indicated a high need for information about medication safety during pregnancy;

- 88% of respondents indicated a high need for information about medication safety during pregnancy;
- 82% of respondents indicated a high need for information about medication safety when breastfeeding;
- Access to and reliability of information is lacking (access/awareness ranged from 43% to 70% and reliability/quality of information as 30% to 70%).

Taking medications for RA always warrants a benefit/risk discussion, most of the time the benefits outweigh the risks as uncontrolled disease carries serious risks for patients as well.

Unfortunately health care providers are working under severe time constraints and medication counselling may be inadequate. Many CAPA Board members have experiences related to simply talking newly diagnosed patients through their concerns and fears about medications as they have read about side effects in advance and are extremely worried about these.

2. Describe any difficulties patients and their families have in using or accessing any of the drugs included in the project.

In addition to the issues seen with methotrexate mentioned in question 6, leflunomide can also cause serious liver issues. Hydroxychloroquine requires ongoing vision monitoring where there are shortages of specialists across the country to regularly follow patients. These vision issues are more common with greater cumulative exposure to the drug so long-term use over a person's lifetime may not be possible. As new drugs come onto the market, different side effects appear. For example, biologics cannot be taken in the event of an infection, patients must be hyper vigilant with a minor illness like a cold or the flu. Many of the drugs cause extreme sun sensitivity and patients must be careful when spending time in the sun. Repeated, weekly injections can result in scarring making future injections difficult and painful. This is also the case with the repeated, routine laboratory testing required with most drugs used for RA.

Biologics are costly, requiring special authorization and patients often encounter issues with getting the drugs approved, as well as affording co-pays. For example, for patients who do not have extended health care benefits, numerous steps are required for special access to these medications. Additionally, even for patients who have extended health care benefits, a co-pay of 20% can mean thousands of dollars annually of out of pocket drug expenses. Not all drugs are effective for everyone, each patient responds differently, and at this point in time, there is no test to predict who will best respond to which treatment. Even when drugs are effective they may only work for a short time and the drug may no longer be effective, necessitating frequent switching for many patients until they find the drug that works best for them. Treatment criteria in Canada warrant that Patients must fail to respond to certain criteria for two disease-modifying drugs in order to access a biologic. For those patients who do not respond to DMARD therapy, it they can result a significant delay to getting their disease under control, missing the optimal six- month window to avoid permanent joint damage.

Some patients report that travel while on a drug that requires refrigeration is a major challenge and is a constant reminder of how their life has become centered around their disease.

Section 4 — Additional Information

1. Please provide any additional information related to this project that would be helpful to CADTH.

CAPA has stated previously that, in addition to the RCT studies being considered for this project it is imperative that the existing Canadian biologic registries and RA cohort data also be included. The registries and cohorts provide fifteen plus years of real world evidence on the actual patient experience, both with biologics and early diagnosis/intervention with disease modifying drugs. While we understand that RCT data is the gold standard, it is also well known that the clinical trial environment is not realistic: many patients live with multiple co-morbidities and take medications for other diseases along with those for RA.

We feel that it must be recognized that there are two classifications of RA patients; the first classification is the patient whose disease has been well managed from the onset of symptoms.

These patients likely had a knowledgeable primary care practitioner who suspected RA as a diagnosis, live in an urban setting with access to more health care practitioners than those in rural settings, or have advocated aggressively for themselves, and as a result have been able to see a rheumatologist within a shorter period of time, and received access to medications earlier as well. The second classification is the patient with long standing disease activity that has not responded well to the available therapies or those who have fallen through the cracks in the health care system. Unfortunately, the data on disability prevention and health care system use reduction has not been adequately captured but we do know that there are significantly fewer inpatient admissions for RA patients in 2016 than prior to 2000 when the first biologic was approved for use in Canada.