

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Sarilumab (Rheumatoid Arthritis)
Name of the patient group	Canadian Arthritis Patient Alliance (CAPA) The Arthritis Society
Name of the primary contact for this submission:	Laurie Proulx/ Deanna Bowlby
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Permission is granted to post this submission	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

CADTH will post this patient input submission on its website if permission is granted.
See [CDR Update — Issue 99](#) for details.

1.1 Submitting Organization

Please provide an overview of the organization that is making the submission, including the purpose or aim(s) of the organization and an outline of the type of membership.

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, assists them to become more effective advocates and seeks to improve the quality of life of all people living with the disease. CAPA believes the first expert on arthritis is the individual who has the disease, as theirs is a unique perspective. We assist members to become advocates not only for themselves but all people with arthritis. CAPA welcomes all Canadians with arthritis and those who support CAPA's goals to become members.

The Arthritis Society has been setting lives in motion for over 65 years. Dedicated to a vision of living well while creating a future without arthritis, The Society is Canada's principal health charity providing education, programs and support to the over 4.6 million Canadians living with arthritis. Since its founding in 1948, The Society has been the largest non-government funder of arthritis research in Canada, investing more than \$190 million in projects that have led to

breakthroughs in the diagnosis, treatment and care of people with arthritis. The Arthritis Society is accredited under Imagine Canada's Standards Program. The website www.arthritis.ca provides more detailed information.

1.2 Conflict of Interest Declarations

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

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

The Arthritis Society does not believe that it or those individuals playing a significant role in compiling this submission have a conflict of interest that influences the information provided in this patient group submission. The Arthritis Society accepts funding from many pharmaceutical companies in order to work towards fulfilling its mission of enabling Canadians with arthritis to live well and be effective self managers and to lead and support arthritis research and care. In order to be fully transparent and meet the request to disclose pharmaceutical manufacturers who have provided support to the organization please be aware that over the past 12 months The Arthritis Society has accepted funding from the following members of the pharmaceutical industry: Abbvie, Amgen, Bayer, Bristol Myers Squibb, Celgene, Eli Lilly, Hospira, Janssen, Merck, Novartis, Pfizer, Purdue, Roche, UCB. The vast majority of The Arthritis Society's funding comes from individual donors as personal charitable giving.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

One of the authors of this submission received honoraria from Sanofi in 2015 in order to provide a presentation of the journey of a person living with inflammatory arthritis.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

One of the authors of this submission was originally diagnosed with Juvenile Idiopathic Arthritis therefore these personal experiences were considered in the development of this submission.

More information was obtained through personal experiences of the Board of Directors of the Canadian Arthritis Patient Alliance in living with inflammatory arthritis. The Arthritis Society had contact with one patient facilitated by a rheumatologist involved in the clinical trials. The Arthritis Society used social media to gather patient testimonials.

2.2 Impact of Condition on Patients

Rheumatoid Arthritis (RA) is a serious, disabling auto-immune disease that affects every aspect of a patients' day-to-day life. Patients are typically diagnosed when they are between the ages of 25 and 50. It affects three times more women than men and 1 in 100 Canadians are affected by RA or roughly 300,000 Canadians. There is currently no cure for RA – once a person develops RA, they live with it for the remainder of their life.

The disease is characterized by inflammation in the joints that destroys the lining of the joint and ultimately the surrounding bone resulting in the need for a total joint replacement. Once damage occurs, it is not reversible and can cause significant pain and disability. It is well documented that RA is a systemic disease and can be accompanied by fatigue and numerous co-morbidities, such as cardiovascular disease, osteoporosis and lung disease.

RA is a challenging disease to manage and physicians and patients often have to try different drugs to find something that works well. One patient said, "Finding the best RA treatment is hit and miss. It took quite some time to find a drug that fit my particular needs." Another patient said, "A lot has happened since I was diagnosed. We have gone through many trial and error paths in order to create a balanced point with my RA." In addition, a patient's immune system can adapt to a drug making it necessary to switch to another treatment when one becomes ineffective. As a result, patients require many medication options as treatment response is not possible to predict and changes over time. Research has shown and it is now common knowledge that newly diagnosed patients should be actively treated early in the disease to avoid irreversible joint damage, control pain and improve overall quality of life for the patient.

When the disease is not controlled, patients endure severe inflammation, pain and fatigue. It can be extremely difficult to undertake the following day to day activities:

- self-care
- sleeping
- pursuing post-secondary education
- becoming and staying employed
- walking
- completing housework, grocery shopping and cooking
- maintaining and pursuing relationships
- having and caring for children
- participating in social activities and hobbies.

Patients said:

- “Battling pain causes fatigue. Fatigue means you can’t do what you used to or what you want to which means a radical change in habits. I struggled to find a new career where I can be productive and also manage pain and fatigue.”
- “Controlling the deterioration of my feet, knees and hands is important. I still curl, but with a push stick. I still fish, but do not hold the rod long. I try to do everything I use to do, only slower and more carefully.”
- “I have pain, interrupted sleep, low energy and fatigue. I have compromised immunity, so I get sick easily and stay sick longer.”
- “Right now the RA is under control and I am functioning well. When I’m having a flare the usual is-fatigue, swelling and pain in hands, ankles, knees, wrists, all over body sore and swollen.”
- “I would like to be able to maintain a cleaner apartment. I need help completing tasks. I would like to be able to accomplish much more, faster and feel better about myself in the process.”
- “Daily activities are totally dependent on how I feel when I wake up. If I have a good night of uninterrupted sleep (10-12 hours), I am able to do more the following day (housework, grocery shopping, etc are difficult). My quality of life has decreased substantially in the past 10 years. I used to lead a very active work/personal life. Now, I expend most of my effort taking care of myself and trying to get well.”

Without control of the disease, major joint surgeries such as joint replacement or fusions can be required and possibly lead to multiple procedures throughout a person’s life. Because of the extensive damage to their joints, some patients who do not respond to the available treatments might also have to use technical or mobility aids such as bath lifts, canes or wheelchairs, have their house/car adapted and rely on para-transit to do daily activities. One patient said, “I need to depend on aids to assist me.”

The disease can also become a serious physical and psychological burden for the person living with arthritis and their families. One patient said, “Dealing with day-to-day issues is challenging, what other people without RA might not find problematic. Also challenging is convincing others, including doctors that I have authentic problems with depression, anxiety & stress.” Another patient said, “Trying to get on with life, but finding it hard when feeling so anxious and down.”

2.3 Patients’ Experiences With Current Therapy

Clinical practice guidelines emphasize early aggressive treatment of RA, which provides the best long-term outcomes for people with RA. A number of treatment approaches are used to manage RA including Non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and disease modifying (conventional synthetic and biological) anti-rheumatic drugs (DMARDs) such as Methotrexate, Etanercept and Infliximab. Effective treatments mean that people with RA do not need to live with the permanent damage, high medical costs (e.g. surgery, mobility aids,

accessible housing) and disability. Early intervention is an absolute necessity in order to allow people with arthritis the opportunity to fully participate in all aspects of life.

Notwithstanding this fact, patients' responses to medication can vary significantly. Some medications are effective for some people with arthritis while not effective for others. Some treatments will only manage the disease for a short period of time before the patients' immune system adapts to a drug presence (i.e. becomes non-responsive to it) and they will have to switch to another medication. In some cases, patients with RA may not adequately respond to any of the biologics currently available. One patient said, "I had to go through a lot of different drugs first before I was able to go on a biologic. I wish there was some way to tell if a biologic would be effective without having to wait six months for each one. I am now on my 6th biologic." Patients need a number of medication options in order to effectively manage their disease throughout their lives. There are also no specific tests that identify which medication will be effective for a person living with rheumatoid arthritis. This means that a person with the disease will need to go on one or more medications on a trial and error basis in order to find a medication that is effective. Often, the treating physician determines which medication is most appropriate based on a number of factors such as patient preferences, mode of administration, anticipated side effects, etc.

While side effects of existing treatments may vary, they can include: nausea and vomiting, extreme fatigue, decreased immune function (as current medications are immunosuppressants), injection reactions, and for biologics, auto-immunity is often developed to treatments after prolonged exposure. Some medications can only be administered through an infusion which can cause long-term issues with vein scarring and it can become increasingly difficult to insert the IV. There can be issues with tolerating Methotrexate (the standard of care) as it causes nausea, vomiting and diarrhea for 24 hours (and sometimes longer) after administration. Patients said, "With methotrexate it's very harsh in the stomach, I really dislike taking it." Another patient said, "Oral methotrexate made me sick for 3-4 days per week with nausea, diarrhea, and extreme fatigue. Using the injectable version of methotrexate, I feel nauseous and tired for one day, which is better. When your drugs cause you to feel unwell, it is a lot easier not to take them."

The patient on the clinical trial for Sarilumab said, "My basic treatment is drug control and a massage every three weeks which works great for the joints. Sarilumab has made the biggest difference in my dealing with RA. I have less inflammation and less pain. It is letting me get my strength and mobility back."

2.4 Impact on Caregivers

Depending on a person's ability to perform daily activities and their ability to be employed, caregivers of people living with RA are relied upon in varying capacities. Depending on the extent of disability or if the patient's disease is not well controlled, the spouse and family may need to help patients with RA with day to day activities such as bathing, getting in and out of bed, and getting dressed. Spouses or family members may need to take additional time off

work in order to assist the patient in activities of daily living. There may be additional costs to care for the person with arthritis if the spouse or family member is unable to do so (e.g. homecare, attendant care). This places strain on relationships and imposes additional financial hardships on the entire family.

These additional responsibilities have an immense emotional toll on both patients and their families. In some situations, a caregiver may give the patient their injection or need to take over family responsibilities while the person with arthritis is receiving their infusion or when medication side effects are being experienced (e.g. nausea, vomiting). The stress of dealing with uncontrolled disease can also cause additional psychological stress for the spouse, children and extended family. It can be difficult to watch the health of a parent deteriorate and this can cause ongoing stress for the child(ren) even when the parent is well.

Additionally, when patients do not have employer-provided insurance, it places additional stress on the spouse/partner to remain employed to retain drug coverage. The medication costs for RA are significant and these costs remain a constant consideration in managing a family's finances.

It is important to highlight that RA affects patients and caregivers and family members profoundly, in all aspects of their lives – and does so from the time of diagnosis and throughout their lives. New treatment options have the potential to ease the burden on patients' families, caregivers and the healthcare system.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The Arthritis Society had contact with one patient facilitated by a rheumatologist involved in the clinical trials.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

The patient on the clinical trial indicated less inflammation, less pain and a better quality of life outcome:

- “The positive is that I can do more things now with Sarilumab than when I was not taking it. Inflammation and pain is down, whether it is Sarilumab or the combination of the drugs I really do not care. Something is working for me. My liver counts are a bit higher, so I am to cut down on Methotrexate, other than that no side effects. The injections every two weeks are not a problem for me so I can feel better. I feel better than I did 5 years ago.”
- “Sarilumab has given me higher expectations for a better life. In fact, I can now go down on the floor and play with my grandkids even though it is still difficult to get up. I would not have thought this possible 5 years ago. I do not expect the deforming of my joints to

stop, but as long as I can keep doing things my body and mind are content with the future.”

Section 4 — Additional Information

Please provide any additional information that would be helpful to CADTH, CDEC, and participating drug plans. This could include suggestions for improving the patient input process, indicating whether the questions are clear, etc. N/A