

## Section 1 — General Information

<b>Name of the drug CADTH is reviewing and indication(s) of interest</b>	Baricitinib (Rheumatoid Arthritis)	
<b>Name of the patient group</b>	Canadian Arthritis Patient Alliance (CAPA) The Arthritis Society	
<b>Name of the primary contact for this submission:</b>		
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<b>Permission is granted to post this submission</b>	<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 Organizations

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 for themselves as well as 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.

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](http://www.arthritis.ca) provides more detailed information.

### 1.2 Conflict of Interest Declaration

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, Amgen, Eli Lilly, Hoffman-La Roche, Janssen, Purdue, Novartis, 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, Pfizer Canada, Rx&D, Schering Canada, the Scleroderma Society, and STA Communications. The Vice President of CAPA is also an independent consultant and has received speaking fees as well as honoraria from AbbVie, Amgen, Eli Lilly, and UCB Pharma in the past year.

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, AstraZeneca, Bayer, Celgene, Eli Lilly, GSK, Hospira, Janssen, Merck, Novartis, Pfizer, Purdue, Roche, Takeda, 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:*

None.

## Section 2 — Condition and Current Therapy Information

### 2.1 Information Gathering

We conducted a brief phone interview with a person who was diagnosed with rheumatoid arthritis 10 years ago, who participated in a clinical trial for baricitinib, and who remains on baricitinib (and has been for a few years). Other information here was obtained through personal experiences of the Board of the Canadian Arthritis Patient Alliance in living with rheumatoid arthritis, in addition to many years of interfacing with our membership. The Arthritis Society had 35 people living with rheumatoid arthritis respond to a social media request for information for this CADTH submission. Of those 35 respondents, none were participants in the clinical trial for baricitinib.

## 2.2 Impact of Condition on Patients

For the patient we interviewed, her first symptom of rheumatoid arthritis (RA) was that her left index finger was swollen like a sausage. Given that her mother had rheumatoid arthritis, she had bloodwork done within a week of her symptom onset by her family physician, and given her high rheumatoid factor results, started on very high doses of ibuprofen. Within a few weeks, she could barely walk from her car to the subway station to get to work in the morning since her feet were so swollen and painful, her arms hurt, and she felt overwhelming fatigue. In addition to these symptoms, she often experienced fevers and life in general became a real struggle. This individual lives by herself, without the support of a spouse or children. This person also feels that she lost her job because of her rheumatoid arthritis – given that she worked for very small firms, her absenteeism due to illness profoundly affected her office’s output. Losing employment as a single person also led to losing any extended health benefits that were contingent upon employment.

Like many people living with RA, a variety of symptoms may be experienced, from swollen and stiff hands, fingers, feet and toes, to feeling pain in other joints of the body (including the neck and shoulder). Some patients experience morning stiffness and swelling which makes getting out of bed and dressing a real challenge. Ongoing fatigue can impact one’s quality of life. People living with RA told us:

- “Stiffness and pain in hand, wrist and feet joints, including significant inflammation. Controlling the inflammation is essential, as well as the pain, so I can continue to work full-time on top of being a mother, wife and working a high stress full-time teaching job. I am limited in many physical activities i.e. cannot run, do yoga, lift heavy objects. The other aspect of RA that is essential to treat is fatigue, which impacts all areas of my functioning.”
- “I have RA in my fingers. The inflammation can often make typing and writing painful.”
- “RA impacts every aspect of my life. It affects my joints, my eyes, and my lungs. Simple tasks most people take for granted take me a long time to complete, doing up a zipper, putting on socks, brushing my teeth, tying my shoes. I have to plan every aspect of my day and am very dependent on family members for help.”
- “Every day is a challenge. Getting dressed. Holding a toothbrush. Organizing medications. Remembering to take medications. Feeling like crap from medications. Wishing you didn't have to take handfuls of pills and stick needles in yourself all the time. Driving is difficult during flares. Not wanting to leave the house or socialize because the medications are making you sick. Having to buy elastic waist pants because your shoulders are so inflamed you can't pull up a pair of jeans. Feeding your kids cereal and bananas instead of cooking supper because you just aren't capable of doing anything else but they need food. Trying to explain to your boss why you're crying in the walk-in cooler when he finds you pressing your severely inflamed hands against the walls one day at work because it provided a moment of relief.”
- “Painful morning stiffness. Using a towel to dry off after a shower, cutting foods, buttons, writing, typing, opening the car door, food preparation, putting on socks and shoes, shaking hands and on it goes. Pain is constant and distracting. Such energy spent trying to tolerate it and the subsequent fatigue.”

- “Fatigue and pain are hard to hide from others. It is a constant struggle for me to try to control these things. I am constantly hiding fatigue and pain to the best of my ability from everyone around me. Stairs are almost impossible for me to do now.”
- “The inflammation which causes excruciating pain and takes away my ability to function, whether that is just getting out of bed or having to use my hands daily as I work as an administrative assistant. There are often days when just the thought of getting out of bed makes me cry, as I know the moment I put weight on my feet I will be in excruciating pain. I have had to adjust my life and give up many activities I once enjoyed - running, horseback riding, long walks, refurbishing - my hands ache more and more these days. With my job, where I must use my hands to type every day, by the end of the day on Fridays I know I'll be wearing my splint for the next two days. Even just wearing jewellery, I used to wear rings on every finger, now due to the swelling I can't wear even my wedding ring. So many changes when one is diagnosed with RA.”

Some people may also experience nodules or ‘goose eggs’ in various joints such as those in wrists, accompanied by pain.

Depression and mental health issues can be significantly associated with RA. The patient we spoke to has been treated twice over 13 years for significant episodes of depression – something she had not experienced before her diagnosis. This is what others living with RA told us:

- “Symptoms that impact my day-to-day life and quality of life: fatigue; pain (of varying amounts); and feelings of depression. The effects of these symptoms on my job are what you'd expect. I cook for a living so, of course, RA makes it much more difficult to physically function. It's also hard to explain to my boss and to my staff why I'm fine then suddenly not fine or the other way around. Invisible illness is nearly impossible to relate to, for anyone not experiencing it.”
- “My self is a shadow of what it was. I was an avid swimmer, cyclist, canoeist, cross country skier, skater, walker and hiker. I still swim and struggle walking, aided by Nordic poles every day. I am also a writer (novelist), which is grinding to a halt because of the fatigue and low feelings accompanying this condition.”

### 2.3 Patients' Experiences With Current Therapy

Like many people who live with RA, the patient we talked to tried a plethora of medications over time to treat her symptoms – though not to cure her, since there is no present cure for RA. Some of the medications she has tried in her 13 years with RA have included: methotrexate by self-injection, Plaquenil, Arava, Remicade (which she had to quit given that she ended up with pleurisy), stayed on Arava, tried Enbrel (which alleviated most of her symptoms for about a year until she started to develop repeated/constant sinus infections), went back to methotrexate and Naproxen (as needed), and over the years has also received cortisone shots when required. This individual stayed on this sub-par combination of drugs for many years, until she went on to a clinical trial for baricitinib. Hearing about the multiple types of medications that a person with RA takes and tries over many years is not an anomaly. Finding a therapy that helps control a person's RA becomes a life-long journey; many therapies work well for years at a time and then for unknown reasons, stop working.

### 2.4 Impact on Caregivers

Depending on a person's ability to cope with activities of daily living and their ability to still be employed, caregivers of people living with RA are relied upon in varying capacities. In some cases, caregivers are required to assist with simple tasks such as bathing, getting in and out of bed, getting dressed, and even using the toilet. The emotional toll on both patients and caregivers in this type of situation cannot be underscored enough. In other situations, a caregiver's burden may not be as great, perhaps giving the patient their injection or needing to take over family responsibilities while the patient is receiving their infusion. Living with a chronic condition as potentially debilitating as RA can profoundly impact the affected person psychologically as well as their caregivers. Additionally, when patients do not have drug coverage options, and their spouse serves as their caregiver, this adds to the burden of disease in unimaginable ways.

It is important to highlight that RA affects patients, caregivers and family members profoundly, in all aspects of their lives – and does so from before their diagnosis and throughout their lives. People living with RA told us:

- “At home, RA creates tension between myself and my husband because he sometimes feels like he's carrying an unfair burden. It could be anything from having to bring in a larger part of the income, to parenting, to plain old housework. My kids are little, but old enough to know their mom isn't like other moms. My daughter cried yesterday because I told her I couldn't go ice-skating with her grade one class. I cried in secret when she wasn't looking. Some days I'm too tired to bathe myself. Some days I sleep in my clothes because I am in so much pain that I am not able to dress myself for work in the morning and since I wake up at 4 am there's no one else up to help me. I could go on but I'm sure you're getting the picture.”
- “My challenges are pain and fatigue mainly. My wife left me saying she did not marry a disabled man.”
- “I am not able to work. I went on disability 6 years ago. I need my husband to shop, clean, wash etc. It takes all my energy to go to my doctors' appointments. I am still able to be in my church choir, although I do not practice with them.”

## Section 3 — Information about the Drug Being Reviewed

### 3.1 Information Gathering

We conducted a brief phone interview with a person who was diagnosed with RA 10 years ago, who participated in a clinical trial for baricitinib, and who remains on baricitinib (and has been for a few years). Other information was obtained through personal experiences of Board members of the Canadian Arthritis Patient Alliance living with RA, in addition to many years of interfacing with our membership. The Arthritis Society had 35 people living with RA respond to a social media request for information for this CADTH submission. Of those 35 respondents, none were in the clinical trial for baricitinib.

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

#### a) *Based on no experience using the drug:*

This is what we heard from people living with RA who had no experience with baricitinib about their expectations:

- “Reduce the inflammation so that I can work - operate day to day without so much excruciating pain.”
- “Looking for fewer flares, less time off work, less money in extra treatments.”
- “I would hope for more good days than bad and to slow the progression of the disease which has already begun to affect several more joints and organs.”
- “If I were to try it, I hope it would control flares allowing for better sleep and less time off work.”
- “Pretty much any improvement would enhance my quality of life right now. As for side effects, I would not be willing to experience anything that makes me miss work regularly. I simply cannot afford the time off. I would consider an adequate improvement in my condition waking up with stiffness and pain that subsided rather than stayed, and infrequent rather than constant flares. I'd like to know what it's like to not be so damned tired all the time.”
- “More energy and less deterioration of joints would be the reason I would consider taking this drug. Also, only if my current medication is not working.”
- “Decreased joint pain and decreased inflammation. Preferably oral dosage with no gastric side effects and minimal drug interactions, resulting in improving consistency of joint health allowing increased activity.”

#### b) *Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:*

Within about 2-3 days of starting baricitinib, the patient we spoke to indicated that she felt immediate relief from a great deal of her RA symptoms. She indicated that the feeling was completely overwhelming and that she “wanted to run instead of walk.” At this point in time, she has been on baricitinib for about 4 years. Overall she indicated that she feels about 90% better than she has since she was originally diagnosed, and her fatigue is significantly improved. The patient indicated she catches colds a lot but is unsure if that is the medication or where she works (in a medical clinic). She indicated that she does not feel that she experiences any real side effects associated with this particular medication. She feels that the drug has been “life-changing” and could not imagine going on another medication given the side effect issues she has experienced with others. While she sometimes still experiences flares that are often part of living with rheumatoid arthritis (i.e. times when one's disease activity is greatly increased), these flares typically only last for a day versus many days on end.

Baricitinib is in pill form (2 pills every morning) and the patient indicated it is much easier to manage than self-injection or infusions of other medications (for example, when she took Enbrel, she had a grapefruit-sized lump for hours post-self-injection, and with her Remicade infusions, she would spend all afternoon to get the infusion, which required time off work). She feels that compared to biologics she has been on in the past, baricitinib has presented her with very few side effects.

#### **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.