

CADTH COMMON DRUG REVIEW

# Patient Input

**OLUMIANT (baricitinib)**

(Eli Lilly Canada Inc.)

Indication: Arthritis, Rheumatoid

CADTH received patient input from:

**Arthritis Consumer Experts**

**The Arthritis Society & Canadian Arthritis Patient Alliance**

January 18, 2019

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**C/O:** Canadian Agency for Drugs and Technologies in Health (CADTH)

**Re:** Patient Input for baricitinib (Olumiant) for rheumatoid arthritis

**Date of submission:** January 18, 2019

**Section 1 — General Information**

**Name of the drug:** baricitinib (Olumiant)

**Indication of interest:** rheumatoid arthritis

**Name of patient group:** Arthritis Consumer Experts

**Name of the primary contact for this submission:**

Cheryl Koehn, President



**Name of author (if different):**

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**Permission is granted to post this submission:** Yes

**Section 1 – About your Patient Group**

Canada's largest, longest running national arthritis patient organization headquartered in Vancouver, BC, Arthritis Consumer Experts (ACE) provides free, science-based information and education programs in both official languages to people with arthritis. ACE serves people living with all forms of arthritis by helping them take control of their disease and improve their quality of life through education and (em)powerment. Founded and led by people with arthritis, ACE also advocates on arthritis health policy issues, through ACE's

JointHealth™ family of programs and the Arthritis Broadcast Network, directly to consumers/patients, media and government. ACE operates as a non-profit in a fully transparent manner and is guided by a strict set of guiding principles, set out by an advisory board comprised of leading scientists, medical professionals and informed arthritis consumers. Ultimately, we are guided by the needs of our members, who are people living with arthritis, and their caregivers.

Link to website: [www.jointhehealth.org](http://www.jointhehealth.org)

## **Section 2 – Information Gathering**

The information was gathered in Canada on the ACE Survey Monkey platform from December, 2018 to January, 2019, without assistance or funding from an outside source. Input was compiled and made grammatically correct by A.Chan and C. Koehn, employees of ACE.

## **Section 3 — Disease Experience**

### **3.1 How does the disease impact the patients' day-to-day life and quality of life?**

Rheumatoid arthritis (RA) has a significant effect on the lives of people living with it and they constantly consider the state of their disease and decide what they can, or more likely, cannot, cope with or achieve, how they can go about their daily lives, and how much help they may need along the way.

- Patient A: Diagnosed with RA on August 13, 2010, after a year of suffering and a diagnosis of post shingles pain and polyrheumatica. They gave up certain athletic activities and can only do gentle activities that are easier on the ankles and feet. Because their current medication treatment works, the only symptom they feel is fatigue.
- Patient B: Has been living with RA for 30 years. Because of their RA, they “walk with a limp, cannot stand for too long, and can only walk short distances”.
- Patient C: Has been living with RA since 2004. They also have lupus, MGUS, CTD, fibromyalgia and spinal stenosis. They added: “I’m depressed because of severe pain. I want to sleep and never wake-up.”
- Patient D: Has been living with RA for 28 years. Here is how RA impacts their life: “I have very difficult to treat RA and I have exhausted all current therapies and remain on prednisone which gives me a lot of side effects, and I require therapy to protect my bones. I can work, but it is difficult for me and I’m about to have my 11<sup>th</sup> orthopaedic surgery for which I will have to take off another 6 weeks on short-term disability.”
- Patient E: Diagnosed with RA in 1996, and also has osteoarthritis and Type 2 Diabetes. RA has “limited my ability to work, volunteer, take care of my house; I have had to learn new ways to maintain an independent life style, it has made it

harder to get involved with people and do things for myself and others.” They feel that physicians don’t communicate with rheumatologists and vice versa.

- Patient F: Diagnosed with RA in 2009. It went into remission after several years but came back in 2017. In addition, they have SLE and a recent diagnosis of MGUS. Living with RA is a daily battle.
- Patient G: Has been living with RA for 8 years and also has hypothyroid. It is important to manage pain, fatigue, and flares: “The fatigue is almost always present, and at times, it takes everything not to crash asleep.”
- Patient H: Has been living with RA for 18 years and lives with constant fatigue, stiffness and pain.
- Patient I: Has been living with RA for 12 years. RA affects their daily life.
- Patient J: Has been living with RA since 2015 and also has thyroid gland problems. They experience pain, joint stiffness, fatigue, and side-effects from current medications.

### **3.2 How does the disease impact the caregivers’ day-to-day life and quality of life?**

Caregivers of people living with rheumatoid arthritis have indicated that time management is very important to them. When patients are in pain, caregivers have to help with house chores and many other aspects of life at home.

- Patient A, I and J: No comments for this section.
- Patient B: “I have not experienced any need for caregivers to date”.
- Patient C: Their caregiver has to take advantage of Family Medical Leave. It is physically taxing on the caregiver because they have to drive Patient C everywhere. In addition, they have to pay for gas and the caregiver’s meals.
- Patient D: “My 80 year old mother and my friends have to help me after I have surgery, and this is a significant burden, as well as having to ask.”
- Patient E: “My caregivers are facing the same challenges as me.”
- Patient F is thankful that her daughter is able to take Family Medical Leave and summarized: “As a patient, we PROJECT a lot...as caregivers, they TAKE a lot.”
- Patient G: “My husband is so patient, and will take over some of my chores (and yes, he has his own!) with no complaint, on the days that are especially bad. Talking to me while I am suffering from a brain fog episode is next to impossible.”
- Patient H: Does not require a caregiver at this time.

### **3.3 Are there any aspects of the illness that are more important to control than others?**

- Patient A: “Pain and flares.”
- Patient B: “Pain and deformation of the joints because it affects how mobile I am.”
- Patient C: “Pain and joint and organ damage.”
- Patient D: “Joint pain and swelling to prevent damage, cardiovascular risk and medication side effects.”
- Patient E: Feels that the cost of the disease affects how they feel and are treated.

- Patient F: “Pain, joint deterioration, treatment and cost.”
- Patient G: “Pain. Fatigue. Brain fog. Ability to exercise. Ability to work consistently at a full time job. It’s disheartening to think that the disease is progressive, and can be doing permanent damage to your joints. It can also affect your organs like lungs, heart, etc. This has little research associated with it which is even more disheartening. Also, many of the existing remedies can be very harmful to the patient.”
- Patient H: “Pain, fatigue, and stiffness.”
- Patient I: No comments for this section.
- Patient J: “Stiffness, insomnia related to pain, medication management and secondary effects.”

#### **Section 4 – Experiences with Currently Available Treatments**

##### **How well are patients managing their disease/condition with currently available treatments?**

- Patient A: Currently taking Humira and it seems to work. They participate in physical activities to stay active. They also visit a registered massage therapist and ensure they get enough rest and sleep. They do not have trouble accessing treatment but added: “I need time to take care of myself, along with all other responsibilities”.
- Patient B: Taking methotrexate (20mg) once a week, and 250mg chloroquine phosphate twice a week. “The meds keep the inflammation under control and keeps me mobile.” Their rheumatologist prescribed methotrexate after trying other medications, including Celebrex. They experienced serious hypertension and cardiac issues due to Celebrex.
- Patient C: Currently taking or has taken the following treatments: Plaquenil, prednisone, methotrexate, Humira, Celebrex, Benlysta infusions, and Rituximab infusions. None of the therapies work. Non-medication therapies include aquatic exercises, diet and weight loss. “Most of my therapies have to be infusions because I have a very sensitive stomach and will develop ulcers.” The following needs must be met: financial support for treatment therapies and travel, and better access to doctors or hospitals.
- Patient D: Currently on methotrexate, prednisone, and Cosentyx even though it is not approved for RA in her province. Xeljanz made them catch viruses all the time; prednisone caused bleeding risks; IL-6 inhibitors caused a clotting problem that led to severe bruising; and infliximab caused frequent colds. All of the other therapies have failed. “I would like to get off prednisone. I also require ankle injections every 8-10 weeks for the swelling. They have just increased my Cosentyx again to try and maintain efficacy.” Adverse effects that are more difficult to tolerate are “nausea and vomiting for 1 day post methotrexate, decreased bone density, excess weight, severe stretch marks and cataracts from corticosteroids.” They experience hardship paying for Cosentyx. “Neither my insurance companies will cover Cosentyx for RA (approved for PsA and AS despite good effect in RA) and fortunately, my province has provided me coverage through special program. I struggle with injection site

reactions from biologics with all but one agent. I hate having to take pills, especially more than once a day. IV infusions are inconvenient and take away from my work.”

- Patient E: Managing their RA with diet, medications, pain management, exercise, and relaxation. They also see counsellors, a psychiatrist, a psychologist, and general practitioners (on the 4<sup>th</sup> one since 2013). It is most difficult to deal with physical pain and learn new ways to maintain an independent lifestyle. “In the current health care system, I don’t have the required cash to access the system to access testing and knowledge that could help me understand how the disease affects my body.”
- Patient F: Tried prednisone, methotrexate, Plaquenil, and immuno-therapy (Methylprednisolone, Rituximab, Benlysta). Side effects from the medications make the “effectiveness not so effective.” Due to GI issues, they have to do IV therapy at hospital every 4 months. It is especially hard to tolerate nausea and weight gain from taking steroids. They want more financial support and find it time-consuming to do infusions and visit their doctors for monthly lab tests.
- Patient G: Takes weekly, injectable methotrexate and Rituxan infusions every 6-8 months. For NSAID, I use Naproxen/Aleve. When diagnosed and while waiting for the drugs to take effect (around 3 months), they needed a cane to walk. “I can’t imagine the quality of life without my meds. Then again, they make the symptoms less. They don’t get rid of them. There is still sufficient pain and fatigue.” This patient lives in a large city and has no problem accessing infusion clinics. Taking the time off work (4 days if getting the Rituxan treatment twice a year) can be a problem. They also commented that blood tests to determine liver damage from methotrexate can be difficult for those not in a larger urban centre. They could not tolerate swallowing the sulfasalazine pills as they were too large and numerous, with too many side effects. With Plaquenil, eye exams were common and they eventually developed eye problems.
- Patient H: Currently taking Enbrel, methotrexate and Celebrex. They also do aqua fit, yoga, Pilates, and step and weight exercises. Pain and fatigue are more difficult to tolerate than other symptoms.
- Patient I: Self-injects medications weekly, which they dislike. They also swim once a week, walk daily, and do stretch exercises. Physical activities are helpful in building muscles.
- Patient J: Currently takes methotrexate, Plaquenil, Vitamin B12, Folic Acid and multivitamins. They experience excruciating stomach pain from methotrexate injections and find it easier to take pills. The symptoms that are difficult to tolerate include stomachaches, diarrheas and bloating. A medication that does not cause ulcers would be ideal.

### **Section 5 – Improved Outcomes**

- Patient A, E, F, and I: No comments for this section.
- Patient B: “Concerned about the potential scary side effects as seen in the US TV shows, unfortunately”. They will try baricitinib, subject to other “acceptable and not serious effects”.

- Patient C: Willing to try baricitinib and expects it to help with pain relief and joint preservation.
- Patient D: “Medications are available with efficacy but they are not available, despite good evidence. If the company chooses not to market it for the disease, it then is not available (for example, Cosentyx had similar effect to other biologics in RA but the company chose not to market it for that, because there is too much competition). We need all the available drugs to us, as there are a lot of us who have been on all available agents. My understanding is that baricitinib is more effective, and less problematic with infections, as well as only once a day.” They are willing to try baricitinib and take the small risk of a serious adverse event even if it only improves disease activity by 50%. It means they can work longer and decrease prednisone needs.
- Patient G: Feels having more information on how to live day-to-day with RA would be very helpful and added: “I was fortunate to have a program available that really helped but wasn’t personalized. And there was no follow up a year later, to see where the problems remained. How do I exercise now? What are my personal problems in the home? How can my family help? What does my boss need to know?”
- Patient H: Hopes the lives of patients will be improved with new therapies such as baricitinib. The ability to perform activities of daily living without pain and limited fatigue would be adequate.
- Patient J: Feels better access to doctors is needed. Also, patients need to have a meaningful conversation with their healthcare professionals to alleviate the fear of “too much meds”.

### **Section 6 – Experience with Drug Under Review**

Although none of the patients interviewed have experience with using baricitinib for rheumatoid arthritis, two provided comments for this section:

- Patient D: Biologics stopped working within 1-3 years and they had to move on to another biologic. Since baricitinib is a once a day tablet, “adherence to medication will be easier and I won’t have to worry about injection site reactions or headaches from injection. If I could go an extended time without needing to switch drugs, that would make everything easier for me.”
- Patient G: When considering new therapies, they feel that “Any new therapy needs to be weighed against the other available therapies. If baricitinib manages my symptoms better, if it manages them the same but with less side effects, if it manages them the same but is cheaper, or easier or more convenient, then yes, I would love to consider it.”

### **Section 7 – Companion Diagnostic Test**

Not applicable to this submission.

### **Section 8 – Biosimilar**



Not applicable to this submission.

### **Section 9 – Anything Else?**

Arthritis Consumer Experts believes that a new, cost-effective therapy with an acceptable safety and efficacy profile can improve the quality of life for people living with severe arthritis, and who are refractory to current Health Canada approved, publicly reimbursed medications. ACE made minor grammatical corrections to input where needed that in no way altered the meaning or intent of the input.

### **Appendix: Conflict of Interest Declaration**

- 1) Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

This submission was researched and written solely by the staff of Arthritis Consumer Experts, free from consultation, advice, influence, or financial support from any outside individual, group or company.

- 2) Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

No.

- 3) List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Arthritis Consumer Experts received a grant-in-aid from Eli Lilly Canada in 2018.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Eli Lilly Canada				X

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Cheryl Koehn

Position: Founder and President

Patient Group: Arthritis Consumer Experts

Date: January 18, 2019

# Patient Input Template for CADTH CDR and pCODR Programs

<b>Name of the Drug and Indication</b>	Baricitinib (Rheumatoid Arthritis)
<b>Name of the Patient Group</b>	The Arthritis Society & Canadian Arthritis Patient Alliance
<b>Author of the Submission</b>	[REDACTED]
<b>Name of the Primary Contact for This Submission</b>	[REDACTED]
<b>Email</b>	[REDACTED]
<b>Telephone Number</b>	[REDACTED]

## 1. About Your Patient Group

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 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 \$200 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.

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. CAPA believes the first expert on arthritis is the person who lives with arthritis, and is an organization for patients run by patients. CAPA welcomes all Canadians with arthritis, and those who support CAPA's goals, to become members.

## 2. Information Gathering

The Arthritis Society engaged 39 people living with rheumatoid arthritis to respond to a social media request for information for this CADTH submission. The data was gathered in February and March 2017 and December 2018 and January 2019 in Canada. Of the 39 respondents, three had experience with baricitinib.

The Canadian Arthritis Patient Alliance 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.

## 3. Disease Experience

For the patient CAPA 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 firm, 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.

As was reported to the Arthritis Society and CAPA, for 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. [Difficulty] 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 jewelry, 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 interviewed by CAPA 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."

#### **4. Experiences With Currently Available Treatments**

Like many people who live with RA, the patient that CAPA interviewed tried a plethora of medications over time to treat her symptoms – though knowing this was 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 combination of drugs for many years, until she went on to a clinical trial for baricitinib. Her experience trying multiple types of medications over many years is not an anomaly, but is common amongst people with RA. 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.

This is what we heard from people living with RA:

- "Medication - somewhat effective. Massage, chiropractor, acupuncture, naturopath - all provide some temporary relief. The cost for all of treatments are more than my insurance. As well the time needed takes me away from work a lot, I wish there were more options available."
- "I started this journey with methotrexate then had to add gold injections- after a year that quit working. Tried other meds that quit working. I have tried three different biologics, chemo, several experimental medications. I'm currently on Xeljanz with Plaquenil, Celebrex and still there are days I have to use prednisone to ease the pain. I live in a region where the rheumatologist is here every six weeks- so if something doesn't go right, I have to wait six weeks to see him. The cost of some of these are outrageous- I don't have extended health coverage for my prescriptions. Last year I lost my job which had an excellent extended health care program. I was able to find another job but the wage is \$7 an hour less and no extended health care. I have to figure out how I'm going to pay to refill my next prescription. Does it suck,? Yeah. Then there are the side effects of these meds. For instance the Plaquenil- every six months I have to go for an eye exam- another cost that I have to try and budget for."

- “Methotrexate, while somewhat effective for controlling symptoms of RA, was prohibitive in method of administration (injection), gastrointestinal side effects, and general feelings of unwellness post-injection, which lasted for several days. I have not noticed side effects with Baricitinib and the method of administration being oral is easy to take. I also take Hydrochloroquine, which seems to have the side effect of weakness, which is problematic. I have not encountered the hardship of cost associated with Baricitinib yet due to my participation in clinical trials, but I imagine it will be prohibitive and will impact my ability to continue on the medication once I am expected to pay for it. This will impact my quality of life because I find that of all the medications I have taken to date, Baricitinib seems to have the best effect with the fewest side effects. With regard to unmet needs, I would list dry mouth and eyes as continuing to be problematic.”
- “NSAIDs didn't do much. Methotrexate really doesn't agree with me. I could move, but the gastro side effects and headaches were terrible. I felt worse on it than on nothing. Cortisone shots helped temporarily. Baricitinib is the only other treatment I've tried. It's great - very few side effects and I can keep up with everything I have to and most things I want to.”

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 ways. 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.”

## 5. Improved Outcomes

RA patients have identified several outcomes that are important to them and that should be considered when evaluating new therapies including:

- route of drug administration (pills vs infusion vs self-injections)
- a reduction in pain and fatigue

- increased mobility
- ability to work and be productive at work
- ability to carry out activities of daily living
- ability to effectively carry out parenting tasks and other important social roles
- reduced infection rates
- affordability of the medication.

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.”

## 6. Experience With Drug Under Review

Within about 2-3 days of starting baricitinib, the patient CAPA interviewed 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 that point in time (in March 2017 when we talked to her), she had 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.

Here is what we also heard from patients who have experience taking Baricitinib:

- “Positive experience using Baricitinib was to return to a similar level of functioning as pre-RA diagnosis. Pain and fatigue remain problematic but compared with methotrexate, Baricitinib has a better effect with many fewer side effects. I have not noticed any side effects with Baricitinib. Easier to take the oral Baricitinib than the injectable methotrexate. Oral methotrexate was not an

option for me due to gastrointestinal side effects. The increased feelings of fatigue and unwellness that are present with methotrexate do not seem to be a problem with baricitinib. I hope that Baricitinib will cause a slowed progression of my RA which in turn will allow me to continue working longer and have a good quality of life as I age.”

- “Most effects I've noticed are positive. My mobility is back to normal. I am back exercising and am starting to recover fitness I lost from before I was on baricitinib. I have little to no pain and my energy has gone back to normal. I rarely miss work due to flares, only if I really push too hard. I do get sick slightly more often and slightly more seriously than before my diagnosis, but not enough to affect my lifestyle. Other than that, I haven't noticed any side effects. It's super easy to use. One little pill every morning and I'm ok. It's had a positive impact on my life. With this treatment, I'm healthy enough to take care of my general health, which makes everything better.”
- “I've only had positive effects of baricitinib. It's easy to use and better than any other treatments I have used in the past. I do not experience any side effects to taking the drug.”

## 7. Companion Diagnostic Test

- N/A

## 8. Anything Else?

- N/A

## Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

No. However the manufacturer (Eli Lilly) did provide us with the names of rheumatologists who conducted clinical trials of Baricitinib in Canada. We reached out to the rheumatologists and had them pass on our contact information to patients about this submission.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

No

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

The Arthritis Society

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000



Amgen				X
Abbvie				X
Bayer Healthcare				X
BMS			X	
Boehringer Ingelheim	X			
Celgene				X
Eli Lilly				X
Eupraxia pharmaceuticals	X			
IMC			X	
Janssen				X
Merck				X
Novartis				X
Pfizer				X
Sanofi			X	
UCB				X

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Helen Anderson  
Position: Senior Manager, Education Services  
Patient Group: The Arthritis Society  
Date: January 18, 2019

Canadian Arthritis Patient Alliance

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Abbvie Corp.				X
Johnson & Johnson		X		
Manulife	X			
Pfizer Canada			X	
Purdue	X			
The Arthritis Society	X			
UCB		X		

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Note that D. Richards is a volunteer Vice President of the Canadian Arthritis Patient Alliance and as a

self-employed consultant has received speaker fees, honoraria and/or consulting fees from AbbVie, Amgen, Eli Lilly, Hoffman-LaRoche, Innomar, Janssen, Manulife, Merck, Novartis, Novo Nordisk, Pfizer, and UCB.

Name: Dawn Richards

Position: Vice-President

Patient Group: Canadian Arthritis Patient Alliance

Date: January 18, 2019