

## CADTH COMMON DRUG REVIEW

# Patient Input

### **upadacitinib (Rinvoq)**

(AbbVie)

Indication: Rinvoq is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more DMARDs. Rinvoq may be used as monotherapy or in combination with nonbiologic DMARDs.

CADTH received patient input from:

**Arthritis Consumer Experts**

**Canadian Arthritis Patient Alliance and Arthritis Society (joint)**

**Canadian Association of Psoriasis Patients and Canadian Psoriasis Network (joint)**

**Canadian Spondylitis Association**

January 29, 2021

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CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

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

**Re:** Patient Input for upadacitinib for psoriatic arthritis

**Date of submission:** January 29, 2021

**Section 1 — General Information**

**Name of the drug:** upadacitinib (Rinvoq®)

**Indication of interest:** psoriatic arthritis

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

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

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████████████████

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

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████████████████████

**Patient group's contact information:**

[feedback@jointhealth.org](mailto:feedback@jointhealth.org)

604-974-1366

Unit 210-1529 West 6<sup>th</sup> Avenue

Vancouver, BC

V6J 1R1

[www.jointhealth.org](http://www.jointhealth.org)

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

**Section 1 – About your Patient Group**

Arthritis Consumer Experts (ACE) is Canada's largest, longest running national arthritis patient organization headquartered in Vancouver, BC, with 50,000 members from coast-to-coast. ACE provides free, science-based information and education programs in English and French to people with arthritis and those who care for and support them. 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 and provides research-based education 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 from patients who completed ACE's patient input survey through SurveyMonkey from December 18, 2020 to January 26, 2021.

## **Section 3 — Disease Experience**

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

Psoriatic arthritis (PsA) has a unique and 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. Because of the visible symptoms of the disease, such as a scaly rash on the skin, patients also experience mental stress.

- **Patient A:** Living with PsA for 47 years and also has fibromyalgia and is living with obesity. "My psoriatic arthritis is under control because of the medication I take and my quality of life is very good as a result."
- **Patient B:** Living with PsA for 22 years. They have "restricted ability to walk distances, difficulty opening door knobs and lids on jars, and using cutlery for meals". This patient experiences joint pain on a daily basis.
- **Patient C:** Living with PsA for 11 years. With medication therapies, they are able to control their PsA and maintain an active and busy life.
- **Patient D:** Living with PsA for 6 months. As a result of their PsA, they experience pain and reduced mobility function.
- **Patient E** was "diagnosed with PsA in 2015, but started to show symptoms in mid-eighties." They experience pain in many joints and require 45 minutes warm-up exercises every morning before their day starts. They also experience big toes problems and have "psoriasis in scalp and on face" that requires lotions.

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

- **Patient A:** "Since I am not a caregiver, I cannot say what these may be."
- **Patient B, C, D:** N/A

- **Patient E:** “None in my case.”

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

- **Patient A:** “Joint damage from inflammation.”
- **Patient B:** “Walking, using hands.”
- **Patient C:** “Maintaining treatment schedule. Missing treatments, particularly my weekly methotrexate shot catches up with me...aches, stiffness, inflammation.”
- **Patient D:** “Lack of mobility.”
- **Patient E:** “Toes and psoriasis.”

## Section 4 – Experiences with Currently Available Treatments

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

- **Patient A** is currently taking Humira and methotrexate. “This is very effective in controlling my psoriatic arthritis. I have so far been lucky in that I haven’t experienced any adverse effects.” This patient has no hardships accessing Humira and methotrexate.
- **Patient B** is currently taking Erelzi, methotrexate, Plaquenil, Tylenol and ibuprofen and is not aware of any adverse effects. “All have moderate success.” This patient has no hardships accessing current therapies.
- **Patient C** is taking a combination of a Remicade infusion every 7 weeks and a weekly dose of methotrexate. They experience feeling of nausea for a couple days after methotrexate and higher level of fatigue all the time. When asked if there are any needs that are not met by current therapy, this patient stated: “Not for me to say – but many friends and relatives have asked about my treatments and their inability to access them or their acceptance of arthritis/pain as part of getting old.” This patient has no hardships in accessing current therapies; they added: “But I have private coverage for Remicade, which is roughly \$3K every 7 weeks – roughly \$21-25,000.”
- **Patient D** is controlling their psoriatic arthritis with medication and exercise; they state that both are not very useful and have no adverse effects. This patient would like warm water therapy to be available but this has stopped due to the pandemic.
- **Patient E:** “Exercise. Scalp lotion. Soak toes in yellow Listerine daily. Ointment on big toes twice a day. Skin cream on face once a day. Tylenol before heavy exercise. No therapy adverse effects.” When asked if there are any needs that are not met by current therapy, this patient stated: “Access to gyms and recreation centres. COVID-19 has closed gyms – tough for exercise issue.” This patient has trouble finding the time to exercise.

## Section 5 – Improved Outcomes

**This section asked patients what they would consider when choosing a therapy.**

- **Patient A:** “Potential side effects. In my case, how small an amount of these powerful drugs can be taken while still being effective (in order to minimize side effects).”
- **Patient B:** Cost
- **Patient C:** Side effects.
- **Patient D:** Investment of time when not really working.
- **Patient E:** Avoid drugs.

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

None of the patients we interviewed have any experience with upadacitinib to treat their psoriatic arthritis. Patient C and D provided additional comments for this section.

- **Patient C:** If new treatment provided desired improvements, ideally, there’d be less stress, less side effects and less fatigue.
- **Patient D:** If new treatment can improve my mobility, it would be greatly welcomed.

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

Not applicable to this submission.

### **Section 8 – Anything Else?**

Arthritis Consumer Experts is providing this patient input submission based on patients living with psoriatic arthritis who completed ACE’s patient input survey on SurveyMonkey between December 18, 2020 and January 26, 2021.

ACE made minor grammatical corrections to input where needed but 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 summarized 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.

A full list of private and public sector organizations providing Arthritis Consumer Experts grants-in-aid over the past 12 months can be found here: <https://jointhealth.org/about-principles.cfm?locale=en-CA>

Specific to this input, Arthritis Consumer Experts has not received any financial payments (grants-in-aid) from AbbVie.

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

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: President

Patient Group: Arthritis Consumer Experts

Date: January 29, 2021

## Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Upadacitinib for psoriatic arthritis
Name of the Patient Group	Canadian Arthritis Patient Alliance (CAPA) & The Arthritis Society
Author of the Submission	[REDACTED]
Name of the Primary Contact for This Submission	[REDACTED]
Email	[REDACTED]
Telephone Number	[REDACTED]

### 1. About Your Patient Group

The Canadian Arthritis Patient Alliance (CAPA) is a grass-roots, patient-driven and managed, 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. Our website is updated regularly and can be viewed at: [www.arthritispatient.ca](http://www.arthritispatient.ca)

The Arthritis Society (AS) has been setting lives in motion for over 70 years. Dedicated to a vision of living in a world where people are free from the devastating affects that arthritis has on the lives of Canadians, the Arthritis 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 Arthritis 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.

### 2. Information Gathering

We developed a survey to hear directly from people living with psoriatic arthritis (PsA) about their experiences with PsA and any experiences taking upadacitinib. The survey was collaboratively developed by the Canadian Arthritis Patient Alliance (CAPA), the Arthritis Society, Canadian Spondylitis Association (CSA), Canadian Association of Psoriasis Patients (CAPP), and Canadian Psoriasis Network (CPN). The design was informed by the lived experiences of the organizations' members, many of whom live with various forms of arthritis. The survey was shared via e-mail, social media, and organization websites from all five organizations, through our respective Canadian networks and communities. The survey was



translated into French to reach a broader national audience, and was open from December 15, 2020 to January 11, 2021. CAPA and the Arthritis Society are making this collaborative submission, while the three remaining organizations who collaborated on the survey design will each be making their own submissions based on survey response data and their unique community perspectives.

An AbbVie contact provided us with names and email contact information of the Canadian rheumatologists who had patients enrolled in the upadacitinib clinical trial. We contacted these rheumatologists and asked them to pass along an outreach letter to patients involved with the clinical trial, inviting them to participate in our survey. This letter described CADTH, explained the Common Drug Review process, and communicated why their input would be of value. The letter also provided a link to the survey as well as contact information for each participating organization, in case they had questions or wanted to get in touch via email or phone.

Fifty-five total online survey responses were received, of which 6 (4 English, 2 French) individuals had experience taking upadacitinib. Survey participants were located across Canada, ranging from British Columbia to Newfoundland and Labrador. One participant was located outside of Canada. The survey collected demographic data, however not all respondents completed this section. Those who provided demographic data (n=27) represented a range of ages from 26 to 80 years old. Most respondents were between the ages of 35 and 80. The vast majority of respondents indicated that their PsA was moderate to severe in terms of its severity.

### 3. Disease Experience

Psoriatic arthritis (PsA) is a chronic, inflammatory, systemic disease of the skin and joints. Symptoms include musculoskeletal pain, stiffness, fatigue and limited range of motion in the joints as well as psoriasis plaques that are itchy, sensitive, red, flaky and cause pain. PsA is also a systemic disease meaning that other parts of the body in addition to joints can be affected, including the eyes and heart. PsA can vary in severity from mild to very severe. A person may experience active periods of disease (commonly known as flares or flare-ups) and times where there is decreased activity or even inactivity (remission). While people who have PsA generally live with a number of the same symptoms, how they experience those symptoms and the severity of PsA can be very different from person to person – PsA is unique to each person who lives with it. There is currently no cure for PsA.

The disease impacts all aspects of a person's life including a variety of activities that people without PsA take for granted such as walking, sleeping, holding a phone, standing, and taking care of every day tasks, such as shopping, running errands, and cooking. Given the limitations in activities of daily living, PsA impacts all aspects of a person's life including workplace participation and productivity, carrying out parenting and other social roles, and relationships with spouses, friends and family members.

When asked about the most significant impacts of PsA on their daily quality of life, respondents expressed that PsA interfered with social connections (78%), self-esteem (69%), family life (66%), mental health (66%), work (60%), friendships (50%), intimacy (44%), and parenting (15%). Other impacts included embarrassment and self-consciousness from symptoms caused by PsA.

*“embarrassing dry skin on head, ears, feet and elbows”*

*“...I certainly have zero desire to find a romantic partner because I don't want anyone seeing me naked because of the psoriasis....”*

People living with the disease are also at risk of co-morbidities, such as depression and mental health issues, diabetes, and cardiovascular disease. Periods of very active disease are called a 'flare' and for some people, flares can be incapacitating. Flares are not predictable in terms of how severe they will be or how long they will last. They may last for a few hours, days, weeks or even months. Because of their unpredictability, flares must be dealt with reactively by people. The unpredictable nature of PsA also often makes it feel like a person is not in control of their disease and can impact their ability to carry out day to day activities and life roles, such as contributing in the workplace.

*"The Fatigue is the worst!!! I don't sleep well! I have been in a Flare since September 2020 [4 months], The Psoriatic Arthritis is starting to affect my pelvis, lower spine, tailbone, my pelvic pain is Unreal!! I am cranky and worn out every day, I'm 51, not 80, but it impacts my daily life!..."*

People living with PsA who completed the survey noted the following symptoms and effects:

*"Joint pain, stiffness, swelling of joints, trouble with mobility"*

*"Chronic fatigue - daily. Worse in the winter than summer months. Energy levels decline dramatically starting 4pm. I am unable to do much socializing after 6pm due to lack of energy. Dinners out are a rare occurrence. Enthesitis - in my wrists, elbows, achilles. My hands are now weak (I'm 50) that carrying grocery bags is uncomfortable. I take a rolling cart whenever I have to carry more than 5lbs. Flares - occur when there is hot weather or I have over-exerted myself exercising. This causes the enthesitis to become painful and I experience extreme body aches and fatigue. Like the flu. This lasts 1-3 days. Gluten and dairy flares me - so I avoid them in my diet. I normally have to pack food when travelling as it's difficult to find gf [gluten-free] options."*

*"Stiffness, pain, fatigue limit my mobility and prevent me from participating in many activities."*

*"I don't have the energy or ability to work a full time job. I can't get income assistance.... I've been waiting for word for some time but so far nothing. Some days I feel hopeless. I am definitely in pain all the time it just varies in intensity. I can't really go out and do things for more than a couple of hours without becoming exhausted. On the rare, pre-Covid times when I'd take a day trip somewhere, it would wipe me out for the next couple of days. There is zero financial support for someone in my situation and if I end up homeless and on the streets at some point, I won't be surprised at all."*

PsA impacts lives in many ways: daily tasks that many well individuals take for granted may become too difficult or exhausting to complete; participating in leisure activities or hobbies can be challenging; while caring for or spending time with family members, including children, spouses/partners and other loved ones, also becomes difficult. Survey respondents described the following symptoms and their impacts on daily activities:

*"Pain in the joints of the fingers and toes. I would like to go for walks but the pain is too bad. I try to knit and it's difficult."*

*"Permanent joint damage; having reduced mobility in some of my joints negatively impacts some activities such as exercise (unable to participate in some forms of exercise), and sometimes more basic activities such as writing, opening doors etc. This joint damage has also impacted my muscle mass (i.e. I have less muscle mass associated with the damaged joint) which further limits my abilities at times. When my psoriasis was really bad, I was extremely self-conscious about it and this impacted my mental health."*

*“Pain all over body. Especially in seat bone area. Pain not just in joints. Goes into tendons and muscles. Unable to do most things I used to enjoy. Canoeing, kayaking, skating, hockey, snowshoeing, snow and water skiing all not able to do anymore. Cannot even work as I never know when I will be so affected by this that it is a struggle to even force myself out of bed. Pain is a constant companion.”*

People indicated difficulties in contributing and participating at school or work due to the fatigue, pain, and other symptoms of the psoriatic arthritis:

*“...Even with the biologics I am on, I still experience pain most days & find I am tired a lot. I make it through my work day & pretty much am exhausted by the time I return home. Living with the pain & fatigue is a constant part of my life now as is the constant fear of a medication failure. Not being able to participate in a lot of [activities] with family & friends is also frustrating. I find myself sad a lot these days too.”*

*“Use of my hands is very painful. I have trouble peeling potatoes, carrots, etc. and continually drop items. My feet are painful, but have been helped with an immune suppressant. Unfortunately, I feel nauseated and other side effects.”*

*“I’m 35 years old... At its worst, I can’t physically get out of bed without help, can’t dress myself...I’ve been trying to maintain a 4 day work week with a lightened work load. I’ve been one of the lucky ones as I’ve had a lot of support at work and they have been trying to make my job manageable, but sometimes it’s very hard even then. I used to be one of the top performers in my company, and now I feel like I’m bottom of the barrel. I worry that my [employer’s] and coworkers’ patience has a limit, and eventually I’ll be seen as detrimental vs an asset. I find myself profusely apologizing for something that is out of my control. My inflammation moves around my body from my toes, feet, knees, lower back, hips, back ribs, Costochondritis, shoulders, elbows, wrists, hands, fingers and ligaments in my arms, shins and Achilles’ tendon. ....I’ve had days I have had to be driven [to work] as I was afraid to operate a vehicle. Besides this affecting my work life, it’s affected my social life. Sometimes even just sending a bunch of texts feels too taxing and I just lack energy.....”*

*“My Poly PsA. The impact from the Joint Pain, Chronic Fatigue daily causes me to limit my activity level during the day. Depending on [the severity of inflammation day to day, adapting] my activity levels from house work to physical fitness. Especially during work days naps are important to get through 8 hours of sitting desk work & hands/fingers typing.”*

PsA’s impacts also extend to others within a person’s support circle, including caregivers such as spouses/partners and children. Often, these people take on additional chores or tasks such as cooking, cleaning, shopping, etc. to support the person living with PsA, and family roles change as spouses / partners take on more tasks, such as supporting their spouses / partners in getting to and from medical appointments.

*“I’m sick of the Pain and Fatigue!! I feel like a Burden to my Husband!”*

*“I had struggled with severe pain for 30 plus years, was very hard to do everyday tasks ,my son thank god for him was always there to help me as opening a simple bottle of water was at times very hard to even open”*

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

Clinical practice guidelines emphasize early aggressive treatment of PsA, which provides the best long-term outcomes for people living with the disease. A number of treatment approaches are used to manage PsA including non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and conventional synthetic Disease Modifying Anti-Rheumatic drugs (csDMARDs) such as Methotrexate, as well as biologic Disease-Modifying Anti-Rheumatic Drugs (bDMARDs), such as Etanercept and Infliximab. Effective treatments mean that people with PsA do not need to live with the permanent damage, high medical costs (e.g. surgery, mobility aids, accessible housing) and disability. Early intervention is critical to allow people with Psoriatic Arthritis the opportunity to fully participate in all aspects of life.

Notwithstanding the fact that numerous medication options exist, 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 patient's immune system adapts to a drug's presence (i.e. becomes non-responsive to it) and they will have to switch to another medication. In some cases, patients with PsA may not adequately respond to any of the DMARD's (conventional and biological) currently available. As a result, 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 PsA. 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. It is also an anxious and stressful experience if medications are not effective and cost thousands of dollars out of pocket. Oftentimes, people with PsA need to make difficult financial choices in order to pay for their medications.

It is also important to note that conventional synthetic DMARDs (csDMARDs) are difficult to take for people living with PsA. Nausea, vomiting and a general malaise can persist for days after treatment with csDMARDs. Due to these experiences, many patients may not wish to take the medicine in question because the medication(s) is too difficult to take. This impacts adherence to treatment, increases health care costs (e.g. more visits to the doctor) and makes it difficult for people living with PsA to work, carry out social roles and participate in other activities of daily living. Toxicity issues (e.g. liver) can also be of concern for people taking csDMARD's, such as Methotrexate, Immuran, and Leflunomide.

To highlight some of these issues, people living with PsA shared their experiences with currently available treatments:

*"My life has been impacted by PsA. I have to spend more time stretching and using anti-inflammatory creams to try and help. It's affected my ability to do housework, cook as it requires standing in one spot which hurts my back, yard work, shopping, standing in lines at stores which are longer now due to COVID. Side effects are a huge problem. They are worse than the disease I feel. MTX [methotrexate] and Sulfasalazine made me sick and I felt worse with them. Having the disease is enough to deal with on its own, let alone the side effects."*

*"Well my brain fog worsening with methotrexate use has greatly affected my work life. I can't do my job effectively if I feel intoxicated, I've had to call in sick on the bad days or I'm afraid I'll make a big mistake and that can cost my company but more importantly, someone's well being as my job does involve some high risk activities. It's also affected my social life as I've previously mentioned. The nausea doesn't allow me to get a good night's sleep as it keeps me up. When I took the methotrexate injection, I had to have someone else administer it as I couldn't bring myself to doing it on myself."*

*"I inject Methotrexate weekly....it has a horrible side effect of making me nauseous, I lose a*

*day of productivity every week because of this. I also find the methotrexate no longer helps the psoriasis. I have been using methotrexate for nearly 25 years.”*

*“I found most drugs I have tried did nothing to help me and would usually make me very nauseous”*

*“I found celecoxib very effective, however I had to stop using it regularly because I had been using it too long at full dose and there was concern I would start to have complications from it. The combination of methotrexate and sulphasalazine has been moderately, or maybe slightly more than moderately effective, however, the methotrexate has been giving me nausea and worsening my brain fog. Additionally, I’ve been hesitant to try Biologics because I’m afraid of needles. I have done weekly methotrexate injections for over 6 months and it gave me anxiety every week to have to put myself through it every time, on top of my monthly bloodwork.”*

*“oral meds stomach upset, cause stomach pain, gastrointestinal issues, headache. Not much pain relief”*

*“The side effects have been the worst. It’s coming to the point I’d rather deal with living with pain than the side effects. I was not able to function with methotrexate, Extreme fatigue, extreme irritability, brain fog, it was horrible. I was very grouchy and not enjoying life. Sulfasalazine - I had fever, chills, a horrible hot tingling rash, fatigue, [I ended] up going to hospital and found out my liver enzymes went up through the roof and I had to come off all medications including my anti-inflammatory. So I spent 2 weeks with no medications and my pain increased more and more each day till I was able to resume my anti-inflammatory. I spent 3 weeks on MTX [methotrexate] and had to stop it. And Sulfasalazine I spent 5 weeks on it and at 4.5 weeks I had the reaction start. My PsA remains uncontrolled. The Meloxicam does not help with my stiffness and muscle tightness. I still get flares. The DMARDs don’t work fast enough to provide relief. It’s a constant battle to deal with, like you’re on a hamster wheel going nowhere and it’s tiring and frustrating.”*

Patients may also pursue medical cannabis and/or non-pharmacological approaches to manage PsA symptoms, such as physiotherapy, occupational therapy, massage therapy, counselling, or acupuncture. These approaches can often help to address the symptoms of the disease, such as pain and fatigue. However, there are significant unmet patient needs in terms of accessing non-pharmacological treatments, often because they are not reimbursed through provincial health care systems, the treatment options are simply not offered, or there are lengthy waits.

*“I have been thinking about cannabis for awhile but my doctor said to hold off”*

*“Methotrexate made me extremely ill and I had to stop. I had an allergic reaction to sulfasalazine. I’m on leflunomide now. It’s working OK, I think. It killed my appetite and I lost 30lbs so that’s cool. CBD and cannabis (THC) have been the only thing to give me pain relief but neither are covered under the NB Drug Plan and I don’t always have the money for it. I can’t take NSAIDs. They trigger my asthma. It would be nice if my medical prescription for cannabis would be recognized by my drug plan.”*

*“...lifestyle changes through diet, sleep and exercise. I have found the most effective changes were cutting Gluten and dairy from my diet. My swollen joints disappeared and my psoriasis also has receded 80% in the past 3 yrs. I get 7-8hrs sleep and daily exercise. This I had to discover through my own research and has been the greatest help in alleviating my symptoms.”*

Patients identified a number of issues in accessing treatment options. Expense, travel, and time required for treatment were all cited as being prohibitive. Some patients also identified a difficulty in access to treatment relating to lack of access to specialists and general practitioner, and/or the COVID-19 pandemic restrictions.

*“My Rheumatologist doesn't want to follow up sooner than her every 3 month schedule which makes it frustrating to figure out the next steps to treatment when you had to abruptly stop a treatment. Which leaves you in limbo for several weeks. Travel to and from appts takes up time. My biggest problem is how my Rheumatologist handles her appointments and scheduling them. Doesn't seem to realize the condition needs attention.”*

*“I live 2.5 hours away from the Toronto Western Hospital Psoriatic Arthritis clinic. I also go to Mount Sinai in Toronto to see my specialist. I live in [name of small town], Ontario Canada, and I have No Family Doctor! I rely on my specialist for any care I get. Right now I'm waiting for an appointment to see a Neurosurgeon, who's office has been so slow as to not answer the referrals they have been sent about me, I have Complex Health issues and not much care... I haven't been able to come in to Toronto to see my Specialists. Telephone appointments stink, and I don't like appointments on my tablet either!”*

*“I am on the NB Drug Plan. It doesn't cover cannabis. I don't have employment. I am 43 and I live with my mother who is 78. She drives me to appointments. I can't afford my own transportation. My GP knows my financial status and we try to work around it. I have an education but life decided to throw a curve ball and I honestly don't know what people in my situation are supposed to do.”*

*“I would love to be on something like Enbrel but it is unattainable for a middleclass person. I make too much to get it for free and I don't make enough to pay for it outright. So unfair.”*

*“Cost of medication is significantly high [even] with insurance coverage. [Without] private insurance it [would be] impossible to afford Biologic medication....”*

## 5. Improved Outcomes

PsA 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
- effective for psoriasis symptoms as well as psoriatic arthritis symptoms.
- 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
- increased quality of life.

Current medications for the treatment of PsA also have a number of negative side effects, such as fatigue which often persists beyond 24 hours (Methotrexate), nausea (Methotrexate, Arava, Immuran), increased infection risk (most DMARDs), liver toxicity and weight gain (Prednisone).

People living with PsA shared the following experiences:

*"I would hope [a new treatment] would not have side effects and I wish it would work on my psoriasis as well as my arthritis. I would hope to gain more confidence in my appearance (psoriasis plaques lessened) so that I would desire to be more social. Being more social would get me out of the house and more active which would help with the everyday aches and pains of arthritis. It's all linked....you cannot separate the arthritis and the psoriasis. They work together against the body and mind unfortunately."*

*"I would like to have reduced joint stiffness, reduced flares and improved joint pain and fatigue."*

*"I would hope for having more good days, being able to go back to working full time and being a productive member of my work team, being able to use an oral drug, not having nausea, being able to be a bit more physically active than I am now. I suppose it would depend what those side effects can be as all the medications available for PsA have their side effects. Overall I tend to prefer having a better quality of life than quantity of life."*

*"I would like for faster symptom relief, instead of 3 months. I don't want serious side effects, I'm not willing to risk my life for a medication. I would rather be disabled from PsA than be in hospital fighting for my life. Medication is to help not cause more harm. If it's causing more harm than the disease then that's just money making for a drug company than actually trying to help patients. And so far my experience is these medications scare me because of their side effects as I was already in hospital from one. Improvement would be less flares to no flares, no stiffness, or less time spent being stiff, less pain, less swelling, less tendon problems, less tight muscles, and more quality to life."*

*"I would like a treatment to [address] the symptoms without creating greater side-effects."*

## 6. Experience With Drug Under Review

From those surveyed, 6 people identified having experience with taking upadacitinib. The respondents shared positive and negative effects of taking upadacitinib:

*"[The] only negative [side effect] as mention[ed] before is a feeling of being cold all the time. I have had 80-90% relief of pain."*

*"It has helped a lot with my pain and joint swelling, I really haven't noticed any side effects. It's definitely better than the injections I take, I hope that taking this now will prevent worsening problems on my joints as I age. It makes day to day easier and less painful"*

*"all positive no negative 100% better than any other meds so far...I think not having as much pain is great for long term and quality of life"*

*"...It allowed me to have a better quality of life. My psoriasis has stopped completely and I have beautiful nails. The pain is really minimal and my arthritis is under control. The side effects are very low."*

*"The drug upadacitinib is really effective because I no longer have psoriasis on hands and pain due to arthritis has diminished dramatically."*

*“Shortness of breath since taking methotrexate and upadacitinib”*

*“I take Rinvoq and am satisfied with the product. I don't think I would take drugs with serious side effects. I wasted several years of my life suffer[ing] and not be[ing] treated because I wanted children.”*

Patients also shared how PsA symptoms were managed while taking upadacitinib:

*“The pain has subsided at least 80-90%. Less time off work has occurred. When taking Methotrexate, I became violently ill.”*

*“Getting up every morning with pain is a challenge! In contrast, with upadacitinib, pain lasts less when you wake up. The look of others, when I had psoriasis on hands was a challenge, now I have beautiful nails and beautiful hands. Maintain[ing] clean[lines] is much easier. Besides, shortness of breath is the only side effect I have observed.”*

*“Joint pain and swelling significantly reduced. Psoriasis is also reduced in most areas”*

*“no side effect and disappearance of skin pain and lesions”*

There were also direct impacts on the lives of patients and their families and respondents shared the following experiences:

*“I am able to move more freely and exercise more often.”*

*“I don't need assistance with these things”*

*“Greater self-esteem and easier to get around”*

*“I have more energy to do activities with my partner. I had support from my partner, he does the shopping. The support of the research center team was very important to me, [to address] my anxieties and my fears about the disease.”*

*“My arthritis was not very active except for skin lesions on the feet but after 10 days of taking Rinvoq everything has disappeared and no limitations to lead an active life”*

## **6. Companion Diagnostic Test**

Not applicable

## **7. Anything Else?**

We felt it was important to share the hope expressed by a patient living with PsA to demonstrate what new treatment options mean to the community:

*“I just hope it helps people and works well, with little side effects!!”*



## Appendix: Patient Group Conflict of Interest Declaration

### Declaration from CAPA

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.

An AbbVie contact provided us with names and email contact information of the rheumatologists in Canada who had patients enrolled in the upadacitinib clinical trial. We contacted these rheumatologists and asked them to pass along an outreach letter to patients involved with the clinical trial, inviting them to participate in our survey. This letter described CADTH, explained the Common Drug Review process, and communicated why their input would be of value. The letter also provided a link to the survey as well as contact information for each participating organization, in case they had questions or wanted to get in touch via email or phone.

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.

We collaborated with three additional organizations to conduct outreach to patient groups in generating survey responses. We collaborated with the Canadian Spondylitis Association, Canadian Association of Psoriasis Patients, and the Canadian Psoriasis Network.

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.

#### 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 Corporation			X	
UCB Canada		X		
Johnson & Johnson	X			
CADTH	X			
SmithSolve LLC	X			
The University of British Columbia	X			
Alcimed	X			
Arthritis Society	X			

University of Alberta	X			
Children's Hospital of Eastern Ontario	X			
Hospital for Sick Kids	X			
Dalhousie University	X			

4. 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: Laurie Proulx  
Position: 2<sup>nd</sup> Vice-President  
Patient Group: Canadian Arthritis Patient Alliance  
Date: January 20, 2021

### Declaration from the Arthritis Society

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.

An AbbVie contact provided us with names and email contact information of the rheumatologists in Canada who had patients enrolled in the upadacitinib clinical trial. We contacted these rheumatologists and asked them to pass along an outreach letter to patients involved with the clinical trial, inviting them to participate in our survey. This letter described CADTH, explained the Common Drug Review process, and communicated why their input would be of value. The letter also provided a link to the survey as well as contact information for each participating organization, in case they had questions or wanted to get in touch via email or phone.

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

We collaborated with three additional organizations to conduct outreach to patient groups in generating survey responses. We collaborated with the Canadian Spondylitis Association, Canadian Association of Psoriasis Patients, and the Canadian Psoriasis Network.

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.

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				X
Alcon			X	
Amgen				X

Boehringer Ingelheim			X	
BMS			X	
Celgene			X	
Eli Lilly				X
Eupraxia Pharmaceuticals	X			
Gilead			X	
Innovative Medicines Canada			X	
J+J Shared Services				X
Janssen				X
Merck				X
Novartis				X
Pfizer				X
Sanofi		X		
UCB				X

5. 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: Director, Information and Support  
Patient Group: The Arthritis Society  
Date: January 20, 2021

# CADTH Reimbursement Review Patient Input Template

Name of the Drug and Indication	Rinvoq (upadacitinib) for psoriatic arthritis
Name of the Patient Group	Canadian Association of Psoriasis Patients Canadian Psoriasis Network
Author of the Submission	[REDACTED]
Name of the Primary Contact for This Submission	[REDACTED]
Email	[REDACTED]
Telephone Number	[REDACTED]

## 1. About Your Patient Group

The Canadian Association of Psoriasis Patients (CAPP) is partnering with the Canadian Psoriasis Network (CPN) to develop this submission.

CAPP ([www.canadianpsoriasis.ca](http://www.canadianpsoriasis.ca)) is a national, not-for-profit organization formed to better serve the needs of psoriasis patients across the country. CAPP’s mission is to be a resource and advocate for psoriatic patients and their families to improve patient care and quality of life.

CPN ([www.canadianpsoriasisnetwork.com](http://www.canadianpsoriasisnetwork.com)) is a national, not-for-profit organization dedicated to improving the quality of life of people in Canada who live with psoriasis and psoriatic arthritis. CPN does this by providing current information on research and treatment options and by working with others to build awareness and advocacy about the complexities of these conditions.

## 2. Information Gathering

CAPP and CPN collaborated with other organizations to develop a **survey** in English and French using Survey Monkey that asked patients and caregivers about their experiences with the disease and the treatment under review (upadacitinib) – specifically, the Arthritis Society ([arthritis.ca](http://arthritis.ca)), the Canadian Arthritis Patient Alliance ([arthritispatient.ca](http://arthritispatient.ca)), and the Canadian Spondylitis Association ([www.spondylitis.ca](http://www.spondylitis.ca)). Each organization participated in the development of the survey and shared the surveys with their respective memberships or patient communities via newsletters, social media channels and websites. CAPP and CPN analyzed the data and prepared this submission.

- The surveys were available from December 15, 2020 to January 18, 2021.
- Overall, there were 85 responses to the English survey and 9 responses to the French survey (8 of whom told us in which province they received their healthcare): 10 respondents were from British Columbia (10.8%), 6 from Alberta (6.5%), 3 from Saskatchewan (3.2%), 17 from Manitoba (19.3%), 30 from Ontario (32.3%), 13 from Quebec (14.0%), 3 from New Brunswick (3.2%), 5 from Nova Scotia (5.4%), 4 from Newfoundland & Labrador (4.3%); no responses were received from Prince

Edward Island, the Northwest Territories or Nunavut. Only one response was from someone outside Canada.

- In addition to PsA, 90.7% of 54 respondents (n=49) across the two surveys indicated they lived with psoriasis, 16.7% (n=9) live with another inflammatory condition, 35.2% (n=19) also live with another type of arthritis, and 33.3% (n=18) live with at least one other condition, including fibromyalgia, borderline personality disorder, eczema, Raynaud's syndrome, scoliosis, hypothyroidism, allergies, asthma, high blood pressure and bladder conditions.
- Of the English responses, 50 people provided their sex: 66% (n=33) were female, 32% (n=16) were male and 2% (n=1) preferred to not identify their sex. Of the French responses, 4 people responded they were female.
- Fifty-four respondents provided information about their age across the English and French surveys, which is grouped here for ease of reference: under 26 years old (n=1), 26-34 years old (n=4), 35-44 years old (n=6), 45-54 years old (n=11), 55-64 years old (n=14), 65-74 years old (n=13), and more than 75 years old (n=5).
- There were six responses from people who have experience with Rinvoq (upadacitinib) for psoriatic arthritis (English n=4, French n=2).

Representatives from the four patient groups reached out to clinics that were involved in clinical trials of Rinvoq (upadacitinib) for PsA. One patient interview was conducted by the Canadian Spondylitis Association Executive Director with a female patient who has lived with PsA for 30 years and with psoriasis her entire life. Notes from this interview were shared with CAPP, CPN, CAPA and the Arthritis Society.

### 3. Disease Experience

Psoriatic arthritis (PsA) is a form of arthritis linked to psoriasis and that is chronic and progressive. This inflammatory disease causes swelling and pain in multiple joints and can sometimes result in **permanent and debilitating joint damage**.

*“...j’ai eu un épisode de gonflement et douleur intense à mon pouce droit, j’ai été obligée de changer d’anti inflammatoire car celui que j’avais ne faisait plus effet. La douleur est partie mais je vois bien que l’articulation est plus grosse qu’avant.”*

Sixty-two respondents identified aspects of their day-to-day lives and quality of life that are affected by PsA:

Aspect	Total (n)	Percentage (%)	Aspect	Total (n)	Percentage (%)
Ability to work	39	62.9	Friendships	26	41.9
Participation in school	1	1.6	Intimacy	31	50.0
Social connections	42	67.7	Self-esteem	41	66.1
Parenting	8	12.9	Mental health	41	66.1
Family life	30	48.4	Other	16	25.8

Specific symptoms of PsA include tendon and ligament inflammation (enthesitis), inflammation of the fluid-filled sheath of a joint (synovium), and sausage-like swelling of an entire digit (dactylitis). The pain and fatigue from this disease can be debilitating. Respondents to the survey emphasized **pain, stiffness, lack of mobility**, and **fatigue** which impact their activities of daily living, their family lives and their ability to work and maintain certain hobbies – it *“impacts all aspects of life from work to sleep to everything in between.”*

*“EXTREMELY painful joints. To the point that walking, climbing stairs (to the 2nd floor where the master bedroom was located), etc. was a challenge. Pain killers and NSAIDs were a minimal daily requirement just to get out of bed and make it through the day... Sometimes not being able to go to work because of*

*the pain. When I was first diagnosed with PsA, my son had just been born. I was not even able to do what many fathers do, and take for granted, and that was hold my son up over my head with my arms, smiling up to him as he would be laughing down to me... That was almost 30 years ago. My son passed in March of 2019 and to this day, I still regret not being able to do that simple thing, that "[rite] of passage"... Holding my infant so up in the air. PsA took that from me..."*

*"Pain in all joints used 5-120 minutes in a day progressively worse during the day. Need to take frequent rests to recharge with bed rest being most beneficial. One or two days with more physical activity than my joints can handle can cause the rest of the week's pain to be worse until I take my dose of methotrexate and begin recovery mostly from bed. My day to day plans are dictated by what I can handle. Planning on going out usually requires leaving chores and other physical activities out the day before and after driving to town and back for more than 4 hours round trip for example. I feel like a quarter of my former self in terms of quality of life."*

*"First flare (diagnosis) it affected my knee, huge swelling, red, hot skin, extreme pain where I could not put weight on the leg. Second flare was knee & ankle. Same as before: whole leg from just above knee down swelled, red & hot, again no weight bearing. Third flare took out knee, ankle & foot. With same as before. Even with the biologics I am on, I still experience pain most days & find I am tired a lot. I make it through my work day & pretty much am exhausted by the time I return home. Living with the pain & fatigue is a constant part of my life now as is the constant fear of a medication failure. Not being able to participate in a lot of this game with family & friends is also frustrating. I find myself sad a lot these days too."*

*"Use of my hands is very painful. I have trouble peeling potatoes, carrots, etc. and continually drop items. My feet are painful, but have been helped with an immune suppressant. Unfortunately, I feel nauseated and [have] other side effects."*

*"Wrist pain prevents me from certain forms of exercise. Fear of injuring joints prevents me from engaging in certain activities. I have general joint laxity which also prevents me from doing certain activities or pursuing some career options."*

*« Douleurs aux articulations des doigts et orteils. J'aimerais aller prendre des marches mais la douleur est trop intense. J'essaie de tricoter et c'est difficile. »*

*"Pain in lower back, swelling and pain in fingers that cause a great deal of stress, especially as a musician."*

*"I no longer can work as a band teacher. Tendons in fingers hands and wrists pain too much to play and/or conduct. On disability pension due to PSA."*

*Mornings and cold weather can exacerbate the situation: "Weakness in hands in the morning and cold weather. Aching and discomfort."*

*"Extreme stiffness in the a.m. preventing me from walking without horrible pain. I end up crawling up the stairs from our downstairs bedroom. Lower back pain is constant. Stiff hands make writing difficult."*

Some patients describe experiencing a **"brain fog" or forgetfulness**, which is frustrating and demoralizing.

*"I'm 35 years old. My symptoms are a roller coaster. Some days I almost feel like my old self and other days can be very difficult. At its worst, I can't physically get out of bed without help, can't dress myself and want to stay in a quiet dark room to preserve my energy and just get through the day somehow. Since my diagnosis, I've been trying to maintain a 4 day work week with a lightened work load. I've been one of the lucky ones as I've had a lot of support at work and they have been trying to make my job manageable, but sometimes it's very hard even then. I used to be one of the top performers in my company, and now I feel like I'm bottom of the barrel. I worry that my work and coworkers' patience has a limit, and eventually I'll be seen as detrimental vs an asset. I find myself profusely apologizing for something that is out of my control. My inflammation moves around my body from my toes, feet, knees, lower back, hips, back ribs, Costochondritis, shoulders, elbows, wrists, hands, fingers and ligaments in my arms, shins and Achilles' tendon. I also have suffered from brain fog, which I think has been just as debilitating, if not more so than the physical pain. When I have brain fog it makes me feel intoxicated, I've said things I wouldn't normally say out loud, my memory can be greatly affected, I've stuttered, forgotten what I wanted to say or words to things. You feel like you're going out of your mind, like you're getting Alzheimer's and it's terrifying. I've*

*had days I have had to be driven as I was afraid to operate a vehicle. Besides this affecting my work life, it's affected my social life. Sometimes even just sending a bunch of texts feels too taxing and I just lack energy. I miss exercising properly and breaking a sweat. Usually all I can manage is a walk around my block with a cane before my knees feel too stiff and swollen. I'm still grateful I can do that, but I miss horseback riding, barn chores and riding my bicycle. You feel like you're alive when you push your body enough to break a sweat. I'm lucky that I still live with my mom who can help with everyday house chores and cooking, otherwise I'm not sure how I would cope."*

**Patients living with both psoriasis and PsA** have to manage the symptoms and impacts of both diseases, which creates greater strain on their mental health and reduces their expectations of a safe and healthy future.

*"Aside from the psoriasis itself and how ugly it is, I have arthritis pain mainly in my hips, knees and feet. Right now I find it difficult to walk because of the pain in my heels. Sometimes I get arthritis pain in my breast bone and it feels like I'm dying. I sometimes get it in my shoulders or neck or back as well. My hands come and go but at one point they were so bad I couldn't hold a pen. I certainly have zero desire to find a romantic partner because I don't want anyone seeing me naked because of the psoriasis. I find I am forgetting words a lot, not sure if that's related to the PsA but it makes me feel stupid. I don't have the energy or ability to work a full time job. I can't get income assistance. My doctor has sent in a form for provincial disability and I've been waiting for word for some time but so far nothing. Some days I feel hopeless. I am definitely in pain all the time it just varies in intensity. I can't really go out and do things for more than a couple of hours without becoming exhausted. On the rare, pre-Covid times when I'd take a day trip somewhere, it would wipe me out for the next couple of days. There is zero financial support for someone in my situation and if I end up homeless and on the streets at some point, I won't be surprised at all."*

*"Fatigue - makes it difficult to engage in activities that provide quality of life; I have recently had to retire from my professional work because of fatigue; I was a professional in private practice with no safety net for such eventualities. Pain in various (variable) joints and areas of soft tissue - interferes with social functioning and physical functioning; often feel frustrated when the pain interferes with me engaging in activities (such as snowshoeing, walking, skiing, etc.) that bring me joy. Skin problems - is embarrassing; I have often been the target of people's rude comments about my appearance which is demoralizing. Depression - side effect of living with the above"*

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

Patients living with psoriatic disease often try a succession of treatments throughout their lives: because of the inflammatory nature of the diseases, treatments that are initially effective can become less effective over time. Patients often describe to CAPP and CPN feeling nervous that they will run out of treatment options as their diseases progress, and they will be left with the significant and debilitating symptoms of uncontrolled psoriasis and psoriatic arthritis.

It is important to note that many people who live with PsA also live with psoriasis. As some drugs are indicated for both diseases, it is not uncommon for people to have some experience taking a treatment indicated for PsA for their psoriasis and vice versa. For patients who take treatments for their psoriasis, these same treatments can but do not always adequately manage their PsA.

*"I am on Taltz, [the] only drug he found worked well for skin and arthritis."*

*"My biologic for psoriasis helps PsA perhaps 10 to 20%."*

*"I take Naproxen, but they switched me to meloxicam, I feel awful on it, it bothers my stomach!! I was on Otezla, it helped my ear and scalp psoriasis, but did nothing for my psoriatic arthritis, for joint pain, enthesitis, plantar fasciitis, etc!"*

*"Taking Cosentyx has cured the skin completely of psoriasis. The damage still exists in my spine and hands with stiffness and pain."*

*"Enbrel worked very well for arthritis but not skin."*

Disease-modifying antirheumatic drugs (DMARDs) are a well-known and often-used treatment for PsA,. Respondents (n=54) had experience with DMARDs both alone and in combination with methotrexate:

apremilast (18.5%; n=10), methotrexate (74.1%, n=40), azathioprine (0.02%, n=1), cyclosporine (13.0%, n=7), hydroxychloroquine (13.0%, n=7), leflunomide (Arava) (14.8%, n=8), sulfasalazine (22.2%, n=12), and salazopyrin (0.04%, n=2).

Existing PsA treatments vary in their effectiveness, according to the patients surveyed:

Treatment	Very ineffective	Mildly ineffective	No difference in symptoms	Mildly effective	Very effective
Non-steroidal anti-inflammatory drugs (NSAIDs); n=53	37.7% (20)	5.7% (3)	18.9% (10)	35.9% (19)	1.9% (1)
Disease-modifying antirheumatic drugs (DMARDs); n=44	25.0% (11)	11.3% (5)	15.9% (7)	36.4% (16)	11.4% (5)
Leflunomide; n=15	40.0% (6)	0 (0)	46.7% (7)	13.3% (2)	0 (0)
Apremilast; n=11	54.6% (6)	0 (0)	18.2% (2)	27.3% (3)	0 (0)
Tofacitinib; n=7	71.4% (5)	0 (0)	28.6% (2)	0 (0)	0 (0)
Hydroxychloroquine; n=10	50.0% (5)	10.0% (1)	30.0% (3)	0 (0)	10.0% (1)
Biologics; n=36	22.2% (8)	0 (0)	5.6 (2)	22.2 (8)	50.0 (18)
Steroid injections; n=26	30.8% (8)	7.7% (2)	15.4% (4)	30.8% (8)	15.4% (4)
Oral steroids; n=19	42.1% (8)	5.3% (1)	15.8% (3)	31.6% (6)	5.3% (1)
Medical cannabis; n=22	18.2% (4)	0 (0)	9.1% (2)	36.4% (8)	36.4% (8)

Some patients also tried naturopathic interventions and found some improvement - *“helped with fatigue...yoga and meditation have helped with mental health side effects”* - but *“not with other symptoms”*.

**Non-steroidal anti-inflammatory drugs (NSAIDs)** can have a helpful effect but it may not last: *“NSAIDs cover the pain but I feel worse after activity and using them.”* One patient reported using naproxen when they flare *“1-2 a month. I am reluctant to take too frequently as it causes digestive issues.”* Others also reported negative effects on other organs: *“I cannot use NSAIDs because it does damage to the kidneys and my levels were below normal on them. After going off one year my levels are normal now.”*

Many patients have experience with **disease-modifying antirheumatic drugs (DMARDs)**. Several respondents had experience with **methotrexate** and noted a variety of side effects, including nausea, raised liver levels, headaches, sore mouth, being *“bedridden with debilitating fatigue for days after each shot”*, *“worsening my brain fog”* and *“feeling ‘worse’ on it in other ways”*:

*“I’ve only tried methotrexate and am currently on it. It manages my PsA quite well but I’m still susceptible to joint injuries and cuts and abrasions can still lead to new psoriatic lesions. The side effects I get are poor sleep, nausea, poor balance, mental fog, runny stool, flatulence, and some GI discomfort. The needs not being met by methotrexate are that it doesn’t completely put my arthritis into remission and it doesn’t completely eliminate my psoriatic lesions. Wishful thinking, I know.”*

*“Methotrexate gave me the most benefit but the 3 days after taking the dose I am weaker, require more naps and I am less tolerable to activity and my eyes are sore.”*

The side effects of **sulphasalazine** were noted by several respondents: *“I had fever, chills, a horrible hot tingling rash and fatigue, ended up going off all medications including my anti-inflammatory. So I spent 2 weeks [with] no medications and my pain increased more and more each day till I was able to resume my anti-inflammatory.... My PsA remains uncontrolled.”* Its benefits can be offset by its impact on mood: *“sulphasalazine almost cost me my marriage due to mood swings”*.

**Cyclosporine** was also noted to impact other organs: *“When I took cyclosporine my kidney function became a problem. I have not been able to achieve comfort with any treatment.”* **Hydroxychloroquine**



(Plaquenil) worsened one respondent's tinnitus. **Leflunomide** was noted by one respondent to *"kill my appetite and I lost 30 lbs so that's cool."*

Some respondents noted that **apremilast** (Otezla) helped their psoriasis but did not improve their PsA, and had challenging side effects, including increased heart rate, nausea, depression and moodiness, diarrhea.

Some respondents had experience with oral **steroids** and steroid injections: *"Steroids seem to give me a false sense of strength that ends up hurting me more when I come off it."*

*"The effects of the steroid injections really didn't last long, max 2-3 months, and I have residual injection site sensitivity to this day on my ankle."*

Several respondents also had experience with different **biologics** but the benefits do not last forever: *"The biologics do a good job until they fail. Then the search is on for the next one that will work."* One respondent noted that he or she is *"on my 5<sup>th</sup> biologic since 2007"*.

Despite the variety of medications available to treat PsA, some respondents noted **there remain unmet needs**: *"Needs that aren't met by these treatments include the ease of consumption/tolerance, largely due to their uncomfortable side effects."* Unmet needs can be particularly acute for **women**: *"I spent over 10 years fighting for help for my pain and being told that it was because I was overweight. As a woman we are often dismissed and our pain is not considered valid. ...The treatment helps but other needs that are not being met are the chronic pain..."*

Many patients noted the challenges they face seeing their specialist, and the costs of many available medications (e.g. biologics).

## 5. Improved Outcomes

Patients living with PsA – and living with both PsA and psoriasis – already experience a raft of side effects from available medications, and generally expressed that they have "had enough of them" and would not be willing to accept more or serious side effects from a new medication. There was specific concern about a compromised immune system, especially during the COVID-19 pandemic. One respondent also expressed concerns about not being able to take live vaccines. Ultimately, they *"don't want to be sicker."*

There are many outcomes patients wish to see in a new medication, foremost among them remission of PsA, improvement in psoriasis (if they are also living with this disease), better pain management, improved mobility, reduced episodes of flares, reduced fatigue, and a longer period of effectiveness than often experienced by patients with existing treatments.

*"Given that this is an oral treatment option, I can see this greatly increasing quality of life for PsA patients who struggle with dealing with the pain and hassle of injection-based medications. Oral medications are much more convenient to take and store, but typically don't have the same powerful, specific efficacy of biologic medications which typically come closer to targeting the "root" of the issue and not just the symptoms. ... If the side effects greatly impede everyday life (nausea, fatigue etc), then I would say that I personally would not be keen to take this medication. However, if we're talking more about "potential risks" such as suppressed immune function leading to increased risk of infection, etc. - I already take that risk with adalimumab, but it would be nice to see data comparing the two on this metric. That's also something to consider given the current state of the pandemic and risk for immunocompromised patients. I would hope that this medication would allow patients to achieve near complete remission from their conditions."*

*"I would hope it would not have side effects and I wish it would work on my psoriasis as well as my arthritis. I would hope to gain more confidence in my appearance (psoriasis plaques lessened) so that I would desire to be more social. Being more social would get me out of the house and more active which would help with the everyday aches and pains of arthritis. It's all linked....you cannot separate the arthritis and the psoriasis. They work together against the body and mind unfortunately."*

*"I would expect it to alleviate symptoms, maybe not completely but very well. I would NOT accept serious side effects. If the side effects are serious, what's the point? Your life will be horrible with or without it. I*

would want a good medication to both clear up the psoriasis and lessen the arthritis pain/brain fog so I could live a normal life.”

## 6. Experience With Drug Under Review

As stated previously, there were six responses from people who indicated that they have experience with Rinvoq (upadacitinib) for psoriatic arthritis (English n=4, French n=2).

Of these survey respondents, five provided their sex (3 female; 2 male) and five provided their age which ranged from 38-75 years old. Four of these respondents were from Manitoba and two were from Quebec. Five indicated that they live with psoriasis. In addition, one lives with another form of arthritis; one lives with another inflammatory condition; and one also lives with borderline personality disorder. Five of the six respondents who have experience with Rinvoq (upadacitinib) indicated that they have used DMARDs.

When asked about their **positive and negative experiences with Rinvoq (upadacitinib)**, they noted:

*“Only negative as mentione[ed] before is feeling of being cold all the time. I have had 80-90% relief of pain.”*

*“It has helped a lot with my pain and joint swelling, I really haven’t noticed any side effects. It’s definitely better than the injections I take, I hope that taking this now will prevent worsening problems on my joints as I age. It makes day to day easier and less painful.”*

*“All positive no negative. 100% better than any other meds so far...I think not having as much pain is great for long term and quality of life.”*

*“Joint pain and swelling significantly reduced. Psoriasis is also reduced in most areas.”*

*« Le Rinvoq est un comprimé pris à tout les jours cela m’a permis d’avoir une qualité de vie bien meilleure. Mon psoriasis a arrêté complètement et j’ai des beaux ongles. La douleur est vraiment minime et mon arthrite est contrôlé. Les effets secondaires sont très faibles. »*

*« Aucun effet secondaire et disparition des douleurs et des lésions cutanés. »*

When asked about the **impact of Rinvoq (upadacitinib) on caregivers and their family** and their day-to-day activities, these six respondents answered:

*“Yes. I am able to move more freely and exercise more often.”*

*“No, I don’t need assistance with these things.”*

*“Some definitely.”*

*“Greater self-esteem and easier to get around.”*

*« Oui, j’ai plus d’énergies pour effectuer des activités avec mon conjoint. J’ai eu du soutien de la part de mon conjoint, il fait les courses. Le soutien de l’équipe du centre de recherche a été très importante pour moi, mes angoisses et mes peurs face à la maladie. »*

*« Mon arthrite n’était pas très actives sauf des lésions cutanés au pieds mais après 10 jours de prise du Rinvoq tout a disparue et aucune limitation pour mener une vie active. »*

As mentioned above, one interview was conducted by the Executive Director with a female patient who has lived with PsA for 30 years and with severe psoriasis her entire life, who also had experience with Rinvoq (upadacitinib) through a clinical trial. Her PsA caused pain and reduced her mobility to the point that she had to retire from her job as a truck driver, which she loved. Her wrist mobility in particular was very impacted by PsA. Her psoriasis covered 87% of her body and led to a life being covered up, not showing her skin in public despite the fact that the sunshine helped with her skin lesions. As well, her toenails were not attached to the nail bed. She was bullied about her skin throughout her life. Both diseases impacted her relationship with her boyfriend.

Her past medication history included methotrexate, “every topical under the sun”, and a couple of biologics that she injected but that were not effective for her.

Her experience with Rinvoq (upadacitinib) was positive: within two weeks after beginning treatment, she was able to walk around her home without walking aids and her pain was significantly better. Her skin was almost entirely clear with the exception of a couple of small spots. Within four weeks, she was able to walk outside without walking aids which was something she was not previously able to do. Her nails began to grow properly again, allowing her less pain and enabling her to wear close-toed shoes. She noted no side effects, despite previously being very prone to them and unable to tolerate other medications. She also commented that as an oral medication this form of treatment was less of a reminder of her diseases than when she used injectable medications.

She has been able to return to work part-time in another capacity (driving and supervising young clients) and she is hoping to go back to full-time work after the COVID-19 pandemic. She feels better than she has in the past 30 years and her relationship with her boyfriend has also improved. Her confidence has improved and she is no longer afraid to be out in public and around friends. She commented that for her, this drug is life-altering, has given her freedom, and she can't believe how much she can move around and not be in pain all the time.

## 7. Companion Diagnostic Test

Not applicable.

## 8. Anything Else?

Like psoriasis, PsA is complicated, frustrating and can be debilitating without access to appropriate treatments. Patients are very different in how they react to changes in lifestyle, topical treatments and biologics. What works for one patient, may not work for the other, even if their symptoms are very similar.

Yet, PsA is a disease that often “falls through the cracks.” Some patients are seen by a dermatologist while others are seen by rheumatologists. Joint pain is not always discussed with a dermatologist and plaques on the skin are not always discussed with rheumatologists. These challenges often lead to delays in diagnosis and consequently severe and irreversible damage to the joints.

It is still not clear which individuals who have psoriasis will get PsA. Roughly 30% of people with psoriasis will develop PsA. Both diseases are caused by the immune system being inappropriately activated. Most of the time (80%), psoriasis comes first but it remains difficult to predict whether a person living with psoriasis will later develop PsA, despite research advances that have identified a number of biomarkers associated with PsA and advances in developing predictive screening tools<sup>1</sup>.

All patients are looking for a treatment that will control all of their symptoms but ultimately they would like a cure to this debilitating disease. Earlier treatment of PsA can result in better outcomes and reduce the risk of permanent and debilitating joint damage. PsA is also linked with an increased risk of cardiovascular disease, specifically atherosclerotic disease (low grade inflammation in blood vessels). Controlling inflammation can reduce the risk of PsA patients later developing heart disease.<sup>2</sup>

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<sup>1</sup> Eder, L. et al., The Prediction of Psoriatic Arthritis Tool (PRESTO) Study – Interim Report, American College of Rheumatology Convergence 2020 conference, online: <https://acrabstracts.org/abstract/the-prediction-of-psoriatic-arthritis-tool-presto-study-interim-report/>.

<sup>2</sup> Eder, L. et al. Cardiovascular Diseases in Psoriasis and Psoriatic Arthritis, The Journal of Rheumatology Supplement June 2019, 95 20-27; DOI: <https://doi.org/10.3899/jrheum.190114>

## Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, 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.

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.**

CAPP and CPN collaborated with other organizations to develop a survey in English and French using Survey Monkey that asked patients and caregivers about their experiences with the disease and the treatment under review (upadacitinib) – specifically, the Arthritis Society (arthritis.ca), the Canadian Arthritis Patient Alliance (arthritispatient.ca), and the Canadian Spondylitis Association (www.spondylitis.ca). Each organization participated in the development of the survey. CAPP and CPN analyzed the data and prepared this submission.

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.**

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 Canada			X	
Amgen Canada			X	
Bausch Health			X	
Boehringer Ingelheim International			X	
Eli Lilly Canada			X	
Janssen Canada			X	
LEO Pharma Canada			X	
Novartis Canada			X	
Novartis Global		X		
UCB 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: Rachael Manion  
 Position: Executive Director  
 Patient Group: Canadian Association of Psoriasis Patients  
 Date: January 28, 2021

## Appendix: Patient Group Conflict of Interest Declaration

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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 Canada				X
Amgen Canada			X	
Bausch Health			X	
Boehringer Ingelheim Canada			X	
Boehringer Ingelheim International	X			
Eli Lilly Canada		X		
Janssen Canada			X	
LEO Pharma Canada			X	
Novartis Canada			X	
Pfizer Canada			X	

UCB Canada		X		
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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: Antonella Scali  
Position: Executive Director  
Patient Group: Canadian Psoriasis Network  
Date: February 1 2021

## CADTH Reimbursement Review Patient Input Template

Name of the Drug and Indication	Rinvoq (upadacitinib) Psoriatic Arthritis (PsA)
Name of the Patient Group	Canadian Spondylitis Association
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	████████████████████
Telephone Number	██████████

### 1. About Your Patient Group

Describe the purpose of your organization. Include a link to your website.

The Canadian Spondylitis Association is a National not-for-profit organization federally registered in Canada. We are the only patient-led, not-for-profit organization focused solely on supporting Canadians living with Spondyloarthritis. Over the last decade, we have developed credible, valuable, and relevant resources for our growing community and the thousands at risk of being diagnosed. It is our mission to be the leading voice for the spondyloarthritis community in Canada, raising awareness and providing support, education and advocacy for patients, caregivers, and health professionals. It is our vision that all those living with, or affected by, spondyloarthritis (SpA) receive timely diagnosis and treatment, make informed choices about their well-being and are supported by a thriving Spondyloarthritis community.

Spondyloarthritis (SpA) describes a group of chronic inflammatory arthritic diseases with common features, including inflammation of the spine, eyes, skin and gastrointestinal tract. These conditions can be painful and debilitating for many – particularly for those with disease progression. This group is also sometimes referred to as spondylitis and spondyloarthropathies. Psoriatic Arthritis is one of the conditions that fall under the umbrella of spondyloarthritis.

Our bi-lingual website is [www.spondylitis.ca](http://www.spondylitis.ca)

### 2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when**

the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

The Canadian Spondylitis Association collaborated with other organizations to develop a survey in English and French using Survey Monkey that asked patients and caregivers about their experiences with the disease and the treatment under review (upadacitinib) – specifically, the Arthritis Society ([arthritis.ca](http://arthritis.ca)), the Canadian Arthritis Patient Alliance ([arthritispatient.ca](http://arthritispatient.ca)), the Canadian Association for Psoriasis Patients ([canadiansporiasis.ca](http://canadiansporiasis.ca)) and the Canadian Psoriasis Network ([canadianpsoriasisnetwork.com](http://canadianpsoriasisnetwork.com)). Each organization participated in the development of the survey and shared the surveys with their respective memberships or patient communities via newsletters, social media channels and websites.

- The surveys were available from December 15, 2020 to January 18, 2021.
- Overall, there were 85 responses to the English survey and 9 responses to the French survey (8 of whom told us in which province they received their healthcare): 10 respondents were from British Columbia (10.8%), 6 from Alberta (6.5%), 3 from Saskatchewan (3.2%), 17 from Manitoba (19.3%), 30 from Ontario (32.3%), 13 from Quebec (14.0%), 3 from New Brunswick (3.2%), 5 from Nova Scotia (5.4%), 4 from Newfoundland & Labrador (4.3%); no responses were received from Prince Edward Island, the Northwest Territories or Nunavut. Only one response was from someone outside Canada.
- Of the English responses, 50 people provided their sex: 66% (n=33) were female, 32% (n=16) were male and 2% (n=1) preferred to not identify their sex. Of the French responses, 4 people responded they were female.
- Fifty-four respondents provided information about their age across the English and French surveys, which is grouped here for ease of reference: under 26 years old (n=1), 26-34 years old (n=4), 35-44 years old (n=6), 45-54 years old (n=11), 55-64 years old (n=14), 65-74 years old (n=13), and more than 75 years old (n=5).
- There were six responses to the survey from people who have experience with upadacitinib for psoriatic arthritis (English n=4, French n=2).

There was one female who also requested to share her input through an interview.

### 3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

For many individuals, the journey being diagnosed with Psoriatic Arthritis can be lengthy and is often frustrating. In many cases individuals struggle without a diagnosis or misdiagnosis for years and it's not until they are referred to a rheumatologist is a diagnosis is made (quickly). For some with skin involvement, delays could be from lack of communication of symptoms (joint pain) to their dermatologist. In addition to living with the symptoms of Psoriatic Arthritis almost all respondents also live with depression, anxiety, sleep issues and fatigue that can be debilitating and disabling.



Living with PsA has a significant negative impact on patient's day-to-day life. Patients who participated in the survey experience varying degrees of negative impact ranging from having limited ability to function normally on a day-to-day basis when compared with loved ones or colleagues to being bedridden, unable to walk without assistance. Tasks as simple as getting out of bed in the morning are difficult, working is an issue for many (some are forced to retire early or are on disability).

People can live in constant pain without remission. PsA can be relentless and leave people living without hope and feeling desperate, withdrawn and isolated.

#### Patient Quotes:

*"EXTREMELY painful joints. To the point that walking, climbing stairs is challenging. Pain killers and NSAID's were a minimal daily requirement just to get out of bed and make it through the day. Sometimes not being able to go to work because of the pain. When I was first diagnosed with PsA my son had just been born. I was not even able to do what many fathers to, and take for granted, and that was hold my son over my head with my arms, smiling at him. That was almost 30 years ago. My son passed in March 2019 and to this I still regret not being able to do that simple thing, that "right of passage" ...holding my infant so up in the air. PsA took that from me.."*

*"Joint pain, stiff joints, lack of range of motion, lack of endurance. Impacts all aspects of life from work to sleep to everything in between."*

*"I lived with constant pain. I spent more time laying around not being able to do any everyday things".*

*"Extreme stiffness in the AM preventing me from walking without horrible pain. I end up crawling up the stairs. My back pain is constant. Stiff hands making writing difficult".*

*"Permanent join damage; having reduced mobility in some of my joints negatively impact activities such as exercise and more basic activities like writing, opening doors, etc. The join damage has also impacted my muscle mass which further limits my abilities".*

The symptoms of PsA impact day-to-day quality of life in a number of ways. The biggest impact was on social connects with 72% of people indicating PsA impacted this most negatively. Close behind self-esteem (69%) and mental health (67%) were reports to be negatively impacted. Also significantly impacted was ability to work (63%), family life (53%) and intimacy (51%)

#### Patient Quotes:

*"I'm sick of the pain and fatigue. I feel like a burden to my husband".*

*"Loss of identity"*

*"I'm tired every day!! I have poor sleep!! I just have to be quiet some days so I can cope".*

## 4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

Many of the current medications available are helpful to some degree. For people living with PsA, any improvement is recognized as a good thing. People are desperate to find something that can give them back some quality of life.

The most effective medications people have been prescribed are biologics with 50% indicating them being “very effective” and 22% mildly effective.

NSAIDS have been mildly effective for 36% of respondents but ineffective for 38% and for 18% there was no difference in symptoms.

DMARDS were mildly effective for 36% and very effective for 11%. For 35%, DMARDS were either very or mildly ineffective.

Other medications including leflunomide, apremilast, tofacitinib were mostly ineffective and made no difference to symptoms.

### *Patient comments:*

*“I was once on Embrel and it worked wonderfully but my health insurance provider wouldn’t cover it without raising my premiums to unpayable amounts. Lasted 6 months on it before I was cut off ☹️”.*

*“MTX was not able to tolerate side effects, had serious reaction to sulfasalazine”.*

*“Every biologic I have tried has given me side effect so bad that I have had to discontinue use. Only prednisone does anything at all and it slowly destroys your body”.*

*“I’m on a DMARD. Only drug that worked well for skin and arthritis”.*

When asked about effectiveness and side effects of treatment options currently available, many patients have tried several medications and found symptoms of both arthritis and psoriasis were not improved. As we know, most, if not all, medications can have side effects. For people living with PsA, side effects range from mild to severe and people’s tolerability is individual. For some people, dealing with side effects but improved mobility and reduction in pain is worth the side effects they experience; while others, the side effects are quite bad and leading them to choose going off a specific medication in search of finding one that is effective and side effects tolerable.

## Patient quotes:

*“Biologics give me thrush! Methotrexate makes me nauseous, Otezla often gives me diarrhea”.*

*“I inject Methotrexate weekly...it has horrible side effect of making me nauseous. I lose a day of productivity every week because of this. I also find the methotrexate no longer helps with psoriasis. I have been using methotrexate for nearly 25 years”.*

*“I’m on my 5<sup>th</sup> biologic since 2007. Sufluazalazine failed. Otezla – Failed, Methotrexate – 7 years stopped working. Humira 3 years stopped working ....”.*

*“Biologics do a good job until they fail. Then the search is on for the next one that will work”.*

*“I haven’t found anything helpful yet!! Percocet is the Best for severe pain, and when I’m in a flare!! Tramadol helped when I got Kidney Stones”.*

## 5. Improved Outcomes

CADTH is interested in patients’ views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

For patients living with a chronic condition, any medication that could bring hope of improved outcomes and improved quality of life should be carefully considered by CADTH. Every individual’s journey is very different – no two the same. A treatment (pharmacologic or non-pharmacologic) that may work for one person may not work for the next. Some people have success with the first medication they are prescribed; while others try and fail on many until they find the one that works for them. Access to all medications approved by health Canada is paramount and supports an unmet for patients living with PsA.

The hopes and expectations from patients living with PsA are that new medications will improve symptoms (reduced joint pain, improved mobility and skin clearance). There were many comments about concern of side effects. Many are looking for faster and lengthier symptom relief vs current experience on some therapies. People are also realistic and understand there is no cure but are looking for some degree of improvement to their health. The degree of improvement is based on each individual’s personal situation.

## Patient quotes:

*“Hope this medication would allow patient to achieve near complete remission from symptoms”.*

*"I would hope it would not have side-effects and I wish it would work on my psoriasis as well as my arthritis. I would hope to gain more confidence in my appearance so that I would desire to be more social. Being more social would get me out of the house and active which would help with the everyday aches and pain of arthritis. It's all linked...you cannot separate the arthritis and the Psoriasis. They work together against the body and mind unfortunately".*

*"I don't expect it to alleviate symptoms, maybe not completely but very well. I would NOT accept serious side effects. If the side effects are serious, what's the point? Your life will be horrible with or without it. I would want a good medication to both clear up the psoriasis and lessen the arthritis pain, brain fog so I could live a normal life".*

*"Better enhanced life and if it's an improvement from our current medications that would be great. Even if it helps slight, I would be happy.*

*"reduced side effects with effect on joint pain"*

*I'm looking for any of the missing 25% to get me closer to normal. No, I'm not willing to risk serious side effects as I can manage with 75%*

*"Effective disease control with fewer side effects".*

*"I would like for a faster symptom relief, instead of 3 months. I don't want serious side effects I'm not willing to risk my life for a medication".*

*"The drug needs to be 8-%+ to be effective. No side effects would be the goal, I have had enough to them. Better quality of life so that the morning you wish you were alive rather than dead. I do mean that literally..".*

## 6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapy's patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

There were 6 patients who completed the survey (4 English / 2 French).

The CSA interviewed the individual and summarized the following insights provided:

### History:

- Female patient has lived with PsA for 30 years
- Has had skin involvement (PsO and Eczema) her entire life
- Past medication history included methotrexate and “every topical under the sun”
- Was on a couple injectable biologics but couldn't recall the name - didn't help
- Patient loves her job as a truck driver but was consequently forced to go onto disability due to the pain and lack of mobility caused by PsA (had to use a walker or cane). Wrist mobility deeply impacted ability to drive.
- Required multiple heating pads to sleep
- Relationship with boyfriend was impacted (due to pain, lack of mobility and skin)
- 87% covered for most of her life with PsO. Led life being covered up. Sister was a bully to her and said she couldn't go outside “looking like that”. She did not have PsO on face or hands but body fully covered. She always tried to wear shorts and short sleeve shirts as much as possible but couldn't stand people looking at her despite the sun being helpful.
- Toe nails were not attached to nail bed.

### Experience with Rinvoq:

- Heard about Rinvoq and pleaded with doctor to be put on clinical trial out of sheer desperation
- At point of going onto Rinvoq, skin was 93% covered, could not walk without either walker or cane and experienced a lot of pain (couldn't take pain medication)
- Two weeks post treatment initiation, skin was almost completely clear with exception of a couple small spots.
- Arthritis pain and mobility was significantly better and was able to move around without aids inside her home
- Within 4 weeks was able to go outside without walking aids
- Started walking which was something she obviously could not previously do
- Friends could not believe the difference

- In addition to skin improvement, nails began to, for first time for as long as she could remember, grow properly allowing her less pain and the ability to wear close toed shoes
- Doctors are amazed that she has no scarring
- Has experienced no side effects despite being prone to side effects and not being able to tolerate other medications
- Oral pill vs injection is very convenient

## Emotional / Social Impact

- Able to start back working in a different capacity but doing what she loves part-time (driving & supervising children aids clients). Hoping to get back to full time post covid
- Feels better than she has in 30 years
- Has given her back her confidence - no longer fears, and actually enjoys, being in public and around friends
- Relationship with boyfriend has improved (they do things together), went on first trip this past summer. Can't really remember the last time they went away
- She is no longer afraid to do anything

## Comments made multiple times (spoke with her for close to 45 min)

- *This drug is life altering. My whole life has changed*
- *One little pill a day has given me my freedom*
- *I'm so grateful for whoever makes this drug*
- *It's a miracle drug*
- *The clearance is incredible*
- *I can't believe how much I can move around and not be in pain all the time*

## Respondents to the survey:

### When asked about experience on Rinvoq (upadacitinib), patients responded:

*"All positive. No negative. 100% better than any other meds for me so far some....I think not having as much pain is great for long term quality of life".*

*"Joint pain and swelling significantly reduced. Psoriasis also reduced in most areas".*

*"It has definitely helped with my pain and joint swelling. I really haven't noticed any side effects. It's definitely better than the injections I take, I hope that taking this now will prevent worsening problems on my joints as I age. It's made day to day easier and less painful.*

*"Only negative as mentioned before is feeling of being cold all the time. I have 80-90% relief of pain".*

*"Rinvoq is a tablet taken every day that has allowed me to have a good quality of life better. My psoriasis has stopped completely and I have beautiful nails. The pain is really minimal and my arthritis is under control. The side effects are very low".*

*"No side effects and relief of pain and skin lesions".*

People reported a positive impact on quality of life being able to do more and feel better about themselves.

#### Patient quotes:

*"I am able to move more freely and exercise more often".*

*"I don't need assistance with things".*

*"Greater self-esteem and easier to get around".*

*"Yes, I have more energy to do activities with my partner. I have support from my partner, he does the shopping. The support of the research center team was very important to me in helping me overcome my anxieties and my fears about the disease".*

*"My arthritis was not very active except for skin lesions on the feet but after 10 days of taking Rinvoq everything disappeared and I no longer have any limitations to leading an active lifestyle".*

## 7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

Not relevant

## 8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

New, innovative medicines provide hope to patients who live with chronic inflammatory diseases, including Psoriatic Arthritis. There is no cure for conditions like Psoriatic Arthritis but there are medications available to Canadians to help manage the symptoms and improve health outcomes. For some, these medications are life changing and give back quality of life.

New treatment options and different classes of medications fill a void in patient and prescriber's unmet needs. The Rinvoq oral formulation is an exciting option for patients. It provides another option for administration and may help lead to improved adherence and ultimately outcomes.

Effective treatments allow Canadians the opportunity to regain self-confidence and re-integrate back into society and personal relationships. Effective disease management can get people back into the workforce and contributing to society. Those with well managed and controlled disease have a positive impact on the healthcare system (less physician appointments, less complications, less trips to the ER department, to name a few.)

For those yet to find relief, it can be a life of darkness, isolation and desperation leaving people spiraling into further depression and anxiousness robbing them of life.

It is important CADTH take into consideration many patients over the course of their journey have tried several and in some cases all the options currently available. New products being studied or new to market provide hope.

Until you have walked in the shoes of someone living with a chronic, debilitating and painful condition, I encourage CADTH to not be the barrier between a patient and a possible treatment that could be life-altering. Although there are options for patients, for some who have tried and failed on treatments currently available, Rinvoq and other new molecules coming to market provide an option and opportunity to reclaim some degree of life.

*Once last patient quote:*

*"I'm 35 years old. My symptoms are a roller coaster. Some days I almost feel like my old self and other days can be very difficult. At its worst, I can't physically get out of bed without help, can't dress myself and want to stay in a quiet dark room to preserve my energy and just get through the day somehow. Since my diagnosis, I've been trying to maintain a 4-day work week with a lightened work load. I've been one of the lucky ones as I've had a lot of support at work and they have been trying to make my job manageable, but sometimes it very hard even then. I used to be of the top performers in my company, and now I feel like I'm bottom of the barrel. I worry that my work and coworkers patience has a limit, and eventually I'll be seen as a detriment vs an asset. I find myself profusely apologizing for something that is out of my control. My inflammation moves around by body from my toes, feet, knees, lower back, hips and back ribs, Costochondritis, shoulders, elbow, wrists, hands, fingers and ligaments in my arms, shins and Achilles' tendon. I also have suffered from brain fog, which I think it has been just as debilitating, if not more so than the physical pain. When I have brain fog it makes me feel intoxicated. I've said things I wouldn't normally say out loud, my memory can be greatly affected, I've suffered forgotten what I wanted to say or words to things. You feel like you are going out of your mind, like you're getting Alzheimer's and it's terrifying. I've had days I have had to be driven as I was afraid to operate a vehicle. Beside this affecting my work life, it's affected my social life. Sometimes even just sending a bunch of texts feels too taxing and I just lack energy. I miss exercising properly and breaking a sweat. Usually all I can manage is a walk around by block with a cane before my knees feel too stiff and swollen. I'm still grateful I can do that, but I miss horseback riding, barn chores and riding my bicycle. You feel like you're alive when you push your body enough to break a sweat. I'm lucky that I still live with my mom who can help with everyday house chores and cooking, otherwise I'm not sure how I would cope.*



## Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, 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.

This submission was completed in its entirety by the Canadian Spondylitis Association.

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.

As mentioned, the collaborating organizations collectively developed the survey questions. The survey was launched by the Arthritis Society and raw data shared with collaborating organizations. The CSA conducted one telephone interview with a patient on Rinvoq.

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.

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			X	
Amgen			X	
Eli Lilly			X	
Novertis			X	
Merck			X	
Pfizer			X	
UCB			X	
Janssen		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: Wendy Gerhart  
 Position: Executive Director  
 Patient Group: Canadian Spondylitis Association  
 Date: January 28, 2021