

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Tofacitinib (psoriatic arthritis)
Name of the Patient Group	The Arthritis Society & Canadian Arthritis Patient Alliance
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1. About Your Patient Group

The Arthritis Society has been setting lives in motion for over 65 years. Dedicated to a vision of living well while creating a future without arthritis, The Society is Canada's principal health charity providing education, programs and support to the over 6 million Canadians living with arthritis. Since its founding in 1948, The Society has been the largest non-government funder of arthritis research in Canada, investing more than \$200 million in projects that have led to breakthroughs in the diagnosis, treatment and care of people with arthritis. The Arthritis Society is accredited under Imagine Canada's Standards Program. The website www.arthritis.ca provides more detailed information.

CAPA is a grass-roots, patient-driven, independent, national education and advocacy organization with members and supporters across Canada. CAPA creates links between Canadians with arthritis to assist them in becoming more effective advocates and to improve their quality of life. CAPA believes the first expert on arthritis is the person who lives with arthritis, and is an organization for patients run by patients. CAPA welcomes all Canadians with arthritis, and those who support CAPA's goals, to become members.

2. Information Gathering

The Arthritis Society engaged 13 people living with psoriatic arthritis to respond to a social media request for information for this CADTH submission. The data was gathered from June 20 to July 27, 2018 in Canada. Of the 13 respondents, one had experience with tofacitinib.

The Canadian Arthritis Patient Alliance contributed information as lived experience experts of living with inflammatory arthritis, including Psoriatic Arthritis. We also received information by interacting with the organization's membership which includes a range of people who live with various forms of arthritis, including Psoriatic Arthritis.

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, flakey and cause pain.

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 the workplace participation and productivity, carrying out parenting and other social roles, and relationships with spouses, friends and family members.

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 bad they will be or how long they will last. They may last for a few hours, days, weeks or even months. Flares must be dealt with reactively by people and the unpredictable nature of PsA 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.

Here is what we heard from PsA patients:

- "Symptoms: swelling of joints in toes (so far only one toe at a time), accompanied by increased sensitivity to pressure resulting in pain. Toe nail becomes brittle, rough, and thicker. The pain is the most important thing to control, followed by the disfigured nail, followed by the swelling. PsA has not prevented me from doing any activities, but has been noticeable during some - especially physical activities that require me to be on my feet. My PsA does not impact other people in my life (other than listening to me whine)."
- "On a day-to-day basis, fatigue is one of the worst symptoms that affects my quality of life. It is difficult for me to balance work and social time because I have to prioritize working, and the extra sleep/down time that I need cuts into social time only. This makes it difficult for me to maintain healthy relationships with friends and family. I also find it more difficult to enjoy some of my favourite activities, such as walking/hiking, due to the impact they have on my joints. I live alone, which sometimes feels like a risk. I enjoy my independence, but there are times where I have been unable to turn on/off a tap, or get out of bed unaided. My reliance on others for some physical tasks definitely affects the dynamic of my relationships."
- "I believe it is most important to control the fluctuation of joint inflammation and pain in PsA. I have trouble planning my weeks because I never know how much pain I will wake up in, and what I will be physically able to do on any given day."
- "Fatigue and constant pain affects many aspects. - from sleeping, physical activities. my partner struggles with the pain and seeing me like that "
- "I am mostly experiencing joint pain and swelling at this time. My psoriasis has been under control with medication for about 1 year. It is important that I am free of pain from arthritis in my joints as well as dry and itchy skin. I am limited in how long I can participate in activities, but I can do most activities. I have restrictions in weight I can lift as well (for example, lifting a normal bowling ball is not possible). PsA affects others in my life when I slow them down. At work it affects others because I can't do all that is required of me and have to ask others to help."
- "PsA affects my hands and feet first when not managed well, then my skin becomes worse. I have limited hand strength due to my PsA."
- "PsA affects daily life by causing pain and stiffness. The important aspects for me to be able to control are pain but also the fatigue that PsA causes. Most activities I can do at this time. It affects other people but having to do more around the house when I am too exhausted to complete chores."

- “Joint pain, weakness, fatigue, swelling, hot joints, psoriasis affect my quality of life. All of those are important to control. I can no longer work or attend leisure activities with my family. I am alone a lot and my family doesn’t understand.”
- “Painful joints, stiffness, fatigue. Control for all these symptoms is important. I am no longer able to hike, ski, golf, play tennis, swim. I find my family and friends no longer ask me to join in when these activities are on the list, limiting my ability to take part and increasing their guilt when I can’t keep up.”
- “Joint pain and stiffness, especially in feet, which affects mobility. There are many activities I’ve had to miss with my young family as a result of mobility issues caused by PsA. This, in turn, impacts my spouse and child as well. For that reason, joint pain and stiffness, especially in feet and knees, are the most important aspects of PsA to control.”
- “Exhaustion. When in a flare I can’t stay awake. When I flare I want to keep my skin patches covered no matter how hot it is outside. Joint pain and tenderness. Sometimes the pain is pronounced, sometimes its dull and nagging. It never goes away. Medications and PsA make it difficult and sometimes impossible to enjoy social activities. Limited alcohol, limited appetite, limited mobility. I am unable to participate in activities where I need to hold things tightly (rides, multiple items etc.). There is a growing distance between my spouse and me because I can’t do things I used to be able to do. Sometimes even selfcare is an issue. Doctors want to talk about symptoms more than impact so I keep a lot of it to myself.”
- “Psoriasis is a daily burden of itch, pain and ugliness. The arthritis affects many joints and is painful and limiting mobility. Both are very important to control. I would really like the psoriasis controlled because it continues to get worse”
- "Swelling, stiffness, pain and fatigue are the main symptoms and problems that affect my day-to-day and quality of life. I think all 4 of these symptoms are important to control. There are many activities that I need to modify or am no longer able to do as a result. The constant swelling and stiffness in joints like my hands or back means that many physical activities, exercises or even chores around the house are inaccessible to me now. Even something like gardening, which requires a lot of bending and hand work can be quite challenging. It impacts my family because more of the responsibility around the house falls on them when I am not feeling well or I am unable to do the things that I should be able to do. "

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 RA including Non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and conventional synthetic Disease Modifying Anti-Rheumatic drugs (csDMARDs) such as Methotrexate and biological Disease-Modifying Anti-Rheumatic Drugs (bDMARD’s), 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 exists, patients’ responses to medication can vary significantly. Some medications are effective for some people with arthritis while not effective for others. Some treatments will only manage the disease for a short period of time before the patients’ immune system adapts to a drug’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 csDMARD's. Due to these experiences, many patients may not wish to take the medicine in question because the medication(s) are 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.

Patients may also pursue non-pharmacological approaches to treatment of PsA, such as physiotherapy, occupational therapy, massage therapy, counselling, acupuncture and medical cannabis. 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 wait lists delaying access to care.

This is what we heard from people living with PsA:

- "I have not received formal treatment for PsA. Before I was correctly diagnosed, I was given an anti-inflammatory which did help some."
- "I have used various doses/forms of methotrexate, alone and in combination with hydroxychloroquine. I haven't found that any dose or combination thus far has managed my PsA for longer than 2 months. It's hard to tell whether I am experiencing fatigue from the PsA or from the treatments I am using, but I have found fatigue particularly challenging to tolerate. I also experience constant hair loss, which is embarrassing and cumbersome, and makes it difficult to shower or do my hair away from home. I currently inject methotrexate on a weekly basis, and I have struggled to find the 30 gauge insulin syringe/needles that I prefer at pharmacies in my area. I have travelled domestically, but I worry about travelling internationally with my medication."
- "I am currently on Humira, which is extremely expensive. I am fortunate to be eligible for assistance. Since I have had breast cancer I am a bit nervous about taking it due to the possibility of certain cancers."
- "I have been on DMARDs with bad side effects from methotrexate at full dose. Enbrel for 5 years and just started Humira. The paperwork for financial support is annoying and then every time something changes (Rx, new insurance, govt program) you have to start over and there are gaps in coverage. I would also like to have to take meds less often. I am forgetful with weekly/biweekly injections and refills on time."
- "Currently only on NSAID. Hardships of taking them is the increased risk of heart attack or stroke. The needs that are being met by treatment are the fatigue issues."
- "I have tried a number of drugs including biologics and nothing except prednisone seems to help. I have had massage therapy which helped but was too expensive to continue with. All drugs have side effects. The photosensitivity is problematic as is the injection site from some drugs. Also with

a lowered immune system as a side effect, I have suffered bouts of pneumonia and abscess teeth and sores. My hope for all the treatments that I tried was some relief and ability to go back to work. This hasn't happened."

- "Sulfasalazine, Methotrexate, Humira, Enbrel. Methotrexate was damaging my liver so stopped. I felt that my arthritis was managed at about 60% with all these treatments. No difficulties taking any of these drugs. 40% of my pain, stiffness and fatigue not being met which impacts my enjoyment of life."
- "I have been on Methotrexate pills and injection that helped some but after 15 months the side effects made me stop due to harsh side effects and nausea daily. I was put on Sulfasalazine and [got] the same side effects. I have been taking Celebrex since day one which helps the arthritis 60% but only using ointment now for psoriasis which helps only 25%..i'm not allowed to try biologics without trying Leflunomide .I was tired of feeling unwell all the time..i cant afford the cost of biologics. I want to try Otezla."
- "My PsA is being treated with Sulfasalazine and Naproxen. I have also gotten a lot of relief from natural supplements, especially Theracurmin and NEM. Custom orthotics have helped with mobility. This combination has actually managed my PsA quite well, although it does get expensive. I have noticed stomach issues from Naproxen and have been able to stop relying on it for pain management thanks to the supplements."
- "Methotrexate by injection makes me nauseous even after 7 years. I hate taking it but it seems to keep the disease from progressing. On additional meds to boost and control inflammation. (Hydroxychloroquine and Celebrex) Skin treatments are more effective with few side effects."
- "I have tried the traditional drug therapies, like NSAIDS and DMARDS. These did not work to manage my symptoms. I then moved into the biologic medications. I have currently exhausted 1 option (Enbrel) and am on the verge of exhausting another (Humira). I have found that there are side effects associated with these medications. I had to stop using the NSAIDS as they were giving me severe stomach pains and ulcers. With the biologics, I get injection site reactions that cause redness and itching and swelling. I've also seen a rise in infections, particularly ones that are hard to treat or get rid of (like a severe staph infection that has lead to reoccurring folliculitis). I have also noticed that some treatments cause my skin issues to be exacerbated. It is incredibly hard to get the treatment that I need. Without private insurance, I would not be able to afford my medications. Even then, they make it difficult to get the medication because of all the requirements that they have. I do not mind giving myself the injections but it did take some time to work up to this and I found that I had great difficulties using the auto injector pens. When I am having a bad day with my hands, this can make injecting difficult. None of my treatments have been perfect. They will help some symptoms but not others."

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
- 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.

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 DMARD's), liver toxicity and weight gain (Prednisone).

People living with PsA told us:

- “Ideally, I am looking at a reduction in pain from any treatment. As of yet, I have not been seriously impacted by PsA and therefore right now I'm not overly keen on any side-effects from seeking treatment.”
- "Improved quality of life, for me, looks like more consistency. I would prefer consistently low levels of pain/inflammation to "very good days" "mixed in with" "very bad days". I am willing to wait longer to fully experience the positive effects of a new treatment, but my expectation would be that, within this time, I would have access to check in with my rheumatologist or another medical professional. I would prefer a treatment that does not rely on supplementary NSAIDs for its efficacy. I would prefer a treatment that I could administer at home; however, I would consider it a fair trade-off if I only have to travel every 6+ weeks for treatment. I would love to hear of a treatment that does not negatively impact my energy levels: I believe this is a gap that is underestimated in current treatments."
- “I want to treat the disease and limit the long term effects to my body. I need to be healthy now, but don't want to shorten my life.”
- “Remission from PsA would be an improvement.”
- “Less pain, stiffness and fatigue would be great so the missing 40% would be nice. I would be able to do more varied activities and have more stamina for the activities of daily living I no longer keep up with. I would be willing to be inconvenienced and experience minor side effects of the new treatment.”
- “I would like a treatment that does not make you unwell and does no damage to your liver and kidneys etc. My quality of life would be more bearable without daily pain and scarring affecting mobility and having to cover up my body in hot weather. I really hope your new drug can help.”
- “I am currently pregnant and have stopped taking all meds. Thankfully my PsA is in remission due to pregnancy, but I fear the eventual flare upon delivery. I have not taken Methotrexate as it is not recommended for women in their child bearing years, so it's important to me that a new medication not affects fertility and be safe to resume while breastfeeding.”
- “A new treatment that didn't cause stomach upset, lowered liver risk, and combated exhaustion would be great.”
- "I expect that my quality of life will improve with treatment. For me, this means that I am less fatigued and have more energy, and that my joint and skin issues are manageable. For instance, less pain and swelling in joints, reduced stiffness and reduced redness and plaques. I would hope that with treatment I am able to do most activities, particularly to work a full day, and to be able to complete most activities without difficulty. I think one of the biggest gaps right now in treatment is the disconnect between what different doctors are able to do. I think that drug companies need to do more research into how these doses will affect certain conditions and the options need to be available to all doctors."

6. Experience With Drug Under Review

Here is what the PsA patient who experienced the drug in review told us:

- “My rheumatologist was able to secure tofacitinib for me and my extended health agreed to pay for it. This drug controlled my symptoms fairly well and was easier to take than most other drugs I have tried. Unfortunately I wasn't able to continue because of repeated infections while on it which stopped soon after stopping the drug.”

7. Companion Diagnostic Test

N/A

8. Anything Else?

Here is what PsA patients wanted to share as their last comments:

- “I am dissatisfied with the economic barriers that prevent me from newer and more advanced treatments. It feels as though newer treatments are a "last resort" for doctors to prescribe, even though many older treatments have serious long-term side effects.”
- "More research and public education on the effects of arthritis. More understanding on not just the pain but the emotional toll it takes on individual and families"
- “In my experience this [tofacitinib] would have been the best drug for controlling symptoms. It didn't seem to present many side effects however since it lowered my immune system dramatically, the infections I suffered, some of which were life threatening, made it impossible to take.”
- “It is nice to think there is another option out there for the treatment of PsA and I would be willing to try it if the rheumatologist offered it.”
- “I think that the more options that we as patients have, the better off we will be. All most people with chronic diseases want is to be a productive member of society - we didn't ask to be ill and I certainly don't enjoy being ill. I just want to be able to live a normal life - I want to work, complete chores around my house and look after my family without difficulty. If there are treatments available that can help us do this, then I think it is worth investing into from the government's perspective.”