

Patient Input Template for CADTH CDR and pCODR Programs

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

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 had 11 people living with psoriatic arthritis respond to a social media request for information for this CADTH submission. The data was gathered from February 8 to March 2, 2018 in Canada. Of the 11 respondents, one had experience with the ixekizumab.

The Canadian Arthritis Patient Alliance contributed information via its experiences of interacting with its membership.

3. Disease Experience

It is important to highlight that psoriatic arthritis (PsA) impacts all aspects of a person's life. Living with PsA is challenging. Symptoms that respondents indicated as having the greatest impact on their day to

day life included significant pain, stiffness, fatigue and limited range of motion in the joints. All symptoms had an impact on daily activities that people without PsA take for granted like the ability to walk distances, hold a phone, stand for any length of time, keep a professional activity, and take care of their family. People also indicated the skin sensitivity, redness, flaking, and pain from plaque psoriasis that accompanies psoriatic arthritis had considerable impact. Depression and mental health issues can be associated with PsA as well. 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, or even weeks. 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 or their ability to do anything about it.

Here is what we heard from PsA patients:

- "Currently I am really good. But a couple years back some of the things that I struggled with included: sitting on the toilet, getting in and out of the car, walking upstairs or downstairs, opening jars, gripping containers especially plastic flat surface or milk cartons, severe fatigue, mood changes, and being able to climb up a ladder. Which brings me to how others in your life were affected - you are changed from the person who you were. I was very active. My husband would always say he could bottle my energy and sell it. But when PsA entered my life it affected my whole life. Depression was a big thing. Not only did I have to deal with it but he had to watch me deal with it. My kids really didn't understand why I was like I was. Adjustment of 180 degrees"
- "Pain/stiffness/swelling especially in the morning and late evening make activity difficult. The fatigue is especially difficult to manage. Lately I'm having difficulty with everything as my hands are useless. This means help with daily tasks and driving."
- "I am tired a lot. My fingers are deformed. I had a knee replacement and will need my hip done soon. Can't go for long walks with my husband like I used to."
- "Limited mobility, extreme fatigue, skin rashes and breakouts. Limited social interaction due to all these things. I also need to pace business and personal travel due to illness. I spend most if my daily energy faking feeling well to appear normal at work."
- "My PsA symptoms are painful knees, fingers and ankles. The pain in my knee got so bad that I can no longer squat or get up from sitting without assistance or holding on to something. I used to do high intensity training but now I am limited to what I can do. I can't squat, jump or bend my knees. Other things are affected, like getting out of the car, using stairs and prolonged activities. I have started nursing school six months ago and am thinking of dropping out due to the inability to carry out physical tasks."
- "Toe nails peeling off, inflamed foot joints and pain, sacroiliac pain upon walking and sitting. Feet numb when sitting. Stabbing pain in my spine when walking any distance. I want to improve my ability to walk and even sit without so much pain. It interferes with every aspect of my day. I am on disability because of it and I feel I am wasting my life. I was an avid runner and a part of the workforce. Now I have nothing but to wonder how far can I push myself today without being in non-stop pain."
- "Symptoms I experience include long periods of morning stiffness and pain in my affected joints. I have fatigue, which is worse when I experience more pain. Pain makes my work difficult (I work in retail where most of my time is spent on my feet and I need to lift heavier items and do repetitive work). I have difficulty sleeping some nights due to pain. There are some activities that I cannot do, especially when I have a flare. If I have a flare it becomes impossible or very difficult to participate in physical activities. I do not feel I can commit to sport teams (ex. curling) because my disease is unpredictable and I do not want to let family and friends down. On days that I am more fatigued, my mood is greatly affected and that can impact people around me. I have to ask for help from friends and family more often because there are some things I cannot do (such as strenuous work at home)."
- « Symptômes: irritations et desquamations de la peau parfois à des endroits très visibles donc désagréable. J'ai des douleurs articulaires importantes. Ces douleurs m'empêchent parfois de faire mon travail de façon efficace et performante. Je ne peux plus faire certains sports étant donné les

douleurs (ex: jogging, ski alpin, patin). Mon quotidien est parfois difficile car je ne peux pas rester debout et/ou marcher plus de 30 minutes consécutives, surtout tôt le matin et en soirée. »

Translation - "Symptoms: Skin chaffing and scaling, sometimes on very visible regions, which is unpleasant. I have considerable joint pains, and this sometimes prevents me from working efficiently and productively. Because I'm in pain, I cannot do certain sports anymore (e.g. jogging, downhill skiing, skating). Daily living can be hard, as I cannot stand or walk for more than 30 minutes at a time, especially early in the morning and at night."

4. Experiences With Currently Available Treatments

As each person is unique, it is inevitable that individuals will react differently to treatments. There is currently no way to predict how a person's PsA will respond to any type of medication. In some cases, the body may develop a resistance to medication requiring changes in the treatment plan. There is no cure for PsA, which means that patients need to go on medications for life, and their disease may adapt to their medications and require changes to be made. As a result, it is essential for patients to have access to an array of medications including: disease modifying anti-rheumatic drugs (DMARDs) which include methotrexate, a combination of biologics and DMARDs; in order to provide options to allow for individualized approaches to disease management. It is important to know that people will often go through many different treatments over the course of their lifetime. As a patient it is frustrating to struggle with a disease and then to also have to go through many different trial and error experiences to find a medication or combinations of medications that might work, even for a short time. It is also an anxious and stressful experience if your medications cost thousands of dollars out of pocket, and sometimes people need to make difficult choices in order to pay for their medications.

This is what we heard from people living with PsA:

- "Sulfasalazine didn't work. Methotrexate - severe side effects including hair loss and debilitating nausea. Enbrel - helped but not enough; getting medication required lots of hoop jumping. Remicade - works best. I have good insurance so I can get the medication but even after all of that my co-pays are nearly \$3000. Without co-pay assistance I still couldn't afford the meds."
- "I am on Enbrel. No side effects so far. No costs problem. I'm on New Brunswick Drug Plan. I'm retired. My needs not being met are: being tired, fingers still deforming. But I'm still able to get around."
- "Methotrexate, folic acid, Celebrex, hydroxychloroquine, vitamins. Methotrexate makes me sick and anxious. Other medication seems to be okay."
- "Current treatment is 6 tablets of Sulfasalazine (oral) per day. I sometimes take Advil or Tylenol to reduce to pain or swelling. It has decreased some of the inflammation in the joints but has not done anything for the pain. I feel the same pain as when symptoms were at its highest. The rheumatologist suggested methotrexate as next step."
- "Medications I have used to include Enbrel, Humira, Stelara. I currently take Cosentyx, Methotrexate, Naproxen, Prednisone, and Leflunomide. I had early success with Enbrel and Humira and eventually these became ineffective after a few years. Stelara was effective in ridding of my psoriasis, but not my arthritis symptoms. I am experiencing slight success with Cosentyx, but it is not 100% and my doctors would like to tweak the dosage. This might not be possible because I am already on a high dosage for my body weight. I also seek treatment through massage and physiotherapy. The worst of side effects I've had is nausea from Methotrexate. I also experienced serious hair loss while I took Stelara, which led to the decision by my medical team to stop that medication. There is a cost in missing work for frequent medical appointments (because Cosentyx and Stelara are only approved to be used for psoriasis and to be prescribed by a dermatologist, I must have appointments with my dermatologist as well as my rheumatologist and family doctor). The cost to cover my deductible for Pharmacare is very high. There is a cost to physiotherapy and massage treatment. I sometimes have difficulty giving myself injections and have to ask for help. Having more non-medication treatments

(massage, physio) recognized as important alternative treatments and having them covered. Having more affordable deductible costs. Needing better access to medication (we really have to jump through hoops for the government to approve medications for me.)”

- “Methotrexate debilitated me. I was on Humira and it worked. I moved to BC and I cannot afford it here because my insurance deductible is so high. Right now I only take Sulfasalazine because it’s all I can afford.”
- « Médicaments : Methotrexate 20mg/sem. Pas d'effets secondaire mais efficacité limitée. Amélioration de +/- 25% de ma qualité de vie. Depuis 3 mois, je prends ixekizumab 80 mg/4 sem. par injection. Les douleurs sont passées de 9/10 à 3-4/10. Mon psoriasis a disparu à plus de 90%. Cependant, comme c'est à titre de recherche, le coût est nul pour moi mais on me dit qu'il sera de plus \$8,000 annuellement ce qui me ferait arrêter le traitement étant donné le coût trop élevé. Ce traitement me satisfait beaucoup actuellement à 80%. »

Translation - “Medications: Methotrexate: 20mg/week. No side effects, but limited effectiveness. Improves quality of life by +/- 25%. I started ixekizumab injections (80 mg/4 weeks) 3 months ago. My pain has gone from 9/10 to 3-4/10. My psoriasis has decreased by more than 90%. It is free as part of a research study; however I have been told it will cost over \$8,000/year. This is too expensive and would make me stop treatment. I am very satisfied (at 80%) with this treatment.”

5. Improved Outcomes

PsA patients have identified several outcomes that are important to them and that should be considered when evaluating new therapies including drug administration (pills vs infusion or self-injections), impact on pain, fatigue, mobility and cost. People living with PsA told us:

- “I would like more energy.”
- “Having energy to keep moving. Having skin you don't need to hide. Having days where you can stay up past 9 pm.”
- “I would like the treatment to allow me regain mobility of my legs. Reducing inflammation is great but if I still cannot do a movement, that is not a successful treatment. If the medication has some effects like some nausea, but allowed me to move properly, then I would see that as a good compromise.”
- “As with all medications, I hope that the outcome will be a great reduction in swelling and pain. This will improve my life because I can then be more active and keep my body healthier, which will help my disease stay at bay. With Cosentyx, the biggest problem I'm noticing is that from one dose to the next dose, the improvement in pain only last about half the time. And now I'm in a situation where I might not be able to take the doses more frequently because I might be at a maximum dosage (as outlined by the government). There are not too many. I already trade off a great deal in my life to manage pain without considering what I would trade off for a medication. I already spend a lot of time taking care of my body and trading off time with friends and family. I already trade off my hard earned money for good medication and treatment. My life is already a series of trade offs, so I don't take well to making more trade offs for medication.”
- “I just want less intense flare ups and fewer of them. On Humira they were much less frequent and intense.”
- “Don't have to think about stiffness. Few side effects of drug. Fix the fatigue.”

Another way to summarize this feedback is that people simply want some degree of normalcy to their lives with PsA.

6. Experience With Drug Under Review

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

- « J'ai pris part à un essai clinique à participation volontaire. Mon psoriasis est contrôlé et a "disparu" à plus de 90%. Douleurs arthritiques: amélioration de plus de 50 à 60% soit passées de 9.5/10 à 3-4/10 actuellement. Aucun effets secondaires ou indésirables. Il est facile à utiliser et l'injection par soi-même n'est pas compliquée à réaliser. Il changera et a changé ma santé et mon état de façon appréciable et ce, seulement depuis 3 mois que je l'utilise. À long terme, je suis convaincu que ce médicament pourra contrôler mon état de santé. Je suis un mesure de mieux faire mon travail au quotidien (inspecteur de bâtiment). »

Translation - "I have participated in a clinical trial on a volunteer basis. My psoriasis is under control and more than 90% of it has 'disappeared'. Arthritis pains: a 50 to 60% improvement, having gone from 9.5/10 to now being 3 or 4/10. No adverse reaction or side effect. It is easy to use, and to self-inject. In only 3 months, it has positively changed – and will change – my health status and condition. I am convinced this medication can stabilize my health condition in the long term. I can now do my job better (as a building inspector)."

7. Companion Diagnostic Test

N/A

8. Anything Else?

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

N/A