

CADTH COMMON DRUG REVIEW

Patient Input

IXEKIZUMAB (TALTZ)

(Eli Lilly Canada Inc.)

Indication: Arthritis, psoriatic

CADTH received patient input for this review from:

Arthritis Consumer Experts

Arthritis Society & Canadian Arthritis Patient Alliance

Canadian Skin Patient Alliance (CSPA), Canadian Association
of Psoriasis Patients and the Canadian Psoriasis Network (CPN)

Canadian Spondylitis Association

March 8, 2018

Disclaimer: The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations.

While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

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.

1. About Your Patient Group

Arthritis Consumer Experts (ACE) is a national patient-led organization that provides science-based information, education and support programs in both official languages to people with arthritis. ACE serves consumers living with all forms of arthritis by helping them take control of their disease and improve their quality of life.

Arthritis Consumer Experts is committed to the following organizational objectives:

To inform, educate and power people with arthritis to help them take control of their disease and improve their quality of life;

To provide evidence-based information in reader-friendly language to people with arthritis, the public, governments and media;

To provide research decision-making training to people with arthritis to help them participate meaningfully in research organizations and in consultations with government.

ACE's membership and program subscribers include people with arthritis, their families, their caregivers, rheumatologists, and other health professionals, elected officials, and senior government bureaucrats.

Link to website: <http://www.jointhehealth.org>

2. Information Gathering

The information was gathered through Arthritis Consumer Experts' (ACE) call for patient input issued on February 8, 2018 and day-to-day interactions with people living with psoriatic arthritis its work with clinical researchers in Canada, and through discussions with consumers and scientific members of the ACE Advisory Board. The data was gathered in Canada from January 2018 to March 2018. Patients who have submitted inputs for a previous submission for psoriatic arthritis on January 17, 2018 authorized the use of their information for future patient inputs for psoriatic arthritis; there are no updates to their disease journey.

3. Disease Experience

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

The patients' day-to-day life is greatly affected by their plaque psoriasis. Unlike most people who can take their physical/mobility abilities for granted, people living with plaque psoriasis must always consider the state of their disease and decide what they can (and cannot) cope with or achieve, how they can go about it, and how much help they may need.

- Patient A has been living with psoriatic arthritis (PsA) for over 15 years. "My life went from waking up and going about my day to planning, struggling and having to be careful of what I do, where I go and the unpredictability of the disease." The symptom that restricts him most is fatigue. He added: "I went through 15 years of pre-biologic joint damage and have been having surgeries to repair this damage."
- Patient B has a baseline level of pain that she has learned to live with. She added: "When I am in a flare, my ability to cope collapses. I have nothing that controls the pain." Like Patient A, fatigue limits her day-to-day life and activities.
- Patient C has PsA and ankylosing spondylitis. The symptoms they experience include inflammation, pain, reduced range of motion in the shoulders, hips and elbows, and sever enthesitis that caused golf ball sized lumps on their Achilles tendons. Social activities are rare as they always feel pain and fatigue. They added: "Lifting, pulling, pushing, carrying things hurt my arms. Driving and working at a desk are exhausting."

- Patient D's ability to walk and stand is very limited. They can only walk for 10 minutes before feeling pain. They are sleep deprived. Emotionally, they feel depressed, helpless, and lose hope. As a result, they have gained 80 pounds in the last 4 years. Patient D can only work part-time.
- According to Patient E, PsA affects her every day. With medications, she can walk 45 minutes per day and do most of the household chores. She needs help with dishes, floor washing, vacuuming and shopping. She can shower but has trouble getting in and out of a bath tub. She has a raised toilet seat and a cushion to sit on. She cannot sit more than 30 minutes at a time because of ischial bursitis.

It is important to note that as a result of the symptoms of psoriatic arthritis (PsA), anxiety, depression, and sleep disorders are prominent amongst people with PsA.

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

Caregivers of patients with PsA have indicated that time is always a concern for them. They have to arrange their day according to the person living with PsA. When patients are in pain, caregivers have to help with house chores.

- Patient A finds it challenging to explain how he feels and the disease itself. His caregivers don't understand what it's like to live with PsA. He added: "My caregivers have been stretched over the years but they are very supportive. PsA has impacted my caregivers just as negatively as me."
- Patient B's family is frustrated with her constant pain and fatigue. She added: "They have given up on trying to help or understand my condition."
- When Patient C feels fatigued, their family members feel stressed and cannot do work or other activities because they would have to look after or help Patient C.
- Like Patient B, Patient D expressed that their caregivers feel frustrated because they do not understand what's wrong.
- Patient E needs help with many household chores, including dishes, floor washing, vacuuming and shopping. Her husband has to drive her to her specialist appointments in another city. She is limited in what she can do when she cares for her young grandchildren.

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

Patients are concerned about side effects over a prolonged period. All the patients agree that they will take the medication that is most effective and that poses the least chance of side effects.

4. Experiences with Currently Available Treatments

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

- Patient A tried 3 biologics. The first and second biologic didn't work. The third one works best but is losing efficacy. He added: "Current available treatments have advanced but my body has so much damage that surgeries are part of my treatment. With the ups and downs of surgery, managing my disease is still a struggle."
- Patient B is currently taking a phosphodiesterase 4 inhibitor. She has tried one anti-TNF biologic but had serious side effects from it – demyelination of her temporal lobes. Her neurologist has forbidden her from going on another anti-TNF biologic.
- Patient C is currently taking methotrexate, Humira and folic acid.
- Patient D is currently taking Simponi and sulfasalazine Celebrex. They also live with Type 2 Diabetes. They added: "Only side effect seems to be terrible dry mouth but not sure which meds cause it."
- Patient E is using Remicade for her PsA. It has worked for the last 70 doses. She had no side effects with Remicade or Enbrel. Enbrel also worked very well on her psoriatic arthritis, better than Remicade, but it stopped working on her plaque psoriasis. She also takes Tylenol Arthritis around the clock because she has allergies to NSAIDs. She is not on any patient assistance or support program. Her doctor fills out the paperwork to get special authority to cover Remicade cost.

5. Improved Outcomes

- Patient A feels that that ixekizumab will be another option in treatment if his current medication loses its efficacy.
- Patient B feels that because ixekizumab is an IL17 inhibitor, it could be a strong candidate for treating her arthritis – as long as demyelination is not a side effect.
- Patient C, D, and E did not submit a response for this section.

In general, patients believe that the best treatment is one that has the fewest side effects. Through ACE's research and education efforts, people with PsA who interact with our organization generally understand there is a high degree of variability of disease and that there is a need for increased research activity into the causes and possible cures for the disease. Patients want new treatments that can control or stop the symptoms of PsA.

6. Experience with Drug Under Review

None of the patients interviewed have experience with using ixekizumab to treat their psoriatic arthritis.

7. Anything Else?

Arthritis Consumer Experts is providing this patient input submission based on patients who have responded to current and past call for patient inputs for the treatment of psoriatic arthritis. Our organization believes that a new therapy for psoriatic arthritis will ultimately improve the lives of people living with the disease.

Appendix 1: Patient Group Conflict of Interest Declaration

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

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

This submission was expressly researched and written by the staff of Arthritis Consumer Experts, free from advice or influence 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.

We interviewed some patients who are in the same network as the Canadian Spondylitis Association.

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

Arthritis Consumer Experts received grants-in-aid from Eli Lilly Canada.

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

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

Name: Cheryl Koehn

Position: Founder and President

Patient Group: Arthritis Consumer Experts

Date: March 8, 2018

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 of 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)."

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No
- 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
- List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

The Arthritis Society

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Amgen				X
Abbvie				X
Celgene				X
Eli Lilly				X
GSK		X		
IMC	X			
Janssen				X
Merck				X
Novartis				X
Pfizer				X
Roche			X	
Sandoz	X			
Sanofi			X	
UCB				X

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

Name: Deanna Bowlby

Position: Senior Manager, Education Programs

Patient Group: The Arthritis Society

Date: March 8, 2018

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
Amgen			X	
Abbvie				X
Janssen		X		
Lilly	X			
Manulife	X			
Novartis	X			
Pfizer (including Pfizer Hospira)			X	
Purdue		X		
Roche			X	
Sanofi			X	
UCB		X		

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Name: Dawn Richards

Position: Vice President

Patient Group: Canadian Arthritis Patient Alliance Date: March 8, 2018

Patient Group

Canadian Skin Patient Alliance (CSPA), Canadian Association of Psoriasis Patients and the Canadian Psoriasis Network (CPN)

1. About Your Patient Group

The Canadian Skin Patient Alliance is working in collaboration with the Canadian Association of Psoriasis Patients (CAPP) as well as the Canadian Psoriasis Network (CPN) for the completion of this submission.

CAPP is a national, non-profit formed to better serve the needs of psoriasis patients across the country. We are a partner organization of the Canadian Skin Patient Alliance and strive to improve the quality of life for all Canadian Psoriasis Patients. Our mission is to be a resource and advocate for psoriatic patients and their families to improve patient care and quality of life.

CPN is a national, non-profit dedicated to improve the quality of life of all Canadians who are living with psoriasis and psoriatic arthritis while vigorously pursuing a cure.

(CSPA is registered patient group with CADTH.)

2. Information Gathering

CSPA and CAPP hosted two different surveys on Survey Monkey in January and February of 2018. One was targeted to ask about the challenges of living with psoriatic arthritis while the other focused more on experience with Taltz. The survey was advertised on our social media platforms, websites, through two different newsletters and personal contacts. In total, we received 32 responses. Respondents had lived with the disease from 2 – 45 years.

All three organizations attempted to contact the research sites to ask them to share the survey link with patients involved in the clinical trial. The response was as usual – can't help as it is a privacy issue, don't have time....It continues to be a challenge to access the patients who have actual experience with the medication despite our best efforts.

This submission is supplemented from information researched from patient websites and on-line disease discussion boards where patients share their experiences with psoriatic arthritis and different treatments.

3. Disease Experience

Psoriatic arthritis is a form of arthritis linked to psoriasis that is chronic and progressive. This inflammatory disease causes joint swelling and pain in multiple joints and can sometimes result in joint deformation. Psoriatic arthritis affects 1-2 people for every 1000 people. Each year, there will be around 6 new cases diagnosed. Men and women are affected equally. The pain and exhaustion from this disease can be debilitating. Mornings and cold weather can exacerbate the situation.

"Mornings start slow. There is a constant ache in my hands and feet."

"Cold weather makes it unbearable and also hot weather as well."

"I wake up in pain...go to bed in pain. You get some relief during the day and next thing you know your flaring. Weight gain from inactivity. Pills and meds continuously. I guess what I'm lucky it's not cancer but I am 49 and wonder where I will be in 10 yrs physically. I have a 14 yr old and I can't even kick a ball around with her."

Not everyone who has psoriasis will get psoriatic arthritis. Most of the time (80%), psoriasis comes first. Psoriasis is a skin disease that causes scaly, red/white plaques. Both diseases are caused by your immune system being inappropriately activated. Of the 32 respondents to our surveys, 73% stated that they had psoriasis first then psoriatic arthritis.

It is still not clear how many people who have psoriasis will get psoriatic arthritis. Estimates range from 4-30%, depending on what part of the world you live in. Only 13% of people with new onset joint pain do not have psoriatic arthritis.

Respondents to our survey explained it in this way:

“Crippling , extreme pain , sleepless nights , swelling in feet to where I can't get a shoe on or see my ankles , and just frustration when it gets so bad.”

“It's living in a very restrictive existence, you have the pain in the joints and you have the ugly plaques of dried skin cells, the itching and burning. You can't wear skirts, dress or shorts because you don't want the world to see your legs!!! You no longer can dye your hair, so you have to accept the grey hair!!!”

“Life limiting. It keeps getting worse. I have kept on doing as much as I can. First I needed a cane. Then a motorized scooter to continue working. Then a special accessible vehicle.. My world keeps getting smaller. Now I need help to go most places. I can still walk in the house, short distances. And do " sitting down" jobs and activities. But I tire easily.”

4. Experiences with Currently Available Treatments

The respondents from the CSPA surveys indicated that these 32 patients have used a variety of treatments from topicals, to biologics to medical cannabis all with varying results.

“It has been very difficult until I started taking simponi. At 26 years old right now I'm so happy I can finally act my age and enjoy the same things my friends do. Simponi has changed my life and I feel like a new person.”

“Have taken a gamut of drugs over the years. Recently used tramacet. Now trying just to use tylenol with muscle relaxer.”

“Medical cannabis at 5 grams per day. Methotrexate.”

“I take a NSAID - meloxicam.”

Many rely on a significant amount of pain relievers and are generally concerned about the amount that they do take.

“Currently using voltarin and ibuprophen for pain.”

“I've noticed that there has been some improvement but I'm concerned about the amount of drugs I have to take daily. Plus I was operated for breast cancer Oct.19 2017 for lumpectomy.”

One patient offered the following: “Patients need to be treated holistically, vs only with drugs i.e., mental wellness should be considered part of treatment plan.”

5. Improved Outcomes

Pain is the number one issue that respondents mentioned that is an issue for them. As one person stated “The pain and being tired from having pain” is what he wished would improve. They also stated that the uncertainty of the disease and when flare-ups will occur play constantly in their lives. “No making plans ahead of time. Pain is debilitating at times.” “Not knowing what tomorrow will bring and how bad this could get and the fatigue sometimes.”

Others stated that they wished that they could do more activities of daily living, without limitations and without pain:

“I wish I could do more with my hands, but I am slowly getting used to my new normal. I do what I can when I am able and when I'm not, I take it easy.”

“I have a hard time walking.”

“Not being able to do certain things that I loved or even not being able to do something as small as removing my shirt.”

Some respondents stated that they wished that the itch and appearance on their skin could be controlled. Others mentioned about the invisible aspects of the disease. “Just because you don’t see a disability doesn’t mean I feel well.”

Caregivers and family members are all affected by the stigma, the depression and self-isolation felt by patients. “Most people don’t understand what it’s like so it’s kind of lonely sometimes. You see how much people take simple things like getting dressed easily or cooking for granted.”

6. Experience with Drug Under Review

Unfortunately, we were unable to find any patients to respond to our surveys with experience with Taltz for psoriatic arthritis.

However, from the patient websites and on-line disease discussion boards, we heard the following:

- It takes time to find a treatment that works for each individual patient:

“I went to Humira, then Enbrel, and then Cosentyx trying to find what would give relief, along with high doses of Prednisone and pain meds, including Oxycodone. Nothing helped and I spent days at a time in bed, unable to walk or work at times, and forcing myself to keep working and going the best I could...totally depressed as I couldn’t hardly walk, rise from sitting or even sleep. I came close to overdosing on pain meds several times, just trying to get relief.

Within 2 weeks of starting taltz, I began to see a marked change in my Psoriasis coverage, until as of November 2017, I am completely clear of Psoriasis, and I feel better than I have for 45 years! I am absolutely thrilled with how well I feel.

I want to encourage others to keep trying the new meds on the market, for relief, until one is found to help you, ...I went through Remicade, Enbrel, Methotrexate, Humira, and Cosentyx before I started Taltz.”

- Others mentioned that Taltz helped their skin but not their joints:

“I have been on Taltz since January and it cleared ALL of my psoriasis, However I also have arthritis and it has done nothing to help it.

- Several patient discussed pain, swelling at the injection site:

“I started Taltz 3 weeks ago and took my second dose 3 days ago. Each time that I have injected it has initially stung for a few seconds, my skin swells, and I have horrible back pain within days. The first time this pain subsided within a few days. This time it hasn’t subsided yet and the pain is worse.”

- Others talked about the impact on pain while on Taltz:

“I have severe PsA and have tried everything. I am on Taltz now, which is helping to a degree. The pain was alot worse before I started it, however I am still in pain on and off most of the day.”

7. Anything Else?

Like psoriasis, psoriatic arthritis 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 there symptoms are very similar. Many wait for the next treatment option in hopes that it will work well for them and achieve 100% effectiveness with limited side effects.

Secondly, psoriatic arthritis is a disease that often “falls through the cracks.” Some patients are seen by a dermatologist while others are seen by rheumatologists. Yet 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 damage to the joints. In fact, a recent article cited two new Scandinavian studies that highlight the considerable room for improvement that exists in psoriatic arthritis outcomes: “...if you think of the treatments that we have and the treat-to-target approach, psoriatic arthritis lags behind rheumatoid arthritis, maybe by a decade.” See full article:

<https://www.mdedge.com/edermatologynews/article/160310/psoriatic-arthritis/psoriatic-arthritis-treatment-were-not-doing-so>.

Although psoriatic arthritis is a chronic condition, early detection and appropriate treatment can help reduce symptoms and prevent joint destruction with treatments such as Taltz.

Lastly, although we were not able to access patients in Canada that have experience with Taltz, this is not reflective of the need for this new treatment but of the current limitations in reaching patients who were involved in the clinical trials.

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.

Appendix 1: Patient Group Conflict of Interest Declaration

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

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

Not applicable to this submission

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

Not applicable to 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
Janssen Canada			X	
Celgene			X	
Novartis			X	
AbbVie Canada				X
Pfizer 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: Kathryn Andrews-Clay

Position: Executive Director

Patient Group: Canadian Skin Patient Alliance

Date: March 7, 2018

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Janssen Canada				X
Novartis			X	
AbbVie Canada			X	
Eli Lilly			X	
Celgene		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: Kathryn Andrews-Clay

Position: Executive Director

Patient Group: Canadian Association of Psoriasis Patients

Date: March 7, 2018

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Janssen Canada				X
AbbVie Canada				X
Eli Lilly			X	
Celgene				X
Leo			X	
Novartis			X	
Amgen				X
Pfizer 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: Glenn Hendricks

Position: Executive Director

Patient Group: Canadian Psoriasis Network

Date: March 7, 2018

1. About Your Patient Group

The Canadian Spondylitis Association is registered with CADTH.

2. Information Gathering

Perspectives were gathered by a survey offered to members of the Canadian Spondylitis Association community. We recruited participants through our facebook community, membership and board. A total of 47 individuals diagnosed with PsA from across Canada participated with a near equal split being female and male.

3. Disease Experience

For many individuals, the road to diagnosed is lengthy and extremely frustrating. In many cases individuals struggle without a diagnosis or misdiagnosis for years and in many cases once they are referred to a rheumatologist a diagnosis is made quickly. In addition to living with the symptoms of Psoriatic Arthritis (joint pain and psoriasis), almost all respondents also live with depression, anxiety and sleep issues that can be debilitating.

Living with PsA has a significant negative impact on patients day-to-day life and overall quality of life. All patients who participated in the survey experienced 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. Tasks as simple as getting out of bed in the morning are difficult never mind working a full day without discomfort or needing some sort of accommodation. A large number of people are on disability and unable to work due to their condition. "Living with PsA definitely impacts my ability to work. As a surgeon, because my hands and my right shoulder are the worst. I cannot work at all". Another commented "I feel stressed and am depressed. I am always fatigued".

Individuals tend to avoid social situations for a number of reasons. Fatigue is a common comment as well as inability to participate (ie. unable to golf, unable to exercise and unable to be active for any length of time without needing to rest, etc). Many miss important family events and activities due to their illness. One patient commented "my whole family gets sad that I cannot partake in a lot of activities. They also give me grief because they have to pick up the slack around the house".

Even those being treated, many experience debilitating symptoms from time to time that negatively impact their quality of life. Those who are on a biologic have significantly improved quality of life. "I was on long term disability for over a year until we found the correct biologic. I'm back at work full time and just passed the 6 month mark".

Included below are some additional direct quotes providing insight into how living with PsA impacts people's lives:

"My ability to walk and stand is very limited. I could walk for half hour to one hour, 4 years ago while max 10 minutes now. Sleep deprivation is still an issue despite using CPAP for sleep apnea. My mood is deeply affected and I frequently feel depressed, helpless and lose hope. I have gained approximately 80lbs in the past 4 years. I still experience a lot of upper and lower back pain with any activity, house cleaning etc, even though I take Methotrexate and Humira. This also affects my sleep. I frequently have problems with my feet experiencing enthesitis or plantar fasciitis. I have not been able to work full time despite needing to in the past 7 years. I can only work on a "casual" basis because I need ample time to recover in between working. I cancel from attending most social events".

"Social activities are rare. I'm tired frequently from pain. Lifting, pulling, pushing, carrying things hurt. Driving and working at a desk are exhausting".

"The fatigue sucks the life out of me. I'm often exhausted and depressed".

“Was planning suicide”.

“It restricts life physically and mentally which has an impact on quality”.

“I forgot to mention the physical and mental struggle of the fatigue since its my only way I remember for being for years now. This disease has caused a lot of conflict between myself and my family as it's hard for people to take what you have seriously. You get labelled as a negative complainer! I have experienced clinical depressions numerous times and isolate to not have to deal with anything”.

“Constantly need help and support. Fatigue and stress of illness are underestimated”.

4. Experiences with Currently Available Treatments

While many who are on a biologic have experienced significant improvement in symptoms and impact on quality of life, people still have symptoms to some degree and some more significant than others. While many who are on a biologic feel controlled, they are hopeful for new treatments on the horizon to offer them options. For people have tried and failed on options currently approved in Canada, new medications provide a hope for them that something will work and they are grateful to have options.

When asked specifically what medications people are taking the majority are on a biologic (Remicade, Humira, Celebrex, Embrel, Otezla, Cimzia, Stelara, Simponi, Cosentyx) with a few on the biosimilar Inflectra. Several are on methotrexate & naproxen. Only a few manage their condition with over the counter medications and opioids.

The side effects that are experienced range from being hard on people's stomachs to nausea and headaches. From respondents answers on the survey, it doesn't appear that any of the side-effects are intolerable and the benefits of treatment out-weigh the side effects. For many they do not experience any side effects.

“Since I started taking Remicade over 15 years ago PsA no longer effects my day to day life. Before starting the medication I was often unable to get out of bed on my own. My mobility was very limited. I could barely lift a glass of water. I now live life almost the same as I did before”.

5. Improved Outcomes

Outcomes that should be considered when evaluating new medications are improved quality of life. Medications that can help patients resume living a normal life. Normal being able to return to work, be self-sufficient, parent without limits and participate, even to some degree in the activities they were able to before they became ill. In addition to medications that can provide hope for some normalcy back into their lives will positively impact patients mental health. Every new medication developed provides an option to patients and hope that something in the new medication just might help them.

Quote: “I've struggled to find out what I have and now I'm struggling with getting on the proper medication for me. I'm extremely tired of fighting to get better and be believed....it's exhausting”.

6. Experience with Drug Under Review

Although none of the people who provided input have experience on Taltz, they were excited to see another option available to Canadians. New therapies provide hope for those who haven't found a medication that works for them and relief to know there are more options available.

7. Anything Else?

New, innovative medicines provide options and hopefully improved outcomes for patients, their loved ones and the physicians helping to manage their condition.

It is challenging for patient groups to access patients on with lived experience (ie. participants in clinical trials) through our individual means and therefore providing information at this point in time of experience on product is limited. Although this submission doesn't include input from patients who have participated in Taltz trials, it's important for CADTH to review medications based on patient lived experiences and impact the disease brings to their lives and the lives of patients loved ones / supports.

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

The submission was completed in its entirety by the Canadian Spondylitis Association with no outside assistance.

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.

Data collection and analysis was completed in its entirety by the Canadian Spondylitis Association through survey monkey and telephone interview.

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
Eli Lilly			X	
Janssen		X		
UCB			X	
Abbvie			X	
Amgen		X		
Novartis			X	
Merck			X	
Pfizer			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: March 8, 2018