

CADTH COMMON DRUG REVIEW

Patient Input

BRODALUMAB (SILIQ)

(Valeant Canada LP)

Indication: Psoriasis, moderate to severe plaque

CADTH received patient input for this review from:

Arthritis Consumer Experts

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

On or before January 4, 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.

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1. About Your 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: www.jointhehealth.org

2. Information Gathering

The information was gathered through Arthritis Consumer Experts' (ACE) call for patient input issued on December 13, 2017 and day-to-day interactions with people living with psoriatic arthritis and plaque psoriasis and 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 in December 2017 and January 2018. Patients who have submitted inputs for a previous submission for plaque psoriasis on September 18, 2017 authorized the use of their information for future patient inputs for plaque psoriasis; there are no updates to their disease journey.

3. Disease Experience

3.1 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 plaque psoriasis since he was 16-years-old. He experiences severe joint pains, especially in the hip, knee, ankle, elbow and spine. He finds it very hard to bend his fingers. Occasionally, he will experience headaches.
- "I'm a patient suffering from rheumatoid arthritis and I take methotrexate injections, which caused plaque psoriasis to appear on my body, my scalp, and my ears", said Patient B. She added: "My plaque psoriasis created thick white scales of skin that I was scratching until they bled and those pieces were all over my floors, my car, and on all areas around me. I was seeing certain plaques get bigger and new ones appear elsewhere." Mentally, she was feeling frustrated, worried and tormented because her rheumatologist informed her that she would have to wait until her body was 99% covered with those infected wounds before her case was taken seriously.

- Patient C said that pain, fatigue, stiffness, and loss of function are the most prevalent and troublesome symptoms of the arthritis component of her PsA. She experiences skin sensitivity, redness, flaking, and pain for her plaque psoriasis. She describes her life with PsA and plaque psoriasis as follows: “My symptoms make daily activities harder and require pacing and prioritizing of activities. For example, even doing daily activities, such as showering, putting on clothing, cooking meals or walking upstairs is painful, and requires more effort and time to do. Because completing daily activities take more time, I am more likely to stop doing social and creative activities due to limited time and energy and increased pain. I can ask for assistance but that is not always available. I stopped working due to pain and fatigue. When my psoriasis is visible and flaking occurs, I feel distressed and embarrassed. I am reluctant to do activities and sports like swimming that would expose my body, arms, and legs in public.”

It is important to note that as a result of the symptoms of psoriatic arthritis (PsA) and plaque psoriasis, anxiety and depression is prominent amongst people with PsA and/or plaque psoriasis.

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

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

According to Patient B, her husband is retired and available to help her out with house chores and drive her around when her back and knees are bad. The downside is that helping her with disease management has reduced the time her husband is available to do part-time consulting work, recreational activities, and socialize with friends.

3.3 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. People living with plaque psoriasis fear they may develop PsA and vice versa. 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

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

Patient A did not provide comments for this section of the patient input.

Patient B did not wish to disclose the name of the medication she is on but notes that there is a great improvement on her scalp and there is less itchiness around the scaly areas. Side effects of her medication include heartburn and dizziness. She is paying for the medication through private health insurance.

Patient C is using a combination of Enbrel and methotrexate. This combination has helped to reduce the number of joints with active inflammation, especially for peripheral joints. As a result of this combination therapy, her psoriasis is under control. Occasionally, she would experience gastrointestinal upset and mucus membrane irritation from using methotrexate; however, she can take folic acid to reduce these side effects. She does not experience any side effect from using Enbrel.

5. Improved Outcomes

Patients believe that the more treatment options there are, the better. Having more options could mean better access to medication, having a backup plan in case the current therapy treatment stops working, and having an economically sound solution in case the current therapy treatment is no longer covered under an insurance plan. As well, they feel that the best treatment is one that has the fewest side effects. Through ACE’s research and education efforts, people with plaque psoriasis and 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 (itchiness, scaling, pain, and flaking) of plaque psoriasis.

6. Experience with Drug Under Review

None of the patients interviewed have experience with using brodalumab to treat their moderate to severe plaque psoriasis.

7. Anything Else?

Arthritis Consumer Experts is providing this patient input submission based on patients who have responded to our previous patient inputs for the treatment of psoriatic arthritis and plaque psoriasis. Some of these patients have indicated to ACE that they developed psoriatic arthritis as a result of their plaque psoriasis or vice versa.

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 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.

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.

Not applicable to this submission. Arthritis Consumer Experts does not receive any funding from Valeant Pharmaceuticals International or its subsidiary branch in Canada.

Patient Group

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

1. About Your 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. Our mission is to provide all current information on treatment and continuing care through education, outreach, research and leading by example.

(CSPA is registered patient group with CADTH.)

2. Information Gathering

The three organizations worked together to inform patients about a patient survey (hosted on Survey Monkey) that was developed specifically to collect information for this patient submission. The survey was live from June 15 to November 30, 2017. The survey was advertised on our social media platforms, websites, through two different newsletters and personal contacts.

The CSPA also sent the link to the investigators involved in the Canadian clinical trials. A few responded saying that the patients “were not interested to be contacted.”

We received a total of 60 responses to this survey. However the usable data is from 45 respondents. And of those 45 patients, 8 were involved in the Brodalumab trials. Of the respondents who completed the demographics section of the survey, 19 were women and 11 were men and their ages ranged from 24-80, with a median age of 56 years.

3. Disease Experience

Psoriasis is a chronic inflammatory skin condition that affects the regeneration of skin cells. Normal skin cells grow, mature and are shed as part of a natural cycle that takes 28 to 30 days. Psoriasis is a skin condition that happens when faulty signals in the body’s immune system trigger new skin cells to form in three to four days instead. Because the skin cells grow too quickly, they are not shed normally. Instead, they pile up on the skin’s surface, creating sores or lesions—often called plaques. Thick, silvery scales form atop these itchy and sometimes painful red patches.

Psoriasis usually affects the elbows, knees and scalp, but it can also occur on the palms of the hands, soles of the feet, nails, genitals and torso. Psoriasis is a persistent, chronic condition that may come and go—flare up then go into remission. During flare-ups, psoriasis causes itchiness and pain in the inflamed skin. Under this stress, the skin may crack and bleed.

Psoriasis can range from a few dandruff-like scales to widespread patches that cover large areas of skin. For many people, psoriasis is nothing more than a nuisance. For others, it’s an embarrassment. And for a few, it’s a painful and disabling condition.

For this survey, we heard that patients have suffered with psoriasis from 2 to 55 years, with an average of 27 years. Lesions are found all over the body, but they are more commonly found on the extremities. Several respondents stated "I have it from head to toe."

From the various symptoms of psoriasis, we asked patients through this survey to let us know what is most bothersome to them. Not surprising, we heard that scaling, itching, pain, flaking and joint pain affected most of the either "frequently, all of the time, or the most troublesome to them." You will note that there are also many psychosocial aspects of this disease, including impact on work life, intimacy and social interactions.

Depression is a significant issue for many living with psoriasis. "At times I sink into depression and cut myself off from any socializing, total unreasonable behavior with my spouse."

"It makes me feel sad that I have psoriasis. Sometimes I don't feel like getting out of bed because I fear that I will have a flare."

"I still did what I had to do but it brought down my self-confidence."

"Haven't been on a vacation in 6 years because of this condition. Had a big problem (at list in the last 3 years) sleeping. Wake up 3-4 times a night scratching and in pain. My confidence to be intimate with my wife of 22 years went downhill. Even though she was/is very supporting and understanding, I just could not get over the way this awful condition made my skin look. I stopped visiting my friends or going to any social events because of the skin flaking all over my clothes and everywhere I sat down. And last but not least the pain and itchiness, the bleeding of the skin it's just exhausting to deal with day in and day out."

Some specific comments about how psoriasis affects day-to-day life:

"Miss work because I have the psoriatic arthritis to go along with it and the pain is horrible, bleeding and itching,, cannot enjoy summer as everyone asks what is that. ,very embarrassing too."

"Before the study I was on, it affected the clothes I wore, go swimming , exercise like squats because my knees would crack and bleed. It was more difficult in my younger years. Sports was really difficult."

"I am excessively tired from dealing with itching, scaling, swelling and bleeding."

"Hairdressers sometimes have issues if my scalp psoriasis is quite heavy. I also believe my hair is thinning as a result of scalp psoriasis. It affects what types of clothing you wear i.e. long sleeve shirts and pants to cover up. Going to a public pool is not an option if its active. It is uncomfortable to wear a bras sometimes and if it's not kept moist it will crack and bleed and stain my clothes and bedding."

"I am retired but still socially very embarrassing. My community services curtailed due to my condition. Unable to partake in most of my grand children's activities. Very frustrating and demoralizing."

"I had to resign my job because I couldn't stand long enough."

"Don't have any energy,,, just want to stay home. embarrassed and paining, gained a lot of weight."

"One day at work I heard a little kid say what's wrong with her hands daddy? The father said I don't know, let's get away from her. The next day I was let go under the probationary period condition of hire, where they do not have to have/give reason for cancelling the job offer. It was a retail supervisory position and they wouldn't take the risk of losing business because you can't hide your hands no matter what business you're in."

The physical, emotional and social aspects of having untreated psoriasis impacted you the most:

	NEVER–	HARDLY EVER–	FREQUENTLY–	ALL THE TIME–	MOST TROUBLESOME FOR ME–
Scale	0.00%	14.29%	28.57%	28.57%	28.57%
Itching	0.00%	0.00%	50.00%	0.00%	50.00%
Pain	16.67%	50.00%	16.67%	0.00%	16.67%
Flaking	0.00%	0.00%	33.33%	50.00%	16.67%
Joint Pain	33.33%	0.00%	50.00%	0.00%	16.67%
Bleeding	0.00%	66.67%	16.67%	0.00%	16.67%
Loss of Sleep	0.00%	28.57%	28.57%	14.29%	28.57%
Affects my concentration at work	0.00%	14.29%	57.14%	0.00%	28.57%
Feelings of depression	0.00%	14.29%	28.57%	28.57%	28.57%
Feelings of Shame	0.00%	16.67%	50.00%	33.33%	0.00%
Feelings of embarrassment	0.00%	0.00%	57.14%	42.86%	0.00%
Affects what kinds of things I can do (e.g. swimming, dancing, sports etc.)	0.00%	14.29%	28.57%	14.29%	42.86%
Affects what kind of jobs I can get	28.57%	14.29%	28.57%	14.29%	14.29%
Problems with intimacy/sex	0.00%	42.86%	28.57%	28.57%	0.00%
Feel I need to hide my skin	14.29%	14.29%	28.57%	42.86%	0.00%
Affects my self confidence	14.29%	14.29%	42.86%	0.00%	28.57%
Affects almost everything I do	14.29%	14.29%	57.14%	0.00%	14.29%

When asked if there are any associated/related conditions or situations that you have to deal with that may be related to your psoriasis, this is what we heard from 42 patients who answered this question:

Depression	85.71%
Joint Pain	28.57%
Diabetes	14.29%
Weight gain	42.86%
Heart disease	14.29%

4. Experiences with Currently Available Treatments

The majority of patients who responded to this survey have used topical treatments while a small percentage of others have used cyclosporine, Humira and Remicade. Respondents reported that long wait times to see a dermatologist, the cost of treatments and access to new treatments were challenging. Some only got treatment that worked for them through clinical trials (different from this one.)

Many reported frustration with topical treatments with little results. “Nobody has time to put cream on 5 times a day and stain your clothes with no results.”

“Stopped taking ointments as it wasn’t working and it kept getting worse. Also creams are hard to use on your scalp when you have lots of hair.”

Side effects of topical treatments are also a deterrent: “Lost hair on my legs. My sex drive almost disappeared. Mood swings became more and more frequent. They lasted and got worst till I stopped using the creams.”

Two respondents were concerned about the effects on immune system: “I refuse to take many of the oral medications because I don’t want to compromise my immune system any more that it has been. I have gluten intolerance and many allergies.”

One person was concerned about “not being able to fight off cancer if I get it” as she is currently on humira. The inconvenience of infusion therapies & phototherapy represent significant barriers for these patients. As well, the infusions have associated costs for patients (in terms of time) & the health-care system.

One patient shared this comment: “Cost is a major factor. I do not have BlueCross or anything and AB Medicare does not cover any prescriptions.”

5. Improved Outcomes

Not surprising from the answer in question #3, the itching, scaling, pain and flaking were listed as the top improvements patients and caregivers would like to see in new treatments.

“I would like new treatments to help EVERYTHING. There is no one aspect of this condition that is acceptable or easy to deal with on any form.”

Patients require access to a treatment that alleviates symptoms in the long term allowing them to live a normal life, go to work, leave the house without having their life interrupted by visits to a phototherapy center 5 times per week or travelling long distances to access infusion centers.

A significant number of respondents reported that weight gain is something that affects them and would like new treatments to address. They believe that their quality of life would be increased if they could be more active/social in their communities.

Caregivers of people living with psoriasis must help patients with excessive house cleaning, bedding change, vacuuming and laundry due to flaking. As well, patients need assistance with applying creams and, in some cases, a helper when going to phototherapy sessions & medical appointments. Also many psoriasis patients also have painful joints, this impedes their ability to do simple every day activities – from food preparation to assisting with clothing and washing, mobility in and out of the house.

“It was very emotional for my wife to see me go through this. The social aspect of our lives was gone. Unable to go on a vacation or having friends over has pushed my wife into a depression state.”

The whole family absorbs the shame as the depression and self-isolation also mean that family members and caregivers live in a dysfunctional setting, where they alone are required to provide the help needed by the patient. One patient noted the impact on her family: “[it] has impacted my husband tremendously in our family business as well as our home life.”

6. Experience with Drug Under Review

Although very few of the 60 respondents had experience with Brodalumab, the responses were very positive and all 8 patients had experience with the treatment through the clinical trials. All of the patients involved in the clinical trial stated that the results were excellent and there were no any side effects except for one patient who stated that she suffered from headaches the day after receiving the injection. Another patient stated that he only experienced side effects when the trial ended and he stopped the Brodalumab. He stated “I experienced mild cripple-ness and pain almost immediately. I am waiting for the medical plan to cover it so that I can start on Brodalumab again.”

Here are some additional comments received:

“This is the only study drug that has ever worked for me. I am totally clear.”

“This drug is a miracle. It helped clear everything, the redness, scales and all.” This patient experienced limited success on Cosentyx and Enbrel.

“Brodalumab managed my itch better than other treatments I tried.”

“I loved it! In one day, I went from 95% covered to 95% clear. This is much better than other treatments I have tried – it’s like I don’t have psoriasis anymore.”

“This is so much easier to use than topicals.”

In terms of the effect on patients’ lives, this is what we heard:

“My well-being is in a better place. I feel like a normal woman again. I am not ashamed of white plaques everywhere.”

“I am so happy to be psoriasis-free.”

All eight respondents felt that Brodalumab should be covered under your provincial and private drug plan for patients with psoriasis.

7. Anything Else?

Psoriasis 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. 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, psoriasis is much more than “just a skin disease.” It is estimated that up to 30 percent of people with psoriasis develop psoriatic arthritis. People with psoriatic disease also are at greater risk of developing cardiovascular disease, depression and other health conditions such as cancer (a 2015 study - <https://www.psoriasis.org/advance/cancer-rates-rise-with-psoriasis-biologics-have-little-effect>, diabetes (a 2012 study - <https://www.psoriasis.org/media/press-releases/psoriasis-tied-higher-risk-type-2-diabetes>), and cardiovascular disease (a 2015 study - <https://www.psoriasis.org/advance/cardiovascular-disease-the-leading-cause-of-death-for-psoriatic-arthritis>.) For these reasons alone, the more effective treatment options available to patients becomes even more important as these co-morbidities have an economic impact on the health system.

Lastly, the number of respondents to this questionnaire who have experience with Brodalumab 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 for psoriasis!

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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
Janssen Canada			X	
Celgene			X	
Novartis			X	
AbbVie Canada				X
Valeant Canada	X			
Leo Pharma	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: December 15, 2017

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		

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Name: Kathryn Andrews-Clay

Position: Executive Director

Patient Group: Canadian Association of Psoriasis Patients

Date: December 15, 2017

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: December 15, 2017