



Common Drug Review *Patient Group Input Submissions*

secukinumab (Cosentyx) for Arthritis, psoriatic

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.

Arthritis Consumer Experts — permission granted to post.

Canadian Arthritis Patient Alliance — permission granted to post.

Canadian Skin Patient Alliance/The Arthritis Society – permission granted to post

Canadian Spondylitis Association – permission granted to post

CADTH received patient group input for this review on or before March 11, 2016.

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.

Arthritis Consumer Experts (ACE Planning and Consulting Inc.)

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	secukinumab (Cosentyx®) for the treatment of psoriatic arthritis (PsA)
Name of the patient group	Arthritis Consumer Experts (ACE Planning and Consulting, Inc.)
Name of the primary contact for this submission:	██████████
Position or title with patient group	██████████
Email	████████████████████
Telephone number(s)	██████████
Name of author (if different)	████████████████████
Patient group's contact information: Email	info@jointhealth.org
Telephone	604-974-1366
Address	#210 - 1529 West 6 th Avenue Vancouver, BC V6J 1R1
Website	www.jointhealth.org

1.1 Submitting Organization

Arthritis Consumer Experts (ACE) is a national 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 empower 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.

1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

Arthritis Consumer Experts receives unrestricted grants-in-aid from the following private and public sector organizations: AbbVie Corporation, Amgen Canada, Arthritis Research Canada, BIOTEC Canada, Canadian Institutes of Health Research, Celgene Inc., Hoffman-La Roche Canada Ltd., Janssen Inc., Pfizer

Canada, Sanofi Canada, UCB Canada Inc. and the University of British Columbia. ACE also receives donations from its community members (people with arthritis) across Canada.

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*

This submission was expressly written by the staff and advisory board members of Arthritis Consumer Experts, free from advice or influence from any outside individual or party.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The information was gathered through a request for patient input from JointHealth™ members and subscribers sent via email and posted on the JointHealth™ website, Facebook and Twitter posts. The submission is based on previous patient input responses. ACE has provided additional organizational comments to augment the individual information.

2.2 Impact of Condition on Patients

The patients' day-to-day life is tremendously impacted by their PsA. Unlike most people who can take their physical/mobility abilities for granted, people living with psoriatic arthritis 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. In severe cases, patients are very troubled by the physical (skin) disease manifestation.

Examples of activities that those living with PsA have difficulty with, include:

- One respondent has been living with psoriatic arthritis for 12 years. She experiences joint pain, pain, stiffness, and has trouble completing simple tasks. She has difficulty sitting, walking up and down stairs, bending to pick up objects, and getting in and out of the bathtub. She also has difficulty completing house chores such as vacuuming, cleaning, and doing the dishes. She has developed ischial bursitis, where her tendons and ligaments are also affected. She needs assistance with grocery shopping.
- “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 another respondent to our call for patient input. Psoriatic arthritis is linked to the skin disease, psoriasis, which causes a scaly-type rash usually occurring on the elbows, knees, and scalp. Psoriasis is considered a significant risk factor for developing psoriatic arthritis – up to 30% of people diagnosed with psoriasis go on to develop psoriatic arthritis. There is documented overlap between diagnosis of RA and PsA.

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 my case was taken seriously.

- Another respondent said that pain, fatigue, stiffness, and loss of function are the most prevalent and troublesome symptoms” of the arthritis component of PsA. She experiences skin sensitivity, redness, flaking, and pain for her psoriasis. She describes her life with PsA 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 up stairs 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 PsA, anxiety and depression is prominent amongst people in this disease group. In a [study](#) conducted by researchers at the University of Toronto of 306 people with psoriatic arthritis, and 135 people with psoriasis alone, it was revealed that 36.6 percent of participants with psoriatic arthritis had anxiety, while 22.2 percent had depression. The rates in patients with psoriasis were lower, at 24.4 percent for anxiety and 9.6 percent for depression.

2.3 Patients’ Experiences With Current Therapy

- The respondent living with PsA is currently on the following medications: Remicade, at 500 mg every 5 weeks; Leflunomide at 20 mg a day; and, Prednisone at 5-10 mg a day. She also takes Tylenol Arthritis for pain management. She has no known side effects with any of her medications. Her doctor has to fill out the forms for special authority each year to cover the cost of the medications.
- The respondent living with RA and plaque psoriasis is currently taking a medication that her dermatologist recommended. She did not wish to disclose the medication name. However, she does notice a great improvement on her scalp, less itchiness around scaly areas. Side effects include heartburn and dizziness. Her blood sugar level has increased, but she and her healthcare team have been monitoring it closely as there is diabetes in her family history. She is paying for the medication through private health insurance.
- The third respondent 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 adverse effects. She does not experience any side effect from using Enbrel. When asked about reimbursement access, she said: “I am fortunate to have group extended health coverage and the BC Fair PharmaCare plan. If I did not have these, it would be difficult to afford Enbrel.”

To summarize, patients believe that more treatment options are needed. Having more options could mean starting on the best therapy for their disease from treatment onset, as well as offers more options available if current therapy fails to work or stops working. 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 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.

2.4 Impact on Caregivers

Caregivers of patients with PsA have indicated that time is always a concern for them. They need to arrange and plan their schedule to accommodate for sudden and emergency requests from the person living with PsA. They have to help with house chores when the patient is in extreme pain, as well as fulfill the financial responsibilities they owe to themselves and their household.

For one respondent, 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.

The patients expressed concerns of adverse effects over a prolonged period. Even though their medication(s) is successful in treating their PsA, a risk of developing other medical conditions is a strong possibility. All the patients agree that they will take the medication that is most effective in treating their PsA and that poses the least chance of adverse effects.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information was gathered through a request for patient input from JointHealth™ members and subscribers sent via email and posted on the JointHealth™ website, Facebook and Twitter posts. The submission is based on previous patient input responses. ACE has provided additional organizational comments to augment the individual information.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) *Based on no experience using the drug:*

Each person living with arthritis responds differently to each medication, and no single therapy is effective in everyone with a particular disease. Reimbursement access to secukinumab means there is another chance for patients to have a treatment that will be effective in managing their disease if another DMARD or biologic used before it, fails. Allowing reimbursement access to the medication can also give professionals the tools to help their patients achieve remission, the ultimate “treat-to-target” goal. A large body of evidence now exists showing the treat-to-target approach reduces the impact of the disease on patients and delivers optimal patient reported outcomes.

ACE recommends a well-rounded treatment plan for PsA that includes medication, education, physiotherapy and occupational therapy, and a healthy diet and an active lifestyle as appropriate. Initiation of the right medication in autoimmune arthritis is vital for helping someone gain back and maintain joint health. A patient’s support network can help the patient achieve an optimal response to therapy.

b) *Based on patients’ experiences with the new drug as part of a clinical trial or through a manufacturer’s compassionate supply:*

None of the patients interviewed previously have been asked about their experience with secukinumab. ACE, like other arthritis organizations in Canada, believes clinical trials are extremely important to advancing research into new, safe and effective treatments. As well, patients across the country who are refractory to current therapies rely on the emerging treatments being tested in clinical trials.

How is the new drug expected to change a patient’s long-term health and well-being?

Patients expressed that they want medications that would lessen their PsA pain so that they can manage to do day-to-day activities. The patients concluded with a plea to the healthcare system to find medications that help people with PsA achieve remission. When a patient achieves remission, they are able to live a normal life free from medication adverse effects and disease symptoms; maximizing their full potential as human beings.

Canadian Arthritis Patient Alliance

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Cosentyx (Secukinumab) for Psoriatic Arthritis (PsA)
Name of the patient group	Canadian Arthritis Patient Alliance
Name of the primary contact for this submission:	[REDACTED]
Position or title with patient group	[REDACTED]
Email	[REDACTED]
Telephone number(s)	[REDACTED]
Patient group's contact information:	
Email	[REDACTED]
Telephone	416-358-5377
Address	204 Gerrard Street East, Unit 3, Toronto, Ontario, M5A 2E6
Website	www.arthritispatient.ca

1.1 Submitting Organization

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. We assist members to become advocates not only for themselves but for all people with arthritis. CAPA believes the first expert on arthritis is the person who lives with arthritis - ours is a unique perspective. CAPA welcomes all Canadians with arthritis and those who support CAPA's goals to become members.

1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

Sources of grants and support received by CAPA in the last year include: AbbVie, Amgen Canada, Hoffman-La Roche, Janssen, Novartis, and UCB Pharma.

Additionally, CAPA has received support in the past from: Arthritis Alliance of Canada, The Arthritis Society, Canadian Institutes for Health Research (Institute for Musculoskeletal Health & Arthritis), Canadian Rheumatology Association, Ontario Rheumatology Association, Pfizer Canada, Rx&D, Schering Canada, the Scleroderma Society, and STA Communications.

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*

None to declare.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

We conducted a brief phone interview with a person who has lived with psoriatic arthritis for close to 30 years, who participated in a clinical trial for Cosentyx, and who remains on Cosentyx (and has been for just over one year). Other information here was obtained through personal experiences of the Board of The Canadian Arthritis Patient Alliance in living with inflammatory arthritis, in addition to many years of interfacing with our membership.

2.2 Impact of Condition on Patients

Psoriatic Arthritis (PsA) is a type of inflammatory arthritis that is a serious, debilitating autoimmune disease, affecting every aspect of a patient's day-to-day life. Patients often experience psoriasis first and about 30% of these patients will go on to experience the onset of PsA symptoms usually between the ages of 20-50. PsA affects men and women relatively equally and as with other forms of inflammatory arthritis, there is currently no cure for PsA – only ways to help alleviate symptoms and hopefully slow the progression of disease. PsA is a chronic illness that one lives for from the onset of symptoms until death.

A patient we spoke to who has lived with PsA for over 30 years described it as follows:

He could not socialize with people because he would “shed his skin. Now I can wear anything that I want [after starting Cosentyx].” He also indicated that he experienced psoriasis rashes from head to toe, with swollen and stiff fingers and hands, and at any time his skin would “rip and bleed,” no matter how careful he was. Additionally he would often lose fingernails due to infection, and furthermore, these infected nails would emit a horrible odour. At times he could not work due to his PsA.

PsA is characterized by inflammation in the joints that destroys the lining of the joint and ultimately the surrounding bone resulting in the need for a total joint replacement. Once damage occurs, it is not reversible and can cause significant pain and disability. There are 5 well-documented patterns of PsA and it can be very different from person to person.

PsA is a challenging to manage and physicians and patients work together to suggest and try different drugs to find something that works well for each patient and their PsA. There are currently no methods that help physicians predict which patients will respond best to which therapies. In addition, a patient's immune system may adapt to a drug, requiring them to switch to another treatment when one becomes ineffective. As a result, patients require many medication options, as they may change medications a number of times during their lifetime.

For those whose PsA is not well-controlled, day to day activities, such as going to school, becoming and staying employed, taking care of oneself (bathing, dressing, activities of daily living) and one's family, and other activities that the healthy general population simply take for granted, become very difficult. PsA is a disease that affects all aspects of a patient's life, not just physical well-being but also psychological well-being. There are many anecdotes of patients covering up their painful psoriasis and being acutely aware of these skin lesions throughout their lifetime. It is vital that inflammation be controlled early and well so that patients can continue to be productive members of society. We can imagine that the economic benefits to society of keeping people living with PsA in the work force and as productive members of society are greater than those required of the healthcare system if patients do not receive treatments for their disease.

2.3 Patients' Experiences With Current Therapy

Both small molecule and biologic disease-modifying anti-rheumatic drugs (DMARDs) are available to treat PsA. The biology of one's response to PsA medications is not currently well understood nor can it be predicted, causing patients with PsA to undertake a blind trial and error approach to find the most suitable treatment for their PsA, and hopefully with minimal side effects. Some patients experience long periods of responding well to a drug, while for unknown reasons, others will need to be exposed to many different drugs before finding the best treatment for their PsA. However it should also be noted that current non-steroidal anti-inflammatory medications and DMARDs (e.g. methotrexate) also cause gastro-intestinal side effects (ranging from feeling like they have the stomach flu to vomiting and nausea) which patients generally simply have to deal with as best they can given that there are not many options for this devastating disease.

With the advent of biologics for the treatment of PsA, a need has been developed for either infusions or injections. This means that some patients have vein scarring and scar tissue from numerous infusions and injections. Patients may also face scheduling issues for infusions and need to take time off work or find someone to deal with family commitments (e.g. babysitting young children). A medication that may be self-injected (on approximately a monthly basis) eliminates some of these issues for patients, as does the ability to travel since currently infusions need to be scheduled around travel dates (or vice versa).

All disease-modifying anti-rheumatic drugs (DMARDs) and biologics suppress the patient's immune system. Biologics suppress the immune system to a greater extent than DMARDs. Infections are always a concern for patients with PsA as even a common cold can quickly turn into a nasty infection, such as pneumonia.

Biologics are extremely costly for patients – while some patients have extended health insurance, others do not, and either rely on their own resources or those of their provincial Ministries of Health for assistance.

2.4 Impact on Caregivers

Depending on a person's ability to cope with activities of daily living and their ability to still be employed, caregivers of people living with PsA are relied upon in varying capacities. In some cases, caregivers are required to assist with simple tasks such as bathing, getting in and out of bed, getting dressed, and even using the toilet. The emotional toll on both patients and caregivers in this type of situation cannot be underscored enough. In other situations, a caregiver's burden may not be as great, perhaps giving the patient their injection or needing to take over family responsibilities while the patient is receiving their infusion. Living with a chronic condition as potentially debilitating as PsA can affect a person profoundly psychologically – including caregivers. Additionally, when patients do not have drug coverage options, if one's spouse is their caregiver, this adds to the burden of disease in ways nearly unimaginable.

It is important to highlight that PsA affects patients and caregivers and family members profoundly, in all aspects of their lives – and does so from before their diagnosis, throughout their lives.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information was obtained through personal experiences of the Board of The Canadian Arthritis Patient Alliance in living with inflammatory arthritis, in addition to many years of interfacing with our membership. We also conducted a brief phone interview with a person who lives with psoriatic arthritis and who participated in a clinical trial for Cosentyx, and who remains on Cosentyx (and who has been on Cosentyx for just over one year).

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) *Based on no experience using the drug:*

From speaking to a person who has lived with PsA for over 30 years who is now on Cosentyx, we were told that within 2 weeks of his starting Cosentyx, his body rash was 90% cleared. While some rash remains on his scalp, since he was diagnosed with PsA, he has never been so rash-free or symptom-free. We ask you to imagine how life-changing taking this medication has been for this individual, simply in that capacity alone. Additionally, he is now able to do things he has not been able to do in a long time, from as simple as socializing and not worrying about his skin flaking, to other activities. Since Cosentyx has decreased the swelling in his joints profoundly, he has been able to lower the amount of the non-steroidal anti-inflammatory that he usually takes as well (he has decreased it from 3 pills/day to 1 pill/day, which will likely have good effects on his stomach and GI). He no longer experiences the stiffness and soreness that he previously did, and he has not experienced any side effects (when he was on methotrexate he experience flu-like symptoms after his weekly dose). Overall this person's quality of life has been dramatically improved by Cosentyx – this is difficult to describe in words, however over the phone was very evident (which he has been on just over one year).

Cosentyx represents a medication for a new target for PsA (i.e. it targets IL-17A) – this presents a significant advance in treatment possibilities for patients with PsA. All other biologic therapies for PsA currently target alpha-TNF, IL-12 or IL-23, so there is a potential that if/when patients no longer respond to those medications, they would have success with Cosentyx. This is an extremely important differentiator for Cosentyx from medications currently available for patients with PsA.

To reiterate the points made in section 2:

- Patients require a number of medication options (including Cosentyx) in order to manage their disease effectively over their life;
- Vein scarring and scar tissue, and infusion site reactions may be a significant issue for patients who receive their medications via transfusion;
- Current therapies often pose a number of gastro-intestinal issues that patients unfortunately simply have to deal with because of a lack of other options;
- The availability of a self-administered monthly medication reduces the amount of time spent by patients and their families on infusions, allowing them increased independence, and most importantly, decreased time spent 'as a patient' immersed in the system.

Section 4 — Additional Information

We would reiterate the comments made on previous submissions here. As a patient organization, we have provided numerous submissions, and since we submit for the same inflammatory arthritis conditions (rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis), it would be great if we could simply reference large portions of those previous submissions for new submissions, if they correspond appropriately. While it may not seem like a lot of work, re-writing and re-working Sections 2.2, 2.3, and 2.4 is quite burdensome for individuals who are primarily volunteers. We again ask that CADTH and CDEC consider allowing us to simply point to those sections of previous submissions unless something has changed dramatically since the last submission.

Canadian Skin Patient Alliance / The Arthritis Society

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Secukinumab (Cosentyx) for psoriatic arthritis (PsA)
Name of the patient group	Canadian Skin Patient Alliance/The Arthritis Society
Name of the primary contact for this submission:	[REDACTED]
Position or title with patient group	[REDACTED]
Email	[REDACTED]
Telephone number(s)	[REDACTED]
Name of author (if different)	[REDACTED]
Patient group's contact information:	
Email	[REDACTED]
Telephone	613-224-4266/ 416-979-7228
Address	136-2446 Bank Street/ 393 University Ave., Suite 1700, Toronto, ON, M5G 1E6
Website	www.canadianskin.ca/www.arthritis.ca

1.1 Submitting Organization

Please note that this submission is being submitted jointly by the Canadian Skin Patient Alliance and The Arthritis Society.

The Canadian Skin Patient Alliance (CSPA) is a non-profit organization that serves patients with dermatological conditions, diseases and traumas in Canada. We focus on education and advocacy for these patients as well as our 20+ Affiliate members, including the Canadian Association of Psoriasis Patients and the Canadian Psoriasis Network. The CSPA has a steady social media community as well as thousands of readers via our award-winning magazine Canadian Skin (A propeau in French).

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 4.6 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 \$190 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.

1.2 Conflict of Interest Declarations

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

The Canadian Skin Patient Alliance has the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements. We have received

project-based and/or unrestricted funding from the following drug manufacturers over the past 12 months: Abbvie, Celgene, Galderma, GlaxoSmithKlein, Janssen, Merck and Novartis. We have specific principles that we follow when working with this Industry.

The Arthritis Society accepts funding from pharmaceutical companies in order to work towards fulfilling its mission of enabling Canadians with arthritis to live well and be effective self managers and to lead and support arthritis research and care. In order to be fully transparent and meet the request to disclose pharmaceutical manufacturers who have provided support to the organization please be aware that over the past 12 months The Arthritis Society has accepted funding from the following members of the pharmaceutical industry: Abbvie, Amgen, Bayer, Bristol Myers Squibb, Celgene, Eli Lilly, Hospira, Janssen, Merck, Novartis, Pfizer, Purdue, Roche, UCB. The vast majority of The Arthritis Society's funding comes from individual donors as personal charitable giving. The Society abides by all Canada Revenue Agency and Imagine Canada requirements, and has specific guidelines on advocacy relating to pharmaceuticals that are available upon request.

The Canadian Skin Patient Alliance and The Arthritis Society do not believe that they or those individuals playing a significant role in compiling this submission have a conflict of interest that influences the information provided in this patient group submission.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information for section two was obtained from the following sources:

- A questionnaire (February 2016) was promoted via CSPA's social media channels to PsA patients or those suffering with PsA related symptoms (16 surveys received).
- CSPA reached out via email to the clinical dermatologists involved in the clinical trials to facilitate 2 patient connections.
- The Society had contact with 2 patients facilitated by rheumatologists involved in the clinical trials.
- CSPA and The Society used social media (Twitter and Facebook) and online discussion boards (26 posts) to gather patient testimonials.

2.2 Impact of Condition on Patients

What aspects of this condition are more important to control than others?

From the February 2016 questionnaire, the primary aspects of psoriatic arthritis (PsA) that patients complained of included:

- Joint pain: 62%
- Care for loved ones was challenging: 58%
- Self-confidence dropped: 50%
- Intimacy / sexuality declined: 50%
- Scales: 42%

In regards to which parts of their body is most affected by PsA:

- Fingers/Hands: 62%
- Legs: 38%
- All over: 30%

How does this condition affect day-to-day life?

One common condition-related symptom that people living with PsA talk about is their pain:

- “On bad pain days I can’t physically be touched without crying out in pain. When the pain gets bad, it usually triggers a seizure. If it rains or snows, getting dressed the next day by myself or even getting out of bed unassisted is nearly impossible. So pretty much every aspect of my life has been greatly impacted!”
- “No offence to people or even the doctors who ask you on a scale of 1 to 10 what is your pain level? When you live with this disease you learn to cope with pain which could end up lower on the scale, while a person experiencing this for first time may be a 10. It’s all the same pain, just everyone's pain tolerance is different and once you live with it for long time you kind of have to get used to it.”
- “A horrible disease which can leave you disabled and mutates your body. Had to stop many activities due to this disease. People need to understand just because you don't show pain does not mean you don't have it.”

Another common condition-related symptom that people living with PsA talk about is their fatigue:

- “Fatigue, stiffness and pain from both the arthritis and the psoriasis. Have suffered with this for some time, so used to it but still depressing to deal with.”
- “Fatigue, pain, brain fog. Pain moves around - shoulder, hand, feet, back, knees. When I get my period it's WAY worse. Everything is harder to do when you have PsA.”
- “The fatigue and pain, sometimes the illness from medications like methotrexate or Simponi. Cannot move as much as I would love to! It affects most vigorous activities. It's *not* the same arthritis that your Aunt Ethel has.”

Here is what we heard from patients about depression:

- “Flare ups can happen at any time, and since it affects your spine, can make it too painful to stand or walk. All this when you are so young. You watch the athlete you were, becoming old, scared and decrepit before your eyes, while your peers play on. You fight depression. You are the youngest in your "learn to live with arthritis" class (held at the old age home) by over 40 yrs. You watch your former life disappear into this new chronic pain reality. And every day you fight to not let it win, and take your spirit.”
- “Depression, anxiety, alcoholism and weight gain - ALL have made my life MISERABLE and I have really suffered from the pain and mental issues.”
- A 59-year-old man wrote, “Severe joint pain sometimes hospitalizes me.” Emotionally this condition takes its toll. “I take anti-depressants. It is uncomfortable, too painful to do simple tasks like opening jars or kneading bread, which is depressing for me as these are the things I like to do.”

Here is what we heard about scales:

- “The disfiguring of the body is sometimes hard to deal with and frustrating at times as well as just not being able to do what you once could.”

Here is what we hear about intimacy:

- One woman, now 80 years old, hasn’t had a romantic relationship since her diagnosis at age 40. Her fingers are crooked. In her words – “Who would even ever want to touch me?”

Here is what we hear from patients about work:

- “I was put on Cosentyx by my dermatologist. I have battled psoriasis my entire life. Only in my hair. Almost 30 now and developed psoriatic arthritis. It’s progressing quickly to me. I am in severe pain all the time. I’m scared that I will be unable to do my job.”
- A 50 year old man reported, “Severe movement limiting arthritis, to the extent that even sleeping is difficult. Job functions severely restricted. Pain an eight out of ten. Severe itching, flaking and redness, about 35% skin coverage.”
- One woman reported she “lost her job due to the medication (methotrexate) and the unsightly breakouts.”

How long have they been suffering?

Our respondents from the February 2016 questionnaire shared the following with regards to how long they have suffered with symptoms of PsA:

- 0-5 years: 54%
- 6-10 years: 15%
- 11 and up: 31%

Are there activities that the patients are unable to do as a result of the condition?

Overall, 62% of patients live continuously with joint pain. As well, here are some specific activities impacted due to PsA symptoms:

- Challenge to care for their loved ones: 58%
- Poor concentration: 28%
- Unable to do chores around the house, such as cleaning: 33%
- Negative impact on ability to sleep: 38%
- Work load &/ or work hours had to be reduced: 38%

Patients are looking for treatments that will significantly reduce pain and, for some, reduce the visible plaques. Patients who are diagnosed early and start treatment immediately are often able to control their disease, avoiding severe joint damage, and are able to lead active lives.

2.3 Patients’ Experiences With Current Therapy

What therapy are patients using for this condition?

From the February 2016 questionnaire, patients reported that they either have used or are still using the following treatment options:

- Nonsteroidal anti-inflammatory drug: 76%
- Methotrexate: 58%
- Etanercept: 58%
- Phototherapy: 51%
- Ustekinumab: 20%
- Apremilast: 20%
- Sulfasalazine: 20%
- Cyclosporine: 20%
- Secukinumab: 17%

How effective is the current therapy in controlling the common aspects of this condition?

- Effectiveness in dealing with overall pain: 40% said it worked “very well.”
- Effectiveness in dealing with swelling: 50% said it worked “somewhat.”
- Effectiveness in dealing with stiffness or pain in your joints: 50% said it worked “very well.”
- How convenient was it to use this treatment: 50% said “not at all”.
- Did you have any issues with accessing the medication due to cost: 40% said “yes.”
- Effectiveness in reducing psoriasis skin plaques and spots: 56% said it worked “very well.”

Are there hardships in accessing current therapy?

- 40% said they had issues accessing their treatment.
- The inconvenience of infusion therapies & phototherapy represent significant barriers. As well, these infusions have associated costs for patients (in terms of time) & the health-care system.

Are there needs, experienced by some or many patients, which are not being met by current therapy?

What are these needs?

- 50% said that their current treatment is NOT convenient for them.
- One patient shared that phototherapy helped her but she had to go faithfully five times a week for six months and now goes to two times per week.

2.4 Impact on Caregivers

In the February 2016 questionnaire, we asked patients about the impact psoriatic arthritis had on the daily routine or lifestyle of their family or caregiver:

- 26 % agreed with this statement: My caregiver's health is at risk due to all that they do to care for me & my psoriatic arthritis.
- 57 % agreed with this statement: My children have been greatly impacted.

Caregivers of people living with psoriatic arthritis must help patients when swollen painful joints impede their ability to do simple every day activities – from food preparation to assisting with clothing and washing, mobility in and out of the house. Dealing with the psoriatic skin lesions which bleed and crack and shed flakes all over means extra vacuuming, frequent bedding changes and more frequent house cleaning and laundry. In some cases, extra help is needed to cope. “Too many times to mention, my mom had to move in with me and my family.”

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 her family grappled with “making me get up and out of bed. Being able to get me motivated against the pain was very difficult.”

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Information for this section three was gathered by several means:

- A questionnaire was promoted via CSPA's social media channels to PsA patients or those suffering with PsA related symptoms (16 surveys received).
- CSPA reached out via email to the clinical dermatologists involved in the clinical trials to facilitate 2 patient connections.
- The Society had contact with 2 patients facilitated by rheumatologists involved in the clinical trials.
- CSPA and The Society used social media (Twitter and Facebook) and online discussion boards to gather patient testimonials (26 postings).

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate?

Patients require access to a treatment that alleviates symptoms in the long term allowing them to live a normal life, work, leave the house without having their life interrupted by visits to a phototherapy centre 2-5 times per week or travelling long distances to access infusion centres. For the patients already taking a biologic, access to new biologic options is key IF their current biologic no longer relieves their pain and suffering.

How much improvement in the condition would be considered adequate? What other benefits might this drug have — for example, fewer hospital visits or less time off work?

Most patients have been suffering for years with debilitating symptoms. Any level of relief from the painful, inflammation and joint damage would be of benefit to patients.

What positive and negative effects does the new drug have on the condition?

- "It has been amazing for me so far (has been on Cosentyx since October 2015) the results are incredible and my joints feel great! I feel normal again."
- "I have a lot of experience with biologics (e.g. Humira) but this medicine didn't work anymore. Also a whole range of medicines I have used (e.g. MTX and diprosalic). And now after two weeks; AMAZING RESULTS!! No red zones on legs, arms and back anymore, no skin parts all over the house. Still not 100% recovery but I would say 70%. And still getting better every day. No problems whatsoever. Little bit nauseous when I take the injections. Far less painful than Humira." (54 year old man)
- "My husband was put on Cosentyx four months ago. He was previously on Enbrel. He has psoriasis and psoriatic arthritis. His lesions have totally cleared up but he had a lot of problems with sinus and upper respiratory tract infections."
- "I've been on Cosentyx now for about 2 months. I've went from about 95% to about 10% barely noticeable coverage. Also the psoriatic arthritis in my ankle is gone. I'm obviously very happy with these results. However, I've also gained about 20 lbs of fat mostly in my stomach area because of the drug. My weight has been very steady over the last 10 years with no significant diet changes, so there's no question it's a side effect of the Cosentyx. I remember Humira did the same thing when it was working several years ago."
- "Cosentyx was the first biologic that helped me at all, and without side effects. Unfortunately at six months it is already losing effectiveness. I am not giving up yet because I am doing significantly better than when I started. These have been the best 6 months I've had since my last flare began two years ago."

- “Taking Secukinumab for PsA.....had severe fatigue on all anti-TNF's despite them working quite well. Am nearly at week four of loading phase and do seem much less stiff, not miracle fast results but some improvement and reduction in celebrex/tramadol etc. I am however getting the dreaded fatigue/low mood.....feels a bit like a head cold/fogginess.....hoping will settle with time.”
- “Secukinumab was moderately effective with the psoriasis after a while, but at the start up of infusions it was amazing. Treatment was a 40 minute drive away which was worthwhile.”

Does the new drug cause adverse effects?

Some patients noted redness at injection site and feeling very sleepy following their treatment. Others reported weight gain, respiratory infections and dark spots (see quotations above).

Which adverse effects are acceptable and which ones are not?

For those mentioning side-effects and that the product worked for them, they believe this treatment would have a positive impact on their lives.

Is the new drug easier to use?

Patients require access to a treatment that is not disruptive to their lives, e.g. visits to a phototherapy centre 2-5 times per week or travelling long distances to access infusion centres.

- “I do know what it means about losing a whole day at the infusion center. For me that was the second worst part...”

How is the new drug expected to change a patient’s long-term health and well-being?

Less time at the phototherapy centres allow patients the opportunity to work a full-day. A healthier patient allows for a better quality of life in relation to work, family life and intimate life, as well as more freedom for the caregivers to live their life too.

Patients with this difficult disease need treatment options. Given that this drug addresses their debilitating arthritis and their challenging skin issues, and is more easily administered, it is our hope that the CDR process will lead to a recommendation to list secukinumab (Cosentyx) for Psoriatic Arthritis.

Section 4 — Additional Information

Both the CSPA and The Society recommend that CADTH look at the schedule of patient input submissions and ensure that there is adequate time for the patient groups to gather data on patient experiences. For patient organizations having to complete 2-3 submissions at the same time can be a drain on the limited resources available for this type of work.

Canadian Spondylitis Association

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	CONSENTYX (SECUKINUMAB) FOR PSORIATIC ARTHRITIS
Name of the patient group	CANADIAN SPONDYLITIS ASSOCIATION
Name of the primary contact for this submission:	[REDACTED]
Position or title with patient group	[REDACTED]
Email	[REDACTED]
Telephone number(s)	[REDACTED]
Patient group's contact information:	
Email	INFO@SPONDYLITIS.CA
Telephone	416 694-5493
Address	18 LONG CRESCENT, TORONTO, ON. M4E 1N6
Website	WWW.SPONDYLITIS.CA

1.1 Submitting Organization

The Canadian Spondylitis Association is an all-volunteer run patient organization to support, educate and advocate for those living with Spondyloarthritis. The aims of the Association are to create awareness of Spondyloarthritis with the objective of reducing the time from onset of disease until diagnosis, to provide information and education (mainly through patient forums with expert speakers) to those living with Spondyloarthritis, including caregivers and family, to enable them to better manage their disease, and to advocate for equal access to treatment options. The Association also facilitates discussion amongst its members and support for each other through its use of social media.

The Association's membership is comprised of individuals from all Provinces and Territories who live with Axial or Peripheral Spondyloarthritis, which includes Ankylosing Spondylitis and Psoriatic Arthritis. Since inception ten years ago, the Association has grown to a membership of over 1,600.

1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

The Canadian Spondylitis Association has received restricted educational and developmental grants from AbbVie, Amgen and Janssen, and restricted travel grants from UCB Canada.

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*

The President, Michael Mallinson, has received honoraria from AbbVie (indirectly) and Novartis.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information was gathered through lived experiences. All members were invited to submit stories of their journeys with Psoriatic Arthritis and answers to the specific questions outlined in this template. The information so gathered was complemented by information gleaned from our Facebook group discussions and from many conversations amongst the Board members (all of whom live with Spondyloarthritis) and with patients, particularly at our forums.

2.2 Impact of Condition on Patients

Psoriatic Arthritis patients are the walking wounded. They endure much pain and a lot of movement limitations that affect everyday life and their working productivity. The psoriasis is very limiting in that it hurts, is itchy, is embarrassing and takes quite some time to manage to avoid infections. If it occurs on the feet and hands it is even more of a problem.

Psoriatic arthritis is marked by joint pain (all joints may be affected), swelling in the fingers and toes, discoloured, indented and crumbling fingernails and toenails, stiff joints in the morning, inflammatory back pain, limited range of motion and fatigue.

Pain, fatigue and loss of range of motion can make daily chores and working difficult. Swollen fingers and toes can also make daily home and work activities difficult and embarrassing. Joint pain and stiffness mean a reduction in the quality of life and limitations on home, work and recreational activities.

2.3 Patients' Experiences With Current Therapy

The first line of medications are NSAIDs, followed by DMARDs, which are effective in this form of Peripheral Spondyloarthritis. Corticosteroids may also be given for short periods to help reduce the swelling in joints. For severe cases and cases where there is spinal involvement, the patient may be prescribed biologic response modifiers, specifically TNF-inhibitors (TNFi). Depending on which Province the patient lives there are four or five TNFi drugs available to treat PsA.

Unfortunately, any individual TNFi is known to be effective in only approximately 70% of patients. Furthermore the efficacy of any individual TNFi can wear off after a period, sometimes months, sometimes years, in an individual patient. This means that about 30% of patients given any particular TNFi will fail on it and of the 70% who do well on it, some will not experience lasting efficacy.

It is known that some PsA patients who started on infliximab or adalimumab, for example, had to switch to the other or golimumab or enteccept. Rotating through the available biologics because one or two are ineffective or their effect soon wears off, is now almost commonplace. Different options are required for a more efficaciously long-lasting, safe drug.

There are side-effects to TNFi therapy. Infections, cold-like symptoms and dizziness as well as injection site allergic reactions were most reported by patients to us.

The biologic drugs are very expensive. While there is access to them through private and public drug plans and manufacturers' support programs, getting access to the drugs on a timely basis is an issue. The cost of the drugs is a deterrent to workplace mobility; some people are fearful of leaving an employer because of worries that a new workplace will not have an adequate drug plan or that they may be refused coverage because of their health and medications.

2.4 Impact on Caregivers

PsA is an insidious, life-long disease. The long time to diagnosis because the disease mimics other conditions can be very demanding for both the patient and their caregiver. Patients can feel that along with the pain, fatigue and depression, they are losing their minds. Caregivers find it hard to understand what is happening when faced with someone who has unexplained health issues, who can be normal and active one day and the next sleep all day. This is also true of patients on biologics. It is a common story that the effect of the drug wears off prior to the next infusion or injection, leading to pain, stiffness and fatigue and leaving caregivers wondering what happened.

Because PsA can appear in the teenage years or 20s, the onset places a physical and mental burden on parents and caregivers. A great deal of patience is required in dealing with young PsA patients because of the ups and downs of their disease and their inability to maintain activities in which they were involved. The symptoms of the disease have an adverse effect on their social, educational and business lives, all things that the caregiver will concern themselves with too. The caregiver, if a parent or spouse/partner of the patient, may also find an economic burden in helping to meet treatment costs.

Biologics offer not only relief and slowing of disease progression for those with PsA, but relieve the mental anguish and physical burden of caregivers.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Information was gathered through lived experiences. All members were invited to submit stories of their journeys with Psoriatic Arthritis and answers to the specific questions outlined in this template. The information so gathered was complemented by information gleaned from our Facebook group discussions and from many conversations amongst the Board members (all of whom live with Spondyloarthritis) and with patients, particularly at our forums.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

Given the information that has been made available about secukinumab and its clinical trials, there is an expectation that this new drug will be more efficacious than TNFi therapy, as safe, possibly cheaper and hopefully effective in PsA patients who have had an inadequate response to TNFi biologics.

As mentioned, a proportion of patients, about 30%, have an inadequate or no response to TNF-inhibitors. New treatment options are desperately needed for these patients. Even for those patients who are on TNFi therapy but whose response may be less than optimal (some patients report feeling better but not by much, on biologics), additional treatment options are required.

All patients who start a biologic drug have concerns about side effects and personally weigh the risks and rewards of taking the drug. On balance, patients will put up with side effects if their sense of overall wellbeing improves for most of the time after they go on the drug.

In general, if there is a reduction in pain, stiffness, fatigue and depression, patients will consider that the therapy has worked. If quality of life improves and there is a return to more normal activities, including work, patients will consider that the therapy has worked. All patients wish for a complete relief from their symptoms and a life unaffected by their disease. Secukinumab promises an improvement in symptoms that is better than that experienced by many who take TNFi biologics.

As improvements in their condition are felt, patients feel they are better able to manage their disease and take active steps to cope with it through, for example, exercise and diet. More treatment options are required to enable all patients to start on the path to improvement. If Cosentyx is approved, the net result will be that more people will suffer a lot less.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

We did not receive any input from anyone who has experienced the drug.

Section 4 — Additional Information

The Canadian Spondylitis Association supports the approval of this new drug.