



Common Drug Review *Patient Group Input Submissions*

secukinumab (Cosentyx) for Psoriasis, moderate to severe plaque

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

Arthritis Consumer Experts (ACE Planning and Consulting, Inc.) — permission granted to post.

Canadian Skin Patient Alliance Canadian Association of Psoriasis Patients — permission granted to post.

CADTH received patient group input for this review on or before December 24, 2014

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	The use of secukinumab for the treatment of moderate to severe plaque psoriasis
Name of patient group	Arthritis Consumer Experts (ACE Planning and Consulting, Inc.)
Name of primary contact for this submission:	[REDACTED]
Position or title with patient group	[REDACTED]
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Website	www.jointhehealth.org
Permission is granted to post this submission	Yes

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) Regarding 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 Centre of Canada, BIOTEC Canada, Bristol-Myers Squibb Canada, Canadian Institutes of Health Research, the Canadian Rheumatology Research Consortium, Celgene Inc., GlaxoSmithKline, Hoffman-La Roche Canada Ltd., Janssen Inc., Pfizer Canada, Purdue Pharma L.P., Sanofi Canada, St. Paul's Hospital (Vancouver) and the University of British Columbia. ACE also receives unsolicited donations from its community members (people with arthritis) across Canada.

b) Regarding those playing a significant role in compiling this submission:

This is not applicable, as it was solely the staff and advisory board of Arthritis Consumer Experts that aided in the compilation of this information.

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. The submission is based on previous patient inputs and interviews we have conducted throughout ACE's 15 years as an organization. Most interviews were conducted with people who are currently living with psoriatic arthritis but have experienced plaque psoriasis. Study show that 30 percent of those living with psoriasis will develop psoriatic arthritis.

2.2 Impact of Condition on Patients

What are the condition-related symptoms and problems that impact the patients' day-to-day life and quality of life?

The patients' day-to-day life is affected greatly 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.

- **Activities at home:** Psoriasis skin lesions can flare up and subside in the elbows, knees, and scalp as well as other parts of the body. Patients have difficulty doing house chores because of a limited range of motion; difficulty getting up and down stairs and in and out of the bathtub; difficulty with cooking; and difficulty getting dressed in the morning. House chores were delayed and often required the use of modified tools to complete. For some, even daily hygiene tasks are compromised.
- **Activities at work:** Patients expressed concern over how other people may perceive their physical appearance. As a result, this affects their focus and performance at work. Mentally, patients have to prepare for possible discrimination and degradation if they want to work in the entertainment or the service industry.

- Lifestyle activities: In a recent patient input related to psoriatic arthritis (PsA), one patient commented that without her PsA medications, she develops pustular psoriasis in her hands and feet. Patients are restricted in what they can do due to a limited range of mobility. When skin lesions occur, they are dependent on friends and family to transport them from one place to another.

2.3 Patients' Experiences With Current Therapy

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

In general, of the patients ACE has spoken with about their experiences of managing their plaque psoriasis and PsA with currently available treatments, their comments and concerns included:

- Intolerance of methotrexate in combination with other medications.
- How their medication is administered.
- The loss of efficacy of their medication over time.
- Time commitment required from them as a patient (taking time off work, travel to and from clinics).

To summarize, patients believe that the more 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 adverse 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.

2.4 Impact on Caregivers

What challenges do caregivers face in caring for patients with this condition? How do treatments impact on the caregivers' daily routine or lifestyle? Are there challenges in dealing with adverse effects related to the current therapy?

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. Patients are concerned about adverse 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 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. The submission is based on previous patient inputs and interviews we have conducted throughout ACE's 15 years as an organization.

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

a) Based on no experience using the drug:

According to all of the patients, it is difficult to determine with certainty that patients' lives will be improved by secukinumab but they are willing to try. Each person living with plaque psoriasis responds differently to each medication, and no single therapy is effective in everyone with a particular form of plaque psoriasis. A patient's support network can help the patient achieve an optimal response to therapy through optimal adherence.

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 or providing feedback through the JointHealth™ website had use secukinumab to treat their plaque psoriasis. However, ACE believes clinical trials are extremely important to advancing research into new 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?

The patients hope that secukinumab will lessen their plaque psoriasis symptoms so that they can manage day-to-day activities and vastly improve their quality of life. The patients concluded with a plea to the healthcare system to find medications that help people with plaque psoriasis and/or PsA achieve remission. When a patient achieves remission, they are able to live a normal life free from adverse effects and maximize their full potential as human beings.

Section 4 — Additional Information

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. Some of these patients have indicated to ACE that they developed psoriatic arthritis as a result of their psoriasis or vice versa.

According to a study published online last month by Menoufia University, Egypt, researching the rheumatic manifestations of psoriasis, 40 out of 100 patients with psoriasis had psoriatic arthritis (PsA) according to **CASPAR (CIASSification criteria for Psoriatic ARthritis)** criteria. One hundred patients with psoriasis were included in the study and they were divided according to the presence of rheumatic manifestations (patients with no rheumatic manifestations, patients with PsA, and patients with other rheumatic manifestations). Researchers used the Psoriasis Area and Severity Index score to assess psoriasis severity and the Moll and Wright Criteria for PsA. The study concludes that the prevalence of PsA was 40% in the studied patients with psoriasis and occurred most commonly at an older age and with a longer duration of psoriasis.

Arthritis Consumer Experts believes that a new therapy for plaque psoriasis will ultimately improve the lives of people living with psoriatic arthritis.

Canadian Skin Patient Alliance Canadian Association of Psoriasis Patients

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Secukinumab for psoriasis
Name of patient group	Canadian Skin Patient Alliance Canadian Association of Psoriasis Patients
Name of primary contact for this submission:	[REDACTED]
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Permission is granted to post this submission	Yes

1.1 Submitting Organization

The Canadian Skin Patient Alliance (CSPA) is a non-profit, for patients, by-patients organization that serves patients with dermatological conditions in Canada. It focuses on education, support and advocacy for these patients and for its 20+-allied/affiliated disease-specific organizations in Canada. It works with and is supported in this submission by the Canadian Association of Psoriasis Patients (CAPP), a non-profit organization that serves psoriasis and psoriatic arthritis patients in Canada. CAPP represents Canadian psoriasis patients at the International Federation of Psoriasis Associations internationally.

1.2 Conflict of Interest Declarations

We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements: CSPA: Abbvie, Amgen, Celgene, GlaxoSmithKlein, Leo Pharma, Merck, Roche, Valeant. CAPP: Abbvie, Amgen, Janssen, Leo Pharma, Celgene, and Pfizer. This submission was prepared/ written solely by the CSPA/CAPP staff without influence from any outside corporate sources.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information for this submission was gathered by several means: Self-addressed, stamped anonymous questionnaires were sent to research physicians who passed them / mailed them to patients who had undergone clinical trials of Secukinumab. Also, we reached out to patients online who had experience with Secukinumab and they completed the online version of our questionnaire via our Facebook page and the Facebook page of our affiliated group, the Canadian Association of Psoriasis Patients. The total number of usable questionnaires we received was 23 with 55% of responses from men.

Over the years, we have also had contact with hundreds of psoriasis and psoriatic arthritis patients who have attended our disease information sessions. When we refer to information sourced from these sessions and feedback we will so indicate. Also we accessed information from the recently completed Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) study. This information was gathered by interviewing by telephone 3426 patients and 781 doctors in 7 countries including Canada.

2.2 Impact of Condition on Patients

Psoriasis patients grapple with cracking, bleeding, crusty, painful, very itchy plaques / lesions, with close to one-half having these symptoms “all over” their body and the other half experiencing symptoms in 3 or more areas of their body. Scaling, itching and flaking were major issues for most patients (86%, 80% and 91%) who responded to our survey. Many suffer pain (61%).

Severity of the disease has traditionally been measured by the amount of body surface area covered (PASI score). However, increasingly patients are letting their doctors know that the impact of the disease can also be affected by where on the body the lesions are and the psychosocial impact of simply having the disease. Historically, psoriasis was thought to be the same as leprosy, as evidenced by the recent analysis of bones taken from leper colony graveyards in Europe. The modern day experience is thankfully better, but people living daily with psoriasis live with the ‘untouchable’ stigma, and fear that their diseased skin flaking off will see them shunned in public places. More than three-quarters in our study felt they needed to hide their skin (78%) or felt embarrassment (70%).

Itch can be profoundly debilitating and many psoriasis patients report losing sleep to itch, and being willing to do “ANYTHING” to make the itch pass, including putting their itchy, bleeding skin in vinegar, or scratching themselves raw, because “pain is preferable to itch”. Itch is completely underestimated by those who do not live with it chronically. It can bring grown men and women to tears. In the MAPP survey, over 40% gave itch as the most common and bothersome symptom. This bears out with what we ourselves know and experience.

¹(Multinational Assessment of Psoriasis and Psoriatic Arthritis Survey. Journal of the American Academy of Dermatology. 2014, [http://www.jaad.org/article/S0190-9622\(14\)00977-3/abstract](http://www.jaad.org/article/S0190-9622(14)00977-3/abstract))¹

Most people living with psoriasis will speak of how limiting the disease is – it affects the things they can do and the places they can go. Swimming or participating in sports where their skin would be exposed can subject them to cruel taunts and disturbing stares. We even heard from a man who was asked to by the management to leave a gym because his skin condition was making *other patrons* uncomfortable! This kind of experience is sadly not uncommon.

Daily life for patients with symptomatic psoriasis may include the inability to consistently go to work, and fear of job loss because of days missed due to pain and psoriasis skin outbreaks. While absenteeism is an issue with patients missing almost a quarter of the work year due to their psoriasis, presenteeism or ability to be present and NOT productive while at work, is a problem with the same frequency.

Psoriasis patients can have substantial sleep issues. More than half of them experienced an average of 11 nights a month with sleep issues resulting in a corresponding 11 days a month with concentration issues. Psoriasis affects patients' ability to be 'themselves.' Even when they are highly functioning, they can lose their jobs when they reveal their psoriasis, and so many keep their disease hidden. It is still a very misunderstood condition.

"I have lost jobs because people were afraid of my scales. I have had problems with day-to-day rituals as the pain and scale was so bad I could not use common soaps etc. to cleanse. I have had total strangers come up to me and comment about my looks especially as I had it on my face."

It's no wonder that these patients feel stigmatized.

This disease impacts self-esteem and relationships. Almost 20% of our respondents specifically reported having plaques / lesions in 'private places', which can impact feelings of attractiveness and sexuality beyond the incredible discomfort of having lesions 'down there'. Almost two-thirds (64%) of Secukinumab patients said their intimacy / sexuality declined and 61% say their self-confidence had dropped.

"Sex life has vanished." Ontario Male, W.

Emotionally, this condition takes its toll. Some patients struggle with feelings of helplessness and frustration with skin that makes them feel like modern-day lepers. Psoriasis affects the clothes they wear, as many use long pants and long sleeves to cover their psoriasis lesions, even in 30 degree Celsius heat. Almost half of our respondents listed weight gain and depression as key issues related to their psoriasis.

There is enormous shame, accompanied by higher rates of depression and suicidality. One young man we know has cut himself off from society, is barely functioning and is teetering on the edge with suicidal ideations, as his severe psoriasis seems to respond for only a year or so on each new medication he has tried. He is living "in hell." He needs new options.

"Depression, anxiety, alcoholism and weight gain - ALL have made my life MISERABLE and I have really suffered from the pain and mental issues."

Several patients in our circles admitted to isolating themselves from others both socially and at work (if they work). Some had given up activities they loved – dancing, participating in sports, gardening, and hiking. Several had either lost or needed to quit their jobs and ended-up on disability coverage.

“I didn’t want to go out socially or travel. Constant flakes in the house and needed to change the bed sheets frequently - every day, due to blood and / or creams.” Ontario Female Patient, A.

“This year we traveled to Australia - we would never have done that if I had not been on Secukinumab.” Ontario Female Patient, A.

Almost 70% of our respondents cited having some joint pain, which limits their lives by limiting physical movement. (We recognize that this exceeds the expected incidence of psoriatic arthritis, which is normally around 30%.) In the MAPP survey, where 4 or more joints were affected, such simple things like bending down to pick up clothing (26%), dressing themselves (15%), getting in and out of bed or a car (15%) and washing or drying their bodies (12%) affected patients. From our patients, we heard about the inability to open drawers, engage in regular housekeeping activities, go shopping, engage in intimate relations without pain and shame, use a computer keyboard, walk up and down steps and bend down to pick things up.

“[Psoriasis] scaling and flakes leave a mess [and it causes me] joint pain, low confidence, tough clothing choices, embarrassment, and I constantly have to explain.” Ontario Female Patient, I.

People living with psoriasis are also affected by co-morbid conditions. In addition to joint pain and depression, those responding to our surveys specifically cited weight gain, diabetes, and heart disease as co-morbid issues with which they also grapple. Having tried a plethora of treatments, almost half of all psoriasis patients (MAPP survey) have given up hope and haven’t consulted their health care provider in the last year.

At the 67th World Health Assembly, the World Health Organization (WHO) member states adopted a resolution on psoriasis, recognizing it as **“a chronic, non-communicable, painful, disfiguring, and disabling disease for which there is no cure.”** The resolution also acknowledges the psychosocial burden of the disease and that many people with psoriasis suffer due to lack of awareness and access to sufficient treatment.

In October 2014, CAPP released the Psoriasis Report Card, which we encourage the committee to review. Downloadable at www.canadianpsoriasis.ca, it shows that Canada and most of the provinces and territories get a failing grade on care for their Psoriasis and psoriatic arthritis patients when measured against accepted standards for access to dermatological care and treatment options.

2.3 Patients’ Experiences With Current Therapy

Prior to trying Secukinumab, our respondents have tried a wide array of treatments to cover their psoriasis. Over 70% of those who responded to us have been on methotrexate, almost 20% on cyclosporine and almost 50% have tried at least one of adalimumab, calcipotriol + betamethasone, etanercept, infliximab, or ustikinumab. About half had tried phototherapy at some point, but had

abandoned it because it either stopped working or the travel/time/ parking costs proved to be too burdensome. Many have tried multiple therapies and multiple approaches to address the symptoms of pain, swelling, and inflammation, skin lesions and itch.

The most common reasons the survey patients gave for stopping past treatments were that they started the trial for Secukinumab. Some patients also discontinued due to their doctor's advice, side effects or the treatment stopped working. Over half felt that their past treatment was not effective in dealing with pain (56%) or stiffness or joint pain (53%).

While almost of respondents had been on methotrexate for between 1 and 15 years, they experienced fear of or actual liver damage and lived with side effects of nausea, headaches and feelings of illness. They stopped because of the persistence of these side effects or because the treatment stopped being effective. In one of our earlier surveys, one respondent had to stop methotrexate almost immediately because he started to haemorrhage internally.

Both cyclosporine and methotrexate are known to have toxicities that could lead to liver or kidney damage. Patients on these less expensive medications are warned, and hopefully monitored, but are more likely to feel higher levels of stress from the fear of these toxic and irreversible organ damage issues, even if they get relief from their symptoms.

Hardships in accessing current therapies include the high costs for most of these, and restricted and complex access wherein patients and/or their doctors must repeatedly fill in forms to qualify.

Psoriasis patients truly do need to have access to a wide array of alternatives as what works for one patient may not work for another and in many cases, even a treatment that has worked may only do so for a relatively short period of time.

2.4 Impact on Caregivers

Caregivers of 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 much more frequent house cleaning and laundry. In some cases, extra help is needed to cope.

"I am always asking for someone to put cream on areas I can't reach." Alberta Male Patient, P. "My wife has to help me put cream on every night." Ontario Male Patient, C.

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

As above, the information for this submission was gathered by several means: Self-addressed, stamped anonymous questionnaires were sent to research physicians who passed them /mailed them to patients who had undergone clinical trials for psoriasis and Secukinumab or were being treated for their psoriatic arthritis off label with Secukinumab. Also, we reached out online to psoriasis patients who had experience with Secukinumab to complete the electronic version of our questionnaire via our Facebook page and the Facebook page of our affiliated group, the Canadian Association of Psoriasis Patients.

Over the years, we have had contact with hundreds of patients who have attended our psoriasis information sessions. When we refer to information sourced from these sessions and feedback we will so indicate.

Also we accessed information from the recently completed Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP)* study. This information was gathered by telephone interviewing a total of 3426 patients and 781 doctors in 7 countries, including Canada.

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

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

While we did not specifically ask this question, generally speaking psoriasis patients are excited to try new medications that may better manage their symptoms.

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

Effect of Secukinumab on Psoriasis

The effect of Secukinumab on psoriasis patients in the clinical trial was generally positive with three-quarters reporting successful symptom management for most skin symptoms such as flaking, itching and scale. Bleeding was better controlled for 68% of patients.

Over half of the respondents wrote positive comments about the effects of Secukinumab on their psoriasis, such as:

"Cleared my psoriasis 99% - only one small patch on left lower leg." Ontario Male, B. "Fantastic. 100% clear. Can't believe it - so happy!" Ontario Female, S.

"My skin has totally cleared up. No psoriasis at all!" Ontario Female, J. "No more red patches, more confidence." Ontario Male, P.

"Symptoms are better - psoriasis almost disappeared, not as much scalp symptoms, less itching, and very good in winter - sore spots are gone." Ontario Female, I.

Just over half also reported better control of moods (55%), sleep and nails (53% each).

Adverse Effects

Only 30% of these Secukinumab trial patients reported limited adverse affects, with none saying these are significant enough to prevent them from taking it, if it were on their drug plan. The most common side effect reported was weight gain (by 3; one of whom gained weight on their prior treatment), with one mention each of constipation and diarrhea.

Ease of Use

The majority (69%) found Secukinumab easier to use than prior treatments, which led to three-quarters (75%) believing they are more likely to stay on the treatment and follow the dosing.

"[Secukinumab] will enable me to live a normal life; I am concerned if I have to come off it now. Ontario Female, A.

"Positively [will stay on Secukinumab]. Confidence was regained being able to wear short sleeve shirts and shorts." Ontario Male, B.

One patient felt the cost of injections might be prohibitive and would prefer pills.

With the positive experience so far, not surprisingly, all of the patients on trial believe their provincial drug plan should cover Secukinumab, along with 90% who believe that for private insurance plans.

Patient's long-term health and well-being

Given that any given biologic treatment or systemic treatment only seems to work for a patient for a fixed amount of time, access to another option provides choice for physicians and their patients to extend the time that a treatment which addresses psoriasis can be administered.

"I was not getting results prior to Secukinumab." Ontario Male, B.

"My skin is 95% clear of psoriasis now and that's all that matters to me." Ontario Male, C.

Patients with this very difficult disease need options. Given that this treatment addresses their psoriasis and their very difficult skin issues quite effectively, and its limited side effects would not prevent compliance, it is our hope, and the hope of the members of the Canadian Association of Psoriasis Patients with whom we are affiliated, that CADTH gives a LIST recommendation for Secukinumab for Psoriasis.

Section 4 — Additional Information

Please provide any additional information that would be helpful to CADTH, CDEC, and participating drug plans. This could include suggestions for improving the patient input process, indicating whether the questions are clear, etc.

We continue to recommend that Section 2.4 also include the impact on family members, not just caregivers, as entire family systems are generally impacted by (skin) diseases.