Template for Submitting Patient Group Input to the Common Drug Review at CADTH

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Cosentyx (Secukinimab) for Psoriatic Arthritis (PsA)
Name of the patient group		Canadian Arthritis Patient Alliance
Name of the primary contact for this submission:		Dawn Richards
Position or title with patient group		Vice President
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Telephone number(s)		
Name of author (if different)		N/A
Patient group's contact information:	Email	Dawn.richards@arthritispatient.ca
	Telephone	
	Address	204 Gerrard Street East, Unit 3, Toronto, Ontario, M5A 2E6
	Website	www.arthritispatient.ca
Permission is granted to post this submission		X Yes ☐ No

CADTH will post this patient input submission on its website if permission is granted. See CDR Update — Issue 99 for details.

- This template form is to be used by patient groups to submit patient group input.
- Individual patients should contact a patient group that is representative of their condition to have their input added to that of the patient group.
- Please ensure that the input is in English, and that it is succinct and clear and in a ready-to-publish format.
- Please use a minimum 11-point font and do not exceed six-typed pages (approximately 3,500 words). You may delete the instructions and examples under each heading for more space.
- Patient input submissions must be provided as a Word document.
- Use the "Submit" link in the table on the Patient Input page to file the submission.
- The patient group input for this drug must be submitted by the deadline date posted on the Patient Input page of the CADTH website to be used in the CDR process.
- Privacy: The information provided in submissions to CADTH will be shared with reviewers, the Canadian Drug Expert Committee (CDEC), publicly funded drug plans that participate in the CDR, and may be included in publicly available documents. All patient input submissions for a drug under review will be collated and summarized in one document that will be posted as part of the CDR Clinical Review Report. All patient input submissions for which permission to post has been granted will be posted in their entirety on the CADTH website. Personal information will not be publicly available.

Should you have any questions about completing this form, please contact CADTH by telephone at 613-226-2553 or email requests@cadth.ca.

For information about the CDR process and CDEC see the CDR section on the CADTH website; for information regarding patient input to CDR and CDEC, see the Patient Input section.

1.1 Submitting Organization

Please provide an overview of the organization that is making the submission, including the purpose or aim(s) of the organization and an outline of the type of membership.

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 - theirs 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

CADTH requires that all participants in the CDR process disclose any conflicts of interest to ensure that the objectivity and credibility of the CDR process is maintained. Patient groups must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. This information is requested for transparency — a declaration of conflict of interest does not negate or preclude the use of the patient input.

(Examples of conflicts of interest include, but are not limited to, financial support from the pharmaceutical industry [e.g., educational or research grants, honorariums, gifts, and salary], as well as affiliations or personal or commercial relationships with drug manufacturers or other interest groups.) The names of all manufacturers providing funding should be listed, not just the manufacturer of the drug under review.

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

In each of the following sections, guidance or examples are provided to help identify the type of information that CADTH, CDEC, and participating drug plans will find most helpful in understanding the needs and preferences of the majority of patients. Objective, experiential information that is representative of the majority of the patient group is preferred. There is no need for patient groups to submit published information, as CADTH's CDR review team and CDEC have access to current scientific

literature through the manufacturer's submission and a rigorous, independent literature search. However, relevant unpublished studies may be submitted in addition to the completed template.

2.1 Information Gathering

Please briefly identify how the information to complete Section 2 was obtained. Was it obtained, for example, through personal experience, focus groups, one-to-one conversations with a number of patients using the current therapy, printed sources, etc.?

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. This individual was referred to CAPA through his rheumatologist. 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

What are the condition-related symptoms and problems that impact the patients' day-to-day life and quality of life? Examples of the type of information that could be included are:

- What aspects of this condition are more important to control than others?
- How does this condition affect day-to-day life?
- Are there activities that the patients are unable to do as a result of the condition?

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 secukinimab]." 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 then 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 their physical well-being but also their 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

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

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, plaquenil and Imuran) 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, so has the need 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). An oral medication eliminates 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 the oral DMARDs. Infections are always a concern for patients with RA 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

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

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, 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 need 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

In this section, guidance or examples are provided to help identify the type of information that CDR, CDEC, and participating drug plans will find most helpful in understanding the needs and preferences of the majority of patients. Objective, experiential information that is representative of most in the patient group is preferred. There is no need for patient groups to submit published information, as CDR and CDEC have access to current scientific literature through the manufacturer's submission and a rigorous, independent literature search. However, relevant unpublished studies may be submitted in addition to the completed template.

3.1 Information Gathering

Please briefly identify how the information to complete Section 3 was obtained. Was it obtained, for example, through personal experience, focus groups, one-to-one conversations with a number of patients using current therapy, printed sources, etc.?

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. This individual was referred to CAPA through his rheumatologist who was an investigator in the clinical trial for Cosentyx.

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:

- Is it expected that the lives of patients will be improved by this new drug, and how?
- Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate?
- Would patients be willing to experience serious adverse effects with the new therapy if they experienced other benefits from the drug?
- 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?

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. 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 stiff 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 (which he has been on just over one year).

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 is a significant issue for patients who need to self-inject or 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 another self-administered monthly medication would reduce the amount of time spent by patients and their families on infusions, allowing them increased independence, and decreased time spent 'as a patient'; and,***

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 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.