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 Ankylosing Spondylitis (AS)
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
Email		Dawn.richards@arthritispatient.ca
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 - 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

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.?

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?

Though not as common as Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS) is another type of inflammatory arthritis that is a serious, debilitating auto-immune disease, affecting every aspect of a patient's day-to-day life. Patients can feel the onset of symptoms in their late teens to early 20s, and often times live for many years in extreme pain without an accurate diagnosis. Most patients have their own stories about their painful and often debilitating journeys to seek a correct diagnosis. Unlike RA, AS affects predominantly men, a pattern that is not well understood. As with other forms of inflammatory arthritis, there is currently no cure for AS – only ways to help alleviate symptoms and hopefully slow the progression of disease – it is a chronic illness that one lives for from the onset of symptoms until death.

The disease is characterized by inflammation in the joints of the spine. This inflammation can spread to involve other parts of the spine and, in the most severe cases, involves the entire spine. As the inflammation continues and the body attempts to repair itself, new bone forms. This results in bones of the spine growing together (fusing), causing the spine to become very stiff and inflexible. Even though new bone has formed, the existing bone may become thin, which increases the risk of fractures.

AS is a challenging disease to manage and physicians and patients often have to try different drugs to find something that works well – there are currently no methods that help physicians predict which patients will respond best to which therapies. In addition, a patient's immune system can adapt to a drug making it necessary to switch to another treatment when one becomes ineffective. As a result, patients require many medication options as treatment response is not possible to predict and changes over time.

For those whose AS is not well controlled, day to day activities, such as participating in post-secondary education, becoming and staying employed, taking care of oneself and one's family, and other activities that the healthy general population simply take for granted, become very difficult. 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 AS 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?

Since the biology of a person's AS response to medications is not currently well understood or able to be predicted, patients with AS undergo trial and error in finding the most suitable treatment for their AS. Some patients experience long periods of responding well to a drug (meaning that their symptoms are well-controlled), while others, for reasons unknown, will need to be exposed to many different drugs over their lifetime to achieve the best treatment of their AS.

With the advent of biologics for the treatment of AS, there has been a need for either infusions or injections. Some patients have vein scarring and scar tissue from numerous infusions and injections. In the most extreme case, a patient would have been giving themselves injections or receiving infusions for over a decade (since biologics were first approved in 2000) – a reality faced by many patients living with AS. 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).

All biologics suppress the patient's immune system. Infections are a concern for patients with AS on biologics since even a common cold can quickly turn into something more serious, 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 AS 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 AS 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 AS 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.

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?

Cosentyx represents a medication for a new target for AS (i.e. it targets IL-17A) – this presents a significant advance in treatment possibilities for patients with AS. All other biologic therapies for AS are currently anti-TNF targeted, so there is a potential that if/when patients no longer respond to those medications, they would have success with Cosentyx. This is a very important differentiating factor for Cosentyx over other medications that are currently available.

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 lifetime;***
- ***Vein scarring and infusion site reactions may be a significant issue for patients who need to receive their medications via transfusion;***
- ***Current therapies often pose a number of side effects 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.'***

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.