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

## Section 1 — General Information

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| **Name of the drug CADTH is reviewing and indication(s) of interest** | | Cimzia for Ankylosing Spondylitis |
| **Name of the patient group** | | The Canadian Arthritis Patient Alliance |
| **Name of the primary contact for this submission:** | | Linda Wilhelm |
| Position or title with patient group | | President |
| Email | | linda.wilhelm@arthritispatient.ca |
| Telephone number(s) | | |
| **Name of author (if different)** | | |
| **Patient group's contact information:** | Email | linda.wilhelm@arthritispatient.ca |
| | Telephone | |
| | Address | Virtual |
| | 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.

### 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, Arthritis Alliance of Canada, The Arthritis Society, Canadian Rheumatology Association, Janssen, Novartis, Ontario Rheumatology Association, and UCB Pharma.

Additionally, CAPA has also received support in the past from: Canadian Institutes for Health Research, Hoffman-La Roche, Pfizer Canada, Rx&D, Schering Canada, 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:*

No conflict

## 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.?

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

### 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?

Ankylosing Spondylitis (AS) is not as common a form of inflammatory arthritis as the more prevalent Rheumatoid Arthritis (RA). Although most types of inflammatory arthritis (IA) affect women more than men, AS is the exception to this. Onset of AS symptoms can occur during the teenage years, lasting a lifetime as there is no cure and impacting the ability to continue to receive an education, as well as launch and maintain a career. There are far fewer treatments available to treat AS; not all the medications that are approved and available to treat RA are shown to be effective in AS. In addition, not every medication that is approved and available works for everyone. AS is a challenging disease to manage; physicians and patients often have to try different drugs to find something that works well for a particular person. In addition, a patient's immune system can adapt to a drug making it necessary to switch to another treatment when one becomes ineffective. We would like to highlight to the review committee (since we understand that the members may not be experts in inflammatory arthritis) that it is not sufficient to only have one or two drugs available to treat AS, patients require as many options as possible since everyone's response to these biologics are different. Perhaps in the future tests may exist that will be better able to predict response to therapies but that point has not yet arrived. AS that is unresponsive to treatments is extremely debilitating and can result in serious, long term disability as well as a major burden to the health care system. This has a disastrous effect on a patient's and their family's quality of life, including both physical and psychological manifestations. It is vital that inflammation be controlled early and well so that patients can continue to be productive members of society.

### 2.3 Patients' Experiences With Current Therapy

How well are patients managing their condition with currently available treatments?
Examples of the types of information that might be included are:

- What therapy are patients using for this condition?
- How effective is the current therapy in controlling the common aspects of this condition?
- Are there adverse effects that are more difficult to tolerate than others?
- Are there hardships in accessing current therapy?
- Are there needs, experienced by some or many patients, which are not being met by current therapy? What are these needs?

As stated in 2.2, not all drugs approved for the more common form of inflammatory arthritis, rheumatoid arthritis are approved for ankylosing spondylitis. These patients have fewer options, AS is a rarer form of IA so there are also more challenges in receiving a diagnosis and accessing treatment as

early as possible which is crucial for an optimum health outcome. Evidence has clearly shown that in order to avoid joint damage patients should be diagnosed and inflammation controlled with six months of onset of symptoms.

Patients who are being considered for treatment with a biologic have generally failed on conventional, less expensive therapies or they were unable to tolerate them because of adverse reactions. Existing therapies include Non-Steroidal Anti-inflammatory Drugs (NSAIDS), analgesics, Disease Modifying Anti-Rheumatic Drugs (DMARDS), biologics and exercise. Many patients with milder disease will do well on NSAIDs and appropriate exercise. DMARDs are effective only with peripheral, not axial, disease and are not effective for all patients.

### 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?

AS is a disease that can appear during late teenage into young adult years and then is a chronic illness (there is no cure), every therapeutic tool available is needed to assist an individual through this period in their life when education and interaction with their peers is so vital to future success.

For those patients whose AS is not well controlled day to day activities such post-secondary education, becoming employed, taking care of oneself, walking, cooking, grocery shopping, house work, being in a relationship, getting married, having and caring for children and social activities can be extremely difficult and in some cases, impossible to undertake. All of the above causes extreme stress not only on the person living with the illness but on their families and caregivers.

## 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, including anklylosing spondylitis. Our Board members have facilitated educational programs for people living with arthritis and CAPA has been interfacing with its membership since 2002.

### 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?

It is expected that patients living with Ankylosing Spondylitis, a rarer form of inflammatory arthritis will have another treatment option to consider that will help alleviate the severe, disabling symptoms of their disease for which some patients develop an immunogenicity response. We strongly believe that patients require access to all approved and available treatment options that have been demonstrated to be safe and effective so that they are able to continue to live full and productive lives as tax paying, productive and contributing citizens.

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

- What positive and negative effects does the new drug have on the condition?
- Which symptoms does the new drug manage better than the existing therapy and which ones does it manage less effectively?
- Does the new drug cause adverse effects?
- Which adverse effects are acceptable and which ones are not?
- Is the new drug easier to use?
- How is the new drug expected to change a patient's long-term health and well-being?

Nothing to add that has not already been stated

## 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.

The Canadian Arthritis Patient Alliance finds it unconscionable that CADTH would put out a call for patient input on a drug that is currently in a queue with no time frame for review by CDEC. Patients living with severe, disabling inflammatory arthritis who have exhausted all their options for treatment are waiting for new therapies with the hope that they will regain some measure of quality of life. CADTH should not be asking for input from patients on potential new treatment options until the option is actually going to be considered by the review committee.