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		Actemra/tocilizumab
Name of the patient group		Canadian Arthritis Patient Alliance
Name of the primary contact for this submission:		Marie-Eve Veilleux
Position or title with patient group		2nd Vice-president
Email		marie-eve.veilleux@arthritispatient.ca
Telephone number(s)		
Name of author (if different)		
Patient group's contact information:	Email	marie-eve.veilleux@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, assists them to become more effective advocates and seeks to improve the quality of life of all people living with the disease. CAPA believes the first expert on arthritis is the individual who has the disease, as theirs is a unique perspective. We assist members to become advocates not only for themselves but all people with arthritis. 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:*

In the past year, CAPA has received both restricted and unrestricted funding and in-kind support from: Abbvie, Amgen, Janssen, Novartis, Pfizer, UCB Pharma, The Ontario Rheumatology Association, The Canadian Rheumatology Association, and The Arthritis Society.

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 had one-on-one conversations with two people living with RA who are currently on Actemra IV. Another member is also using Actemra IV, but for Juvenile Idiopathic Arthritis (JIA). More information was obtained through personal experiences of the Board of the Canadian Arthritis Patient Alliance in living with inflammatory arthritis and using IV drugs versus subcutaneous drugs.
We also consulted websites such as www.arthritis.ca to collect information about RA.

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?

Rheumatoid Arthritis (RA) is the most common form of inflammatory arthritis. It affects approximately 300 000 Canadians. More women have RA and it is most often diagnosed between the ages of 25 and 50. It is the leading cause of disability in Canada. In RA, the body's immune system attacks the joint lining and sometimes other internal organs. Swelling in the joint causes pain and destruction. It is now common knowledge that newly diagnosed patients should be treated early in the disease to avoid irreversible joint damage, control pain and improve overall quality of life for the patient.

When RA is not controlled, patients experience significant pain and joint stiffness. They feel tired and can lack concentration. Consequently, this affects their ability to go on with their normal activities, such as work, school, family life, etc. Ultimately, if no medication can stop RA progression, it can lead to major joint surgeries such has joint replacements or joint fusions. Because of the extensive damage to their joints, some patients who do not respond to the available treatments might also have to use technical or mobility aids such has bath lifts, canes or wheelchairs, have their house/car adapted and rely paratransit to do daily activities.

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?

RA is treated with several types of medication, used alone or in combinations. Non-steroidal anti-inflammatory drugs (NSAIDS) and corticosteroids are used to control overall joint inflammation. They provide the patient some relief, but other types of medication are necessary to decrease and prevent

disease progression. One of those types is disease-modifying anti-rheumatic drugs (DMARD) with drugs such as methotrexate, plaquenil, etc. DMARDs are associated with some important health risks, so physicians and patients must balance these risks with the potential benefits of taking the drug when choosing the best course of treatment. In the last two decades, a new type of medication was developed: biologics. These medications, including the drug reviewed here, have proven to be very effective in slowing disease progress and preventing disability. Two CAPA members contacted specifically mentioned that Actemra was the most successful of the biologics they had used so far. Unfortunately, biologics in general have their downsides: they suppress the immune system, making patients at high risk of infection. Biologics also take some time to become effective and some patients do not respond to them and need to try a number of them before finding one that works. Their effectiveness decreases over time forcing patients to change their medication from time to time. They are also very expensive.

Biologics are administered either subcutaneously or intravenously (IV). Actemra is currently only reimbursed in its IV form which causes some burden on the patients. For example, the three people reached by CAPA reported that they had to travel to a clinic to receive their drug – as opposed to some IV biologics that can be administered at home. The time involved in receiving the medication (approx. 1.5 hours plus travel time) was a great hassle to everyone we spoke with. One member, a 39 year old woman with moderate to severe arthritis, shared that it takes her "*a total of 2.5 hours of time away from work*" every month. Another woman with RA mentioned that she did not like to receive Actemra at the clinic because on top of having to travel, the clinic made her feel "*like we are cattle, squashed in a clinic with uncomfortable chairs, with people who do not speak to each other, not even the nurses*". She added that having to come to a clinic every 4 weeks will prevent her from travelling for longer periods of time when her husband retires. Furthermore, she shared that IV is painful, especially when the nurses "*blows your vein, and you are left with massive bruises".* A very common issue raised by CAPA Board members is that many have a great deal of vein scarring making it extremely difficult for nurses to insert the IV needle. One member reported that at each infusion of Actemra, she had to endure approximately 8 IV needle attempts before the nurse can find a vein that works. The consensus was that everyone would prefer to receive this medication subcutaneously either with an auto-injector or a pre-filled syringe.

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?

In the cases where the patient is severely disabled, provincial governments will provide some services to people with RA. Because RA develops earlier in life, some patients will not be able to access these services because they do not fit the reimbursement profile in which services are monopolized by the elderly. They will then have to rely on their significant others or their families for support. In some situations, people with RA will need to rely on caregivers for assistance like getting dressed or cooking during a flare or after a surgery. One young adult with severe juvenile rheumatoid arthritis shared that she had to rely on her mother a lot even when she lived on her own. This caused a lot of tension and prevented them from having a regular adult mother-daughter relationship. Specific to IV Actemra, one patient mentioned that she often saw spouses in the waiting room because they had to drive the patient to the clinic.

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.?

We had one-on-one conversations with two people living with RA who are currently on Actemra IV. Another member is also using Actemra IV, but for Juvenile Rheumatoid Arthritis (JRA). More information was obtained through personal experiences of the Board of the Canadian Arthritis Patient Alliance in living with inflammatory arthritis and using IV drugs versus subcutaneous drugs.

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 a patient perspective, the drug reviewed will greatly improve the lives of patients with RA because a subcutaneous drug would give them more freedom and control over its administration. They would not have to take time off work or arrange their schedules and travel arrangements to visit the clinic monthly. They would be able to inject in the comfort of their home. Patients with difficult veins would not have to endure having many needles stuck in their arms every 4 weeks. Overall, patients would be able to take the same efficient drug but it would be administered in a more pleasant way. Patients would benefit from the positive effects of Actemra in controlling RA and ultimately be less at risk of becoming disabled and a burden to the public health system and their caregivers.

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 in addition to what has already been mentioned in the submission

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 for a drug that is currently in a queue with no set time frame for when this drug will be made available to patients who are currently waiting for access to it. As mentioned in this submission patients endure a degree of hardship with the IV form of Actemra and will find the self-injectable indication much easier to use but because of CADTH's queue they have no idea when the new form will be accessible to them.