Ontario

Ministry of Health and Long-Term Care

Ontario Public Drug Programs
5700 Yonge Street, 3rd Floor
Toronto ON M2M 4K5

Submission of Patient Evidence

Please send completed submission and/or any additional relevant information to the Ontario Public Drug Programs, Patient Evidence Submission, 5700 Yonge Street, 3rd Floor, Toronto ON M2M 4K5, fax to 416 327-8123 or email to PatientSubmission.OPDP@ontario.ca.

Section I - Author Information

Date *(yyyy/mm/dd)*	Drug and Indication
2014-11-25	Infliximab (Inflectra) / Psoriatic Arthritis

Author	Patient Advocacy Group
Dawn Richards	Canadian Arthritis Patient Alliance

Unit No.	Street No.	Street Name	PO Box

City/Town	Province	Postal Code
Toronto	On	

Telephone No. (incl. area code)	Extension	Email Address
		dawn.richards@arthritispatient.ca

Section II - Conflict of Interest Declaration

The author and the patient group must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. Examples of conflicts of interest include, but are not limited to, financial support from the pharmaceutical industry *(such as educational/research grants, honoraria, gifts, and salary),* as well as affiliations or personal/commercial relationships with drug manufacturers or other interest groups.

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, Hoffman-LaRoche, Janssen, Novartis, Ontario Rheumatology Association, Pfizer Canada, Rx&D and UCB Pharma. Additionally, CAPA has also received support in the past from: Canadian Institutes for Health Research, Schering Canada, Scleroderma Society, and STA Communications. The author has also received consulting fees from AbbVie Canada, Hoffman-LaRoche, Janssen Canada, NovoNordisk, and Pfizer Canada.

Section III - Impact of the Disease/Condition

What symptoms and problems do patients have as a result of the disease/condition? How does the condition affect day-to-day life? For example, are there activities that patients are not able to do as a result of the condition?

Psoriatic Arthritis (PSA) is characterized by inflammation in the joints that destroys the joint lining and the surrounding bone, often requiring total joint replacement. Damage is irreversible and causes significant pain and disability. PSA is a systemic disease and can be accompanied by fatigue and numerous co-morbidities, such as cardiovascular disease, osteoporosis and lung disease. PSA involves joint inflammation, stiffness in the mornings, fatigue, and lack of ability to perform independent functions of daily living.

All daily activities of a person's life are affected who have PSA. For those whose PSA is not well controlled, day to day activities, such as participating in post-secondary education, becoming and staying 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.

Treatment outcomes that matter most to patients

What are the most important aspects of the condition that patients would like to see addressed by treatments?
In terms of treatment efficacy and side effects, what are patients getting from the existing treatments and what would patients like new treatments to do differently?
Are there other practical implications to be considered in determining the value of a treatment? For example, how do treatments impact patients' or caregivers' daily routine or lifestyle?
In addition to the drug cost, are there other financial implications to patients or caregivers *(e.g. traveling cost, time away from work, drug disposal issues, drug administration supplies)*?

People with PSA simply want to live independent and productive lives just like others. It is important to keep joints functioning and people able to take care of their families, work, and live a fulfilling life. Getting inflammation under control to minimize joint damage and fatigue is important. Currently there is no way to predict who will respond to which medications for PSA treatment. While side effects of existing treatments may vary, they can include: nausea and vomiting, extreme fatigue, decreased immune function (as current medications are immuno-suppressant in nature), injection reactions, and for biologics, auto-immunity is often developed to treatments after prolonged exposure to them.

When people have well-controlled PSA, they can successfully function and contribute to society- in every way relating to family, friends, a social life, and work. New treatments for patients have enabled this but we continue to require more options for patients, due to the inability to predict who will respond to which medications or the length of response, given the development of auto-antibodies to biologic medications. New medications have enabled people with PSA to literally walk again after being in a wheelchair, and have allowed them the freedom and mobility never thought possible. This has also eased the burden on their families and caregivers. We can imagine the economic impact of having someone work versus the possibility of them not working and entering in and out of the hospital system for many years.

Although cost of treatment is important, it's not the only factor, and we ask that the implications of forced switching be considered carefully.

Information from patients who have used this drug

For patients who have used this drug as part of a clinical trial or from a manufacturer's compassionate supply or have purchased it through other means (private insurance or paid out of pocket).

What positive and negative impacts does the drug have on the condition?
Which symptoms is the drug best or worst at treating *(advantages and disadvantages)*?
What difference does the drug make to patients' long-term health and wellbeing?
What are the side effects of the drug, which ones are patients prepared to put up with, and which ones do they find unacceptable?
How does the drug compared with other available treatments in terms of efficacy, side effects and other practical implications *(e.g. administration, time, costs)*?

We have not heard from any patients who have taken this drug yet. However since we do know the effects that the innovator drug, Remicade, has had on patients and given that Remicade and Inflectra are the same molecule with slightly different glycosylation patterns, we imagine that the impact of Inflectra will be similar especially based on what is seen in the Product Monograph. For Remicade, the most common adverse reactions are infections, allergic reactions and infusion-related reactions. The Product Monograph for Inflectra indicates that the types of adverse reactions are similar to Remicade- offering patients this SEB will not alleviate typical side effects that are also found with Remicade. We ask that consideration is offered to patient who do not well tolerate IV medications, though, and if self-injectable options are available, that more than cost is considered in terms of selecting the right drug for the right patient.

Patients rely on support programs provided by the originator company to help them maintain efficient access to receiving their medication and to be informed and properly taught about a medication's administration, assistance with drug cost coverage, and for general questions about their treatment. This patient support program is an important part of a patient receiving these complex biologic drugs.

Confirmation of Authorship:

☒ I declare that I am the sole author of this submission and confirm that no other parties had input into the submission.	**Signature**	Date *(yyyy/mm/dd)* 2014-11-28