

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) 2015-03-07		Drug and Indication Cimzia / Ankylosing Spondylitis	
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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, Eli Lilly 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?

Ankylosing Spondylitis (AS) is an inflammatory arthritis that affects the joints of the spine, and as such, affects every aspect of a patient's day-to-day life. Generally the onset of symptoms for AS occurs in the late teens to early 20s, and often times patients live for many years in extreme pain without an accurate diagnosis (it is not uncommon for AS to require 10-15 years before it is properly diagnosed and then treated). AS affects mostly men and there is currently no cure for it. Patients live with this chronic illness, taking medications to treat its symptoms and slow the progression of disease and its irreversible damage.

For people with AS, all of their daily activities are affected. In 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, 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*)?

As all people with a chronic illness, people with AS simply want to live independently and productively. Maintaining joint function and abilities to take care of families, work, and simply live a fulfilling life are important. Controlling inflammation to minimize joint damage and fatigue are important. There is no way to predict who will respond to which medications for AS treatment. While treatment side effects may vary for individuals, they may include: nausea and vomiting, extreme fatigue, decreased immune function (medications are immuno-suppressants), injection reactions, and for biologics, auto-immunity is often developed to treatments after prolonged exposure to them. When patients are not doing well with their chronic illness, there are also many potential impacts on one's mental health, from affecting one's self worth to depression.

People with well-controlled AS can function and contribute to society. New treatments available to patients have enabled this - however, more options are required to treat AS, given the inability to predict who will respond to which medications, or how long their response will be, especially given the development of auto-antibodies to biologic medications. Biologics have enabled people with AS to be productive members of society, which has 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.

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 patients taking this drug yet. In general, like other biologics, Cimzia, has similar side effects such as allergic reactions, infections, and cold-like symptoms. As discussed extensively above, AS is a chronic illness without a cure, and for which many patients will require many treatment options over their lifetime. So much is unknown currently about AS and its treatment options, including why some treatments stop being effective for some patients and which patients will respond to which medications. As such we know that increasing the toolbox of available treatments for patients with AS by their healthcare professionals is important. Additionally we know that the costs of patients with AS struggling with their disease (physically, emotionally, and to the healthcare system and their families and friends), far outweigh the benefits of doing well with living with a chronic disease (being productive and contributing members of society, including at home and with family and friends). Furthermore, being a self-injectable provides patients and their families flexibility with respect to administration - this can be done on their time in the comfort of their own home without the need to visit a medical facility or infusion clinic.

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)

2015-03-07
