

## 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, 3<sup>rd</sup> Floor, Toronto ON M2M 4K5, fax to 416 327-8123 or email to [PatientSubmission.OPDP@ontario.ca](mailto:PatientSubmission.OPDP@ontario.ca).*

### Section I - Author Information

Date (yyyy/mm/dd) 2015-11-19		Drug and Indication Apremilas (Otezla)/ Psoriatic Arthritis	
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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 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?

Psoriatic Arthritis (PSA) is characterized by inflammation in the joints (often hips, knees and spine) that destroys the joint lining and surrounding bone, often requiring total joint replacement. Joint damage is irreversible and causes significant pain and disability. PSA is a systemic disease, not just affecting joints, and is often accompanied by fatigue and numerous co-morbidities, such as cardiovascular disease, painful psoriasis (skin plaques) and lung disease. Besides joint inflammation, PSA includes morning stiffness, fatigue, and lack of ability to perform independent daily living functions.

All daily activities are affected for those who live with PSA. In addition to significant mental anguish, day to day activities which are taken for granted by healthy individuals such as 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, even impossible to undertake.

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**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*)?

Like all patients, people with PSA simply wish to live independent and productive lives. Maintaining joint functioning enables people to: take care of themselves and their families, work, and simply live well. Controlling inflammation 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-suppressants), injection reactions, and for biologics, auto-immunity is often developed to treatments after prolonged exposure.

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, and given the development of auto-antibodies to biologic medications. New medications for PSA have been life-changing, allowing persons living with PSA freedom and mobility never imagined. This has also eased the burden on their families and caregivers and our healthcare system. We ask you to view 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 you consider patients as people, not simply as costs in the healthcare system.

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**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, we are aware that multiple options are required for patients with PSA - since we currently do not have any evidence-based guides for placing people on the best drug for them from the time of their diagnosis. Unfortunately we do not have evidence at this time on how long someone will respond to a particular treatment for PSA either. As a result, people with PSA, like others with other forms of inflammatory arthritis, will often be on many different medications over their lifetime. We ask that you consider this medication as another option for patients with PSA.

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**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)

2015-11-19

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