



## Common Drug Review *Patient Group Input Submissions*

### **apremilast (Otezla) for Arthritis, psoriatic**

**Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.**

Arthritis Consumer Experts (ACE Planning and Consulting, Inc.) — permission granted to post.

Canadian Arthritis Patient Alliance — permission granted to post.

### **CADTH received patient group input for this review on or before May 21, 2015**

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

## Arthritis Consumer Experts (ACE Planning and Consulting, Inc.)

### Section 1 — General Information

<b>Name of the drug CADTH is reviewing and indication(s) of interest</b>	The use of apremilast (Otezla®) for the treatment of psoriatic arthritis (PsA)
<b>Name of the patient group</b>	Arthritis Consumer Experts (ACE Planning and Consulting, Inc.)
<b>Name of the primary contact for this submission:</b>	██████████
Position or title with patient group	██████████
Email	████████████████████
Telephone number(s)	██████████
<b>Name of author (if different)</b>	████████████████████
<b>Patient group's contact information:</b> Email	<a href="mailto:info@jointhealth.org">info@jointhealth.org</a>
Telephone	606-974-1366
Address	200A - 1228 Hamilton Street Vancouver, BC V6B 6L2
Website	<a href="http://www.jointhealth.org">www.jointhealth.org</a>
<b>Permission is granted to post this submission</b>	Yes

#### 1.1 Submitting Organization

Arthritis Consumer Experts (ACE) is a national organization that provides science-based information, education and support programs in both official languages to people with arthritis. ACE serves consumers living with all forms of arthritis by helping them take control of their disease and improve their quality of life.

Arthritis Consumer Experts is committed to the following organizational objectives:

- To inform, educate and empower people with arthritis to help them take control of their disease and improve their quality of life;
- To provide evidence-based information in reader-friendly language to people with arthritis, the public, governments and media;
- To provide research decision-making training to people with arthritis to help them participate meaningfully in research organizations and in consultations with government.

ACE's membership and program subscribers include people with arthritis, their families, their caregivers, rheumatologists, and other health professionals, elected officials, and senior government bureaucrats.

#### 1.2 Conflict of Interest Declarations

a) *Regarding corporate members and joint working, sponsorship, or funding arrangements:*

Arthritis Consumer Experts receives unrestricted grants-in-aid from the following private and public sector organizations: AbbVie Corporation, Amgen Canada, Arthritis Research Canada, BIOTEC Canada,

Canadian Institutes of Health Research, Celgene Inc., Hoffman-La Roche Canada Ltd., Janssen Inc., Pfizer Canada, Purdue Pharma L.P., UCB Canada Inc., and the University of British Columbia. ACE also receives unsolicited donations from its community members (people with arthritis) across Canada.

b) *Regarding those playing a significant role in compiling this submission:*

This is not applicable; only the staff and advisory board members of Arthritis Consumer Experts aided in the compilation of this information.

## Section 2 — Condition and Current Therapy Information

### 2.1 Information Gathering

The information was gathered through a request for patient input from JointHealth™ members and subscribers sent via email and posted on the JointHealth™ website, Facebook and Twitter posts. The submission is based on three subscribers who responded to a call for patient input dated May 6, 2015. ACE has provided additional organizational comments to augment the individual information.

### 2.2 Impact of Condition on Patients

The patients' day-to-day life is tremendously impacted by their PsA. Unlike most people who can take their physical/mobility abilities for granted, people living with psoriatic arthritis must always consider the state of their disease and decide what they can (and cannot) cope with, or achieve, how they can go about it, and how much help they may need. In severe cases, patients are very troubled by the physical (skin) disease manifestation.

Examples of activities that those living with PsA have difficulty with, include:

- One respondent has been living with psoriatic arthritis for 12 years. She experiences joint pain, pain, stiffness, and has trouble completing simple tasks. She has difficulty sitting, walking up and down stairs, bending to pick up objects, and getting in and out of the bathtub. She also has difficulty completing house chores such as vacuuming, cleaning, and doing the dishes. She has developed ischial bursitis, where her tendons and ligaments are also affected. She needs assistance with grocery shopping.
- “I’m a patient suffering from rheumatoid arthritis and I take methotrexate injections, which caused plaque psoriasis to appear on my body, my scalp, and my ears,” said another respondent to our call for patient input. Psoriatic arthritis is linked to the skin disease, psoriasis, which causes a scaly-type rash usually occurring on the elbows, knees, and scalp. Psoriasis is considered a significant risk factor for developing psoriatic arthritis – up to 30% of people diagnosed with psoriasis go on to develop psoriatic arthritis. There is documented overlap between diagnosis of RA and PsA.

My plaque psoriasis “created thick white scales of skin that I was scratching until they bled and those pieces were all over my floors, my car, and on all areas around me. I was seeing certain plaques get bigger and new ones appear elsewhere.” Mentally, she was feeling frustrated, worried and tormented because her rheumatologist informed her that she would have to wait until her body was 99% covered with those infected wounds before my case was taken seriously.

- Another respondent said that pain, fatigue, stiffness, and loss of function are the most prevalent and troublesome symptoms” of the arthritis component of PsA. She experiences skin sensitivity, redness, flaking, and pain for her psoriasis. She describes her life with PsA as follows: “My symptoms make daily activities harder and require pacing and prioritizing of activities. For example, even doing daily activities, such as showering, putting on clothing, cooking meals or walking up

stairs is painful, and requires more effort and time to do. Because completing daily activities take more time, I am more likely to stop doing social and creative activities due to limited time and energy and increased pain. I can ask for assistance but that is not always available. I stopped working due to pain and fatigue. When my psoriasis is visible and flaking occurs, I feel distressed and embarrassed. I am reluctant to do activities and sports like swimming that would expose my body, arms, and legs in public.”

It is important to note that as a result of the symptoms of PsA, anxiety and depression is prominent amongst people in this disease group. In a [study](#) by the University of Toronto of 306 people with psoriatic arthritis, and 135 people with psoriasis alone, it was revealed that 36.6 percent of participants with psoriatic arthritis had anxiety, while 22.2 percent had depression. The rates in patients with psoriasis were lower, at 24.4 percent for anxiety and 9.6 percent for depression.

### **2.3 Patients’ Experiences With Current Therapy**

- The respondent living with PsA is currently on the following medications: Remicade, at 500 mg every 5 weeks; Leflunomide at 20 mg a day; and, Prednisone at 5-10 mg a day. She also takes Tylenol Arthritis for pain management. She has no known side effects with any of her medications. Her doctor has to fill out the forms for special authority each year to cover the cost of the medications.
- The respondent living with RA and plaque psoriasis is currently taking a medication that her dermatologist recommended. She did not wish to disclose the medication name. However, she does notice a great improvement on her scalp, less itchiness around scaly areas. Side effects include heartburn and dizziness. Her blood sugar level has increased, but she and her healthcare team have been monitoring it closely as there is diabetes in her family history. She is paying for the medication through private health insurance.
- The third respondent is using a combination of Enbrel and methotrexate. This combination has helped to reduce the number of joints with active inflammation, especially for peripheral joints. As a result of this combination therapy, her psoriasis is under control. Occasionally, she would experience gastrointestinal upset and mucus membrane irritation from using methotrexate; however, she can take folic acid to reduce these adverse effects. She does not experience any side effect from using Enbrel. When asked about reimbursement access, she said: “I am fortunate to have group extended health coverage and the BC Fair PharmaCare plan. If I did not have these, it would be difficult to afford Enbrel.”

To summarize, patients believe that the more options there are, the better. Having more options could mean better access to medication, having a backup plan in case the current therapy treatment stops working, and having an economically sound solution in case the current therapy treatment is no longer covered under an insurance plan. As well, they feel that the best treatment is one that has the fewest adverse effects. Through ACE’s research and education efforts, people with PsA who interact with our organization generally understand there is a high degree of variability of disease and that there is a need for increased research activity into the causes and possible cures for the disease.

### **2.4 Impact on Caregivers**

Caregivers of patients with PsA have indicated that time is always a concern for them. They need to arrange and plan their schedule to accommodate for sudden and emergency requests from the person living with PsA. They have to help with house chores when the patient is in extreme pain, as well as fulfill the financial responsibilities they owe to themselves and their household.

For one respondent, her husband is retired and available to help her out with house chores and drive her around when her back and knees are bad. The downside is that helping her with disease management has reduced the time her husband is available to do part-time consulting work, recreational activities, and socialize with friends.

The patients expressed concerns of adverse effects over a prolonged period. Even though their medication(s) is successful in treating their PsA, a risk of developing other medical conditions is a strong possibility. All the patients agree that they will take the medication that is most effective in treating their PsA and that poses the least chance of adverse effects.

## Section 3 — Information about the Drug Being Reviewed

### 3.1 Information Gathering

The information was gathered through a request for patient input from JointHealth™ members and subscribers sent via email and posted on the JointHealth™ website, Facebook and Twitter posts. The submission is based on three subscribers who responded to a call for patient input dated May 6, 2015. ACE has provided additional organizational comments to augment the individual information.

### 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:*

It is difficult to determine with certainty that patients' lives will be improved by apremilast. One respondent commented: "It sounds like taking 1 or 2 oral medications would be easy to take. However, I would not be willing to experience serious adverse effects with apremilast." She expects any success story to parallel the results from the data and studies of previous treatment methods for other similar medication.

Another respondent agrees that her life would be improved by apremilast; "if it reduced inflammation, it could reduce pain, improve function, and prevent further joint damage. This could allow more participation in daily activities, social life, and work. It may decrease complications and need for hospitalization and other treatment."

She further comments: "Apremilast is a non-TNF inhibitor option for medication. The only approved drugs for PsA at present are TNF. I have already used 2 of the 5 drugs approved in British Columbia. Over time, I may need other options and I have been told that if one TNF inhibitor becomes less effective, it is less likely that others will work. A drug from another class would provide more options. Also, being able to take an oral drug rather than via an injection would be easier to take and have fewer issues around storage." She is willing to experience adverse effects related to apremilast if the improvement was significant (at least 50% improvement) and the side effects were not life threatening.

Each person living with arthritis responds differently to each medication, and no single biologic therapy (the current gold standard therapy for severe PsA) is effective in everyone with a particular disease. In the patients' opinion, reimbursement access to apremilast means there is another chance for them to have a treatment that will be effective in managing their disease if another biologic(s) used before it, fails. Allowing reimbursement access to the medication can also give professionals the tools to help their patients achieve remission.

ACE recommends a well-rounded treatment plan for PsA that includes medication, education, physiotherapy and occupational therapy, and a healthy diet. Initiation of the right medication in autoimmune arthritis is vital for helping someone gain back and maintain joint health. A patient's support network can help the patient achieve an optimal response to therapy.

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

None of the patients providing input have experience with using apremilast to treat their PsA. ACE, like other arthritis organizations in Canada, believes clinical trials are extremely important to advancing research into new, safe and effective treatments. As well, patients across the country who are refractory to current therapies rely on the emerging treatments being tested in clinical trials.

***How is the new drug expected to change a patient's long-term health and well-being?***

The patients hoped that apremilast would lessen their PsA pain so that they can manage to do day-to-day activities. The patients concluded with a plea to the healthcare system to find medications that help people with PsA achieve remission. When a patient achieves remission, they are able to live a normal life free from medication adverse effects and disease symptoms; maximizing their full potential as human beings.

#### **Section 4 — Additional Information**

To conclude this patient input, ACE wants to highlight the importance of the patient input process to patients, as proven by this patient comment: "I am very concerned about my health and I do everything in my power to help keep that gift of life. I hope that my comments will help you in your research and improve the lives of patients suffering from this ailment."

# Canadian Arthritis Patient Alliance

## Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Otezla (Apremilast)
Name of the patient group	Canadian Arthritis Patient Alliance
Name of the primary contact for this submission:	██████████
Position or title with patient group	██████████
Email	██
Telephone number(s)	██████████
Name of author (if different)	
Patient group's contact information: Email	██
Telephone	██████████
Address	
Website	<a href="http://www.arthritispatient.ca">www.arthritispatient.ca</a>
Permission is granted to post this submission	Yes

### 1.1 Submitting Organization

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 to assist them in becoming more effective advocates and to improve their quality of life. We assist members to become advocates not only for themselves but all people with arthritis. CAPA believes the first expert on arthritis is the person who lives with arthritis as theirs is a unique perspective. CAPA welcomes all Canadians with arthritis and those who support CAPA's goals to become members.

### 1.2 Conflict of Interest Declarations

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 Institutes for Health Research (Institute for Musculoskeletal Health & Arthritis), Canadian Rheumatology Association, Hoffman-La Roche, Janssen, Novartis, Pfizer Canada, Rx&D, and UCB Pharma.

Additionally, CAPA has received support in the past from: the Ontario Rheumatology Association, Schering Canada, the 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:*

None to declare.

## Section 2 — Condition and Current Therapy Information

### 2.1 Information Gathering

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. We posted a request for information based on our members who have experience living with psoriatic arthritis and using Otezla, however we did not receive information from such individuals for this submission

### 2.2 Impact of Condition on Patients

Psoriatic Arthritis (PsA) is a type of inflammatory arthritis that is a serious, debilitating autoimmune disease, affecting every aspect of a patient's day-to-day life. Patients often experience psoriasis first and about 30% of these patients will go on to experience the onset of PsA symptoms usually between the ages of 20-50. PsA affects men and women relatively equally and as with other forms of inflammatory arthritis, there is currently no cure for PsA – only ways to help alleviate symptoms and hopefully slow the progression of disease. PsA is a chronic illness that one lives for from the onset of symptoms until death.

PsA is characterized by inflammation in the joints that destroys the lining of the joint and ultimately the surrounding bone resulting in the need for a total joint replacement. Once damage occurs, it is not reversible and can cause significant pain and disability. There are 5 well-documented patterns of PsA and it can be very different from person to person.

PsA is a challenging to manage and physicians and patients work together to suggest and try different drugs to find something that works well for each patient and their PsA. There are currently no methods that help physicians predict which patients will respond best to which therapies. In addition, a patient's immune system may adapt to a drug, requiring them to then switch to another treatment when one becomes ineffective. As a result, patients require many medication options, as they may change medications a number of times during their lifetime.

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 (bathing, dressing, activities of daily living) and one's family, and other activities that the healthy general population simply take for granted, become very difficult. PsA is a disease that affects all aspects of a patient's life, not just their physical well-being but also their psychological well-being. There are many anecdotes of patients covering up their painful psoriasis and being acutely aware of these skin lesions throughout their lifetime. It is vital that inflammation be controlled early and well so that patients can continue to be productive members of society. We can imagine that the economic benefits to society of keeping people living with PsA in the work force and as productive members of society are greater than those required of the healthcare system if patients do not receive treatments for their disease.

### 2.3 Patients' Experiences With Current Therapy

Both small molecule and biologic disease-modifying anti-rheumatic drugs (DMARDs) are available to treat PsA. The biology of one's response to PsA medications is not currently well understood nor can it be predicted, causing patients with PsA to undertake a blind trial and error approach to find the most suitable treatment for their PsA, and with minimal side effects. Some patients experience long periods of responding well to a drug, while for unknown reasons, others will need to be exposed to many different drugs before finding the best treatment for their PsA. However it should also be noted that

current non-steroidal anti-inflammatory medications and DMARDs (e.g. methotrexate, plaquenil and Imuran) also cause gastro-intestinal side effects which patients generally simply have to deal with as best they can given that there are not many options for this devastating disease.

With the advent of biologics for the treatment of PsA, so has the need for either infusions or injections. This means that some patients have vein scarring and scar tissue from numerous infusions and injections. Patients may also face scheduling issues for infusions and need to take time off work or find someone to deal with family commitments (e.g. babysitting young children). An oral medication eliminates these issues for patients, as does the ability to travel since currently infusions need to be scheduled around travel dates (or vice versa).

All disease-modifying anti-rheumatic drugs (DMARDs) and biologics suppress the patient's immune system. Biologics suppress the immune system to a greater extent than the oral DMARDs. Infections are always a concern for patients with RA as even a common cold can quickly turn into a nasty infection, such as pneumonia. The use of Otezla provides patients with the option of taking a medication which suppresses the immune system less thereby lowering a patient's risk of serious infection. Furthermore, Otezla is a small molecular PDE4 inhibitor – this is the first new oral medication for PsA in about 15 years, and also represents a significant understanding in PsA biology.

Biologics are extremely costly for patients – while some patients have extended health insurance, others do not, and either rely on their own resources or those of their provincial Ministries of Health for assistance.

## **2.4 Impact on Caregivers**

Depending on a person's ability to cope with activities of daily living and their ability to still be employed, caregivers of people living with PsA are relied upon in varying capacities. In some cases, caregivers are required to assist with simple tasks such as bathing, getting in and out of bed, getting dressed, even using the toilet. The emotional toll on both patients and caregivers in this type of situation cannot be underscored enough. In other situations, a caregiver's burden may not be as great, perhaps giving the patient their injection or need to take over family responsibilities while the patient is receiving their infusion. Living with a chronic condition as potentially debilitating as PsA can affect a person profoundly psychologically – including caregivers. Additionally, when patients do not have drug coverage options, if one's spouse is their caregiver, this adds to the burden of disease in ways nearly unimaginable.

It is important to highlight that PsA affects patients and caregivers and family members profoundly, in all aspects of their lives – and does so from before their diagnosis, throughout their lives.

## Section 3 — Information about the Drug Being Reviewed

### 3.1 Information Gathering

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. We posted a request for information based on our members who have experience living with psoriatic arthritis and using Otezla, however we did not receive information from such individuals for this submission.

### 3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

To reiterate the points made in section 2:

- Patients require a number of medication options (including Otezla) in order to manage their disease effectively over their life;
- Vein scarring and scar tissue is a significant issue for patients who need to self-inject or receive their medications via transfusion, and an oral medication would eliminate these issues for patients;
- Current therapies often pose a number of gastro-intestinal issues that patients unfortunately simply have to deal with because of a lack of other options;
- The availability of another oral medication (taken morning and night) would reduce the amount of time spent by patients and their families on injections and infusions, allowing them increased independence, and decreased time spent 'as a patient'; and,
- Otezla targets a different molecule than currently available DMARDs (it is a PDE4 inhibitor) and for some patients, it is conceivable that targeting this molecule will provide significant relief of their PsA symptoms.

## Section 4 — Additional Information

As a patient organization, we have provided numerous submissions this year, and since we have submitted for the same inflammatory arthritis conditions (rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis), it would be great if we could simply reference large portions of those previous submissions for new submissions, if they correspond appropriately. While it may not seem like a lot of work, re-writing and re-working Sections 2.2, 2.3, and 2.4 is quite burdensome. I would ask that CADTH and CDEC consider us simply pointing to those sections of previous submissions unless something has changed dramatically since the last submission.