



## Common Drug Review *Patient Group Input Submissions*

**apremilast (Otezla)** for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

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

Canadian Skin Patient Alliance — permission granted to post.

### **CADTH received patient group input for this review on or before March 21, 2016**

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. This includes patient input received from individual patients and caregivers as part of that pilot project.

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.

## Canadian Skin Patient Alliance

### Section 1 — General Information

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

#### 1.1 Submitting Organization

The Canadian Skin Patient Alliance (CSPA) is a non-profit organization that serves patients with dermatological conditions, diseases and traumas in Canada. We focus on education and advocacy for these patients as well as our 20+ Affiliate members, including the Canadian Association of Psoriasis Patients and the Canadian Psoriasis Network. The CSPA has a steady social media community as well as thousands of readers via our award-winning magazine Canadian Skin (À Propeau in French).

#### 1.2 Conflict of Interest Declarations

The Canadian Skin Patient Alliance has the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements. We have received project-based and/or unrestricted funding from the following drug manufacturers over the past 12 months: Abbvie, Celgene, Galderma, GlaxoSmithKlein, Janssen, Merck and Novartis. We have specific principles in place that we follow when working with this industry.

The Canadian Skin Patient Alliance does not believe that they or those individuals playing a significant role in compiling this submission have a conflict of interest that influences the information provided in this patient group submission.

### Section 2 — Condition and Current Therapy Information

#### 2.1 Information Gathering

Information for section two was obtained from the following sources:

- A questionnaire (February 2016) was promoted via CSPA's social media channels to psoriasis patients or those suffering with psoriasis related symptoms (41 surveys received).

- CSPA used social media (Twitter and Facebook) and online discussion boards (16 posts) to gather patient testimonials.
- A questionnaire (September 2014) was promoted via CSPA's social media channels to psoriasis patients or those suffering with psoriasis related symptoms (51 surveys received).
- In 2014, CSPA reached out via email to the clinical dermatologists involved in the clinical trials to facilitate 2 patient connections.

### 2.2 Impact of Condition on Patients

*What aspects of this condition are more important to control than others?*

From the February 2016 questionnaire, the primary aspects of psoriasis that patients complained of included:

- Felt embarrassed: 66%
- Scales: 66%
- A drop in self-confidence: 65%
- Itching: 63%
- Joint pain: 63%
- Clothing options became limited: 61%
- Felt depressed: 60%
- Flaking: 57%

*How does this condition affect day-to-day life?*

One common condition-related symptom that people living with psoriasis talk about is their feeling of embarrassment:

- "The way people look at you....like they might get it."
- "Patch behind ear, very irritating and embarrassing, [I] have to wear hair longer to try and hide condition."
- "Depending on how bad my scalp is each day determines what I wear and where I go."
- "[Having psoriasis] means hair loss, lesions effect my confidence in looking for work. I have given up on having a relationship."
- "When my psoriasis did affect my day, I was self-conscious, embarrassed. It affected my choice of clothing. Fixing my hair to hide psoriasis in hair. I felt I needed to explain to friends what it was, that I wasn't contagious."
- "Constant concern about getting psoriasis flakes over everything; bleeding on clothes and objects; getting oily ointments over everything that touches my body, including the car armrests. There are vanity issues as well about appearance, but I try not to be affected by these. Every once in a while, comments in public pools, and by children anywhere, can be embarrassing."

Another common condition-related symptom that people living with psoriasis talk about is the flaking:

- "I have had to leave to go home to change my clothes due to flaking."
- "Flaking is embarrassing as well as noticeable scales. It affects what I wear to hide skin. I don't go to the beach or similar places."
- "Skin flakes on couch and bed."
- "When we travel, we bring our own linens."
- "Increased time we clean, managing flaking."

Here is what we heard from patients about scales:

- "I don't want to go out because my sores will be seen".

- “I have lost jobs because people were afraid of my scales, I have had problems with day to day rituals as the pain and scale was so bad I could not use common soaps etc. to cleanse, I have had total strangers come up to me and comment about my looks especially as I had it on my face.”
- “[They] cause me embarrassment as people ask what is wrong with my legs. So I have given up wearing dresses and just wear pants. Wish I could be a bit more feminine when getting dressed up.”

Here is what we heard about intimacy:

- “Psoriasis on your manhood is not a pleasant situation.”
- “Yes, it affects me. Because I am single since I was born, I don't expose myself to others. How do you have intimacy with someone when you are covered with red patches, flaking like crazy the whole life? It's not easy.”
- “Even after being together for four years, I was still embarrassed to show myself completely naked.”

Here is what one patient says about work:

- “[...] I have battled psoriasis my entire life. Only in my hair. Almost 30 now and it's progressing quickly to me. I am in severe pain all the time. I'm scared that I will be unable to do my job.”

### *How long have they been suffering?*

Our respondents from the February 2016 questionnaire shared the following with regards to how long they have suffered with symptoms of Psoriasis:

- 0-5 years: 24%
- 6-19 years: 24%
- 20 and up: 51%

### *Are there activities that the patients are unable to do as a result of the condition?*

Overall, 63% of patients live continuously with joint pain and 60% with depression. As well, here are some specific activities impacted (occasionally or frequently) due to psoriasis symptoms:

- Poor concentration: 81%
- Negative impact on ability to sleep: 73%
- Challenge to care for their loved ones: 59%
- Work load &/ or work hours had to be reduced: 53%
- Unable to do chores around the house, such as cleaning: 43%

Patients are looking for treatments that will significantly these symptoms: reduce scales, flakes, reduce the pain & itch, etc.

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

From the February 2016 questionnaire, patients reported that they either have used or are still using the following treatment options:

- Topical ointments, creams, gels or foam: 97%
- Phototherapy: 52%
- Methotrexate: 39%
- Adalimumab: 23%
- Infliximab: 15%
- Etanercept: 15%
- Ustekinumab: 15%
- Cyclosporine: 15%

*How effective is the current therapy in controlling the common aspects of this condition?*

- Effectiveness in reducing psoriasis skin plaques and spots: 42% said it worked “somewhat.”
- Effectiveness in dealing with overall pain: 30% said it worked “very well.”
- Effectiveness in dealing with scale, redness and shedding: 31% said it worked “very well.”
- Effectiveness in dealing with stiffness or pain: 37% said it “didn’t work at all”
- How convenient was it to use this treatment: 53% said “okay”.

*Are there hardships in accessing current therapy?*

- 24% said they had issues accessing their treatment.
- The inconvenience of infusion therapies & phototherapy represent significant barriers for these patients. As well, the infusions have associated costs for patients (in terms of time) & the health-care system.
- One patient shared his thoughts: “Cost is a major factor. I do not have BlueCross or anything and AB Medicare does not cover any prescriptions.”

*Are there needs, experienced by some or many patients, which are not being met by current therapy?*

*What are these needs?*

- Patients shared they had to stop taking current treatments due to heart disease, stomach issues or simply because it did not work for them.
- One patient shared that phototherapy helped her but she had to go faithfully five times a week for six months and now only goes to two times per week.

## **2.4 Impact on Caregivers**

In the February 2016 questionnaire, we asked patients about the impact psoriasis had on the daily routine or lifestyle of their family or caregiver:

- 24 % agreed with this statement: My caregiver's health is at risk due to all that they do to care for me & my psoriasis.
- 19 % agreed with this statement: My children have been greatly impacted.

Caregivers of people living with psoriasis must help patients with excessive house cleaning, bedding change, vacuuming and laundry due to flaking. As well, patients need assistance with applying creams and, in some cases, a helper when going to phototherapy sessions & medical appointments. Also many psoriasis patients also have painful joints, this impedes their ability to do simple every day activities – from food preparation to assisting with clothing and washing, mobility in and out of the house.

The whole family absorbs the shame as the depression and self-isolation also mean that family members and caregivers live in a dysfunctional setting, where they alone are required to provide the help needed by the patient. One patient noted the impact on her family: “[it] has impacted my husband tremendously in our family business as well as our home life.”

## **Section 3 — Information about the Drug Being Reviewed**

### **3.1 Information Gathering**

Information for this section three was gathered by several means:

- A questionnaire (February 2016) was promoted via CSPA’s social media channels to psoriasis patients or those suffering with psoriasis related symptoms (41 surveys received).
- CSPA used social media (Twitter and Facebook) and online discussion boards (16 posts) to gather patient testimonials.

- A questionnaire (September 2014) was promoted via CSPA's social media channels to psoriasis patients or those suffering with psoriasis related symptoms (51 surveys received).
- In 2014, CSPA reached out via email to the clinical dermatologists involved in the clinical trials to facilitate 2 patient connections.

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

*Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate?*

Patients require access to a treatment that alleviates symptoms in the long term allowing them to live a normal life, go to work, leave the house without having their life interrupted by visits to a phototherapy centre 2-5 times per week or travelling long distances to access infusion centres. For the patients already taking a biologic, access to new biologic options is key IF their current biologic no longer relieves their pain and suffering. As well, an oral option for those with needle phobias is a huge bonus.

*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?*

Over half of the patients we surveyed in February 2016 have been living with psoriasis for over 20 years. Any relief from the itch, scales, flaking and associated joint pain would be of benefit to patients and would have a positive impact on their quality of life.

*What positive and negative effects does the new drug have on the condition?*

- "I have had extensive plaque psoriasis for over 30 years. I have tried virtually every treatment out there over the years. Two weeks ago I started on the Otezla titration pack. I experienced a stomach "tightness" but this dissipated within 2 hours. I have also experienced a mild to moderate dizzy sensation within 2 hours or so of the dose. The symptoms, which were not too bad to start with, have diminished over the last two weeks. After 2 weeks on the medication I can see a marked improvement in my scalp as well as my face and torso. I would estimate a 70% improvement on my scalp and face and a probably an 80% to 90% improvement on my arms and torso."
- "I was on Humira, but worried about the potential very serious side effects. Found Otezla, with little side effect concern, and switched. Been over a year and I am very happy with the results and freedom from worry. I get relief from skin psoriasis (and also for my psoriatic arthritis.) Highly recommend it."
- "After one year[on Otezla], I do not have any side effects at all when taking Otezla - no migraines or stomach aches (I did have both for about three months) I also do not have any lesions on my scalp and had one very, very mild outbreak on my legs about a month ago that cleared up quickly. My hands are 95% clear and my feet - about 75%, with no fissures on either. To me, this is a huge success."
- I too have been on Otezla for over a year. TNF's were not successful for me. At first, the results were quite promising and I experienced far less pain from PsA and had less flares from psoriasis. However, over time there has been a marked decline in efficacy. Joints that did not bother me before Otezla have hurt consistently. Skin flares also resumed. On top of that, I have experienced muscle spasms. I tried going off of the Otezla but the pain was awful.
- "I'm on week 4 and it's really getting better. I've had it for 22 years...elbows, knees, scalp is the worse. Topicals weren't doing anything so I decided it was worth a try. Having all the common side effects (which kind of sucks) but I'm hoping to be CLEAR by summer!!! This would be the first time in my life since I was 17 that I have a chance of being clear."

- “I have been on Otezla for six weeks and my psoriasis started to get better the very first week. Side effects were minimal and only for a very short time. First time without pain, itching, etc. in almost six years. It has been an excellent choice for me.”
- “Been on Enbrel for the last 6 years. The Enbrel hasn't improved my swelling or skin patches for over the last year or so, but it is preventing it from getting worse. Since being on Otezla the swelling has gone down and skins patches appear to be clearing up. Amazing for only 5 days.”
- “The Otezla brought marked improvement after taking it for a month. But I did have to cut the dosage in half because while I had no diarrhea I did have bowel movements 6-8 times a day. That problem has settled down but I am now having stomach cramps and reduced appetite. It's nothing I can't live with but it is somewhat constant. Everything comes with a trade-off I guess.”

### *Does the new drug cause adverse effects?*

Some patients noted: headaches, stomach issues (see quotations above), body aches, and insomnia.

Note: many patients shared that many of the symptoms were short term.

One patient shares his/her experience with side-effects:

“I am into day 6 and had a rocky start, but things are looking up. The transitions have been a little brutal. Symptoms included headache, nausea, upset stomach, and a slight essential tremor like being over-caffeinated for about 40 minutes (it only happened after the first 20 and first 30 mg pills). All symptoms have generally subsided except for a slight headache beginning about an hour after taking it.”

### *Which adverse effects are acceptable and which ones are not?*

For those mentioning side-effects and that the product worked for them, the majority of the patients stated that this treatment is having a positive impact on their lives.

### *Is the new drug easier to use?*

In terms of ease of use, Otezla patients find the oral dosing to be very convenient. In our February 2016 survey, 71% of those taking Otezla said that it was easier to use than their previous treatment(s.) From our communications with psoriasis patients, we know that issues with transporting biologics for travel and needle phobia are issues that affect patients who are recommended for biologics. Otezla makes an appreciable difference in adherence and burden of the medication protocol

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

Patients stated having significantly clearer skin for the first time in 22 years, another 30 years!

For others, less time at the phototherapy centres allow them the opportunity to work a full-day. A healthier patient allows for a better quality of life in relation to work, family life and intimate life, as well as more freedom for the caregivers too.

In our February 2016 survey, we asked patients about balancing access to treatment vs increasing provincial health care costs:

- 86 % agreed that offering treatments that could help patients get back to a normal life and back to work is a crucial in the prevention of long term health expenses for psoriasis patients.
- 92% agreed that more treatments for psoriasis patients provide more options for doctors to help treat their patient.

Patients with this difficult, life-impacting disease need a variety of treatment options, to find one that works best for them, particularly once another treatment stops working. Given that this drug addresses

their psoriasis, their pain, and is more easily administered with minimal side effects, we believe that the CDR process should lead to a recommendation to list Apremilast (Otezla) for psoriasis.

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

As mentioned in a previous submission, the CSPA recommends that CADTH look at the schedule of patient input submissions and ensure that there is adequate time for the patient groups to gather data on patient experiences. For patient organizations, having to complete 2-3 submissions at the same time, it can be a drain on the limited resources available for this type of work.