



## Common Drug Review *Patient Group Input Submissions*

### **omalizumab (Xolair) for Urticaria, chronic idiopathic**

**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 October 14, 2014**

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.

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## Canadian Skin Patient Alliance

### Section 1 — General Information

<b>Name of the drug CADTH is reviewing and indication(s) of interest</b>	Omalizumab (Xolair)
<b>Name of the patient group</b>	Canadian Skin Patient Alliance
<b>Name of the primary contact for this submission:</b>	[REDACTED]
Position or title with patient group	[REDACTED]
Email	[REDACTED]
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<b>Name of author (if different)</b>	
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<b>Permission is granted to post this submission</b>	Yes

#### 1.1 Submitting Organization

The Canadian Skin Patient Alliance is a non-profit, for patients, by-patients organization that serves patients with dermatological conditions in Canada. It focuses on education, support and advocacy for these patients and for its 20+ allied/affiliated disease-specific organizations in Canada.

#### 1.2 Conflict of Interest Declarations

*We have the following declaration(s) of conflict of interest:* Abbvie, Amgen, Celgene, GlaxoSmithKline, Leo Pharma, Janssen, Merck, Roche, and Valeant have provided funding support over the past twelve months. We have not received funding from Novartis, the manufacturer of Xolair for over a year, and even then it was for specific unrelated outreach projects. We are in discussion on some project-specific funding for 2015.

### Section 2 — Condition and Current Therapy Information

#### 2.1 Information Gathering

Information for this submission was gathered via questionnaires, and individual interviews. Two dermatologists (Ontario and Quebec) were asked to share a questionnaire with their patients with chronic idiopathic urticaria (CIU) also commonly called chronic spontaneous urticaria (CSU). Also, we reached out to CSU patients online via Facebook who had experience with Xolair and they completed the online version of our questionnaire. Twenty-five questionnaire responses were received. People who responded had been living with CSU for an average of 12 years with a range of 7 months to 39 years. Two patients (who gave permission) were contacted by phone for a more in-depth conversation.

#### 2.2 Impact of Condition on Patients

People living with CSU struggle with randomly occurring, extremely itchy and/or burning raised red wheals on their skin, often accompanied by angioedema. Attacks can typically last up to six weeks. Half of our responders have a history of the disease affecting the whole body, and 76% have a common experience of symptoms on the face. The most troublesome symptoms were itching and hives and angioedema and these were the symptoms listed by patients as being the most important to control,

with itching being the most mentioned (60%). Swelling and visible wheals, especially those on the face result in emotional distress and social isolation.

People living with CSU live their lives anxiously fearing an attack which can come on at any time, in public or at work. It affects their sleep (96%) as the itch can be unbearable, resulting in fatigue and reduced concentration at work (88%). They grapple with anxiety (88%), depression (76%), and feelings of shame (68%). Their CSU limits the things they can do like swimming, gardening, and outdoor sports (92%) and plays a role in the foods they can eat (72%). Almost 50% indicated it affected the jobs they can get. One respondent who has lived with the disease for 39 years used to experience anaphylactic shock 3 times a week, and “*missed work frequently. .. had no social life.*” She was “*living in fear of dying.*”

Worst of all their CSU affects the self –confidence of almost all (92%) and they feel they need to hide their skin (96%). Not surprisingly 80% indicated they had problems with intimacy and sex and 92% claimed their CSU “*affects everything I do.*”

*I've had severe swelling of the lips, leading to feeling uncomfortable in public situations and affecting my self-esteem. Because instances of CSU have been unpredictable, I have also been anxious in not knowing if I will have a flare during an important life event.*

*I used to miss work all the time. People asked a lot of questions. Simply sitting in a chair would be painful due to the plaques on the back of my legs.*

*Sometimes my plaques and angiodema are so bad I can't go out in public.*

*Some days I could not do basic activities of daily living. There are days I cannot use my hands to put my hair up, open a pill bottle or even hold a glass of water.*

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

Currently covered therapies used by CSU patients who responded included Reactine and other OTC antihistamines, doxepin and plaquenil, and prednisone. Most were generally only somewhat effective, with all options bringing unwanted and mostly intolerable side effects. Sleep issues, weight gain, “trouble expressing myself...finding words,” sensitivity to light, and irritable bowels are some side effects listed. Those on antihistamines complained of fatigue and drowsiness, which impacted their ability to focus and work. For two people, prednisone worked very well for their CSU but the characteristic prednisone side effects made it a poor treatment option for constant use. One person listed IVIG treatments but struggled with nausea and contracted aseptic meningitis. Most of the therapies previously used were easily available.

The unmet needs of patients with CSU are for a treatment that effectively deals with the urticarial, the itch and the angioedema with no or tolerable side effects. There is currently no such treatment on Canada's public formularies for CSU.

*Over the 35 years my bouts with CSU have ranged from mild/moderate to very severe. Over the past 8 years I have been dealing with very severe and debilitating symptoms that made it difficult to work without being extremely medicated. These symptoms include large extremely itchy hives on my legs and arms making it difficult to wear clothing as well as angiodema on my eyes, lips, and hands.*

### 2.4 Impact on Caregivers

Since care givers are often family members, this is a disease that affects the whole family unit. When loved ones are driven crazy by itch, are visually deformed and crippled by angioedema, everyone around them “feels helpless.” Sexual difficulties can impact a marriage. The worry and stress caused by the randomness of CSU attacks affects the caregiver and the family unit as activities must revolve around a physical state that can change on a dime. The feelings of shame and depression often resulting in social isolation of the patient is felt by all. “They have to put up with my anxiety and depression. Plus now that I have damage to my back due to prednisone use, I need help doing household chores and cannot participate in some sports.” There is financial stress when work is interrupted or lost. Because CSU patients sometimes can’t move or are too tired or their urticaria is visible and disfiguring, caregivers and families must step up and take over parenting duties.

*Yes, it impacts every aspect of your life, friends, family. For me, I have been allergic to the world my whole life, and my friends and family are continually impacted ...it is extremely difficult to not know what causes a reaction. I have had to leave work for days at a time to deal with these reactions. It could be something so minor, or something so big. My students just run to the office and know the drill if, "Miss" is having a reaction.... I also live in an extremely controlled environment. I know the products to buy, and eat. But, it is in the uncontrolled settings which can make life extremely unpredictable, and can cause a severe reaction.*

Current therapies are generally easily administered, but the side effects so greatly affect the functionality of the patient that they can need help with self-care, grooming, washing and other basic functions.

## Section 3 — Information about the Drug Being Reviewed

### 3.1 Information Gathering

See 2.1

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

All but one respondent had experience with the new drug, Xolair as part of a clinical trial. Positive effects cited: Good control of CSU with great reduction or eradication of symptoms, “Xolair has given me my life back”. Five CSU patients were able to drastically reduce their intake of prednisone or antihistamines. Seventy-nine percent indicated that Xolair alone was effectively managing their CSU. *“Other meds before only controlled the itch and sleep issues. Xolair is the only one that treats the skin eruptions and swelling.”*

Negative effects included the cost of the medication and the minority (25%) of patients who had side effects mentioned headaches, and some tiredness right after receiving their injection but noted these went away. *“Minor headache, joint pain, and tired for a few days after monthly injection. SO WORTH IT.”* One broke out in hives after an injection, but reports good results after now having had 7 treatments.

All patients expressed that Xolair manages their symptoms better than previous treatments and that there were NO symptoms that Xolair does not manage as well as previous treatments. Xolair may be seen by some as less easy to use than self-administered pills, but patients were willing to undergo the time, cost and expense of monthly specialist visits as *“the benefits make it well worth it.”*

When asked “How do you think taking Xolair will affect your long term health and well-being,” all CSU patients responded positively and some expressed their hopes. This “life-changer” has *“a very positive effect on my life and I hope it will be for a long time.”*

*“I am hoping it will continue to control the devastating effects of my chronic hives.”*

## Section 4 — Additional Information

It is important that this treatment be available to patients on public plans. Given that CSU affects the ability to work, patients with this condition may be less likely to have access to private insurance.

*From a CSU patient:*

*I have been taking prednisone for many years to deal with my chronic hives. Before taking prednisone I was unable to work for a couple of weeks at a time. Last winter I suffered an spontaneous compression fracture to a vertebra. This was apparently a classic prednisone effect. Since that time I have endeavoured to stay off prednisone, but I can only manage to do that with the 300mg Xolair treatments which I am now doing every four weeks. Xolair may literally save my life, or at least preserve the remaining quality of life that I have now that my back has been compromised. Without Xolair, I would have to revert to prednisone and would end up using much more of the health system dollars than the preventive treatment. I am nearing retirement, so I cannot afford to spend almost \$18,000 per year for Xolair shots. That would be the total of my CPP and OAS payments, leaving me with no income.*