

omalizumab (Xolair) for Asthma, severe persistent

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

Asthma Society of Canada/National Asthma Patient Alliance — permission granted to post.

British Columbia Lung Association and Lung Groups — permission granted to post.

Ontario Lung Association — permission granted to post.

CADTH received patient group input for this review on or before November 25, 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. 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.

Asthma Society of Canada/National Asthma Patient Alliance

Section 1 — General Information

Name of the drug CADTH is reviewing a indication(s) of interest	nd	Xolair (omalizumab)
Name of the patient group		Asthma Society of Canada/National Asthma Patient Alliance
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1.1 Submitting Organization

The Asthma Society of Canada (ASC) is a national charitable volunteer-supported organization solely devoted to enhancing the quality of life and health for people living with asthma and associated allergies through education and research. The ASC has a 41-year reputation of providing health education services to patients, caregivers and health care professionals. The ASC offers evidence-based and age-appropriate asthma and allergy education, and disease management programs. Our *vision* at the ASC is to empower every child and adult with asthma in Canada to live an active and symptom-free life. Our *mission* is to be a balanced voice for asthma in Canada, advancing optimal self-management, prevention, research and health care.

We help patients to take control of their disease by providing credible and leading edge information and the guidance and education they need to live their lives symptom free. We lead and advocate for the best interests of Canadians with asthma through effective collaboration with policy-makers, researchers and health care providers. The *goals* established by our Board of Directors and operationalized in our three-year strategic plan are to: be the balanced voice in Canada advocating for patients with respiratory allergies and asthma; promote the best interest of asthma and respiratory allergy patients through effective collaboration with policy-makers, researchers and health care providers; educate and counsel patients to take control of their symptoms through effective self-management; engage in meaningful research to improve asthma prevention and management strategies; and be a respected role model and a well-managed association in the non-profit disease management sector in Canada.

The ASC established the National Asthma Patient Alliance (NAPA), a grass-root patient group of the ASC in 2007 with an outreach to over 5000 asthma and allergy patients. It is overseen by an Executive Committee made up of volunteers from across Canada. It is the collective voice of patients with asthma

and associated allergies sharing information, doing advocacy. Its programs include Team Asthma, Asthma Ambassadors and AsthmaPAC, the Patient Advocacy Committee.

1.2 Conflict of Interest Declarations

- a) The ASC receives approximately 20 percent of its revenue from research-based pharmaceutical companies through unrestricted grants and occasional consulting fees and other fee for service contracts. In 2015 funds have been received from GlaxoSmithKline, Novartis, AstraZeneca, Roche Canada, Boehringer-Ingelheim International, Merck, Takeda, Teva Innovation Canada, Sanofi, Sanofi Pasteur and Johnson & Johnson. We do not have a conflict of interest with regards to corporate members and joint working arrangements.
- b) The ASC requested and received a medical briefing from Novartis previously with regards to Xolair. We did not receive any additional assistance in compiling this submission.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information for this Submission was attained through the Asthma Society of Canada's Severe Asthma: The Canadian Patient Journey, the first patient study to look specifically at how this disease impacts the lives of everyday Canadians with Severe Asthma. The study, conducted in 2013 and released in the Spring of 2014, examined patients in four urban centres located in three provinces (Alberta, Ontario and Quebec) using a mixed method approach consisting of a qualitative survey (n=24) involving a lengthy personal interview and a complementary online quantitative survey (n=200) of patients from across Canada to validate the results of the in-depth interviews.

Patient recruitment involved direct outreach to members of the National Asthma Patient Alliance (NAPA), through the Canadian Severe Asthma Network as well as promotion through local asthma clinics and relevant healthcare centres. Regarding the surveyed and interviewed population, all participants are those who live with controlled or uncontrolled Severe Asthma, and who have been diagnosed with asthma by a physician. 75% of interviewed participants were between 30 and 60 years old, with 25% being diagnosed with asthma before the age of five, and another 25% being diagnosed with asthma in their 30s. Nearly all participants were diagnosed with Severe Asthma as adults.

2.2 Impact of Condition on Patients

Canadian specific studies show that up to 53% of Canadian patients with asthma are poorly controlled. Severe Asthma is a chronic condition that limits social activities and leads to a decline in health. People with Severe Asthma remark about how the condition isolates them – it is hard to stay social with unpredictable flare-ups, and it becomes difficult to stay active when physical exertion exacerbates Severe Asthma.

The physical toll the disease takes on the patient is often followed by a social toll, and it is not uncommon to hear Severe Asthma patients lament how diminished they feel about themselves and how Severe Asthma strains their family life. One man says that Severe Asthma keeps him from doing the things he loves, like taking his son biking. "I'm just so tired that I can't do anything anymore. Severe Asthma has changed everything," he says.

Activities that other Canadians take for granted continue to be the dream of people with Severe Asthma. A significant number of patients indicated that the most important aspect of their asthma to control was the ability to sleep without night-time symptoms with 87% selecting this choice.

Additionally, 75% indicated daytime exacerbations (attacks) were the most important aspect to control. A slightly smaller number identified medication cost and frequency of dosage as the most important aspect. Patients clearly identified that when it comes to controlling their asthma, the key factors are the ones that directly impact their overall health and well-being.

Patients were asked how asthma directly affected their day to day life. More than 7 in 10 (71%) indicated that asthma limits the type and amount of physical activity making it more difficult and unlikely for them to get sufficient exercise. More than half (55%) mentioned that the lost productivity of their asthma, having to miss days of work or school had a significant impact. 40% indicated that their Severe Asthma affected their work or school "a great deal". Other options of note was the negative stigma of asthma (64.6%) and the impact of asthma on their family and/or caregiver (80%).

Finally, patients were asked if there were activities which they were unable to do as a result of their asthma. Overwhelmingly, the participants indicated that physical activities, such as exercising and spending time outdoors was the area where they were the most limited, with 80% selecting that option. 87% noted that their asthma impacted their sleep, while 66% felt that their asthma impacted their ability to participate in social activities. Other feedback received included patients who indicated their asthma affected their job opportunities, their personal relationships and day-to-day housework and home upkeep.

2.3 Patients' Experiences With Current Therapy

Asthma, the third-most common chronic disease in Canada, affects nearly 3 million Canadians. Severe Asthma (SA), a more severe form of asthma and a greater threat to health, impacts the health and wealth of between 150,000 and 250,000 Canadians. Our patient survey participants were screened to ensure that all had Severe Asthma.

For many, asthma is not controlled. Only 17% of the study's respondents believe their asthma is well controlled. Half believe their asthma is adequately controlled, 27% believe their asthma is not well controlled and 8% don't believe their asthma is controlled at all.

Many patients report going through several years of trying different medications before finding the medication, or combination of medications, that will keep their asthma manageable. Some participants report having spent up to seven years experimenting with treatments before finding the right treatment.

Financial challenges create significant barriers to better health outcomes. Many patients cannot afford their medication and many insurance carriers do not provide complete coverage to asthma patients. The expense of medications causes additional stress for many patients. A significant number of participants did not have complete coverage (if any) and reported skipping or delaying their prescription until they could afford it. One participant indicated that he simply cannot afford the treatment recommended by his doctor. "Asthma is very expensive," explains one participant. "People don't realize how much the asthma drugs cost. When you are on a disability pension, even when insurance covers three-quarters, the other 25% kills you."

The majority of respondents to the study reported that they use asthma medications on a daily basis. Most respondents (83.5%) use their controller medication daily, with 71.1% using it at least twice per day. Many respondents (42.2%) use their reliever medication daily, with 28.8% using it at least twice per day.

A surprising number of patients are not receiving information about the newest kinds of therapies for their asthma. Only 27.4% of respondents felt that they had access to information and services for newer treatment options for Severe Asthma. Patients knew little about new biologics available for treatment of Severe Asthma and none had heard of bronchial thermoplasty despite its availability in several centres geographically near interview participants.

2.4 Impact on Caregivers

Asthma creates social barriers for some patients. More than half of respondents (64.6%) said they have felt stigmatized at some point because of their asthma, with 22.2% saying they feel stigmatized "quite often." Similarly, 66% of respondents feel that their asthma interferes with the quality of their social interactions with others, and 23% feel this way "quite often."

The largest effect of asthma on caregivers is the worry and fear they face that their loved on will suffer an exacerbation of an asthma attack. Asthma affects family members, too. Most respondents (80%) reported that they, or a family member, experienced trouble sleeping in the last three months because of their asthma symptoms.

Severe Asthma attacks tend to be lengthy and costly. Approximately 30% of our respondents missed work or school because of their asthma. Of these, 65.9% missed five days or more. A third of those who missed work or school (31.9%) missed 10 days or more, amounting to approximately 10% of total respondents.

Severe Asthma is an emergency condition for many patients. Almost half of respondents (48%) visited an emergency room because of their asthma in the 12 months preceding the study. A third went more than once during this period. One in five had been admitted to the hospital because of asthma in the preceding 12 months, with one in ten having been hospitalized more than once.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

As above, in Section 2.

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

It is not uncommon for asthma patients to journey through an experimentation with a multitude of pharmaceutical treatment options before finding the right combination to achieve optimal control of symptoms. Numerous patients interviewed indicated they had been prescribed upwards of 10 medications over their lifetime before finding the appropriate treatment. This often coincided with an eventual diagnosis of Severe Asthma. As the only available biologic treatment for Severe Asthma currently available in Canada, Xolair represents a new treatment option which could benefit asthma patients who have not previously been able to achieve proper control of their disease.

Of the 196 patients who completed the quantitative online survey, 9 indicated that they were currently taking Xolair. Patients provided valuable responses to questions about their asthma treatment, control and barriers to optimal management. Patient's anecdotal comments were also included. When asked about how many times they needed to take medication for relief of coughing, wheezing, chest tightness or shortness of breath, one patient taking Xolair responded "most of my symptoms have gone away"

since I have been on Xolair, which I started 1 year ago." This is not dissimilar to comments we receive from other asthma patients from across the country in phone calls and emails to our office.

Interesting comparisons emerged of those patients surveyed who indicated they were taking Xolair, versus the remaining patients who participated. For example, when asked how many times in the last 12 months they had been to an emergency department for asthma, 83% of Xolair patients had zero visits, while only 52% of the main surveyed population answered similarly. When asked how many times they'd been admitted to hospital with asthma, 100% of Xolair patients answered zero, while 81% of the main surveyed population replied similarly. Finally, when asked if they had missed work or school because of asthma in the past 12 months, 83% of Xolair patients replied no, compared to 51% of the general surveyed population.

Patients were asked to describe their ideal treatment option. 50% felt that the frequency and convenience was very important. Meanwhile, 83% felt it was somewhat or very important that the drug be affordable to patients, and that it work quickly. Patients were evenly split on the favourability of receiving medication by injection once per month with 50% liking it a lot and 33% neither disliking it or liking it and 17% somewhat disliking it. However when asked to choose between a pill once per day, an injection once per month, a pill once per month and an injection once per month, 50% selected the once per month injection.

Finally, patients were asked what else government and/or private payer plans could do to provide patients with adequate coverage for medications to treat their asthma. 83% indicated they'd want more of full coverage of medication costs, 67% of respondents selected lower the cost, assist or provide better coverage for low income families, cover more/better treatment options and invest in research for new treatments. These concerns about cost are emphasized by the fact that 50% of those surveyed had been denied coverage for Severe Asthma treatments by their insurance company or government insurance programs in the past.

Section 4 — Additional Information

In general, NAPA members have expressed a desire for increased coverage and funding to provide access to new treatments for Severe Asthma. Provincial coverage varies, but access for Xolair is extremely limited and requires the patient to overcome considerable bureaucratic hurdles which is both time consuming and stressful, which in and of itself can further exacerbate asthma symptoms.

British Columbia Lung Association & Lung Groups

Section 1 — General Information

Name of the drug CADTH is reviewing a indication(s) of interest	nd	Xolair(Omalizumab)
Name of the patient group		British Columbia Lung Association & Lung Groups
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1.1 Submitting Organization

The Mission of the British Columbia Lung Association (BCLA) is to improve lung health and to lead lung health initiatives. Our vision is healthy lungs for everyone. Our role is to improve respiratory health and overall quality of life through programs, education, research, training, treatment, advocacy and prevention of lung disease.

The BCLA is a major Canadian charitable organization with more than a century of experience and leadership in lung disease prevention, treatment and management. Today our areas of interest and expertise include the entire scope of respiratory diseases including Asthma, Idiopathic Pulmonary Fibrosis, COPD (chronic bronchitis and emphysema), lung cancer, sleep apnea and tuberculosis. We work together with the Canadian Lung Association and other partners to help the one in five Canadian who have breathing problems.

Our staff and volunteers include health professionals and interested individuals and patients with a broad range of training and experience in lung disease and lung health that enables our organization to develop and lead programs of education and health promotion at the highest standard. The British Columbia Lung Association provides approximately \$1.2 million each year to internationally recognized physicians and scientist doing research in BC on lung diseases. All funding proposals go through rigorous national peer review system so that the most promising research can be explored. This world class research is discovering the causes of lung disease, finding new treatments, and giving hope for a future free of lung disease.

1.2 Conflict of Interest Declarations

The British Columbia Lung Association has several sources of funding for programs and operations and is supported by individual and corporate donations, and through service contracts with government organizations. Funding sources include direct mail campaigns such as the Christmas Seals campaign, memorial giving, bequests, Special events such as Climb the Wall: Stair Climb for the fight against lung disease!, Bicycle Trek for life and breath and our RUSH event. The Lung Association, does, from time to time receive program grants from health industry/pharmaceutical companies. Our relations and interactions with pharmaceutical companies remain transparent and positions of the Lung Association are developed without industry influence.

The BCLA has received health educator's program grants from the following pharmaceutical companies: Grifols, GlaxoSmithKline, InterMune, Astra Zeneca, Boehringer Ingelheim, Pfizer, Novartis and Merck Frosst.

a) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

Neither the principal author, nor the BCLA, has conflicts to declare in respect to the compiling of this submission

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The BCLA is significantly invested and involved in Asthma and other respiratory disease research and provision of patient services and programs. We have Certified Respiratory Educators on staff that can provide expert educational consultations to respiratory patients, their family members and caregivers dealing with Asthma and other lung diseases. The vast knowledge and experience garnered through research, best practice guidelines and direct involvement with patients is the basis of the information provided.

2.2 Impact of Condition on Patients

Asthma is a common chronic respiratory disease affecting 1-18% of the population. There are more than 300,000 asthma diagnosed patients in BC. It is characterized by variable symptoms of wheeze, shortness of breath, chest tightness and or chough and by variable expiratory airflow limitation. Both symptoms and airflow limitation characteristically vary over time and in intensity. These variations are often triggered by factors such as exercise, allergen or irritant exposure in weather or viral respiratory infections.

Symptoms and airflow limitation may resolve spontaneously or in response to medication, and may sometimes be absent for weeks or months at a time. On the other hand patients can experience episodic flare-ups (exacerbations) of asthma that is life- threatening and carry a significant burden to patients, their family and the community.

Approximately 5% of asthma patients have severe asthma which is often inadequately controlled by inhaled corticosteroid (ICS) and long -acting B2 agonists (LABA). The Canadian Thoracic Society and the Global Initiative for Asthma (GINA) guidelines recommend an approach of aiming for best possible results in terms of symptoms, rescue medication use and lung function. These patients are at high risk of severe exacerbation and death and have few therapeutic options available. Patients with severe asthma

have the greatest medical need among the asthmatic population today and represent the greatest economic cost (>50% of total asthma related health care cost)

Lung attacks or flare-ups drive disease progression. As the disease progresses frequency of flare-ups increase, overall lung function and lung health typically decline and risk of hospital admission increases as well as rate of mortality.

2.3 Patients' Experiences With Current Therapy

The therapies used and recommended by the Canadian Thoracic Society such as (ICS, LABA) Omalizumab, a monoclonal anti-immunoglobulin (Ig) E antibody has been extensively evaluated in allergic respiratory disease. Omalizumab significantly reduced exacerbations and the use of Inhaled corticosteroid (ICS). It was also reported that benefits in patients with perennial allergic rhinitis. Asthma related quality of life (QoL) was improved and it was well tolerated during long-term use. Despite use of high-dose ICS and LABA therapy and often other therapies Omalizumab significantly reduced the rate of clinically significant flare-ups, severe exacerbations and emergency visits. Omalizumab is effective and should be considered as add-on therapy for patients with inadequately controlled severe persistent asthma who have a significant unmet need despite best available therapy. (INNOVATE STUDY)

Since Omalizumab is not yet funded by provincial/territorial drug program, patients can only access the treatment through private insurance or personal financial means. Today, Omalizumab remains out of reach for many patients especially seniors who no longer have private coverage and rely strictly on government funding for access.

Unmet Needs: Of critical importance to the treatment of asthma are medicines that will help reduce or stop the progression of the disease and subsequent hospitalizations. Additional therapies are needed that go beyond symptomatic relief. New treatments are urgently needed that will work to improve overall lung function. New treatment options are required as the disease progresses. The BCLA believes that access to asthma medications will serve to reduce cost on admissions to hospital and improve the overall lung health of patients with asthma. The BCLA support the quick access to respiratory medications such as that for severe asthma patients and recommended by the Canadian Thoracic Society

We recognize that not all patients or individuals respond the same to various types of formulations of medications and BCLA support having access to the medications to which a particular patient responds better.

We also recognize that not all patients are able to use inhalation devices effectively and we also support having access to the inhalation devices which the patient are able to use correctly. Delivery of the medication effectively is important in the treatment of asthma. The new medication is given as a subcutaneous injection by the doctor or nurse in XHALE program. The XHALE program is confidential patient support service. It is designed to make the treatment as easy and convenient as possible. Unmet Needs: Medications are of critical importance in the treatment and management of asthma. It improves lung function and breathing, reduce lung attacks and prevent patients with repeat admission to hospital there by improving the lives of severe asthma patients.

2.4 Impact on Caregivers

Our health care system places a lot of demands on both the patient and caregivers. Caregivers are often the spouse, the children, Mom's, Dad's and other relations. Financial challenges are the obvious ones, depending on the level of reimbursement for medicine.

Another major impact identified by patients and care givers is physical activity. The impact is most noticeable on patients' progressive inability to perform day to day tasks as they begin to notice that they had previously taken for granted (e.g. absenteeism from school in children and for the adult inability to do normal activities)

As the patient's condition deteriorates, they tend to stay at home more which means that their fitness levels further deteriorate and their body's ability to use oxygen efficiently is further compromised. As the condition progresses, further compromises are made in patient's independence with huge implications for caregivers. Patients with Severe Asthma and their caregivers experience anxiety and depression. This disease has a progressive debilitating course and sadly it increases mortality.

Caring for someone with Severe Asthma can be both physically and emotionally demanding. Caregivers may experience a great deal of stress and anxiety, resulting from their loved one's deterioration. Frequently these feelings have a negative impact on the caregiver's health and well-being. Frequent visits to medical professionals, increasing medical needs, restrictions in activities leading to the caregiver taking a larger role may impact the caregiver significantly. The BCLA sponsor a number of support groups called "Better Breather's Group" for individuals with Lung Conditions and their caregivers and helps the caregiver cope more effectively.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The BCLA is significantly invested and involved in Asthma and other respiratory research and provision of patient's services and programs. We have Certified Respiratory Educators on staff that provide educational expert consultations to respiratory patients with Asthma, their family members and caregivers. The vast knowledge and experience garnered through research, best practice guidelines and direct involvement with patients is the basis of the 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:

The British Columbia Lung Association on behalf of our lung patients with asthma can benefit with the add-on therapy of Omalizumab (Xolair) who do not respond on the other asthma medications. We urge CDR at CADATH for the easy access and approval of Omalizumab medication for patients with severe asthma. It is also imperative to make easy access to our Asthma patients in the Provincial/Teritorial drug formularies.

We support access to those medications recommended by the CTS.

There have been clinical trials on Omalizumab in several pulmonary research clinics in BC. Omalizumab is an effective advance in the treatment of severe asthma.

Patient's experience:" Mr.R.M has been taking Omalizumab for more than 2 years has had an improvement in his quality of life, can now enjoy his environment, can go out, has had less lung attacks and less hospitalization."

Patient's experience: "Mr. B.L Omalizumab changed his life, changed his health and feeling much better, sleeping better, treated his depression, allergies and needed less asthma medications as well as less asthma exacerbation (flare-up)"

Patient's experience:" Ms. S. Has been taking Omalizumab for 3 years and has described her life as miraculously changed with the use of Omalizamub, has been able to come back and work and been healthy. The biggest impact for her she has been able to stop the use of oral prednisone. The medication was able to prevent the ABPA fungal plugs from causing her pneumonia. Her overall immunity has greatly improved. It has also decreased her sinus infection. She had had no ER visits or hospitalization"

These are some patient's experiences from Dr. M. FitzGerald, Dr. B. Schellenberg, & Dr. G. Luciuk's

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

Some negative side effects are the usual: Injection site bruising, viral infections, sinusitis, headache and sore throat. Please refer to 3.2

Section 4 — Additional Information

On behalf of our Severe Asthma patient's (5% of severe asthma patient's in BC), please make easy access to our patients who can benefit from Omalizumab (Xolair) Many ...many ...thanks.

Ontario Lung Association

Section 1 — General Information

Name of the drug CADTH is reviewing a indication(s) of interest	nd	Name = Xolair / Omalizumab Indication = Asthma, severe persistent
Name of the patient group		Ontario Lung Association
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1.1 Submitting Organization

The Ontario Lung Association is a registered charity that assists and empowers people living with or caring for others with lung disease. It is a recognized leader, voice and primary resource in the prevention and control of respiratory illness, tobacco cessation and prevention, and air quality and its effects on lung health. The Association provides programs and services to patients and health-care providers, invests in lung research and advocates for improved policies on lung health. It is run by a board of directors and has approximately 70 employees, supported by thousands of dedicated volunteers and works out of a provincial office in Toronto and nine community offices throughout Ontario. The Ontario Lung Association is part of a federated model and works closely with 9 other provincial lung associations and the Canadian Lung Association.

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:

The Ontario Lung Association receives sponsorship and grants from a number of pharmaceutical companies which support educational and research initiatives. Companies who provide funding to the Ontario Lung Association include: Pfizer, GlaxoSmithKline, Boehringer Ingelheim, AstraZeneca, Merck, Novartis, J&J, Roche, RX&D, Eli Lilly and the Ontario Home Respiratory Services Association (OHRSA). None of these organizations participated in any way in this submission.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

(Nothing to declare)

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The information provided in section two was obtained from 5 recently completed on-line surveys by people living with asthma, as well as input from a certified respiratory educator.

2.2 Impact of Condition on Patients

The symptoms and challenges that people experience as a result of Asthma are coughing (with or without mucus), wheezing, shortness of breath, difficulty fighting infections and fatigue. When asked whether this condition affected their day-to-day life, respondents indicated that it did indeed impact both their physical and leisure activities, as well as their financial situation and family relationships. Activity restriction was noted several times throughout the survey. A couple of direct quotes are:

- "It can limit or restrict activities, interfere with work (both in terms of attendance and concentration and performance while at work) and make daily activities more difficult."
- "I would like no restrictions in activities."

The aspects of the condition that are most important to control for people living with it are shortness of breath, coughing, wheezing and fatigue – they would also like to have increased energy and a better ability to fight infections.

2.3 Patients' Experiences With Current Therapy

Treatments tried by those who completed the survey included: ICS and LABA (Symbicort), LAAC (Spiriva Respimat), Antihistamine (Reactine 20 mg BID), Antiluekotriene (Singulair), SABA (Ventolin) PRN, and one person had just started anti-IGE (Xolair).

Current treatments do provide some relief for: shortness of breath, cough, poor appetite and the inability to fight infection, but patients also indicated they want to experience a greater improvement of these symptoms and their overall goal was less of a medication burden. The only side effects indicated from using the above-mentioned dugs included low energy.

When asked about whether the treatments affected their life in any other way, the respondents indicated that the time required to travel to health-care settings, the time required off work for these appointments and the changes to their daily routine to accommodate treatment did impact their life in a negative way.

2.4 Impact on Caregivers

No information was received for this question.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information provided in section two was obtained from 5 recently completed on-line surveys by people living with asthma, as well as input from a certified respiratory educator.

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:

Key treatment outcomes of asthma that patients would most like addressed are: reduced shortness of breath, reduced coughing, reduced fatigue and improved appetite. They would like an improved ability to fight infections and to have a higher energy level. Ideally, patients would experience an improved quality of life and improved lung function.

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

Only one patient within this evidence group submission has used the drug Xolair. He/she indicated that when comparing it to other drug treatments it rated "worse than" in the areas of administration of drug and the time to accommodate treatment, but the "same as" in terms of cost burden, side effects and treatment of the condition. The one side effect of Xolair that this patient indicated as least bearable was the impact to mood.

When asked about hardships / difficulties accessing this therapy, the response was: "Xolair injections are hard to access – they must be done in a trained clinic during office hours. For me this is over an hour from my home and I work full time. Injections must be booked monthly with fairly limited flexibility. All other medications are more easily accessed."