Common Drug Review
Patient Group Input Submissions

onabotulinumtoxinA (Botox) for overactive bladder

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
The Canadian Continence Foundation — permission granted to post.

CADTH received patient group input for this review on or before June 2, 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.

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.

The Canadian Continence Foundation

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Botox Overactive bladder
Name of patient group	The Canadian Continence Foundation
Name of 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]
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1.1 Submitting Organization

Founded in 1986, The Canadian Continence Foundation (formerly The Simon Foundation for Continence Canada) is the only national non-profit organization serving the interest of people experiencing incontinence. The organization is lead by people with incontinence and by professionals from all health disciplines. The Canadian Continence Foundation (TCCF) is supported by donations from the public, healthcare professionals and private industry. The mission of the Foundation is to enhance the quality of life for people experiencing incontinence by helping, them and/or their caregivers, to confidently seek and access cures and treatment options. To this end, the Foundation will implement and encourage important public and professional education, support, advocacy and research to advance incontinence treatment and/or management.

TCCF offers a wealth of information on incontinence. Books, videotapes, and newsletters are available. We operate a toll free number at 1-800-265-9575. Each year TCCF responds to thousands of requests for information and education from people experiencing incontinence, healthcare professionals, and industry.

The Foundation interacts with the media to increase public awareness and knowledge of incontinence and to encourage people to seek help. It also provides individuals with lists of specialists in their local area. The Foundation initiated and now coordinates Incontinence Awareness Month in November of each year, promoting public and professional awareness-building and educational activities about incontinence around the country.

TCCF encourages and supports research to advance incontinence management/treatment.The role of patient advocacy groups in imp roving health care and services through community knowledge transfer and government lobbying has been recently appreciated. Incontinence advocacy groups like TCCF strive to ensure that all incontinent Canadian consumers have access to evidence-based medical therapy and that their quality of life is given serious consideration by health policy makers because incontinence is still a stigmatized and taboo condition amongst Canadians. As such, incontinence is often suffered in silence without seeking health care.

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:
TCCF has multiple sources of funding for programs and operations and is supported by individual and corporate donations. Funding sources include: donations from individuals, healthcare professionals and industry. TCCF does not receive any government funding.

Our relationship and interactions with pharmaceutical companies remains as transparent as possible and the policy positions of the TCCF are developed with input from a large number of stakeholders. Corporate relationships are ongoing with the intention of achieving TCCF goals as they relate to patient support and education.

TCCF has currently received both restricted and unrestricted educational grants from the following health care companies: Allergan, Astellas, Laborie, Tena - a Personal Care brand by SCA.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:
None.

2. Condition and Current Therapy Information

2.1 Information Gathering

We conducted a cross-sectional, population-based survey on a random cohort of Canadian people who are known to suffer from OAB and are currently taking treatment. Patients were identified through TCCF database and contacted to respond to an on-line questionnaire on our website. Their primary family caregiver was also requested to contribute to one question. Participation was voluntary knowing that the results will be anonymous and confidential.

The questionnaire consisted of 11 items with closed and open responses to capture patients (and caregivers) experience in their own words. The survey was available in French and English. Of the 100 patients recruited, 76 completed the questionnaire (76% response rate). The survey was conducted and completed between September 1 and 30th, 2013.

2.2 Impact of Condition on Patients

Urinary incontinence (UI) means losing urine when you don't want to. UI is an embarrassing and debilitating symptom with an adverse impact on the quality of life and economic burden that is becoming a significant public health problem. As many as 3.3 million Canadians- nearly 10% of the population- experience some form of UI. Unfortunately, very few people talk to their doctor about their symptoms. According to the Canadian Urinary Bladder Survey, 16% of men and 33% of women over the age of 40 have symptoms of UI but only 26% have discussed the symptom with their doctor. This is a conservative estimate as a recent epidemiological survey conducted by TCCF this year has found that 36% of community dwelling women suffer from UI.

An overactive bladder (OAB) is the feeling of an urgent and painful desire to go to the washroom (urgency) which is very frequent (frequency) especially at night (nocturia) and is sometimes associated with leaking urine involuntarily if you do not reach the washroom on time (urge urinary incontinence). About half of people with OAB have urge urinary incontinence but you can have OAB without UI. OAB is one of the principal causes of UI in both men and women and usually results from "untimely" contractions of the involuntary muscle of the urinary bladder. As yet, the cause of this condition is incompletely understood and therefore the results of available treatment including drugs are usually disappointing.

Anti-cholinergic agents are the mainstay of pharmacological treatment of OAB because of the ability to reduce bladder contractions and associated symptoms in most patients. These drugs are, however, associated with poor tolerability and relatively poor patients' compliance because of the high incidence of anti-cholinergic adverse effects such as dry mouth, blurred vision, and constipation. Due to these side effects many patients try one OAB medication after another, only to cease treatment completely leaving them in the vulnerable position of nighttime falls while rushing to the bathroom, desperation and hopelessness as they resort back to the use of absorbent products. TCCF receives many enquiries regarding what other options are available when OAB medications are not tolerable.

Urge incontinence is the leakage of urine that happens with sudden, intense urges to go to the bathroom. You may only have a few seconds to get to the toilet. People with urge incontinence may also need to urinate often, sometimes getting up several times during the night. This leads to sleep disturbances and may cause falls and fractures, particularly in the elderly. The sound of running water or drinking even a small amount of water may lead to incontinence. Due to the suddenness of the symptoms, people living with this condition revert to, "toilet mapping," meaning that they are unable to leave their homes without first knowing where all toilets en route of the trip or journey are. This of course is very limiting and sometimes impossible, thereby greatly restricting the incontinent patient's mobility, in turn causing isolation and depression. Avoiding sex and intimate relations is another problem because of the odor of urine. There is also an additional cost for absorbent products, laundry, drugs and a considerable workload on family caregivers. Falls and incontinence are 2 of the 4 leading causes for placement in Long Term Care, (LTC) facilities in Canada, it is a heavy cost burden to society. On an individual basis the cost of absorbent products is staggering, particularly for those on a fixed low income, TCCF receives more enquiries regarding subsidies for these than any other. No subsidies are available, thus people go without the needed protection, stay home soiling themselves and then are placed in LTC along with becoming more isolated and depressed.

In our survey, all participants had multiple complaints that is typical of OAB- 82% of had urinary urgency (failure to be able to postpone the need to urinate), 82% had urge incontinence (leakage of urine when

one gets the urge to urinate), 58% had frequency of urination (the need to urinate at least 8 times per day) and 55% had nocturia (the need to get up at night to urinate, interrupting sleep). Based on our survey, people with OAB had the following problems in day-to-day life in their own word (in order of frequency of single responses because some people gave more than one response):

1. Not leaving your home as often as you would like
2. Not going on holiday
3. Having to "toilet map" before leaving home
4. Not using public transport
5. Decline in sexual activity
6. Not entering into new intimate relationships
7. Fear of odor
8. Decreased ability to work/work productivity
9. Interrupted sleep because of the need to use the toilet
10. Financial burden of incontinence supplies

Based on our survey, people with OAB desire the following changes in day-to-day life in their own words (in order of frequency of single responses because some people gave more than one response):

1. Limit the number of incontinent episodes they experience daily or weekly
2. Decrease the number of times a day they have to urinate, especially at night which interrupts sleep patterns and may cause serious complications like fractures
3. Stop having to wear disposable pads, adult diapers or anything else to absorb urine
4. Control when and where they urinate outside the home
5. Not having to limit social activities because of being afraid of having an “accident”
6. Able to pay for absorbent products and extra costs of incontinence care

2.3 Patients’ Experiences with Current Therapy

Two thirds of patients were already taking anti-cholinergic medications prescribed by their care provider and one third was using behavioral treatment with counselors support to help manage their OAB. The current treatment was considered very effective by 6%, somewhat effective by 42%, not very effective by 37% and not effective by 15%. In those who were taking anti-cholinergic medications, 43% stopped using the drug because of lack of effectiveness and/or side effects. The side effects reported in order of frequency were dry mouth, constipation, blurred vision, not being able to drive and cognitive impairment such as can't think clearly and forgetful.

The following is a quote from a person interviewed: “I have been paralyzed, blind, cognitively challenged but my worst symptom has always been OAB.

Mobility aids and medications for annoying symptoms made it possible for me to continue with Facilitating three MS Support Groups and being a media representative for the MS Society. But the OAB was the only symptom that was getting worse and affecting my quality of life.

Having to wear big pads, self catheterizing, taking medication which made speaking difficult (like putting crazy glue in my lipstick) did not help the frequency of required washroom breaks. It was becoming embarrassing and sometimes disruptive to outings, both formal and family related. My daughter even apologized for buying a split level home as there were many levels and always stairs to get to a washroom.”

It describes exactly the impact that OAB has on its sufferers and due to its stigmatization goes largely unnoticed.

Based on our survey, people with OAB who were under treatment still had the following problems in day-to-day life in their own words (in order of frequency of single responses because some people gave more than one response):

1. Stopping for toilet on way to work
2. Getting up from seated without leakage or completely losing control
3. The endless preoccupation and seemingly endless balancing of diet and exercise, planning out overnight visits and trying to get back to hiking
4. Explaining it all once again to yet another urologist who has heard it all before and has very little to offer
5. Not wetting myself
6. Loss of self esteem and sense of control of my life
7. Irritation of vulva and hygiene
8. Fear of embarrassment when I have a sudden "explosion" of urine over the protection and onto my clothing. Things don't always protect the way you expect them to
9. “Accidents" cause embarrassment
10. Taking extra clothing for the 'just in case' time

2.4 Impact on Caregivers

Based on our survey, family caregivers of people with OAB had the following problems in day-to-day life in their own words (in order of frequency of single responses because some people gave more than one response):

1. Having to change absorbent products
2. Getting them to the toilet frequently and on time
3. Frequent laundry changes
4. Eliminating odors and cleaning up "accidents"
5. Getting up in the night

Caregivers lives are as much impacted as the OAB patient, they feel loyal to the patient, (frequently their spouse), they suffer the burden of absorbent product costs, remain at home with the patient; not attending family or social gatherings or attending these events alone. Frequently trips and vacations are no longer a part of life as the OAB patient does not feel secure enough to take them.

3. Information about the Drug Being Reviewed

3.1 Information Gathering

Interviews were conducted with patients whom had previously had Botox treatment for OAB, we have also included patient and caregiver experience gathered by TCCF over the years as it pertains to Botox and OAB.

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:
Based on our survey, people with OAB who were under treatment had the following expectations of a new drug in their own words:

1. Better able to control symptoms
2. Reduce side effects from current medications/treatments
3. Improves my quality of life and enjoy my life without constant worry of leakage
4. Allows me to have uninterrupted sleep
5. Ease of use

b) Based on patients' experiences with the new drug as part of a clinical trial or through manufacturer's compassionate supply:
TCCF has heard from many individuals who have had life changing results with Botox therapy, we have received many enquiries as to how this therapy could be covered, rather than out-of-pocket, because invariably patients cannot continue due to cost. One patient told me the following: "The procedure was almost completely painless and after one week, I packed away all of my bulkie Poise pads and felt free. My family could not believe that we could actually go out and not look for washrooms as the first order of business.

I have had five treatments and do not have to worry about leaks or frantic dashes to a washroom. I can sit through an entire movie with out clamouring over people to get to the washroom. I went to a cottage with one of my daughters this summer and we did not have to stop once for a bathroom break. It was a three hour drive. Good thing too as we travel with two dogs and a cat.

Bottom line is that Botox for OAB has given me back my quality of life. It has made a huge change in my ability and desire to attend events. And there are no longer any activities that are unachievable".
Another woman told me, "It was a miracle".

The people who contacted TCCF who had undergone Botox therapy, and wanted help with reimbursement had all used the therapy after other OAB medications had failed, either due to lack of compliance because of side effects i.e. dry mouth, or because the medication had not controlled the incontinence.