Common Drug Review
Patient Group Input Submissions

abobotulinumtoxinA (Dysport Therapeutic ULS) for the symptomatic treatment of focal spasticity affection the upper limbs in adults

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
March of Dimes Canada - LIFE Toronto group surveyed — permission not granted to post.
Multiple Sclerosis Society of Canada — permission granted to post.

CADTH received patient group input for this review on or before May 8, 2017

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.

March of Dimes Canada – LIFE Toronto Group Surveyed

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Dysport Therapeutic (abobotulinumtoxinA)
Name of the patient group	March of Dimes Canada – LIFE Toronto Group Surveyed
Name of the primary contact for this submission:	[redacted]
Position or title with patient group	
Email	[redacted]
Telephone number(s)	[redacted]
Name of author (if different)	
Patient group's contact information: Email	
Telephone	
Address	
Website	
Permission is granted to post this submission	No

The patient group has not granted permission to post its patient input submission. As announced in *CDR Update — Issue 99*, when permission is not granted, CADTH will post on its website that a patient submission was received, but it was not posted at the request of the submitter.

The patient input that was provided in this submission, along with all other patient input received for this drug, is included in the summary of patient input that is contained in the posted *CDR Clinical Review Report*.

Multiple Sclerosis Society of Canada

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Dysport Therapeutic (abobotulinumtoxinA)
Name of the patient group		Multiple Sclerosis Society of Canada
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)		
Patient group's contact information:	Email	info@mssociety.ca
	Telephone	1-800-268-7582
	Address	250 Dundas St W. Suite 500 Toronto, ON M5T 2Z5
	Website	www.mssociety.ca
Permission is granted to post this submission		X Yes ☐ No

1.1 Submitting Organization

The Multiple Sclerosis Society of Canada provides services to people with multiple sclerosis, their families and caregivers, and funds research to find the cause and cure for the disease. The mission of the MS Society is to be *a leader in finding a cure for multiple sclerosis and enabling people affected by MS to enhance their quality of life.* The mission is reflected in the organization's daily activities, which aim to support research into the cause, treatment and cure of MS, and provide programs and services that assist people with MS and their families. Since 1948 the MS Society has contributed over $160 million towards MS research. This investment has enabled the advancement of critical knowledge of MS, and the development of a pipeline of exceptional MS researchers.

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:*
Between 2016 and 2017, the MS Society received educational grants from the following companies: Bayer, Biogen, EMD Serono, Novartis, Pfizer, Genzyme – A Sanofi Company, Allergan, Roche and Teva Neuroscience. The contributions totalled less than two per cent of the MS Society's overall revenue and are subject to strict policies that prevent any control or influence by the donor on MS Society decision-making.

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. This submission was developed and prepared solely by MS Society staff.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information for this report was gathered through a survey about upper limb spasticity and its management. The survey was posted to the MS Society of Canada's social media channels in both

English and French on 1 May, 2017, and polling closed on 7 May, 2017. In total, 64 people responded to the survey. Approximately 90% of respondents were women living with relapsing-remitting MS ranging in age from 31 to 70. Less than half of all respondents have been living with the disease between two to five years. About 17% of all respondents stated they had been living with the disease between 5-10 years and 11-20 years. Less than 20% of respondents reported living with primary progressive MS or secondary-progressive MS.

2.2 Impact of Condition on Patients

Multiple sclerosis is an unpredictable, sometimes disabling disease of the central nervous system for which there is no cure. MS occurs because of damage to myelin, the protective covering wrapped around nerve fibres within the CNS. Approximately 85-90% of people diagnosed with MS follow a relapsing-remitting course, wherein they experience 'attacks' caused by bouts of inflammation in the CNS, followed by full or near complete recovery. Within approximately 10 to 20 years, about half of these individuals are likely to develop secondary progressive MS, a form of the disease that steadily worsens over time and is marked by fewer or no attacks and advanced disability. The remaining 10% of people are diagnosed with primary-progressive MS, characterized by a steady worsening of disease that is not preceded by a relapsing-remitting course. Most people are diagnosed between the ages of 15 to 40 and it is more commonly diagnosed in women than men.

The episodic nature of MS and its symptoms can have a negative impact on an individual living with MS as well as their family members and communities. MS can interfere with, or introduce a barrier to employment, education, physical activity, family commitments, interpersonal relationships and social and recreational life.

MS symptoms are varied and may include fatigue, difficulty in walking, visual impairment, cognitive difficulties, depression, bladder problems, pain, balance, sexual dysfunction, spasticity, tremor, weakness and difficulty speaking and swallowing. Depending on the type and severity of the symptom, an individual's quality of life can be greatly impacted.

Upper limb spasticity can greatly affect activities of daily living and has been associated with unemployment[i]. More than half of all respondents indicated that upper limb spasticity affected recreational activities *a lot*. Other aspects of life affected *a lot* by upper limb spasticity included; the ability to care for children or other family members, driving, self-care (washing, dressing, toileting), mobility limitations, remaining in the work force, socializing, sleep and living independently.

~Spasms may seem like a small issue to some but it impacts everything we do every day.

2.3 Patients' Experiences With Current Therapy

Upper limb spasticity is typically managed with exercise, physiotherapy and occupational therapy and medications. Most medications prescribed for the management of upper limb spasticity carry unwanted and troublesome side effects. About 36% of all respondents reported that they manage upper limb spasticity through exercise. Twenty per cent stated they do not treat this symptom, and 30% of all respondents said they manage spasticity with muscle relaxants and anticonvulsant medications. Of those who stated they use a medication, less than 5% were *very satisfied* with the efficacy of the treatment. Undesirable or troublesome side effects of the medications reported included; weakness, numbness and tingling, blurred vision, fatigue and difficulty sleeping. The reported side effects are also common symptoms of MS, making it challenging to identify which is a side effect of the medication or a

symptom of the disease. Although the medications may manage the spasticity, many of the side effects continue to present barriers to employment, driving and independent living.

~Reduce the number of spasms without added side effects.

~I am still working full time and both my physiatrist and neurologist feel I should not take any medication that may be sedating so that I can continue to drive and work. If therapies available could less sedating those of us still working could benefit.

2.4 Impact on Caregivers

Depending on the type and severity of MS, a caregiver's role can range from providing emotional support and assistance with medication administration, to helping with activities of daily living such as personal care, feeding and transportation to and from appointments. Caregivers who responded to the poll stated that they were required to assist the person they care for with activities of daily living due to upper limb spasticity. Four caregivers participated in this survey.

Section 3 — Information about the Drug Being Reviewed

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

Only one respondent had been made aware of Dysport as treatment for upper limb spasticity by their physician. None of the respondents had experience with Dysport for upper limb spasticity.

Based on clinical trial data, Dysport is expected to provide people with an effective therapy for upper limb spasticity for up to 20 weeks without the adverse side effects of commonly used muscle relaxant or anticonvulsant medications, allowing individuals to remain in the workforce, able to care for their families, continue living independently and ultimately improving their quality of life.

Section 4 — Additional Information

The MS Society strongly advocates for individual choice of therapy based on lifestyle, perceived benefit vs risk and individual preference of administration. Upper limb spasticity can be challenging to manage and can negatively impact an individuals' quality of life. Dysport will provide people living with MS who experience upper limb spasticity with a therapy option that carries minimal side effects for up to 20 weeks.

---

[i] Upper limb impairment is associated with use of assistive devices and unemployment in multiple sclerosis.
Marrie RA, Cutter GR, Tyry T, Cofield SS, Fox R, Salter A. Mult Scler Relat Disord. 2017 Apr;13:87-92. doi: 10.1016/j.msard.2017.02.013. Epub 2017 Feb 20.