



## Common Drug Review *Patient Group Input Submissions*

### **Peginterferon beta-1a (Plegridy) for multiple sclerosis, relapsing**

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

Multiple Sclerosis Society of Canada — permission granted to post.

**CADTH received patient group input for this review on or before July 23, 2015.**

Disclaimer: The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations.

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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.

## Multiple Sclerosis Society of Canada

### Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Plegridy (peginterferon beta-1a)
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]
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Name of author (if different)	
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Permission is granted to post this submission	Yes

#### 1.1 Submitting Organization

The Multiple Sclerosis Society of Canada is the only national voluntary organization in Canada that supports both MS research and services. 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. An estimated 13,500 volunteers carry out supportive programs, fundraising events, public awareness campaigns and government relations activities. Since 1948, the MS Society has contributed over \$150 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. As a result, the MS Society has become one of the largest funders of MS research in the world, and continues to lead the search for a cure.

#### 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 2014 and 2015, the MS Society received unrestricted educational grants from the following companies: Bayer, Biogen, EMD Serono, Novartis, Pfizer, Genzyme – A Sanofi Company, Allergan, 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 submission was obtained from publicly available information about the impact of MS and through an online survey posted from July 8, 2015 to July 17, 2015. The survey was offered in English and French and was shared with people affected by MS through various channels (social media, e-newsletters, and email). This survey had 158 respondents and invited feedback from people living with MS who may or may not have had experience with peginterferon beta-1a. In this survey, 76% of respondents were women and the rest were men. Most respondents had MS (90%), whereas the others self-identified as caregivers (9%). Respondent's ages ranged from less than 20 to more than 70, although the majority were between the ages of 45 to 54. The length of diagnosis varied from less than 2 years to more than 20 years, with the highest percentage (26%) being diagnosed between 11 years to 20 years. The type of MS reported by respondents included: clinically isolated syndrome (2%), relapsing-remitting (71%), secondary-progressive (15%), primary-progressive (10%), and "do not know" (2%). Limitations to the survey: This survey only reflects the views of those who chose to answer the survey at a particular point in time.

### 2.2 Impact of Condition on Patients

Multiple sclerosis is an unpredictable, often disabling disease of the central nervous system (CNS). MS occurs as a result of damage to myelin, the protective covering wrapped around nerve fibres (axons) within the CNS. When this happens, the usual flow of nerve impulses along the axons is interrupted or lost. The result may be a wide variety of symptoms, depending upon what part or parts of the CNS are affected. The most commonly reported symptoms include fatigue, difficulty in walking, visual impairment, cognition problems, depression, bladder problems, paresthesia, heat intolerance, and pain. Other symptoms may include issues with balance or dizziness, sexual dysfunction, spasticity, tremor, weakness and difficulty speaking and swallowing. MS can occur at any age, but is usually diagnosed between the ages of 15 to 40, peak years for education, career and family-building. It has been diagnosed in children as young as two years old, and adults over 50. MS is three times as likely to occur in women as in men. Depending on the type and severity of the symptom, an individual's quality of life can be greatly impacted. Symptoms can have a negative impact on an individual living with MS as well as their family members. MS can interfere with, or introduce a barrier to employment, education, physical activity, family commitments, interpersonal relationships and social and recreational life.

***"MS sucks. It costs the patients, their families, and their caregivers enormous amounts of money to cope with the disease. Many people living with MS must work fewer hours or leave the work force entirely because of symptoms and the negative social effects of chronic illness."***

Each individual's experience with MS is different. Some people may present with a host of debilitating symptoms, while others may have a relatively mild course of MS and experience few symptoms or relapses. It is impossible to predict what course the disease might take and how individuals will be affected over time. Approximately 85% of people diagnosed with MS will have a relapsing-remitting course, where they experience "attacks" caused by inflammation in the CNS, followed by a period of recovery or "remission". Within about 10 to 20 years, close to half of these individuals are estimated to go on to develop secondary-progressive MS, a more progressive form of the disease marked by fewer or no attacks and increased disability progression. Approximately 10% of people are diagnosed with primary progressive MS, a progressive course from the very beginning with steadily worsening disease and disability progression. Five percent of people will be diagnosed with progressive relapsing MS, in which people experience relapses with steadily worsening disease from the beginning.

**2.3 Patients’ Experiences With Current Therapy**

Currently, people living with relapsing forms of MS (relapsing-remitting and secondary progressive with relapses) can choose from eight available initial or “first-line” treatments. In addition, there are three subsequent treatments which are available to people whose MS does not respond to first-line therapies. Interferons and glatiramer acetate have been shown in clinical trials to reduce the frequency of relapses by about one-third compared to placebo. Newer therapies, including natalizumab, fingolimod, dimethyl fumarate, teriflunomide and alemtuzumab have been shown in clinical trials to be effective in reducing relapses by about 50 to 60 per cent as well as reduce the risk of disability progression compared to placebo. All therapies for MS are thought to work by modulating the immune system, thereby reducing inflammation in the central nervous system.

<b>INJECTED OPTIONS (INITIAL)</b>		
Interferon beta-1a	Avonex	One 30mcg injection into the muscle once a week
Interferon beta-1a	Rebif	One 44 mcg injection under the skin three times per week or, One dose of 22 mcg injected under the skin three times per week.
Interferon beta-1b	Betaseron	One 250 mcg injection under the skin every other day.
Interferon beta-1b	Extavia	One 250 mcg injection under the skin every other day.
Glatiramer acetate	Copaxone	One 20 mg injection under the skin daily.
<b>ORAL OPTIONS (INITIAL)</b>		
Dimethyl fumarate	Tecfidera	Two 120mg capsules taken orally, twice daily or one 240mg capsule taken orally, twice daily.
Teriflunomide	Aubagio	One 14mg tablet taken orally daily.
<b>ORAL OPTIONS (SUBSEQUENT)</b>		
Fingolimod	Gilenya	One 0.5mg capsule taken orally daily.
<b>INFUSION OPTIONS (SUBSEQUENT)</b>		
Natalizumab	Tysabri	One 300mg IV infusion every four weeks.
Alemtuzumab	Lemtrada	One 0.5mg IV infusion daily for five days in year 1 of treatment, and one 0.5mg IV infusion for three days in year 2.

Sixty-three per cent of all respondents indicated that they are currently taking an MS therapy. The top three disease-modifying therapies (DMTs) taken by respondents are dimethyl fumarate (24%), interferon beta-1a [Avonex] (22%) and glatiramer acetate (18%). The majority of respondents had been on therapy for five years or less (81%), the remaining respondents were on therapy six years or longer. Of those who had been on a therapy, over half reported the therapy they are taking is effective in managing their disease. Based on the results of the survey, treatment effects varied greatly between individuals indicating that there is no “one size fits all” therapy and that an increased range of options is vital.

***“There are some therapies that do not work for everyone. The more options there are, the better it is and the more likely people living with MS will find something that works.”***

The most commonly reported side effects were flu-like symptoms, injection site reactions, flushing and headaches. These are known and expected side effects of the top three therapies reported above. When asked what lifestyle factors were negatively impacted by therapy-related side effects, the majority of respondents reported an impact on regular physical activity (75%), followed by work performance (65%) and attending social events (53%).

The majority of respondents did not experience challenges in accessing their therapy. Less than a quarter of the respondents identified cost as being a challenge, as well as, access to public funds (14%), challenges with administration of the therapy (11%) and access to private insurance (9%). Although more than half of the respondents reported that their DMT was effective, less than half (43%) reported that it met all of their needs.

***“I want a therapy that I don't have to inject every day and HOPE that it works, that I don't hit a sore spot and be in pain for the rest of the day. When you have kids to look after, looking after yourself comes second. A treatment that would be affordable and easy would be amazing.”***

***“The stress of having to worry about how you are going to pay for the cost of these drugs can take a toll on people. It's also a hassle to have that you have to frequently go through the reimbursement approval process.”***

Current therapies provide individuals with options related to administration (injected or oral), dosing schedules (as per table above) and expected side effects. Having choices allow individuals to select a therapy that can accommodate their lifestyle as much as possible. However, despite the range of options, individuals with MS are still significantly impacted by the administration burden and discomfort that comes with many of the therapies.

***“It is hard enough to live with MS and adding complex therapies to a daily routine can make it even more difficult”***

When asked which lifestyle aspect was most important when choosing an MS therapy, seventy percent of those who responded to the survey said that the ability to maintain regular physical activity was of the highest importance. Physical activity was closely followed by the ability to remain at work (61%), meeting family commitments (58%), ability to travel (50%) and the ability to start a family (12%). Because no two people have the same experience with the disease, or make the same lifestyle choices, the ability to select a treatment from a variety of therapy options is key for people affected by MS to maintain their quality of life and adhere to the medication as prescribed by their physician.

***“It provides an option for those with compliance issues as the dosing is less often or as in my case it would mean I would not be impacted by the side effects of the medication as often.”***

### **2.4 Impact on Caregivers**

Providing care for someone with MS can be deeply satisfying, but can also be physically and emotionally exhausting. Providing care to a person may involve helping with injections of a disease-modifying therapy, and/or offering support in dealing with the medical team. Just over half of those who self-identified as a caregiver for someone living with MS said they provided assistance all of the time, or some of the time with administration of a disease-modifying therapy. About the same percentage of

respondents indicated that providing assistance with administration of a DMT impacted their daily routines and lifestyle.

***“She is always tired, my time is dedicated to be there for her and her son, she is stable but not independent.”***

For caregivers who provide assistance with administration of injected DMTs, the introduction of a decreased dosing schedule may significantly decrease the amount of time they will need to take away from work and other commitments.

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

#### 3.1 Information Gathering

Same as section 2.1

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

The majority of respondents had no experience with peginterferon beta-1a (97%) and very few had been informed about the therapy by their prescribing physician (89%). Of those who had been informed by their physician, the information related to them about the new treatment focused on its reduced dosing schedule.

***“To reduce the number of times a month I would need to deal with the side effects of the medication.”***

Based on the respondents’ knowledge of Plegridy, about 27% felt that it would fill an unmet need that current therapies do not. About 60% of those who completed the survey felt that a reduced dosing schedule would benefit the lives of those affected by MS, and that people would be more likely to take the medication as prescribed by their physician.

***“A therapy for MS treatment should be as convenient and easy to use in order to facilitate long term adherence. The bottom line is the easier they are to take, the better they will do with the disease.”***

As with many medications, adherence can be an issue. Frequent injections can lead to administration burden for many reasons including unwanted side-effects, inconvenience of frequent injections or, an individual may not be able to self-administer the injection. This new formulation of interferon beta-1a presents individuals with an opportunity to lessen the burden, and gain back some freedom by only having to take the drug once every two weeks.

***“Easier to go on vacation and live a normal life.”***

***“Better treatment and less stress over drug costs means healthier patients for longer periods of time and overall less cost on the medical system.”***

Approximately 2% said they had taken or were currently taking peginterferon beta-1a however none of the respondents provided details about their experience with the new therapy. Based on the comments related to the reduced dosing schedule, it would be expected that Plegridy may provide individuals with an easier administration route. Side effects are not expected to differ from the currently known side effects of interferon beta-1a therapy however they will be limited to twice a month rather than weekly

or several times weekly. Plegridy is available as an auto-injector (pen) as well as pre-filled syringe similar to other comparative injected therapies on the market. It is expected that Plegridy will be priced competitively with other interferon formulations, which currently range between \$18,000 and \$25,000 per year.

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

***“I think it's very important that we have as many choices of a disease-modifying drug as possible as no one of these medications is right for every one of us with MS.”***

Early treatment is critical for those who are newly diagnosed with relapsing forms of MS. Available therapies help to control some of the inflammation that damages axons, reduce the frequency and severity of attacks, and slow disease progression. Because MS is so variable, providing individuals with as many options as possible allows them to weigh the risks versus the benefits and customize therapy to their status of health, personal preferences and lifestyles. Having choices also helps people regain control of their lives as they face a disease that is so unpredictable. Based on the comments shared in this report it is clear that the ability to choose a therapy that best meets the personal needs for individuals is a key aspect to maintaining quality of life and adherence to treatment.