CADTH

CADTH COMMON DRUG REVIEW

Patient Group Input Submissions

GLATIRAMER ACETATE (GLATECT™)

(Pendopharm, a division of Pharmascience Inc.)

Indication: (GLATECT) (glatiramer acetate injection) is indicated for: Treatment of ambulatory patients with relapsing-remitting multiple sclerosis (RRMS), including patients who have experienced a single demyelinating event and have lesions typical of multiple sclerosis on brain MRI:

- to decrease the frequency of clinical exacerbations
- to reduce the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans.

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glatiramer acetate (Glatect) for relapsing remitting multiple sclerosis and clinically isolated syndrome

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 February 10, 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.

MS Society

General Information

Name of the drug CADTH is reviewing and indication(s) of interest	GLATECT™ glatiramer acetate (SEB non-biologic)
Indication of interest	Relapsing remitting multiple sclerosis and clinically isolated syndrome
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	Information Curator
Email	[redacted]
Telephone number(s)	[redacted]
Name of author (if different)	
Patient group's contact information:	
Email	info@mssociety.ca
Telephone	1-416-922-6065
Address	250 Dundas St W. Suite 500 Toronto, ON M5T 2Z5
Website	mssociety.ca
Permission is granted to post this submission	Yes

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 $140 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.

How to Complete This Submission Template

Information Gathering

Information for this section was gathered from publicly available information about the impact of MS and through a survey posted to the MS Society of Canada website and social media channels from January 23, 2017 to February 5, 2017. The survey was offered in English and French and was shared with Canadians affected by MS. This survey invited feedback from people living with MS who may or may not have had experience with Copaxone 20mg as well as their opinion and current understanding of SEBs. Respondents with MS and their caregivers answered a series of questions about themselves, how MS impacts them, their experience with existing drug therapies, and their expectations of future therapies.

Information About the Submitting Patient Group

Submitting Patient Group

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 $140 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.

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, 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.

Disease/Condition and Current Treatment Information

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.

The most common symptoms of MS include fatigue, difficulty in walking, visual impairment, cognitive difficulties, depression, bladder problems, and pain. Other symptoms may include issues with balance, sexual dysfunction, spasticity, tremor, weakness and difficulty speaking and swallowing. Most people are diagnosed between the ages of 15 to 40 however MS can occur at any age, including in children as young as two years old, and adults over 50. MS is more commonly diagnosed in women than men, and is prevalent in Northern countries. Depending on the type and severity of the symptom, an individual's quality of life can be greatly impacted. 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.

"I currently can not work, I had to discontinue attending post secondary school, change career paths and move back home with my parents. Every day life is completely different than before I had MS."

"It's ruined my life I can't do the things that I once could it's taken my vision, balance & coordination just to name a few."

Patients' Experience with the Current Treatment

There are 13 disease modifying medications (DMT) approved as treatment for relapsing MS (relapsing remitting MS and secondary progressive MS with relapses). Currently there are no approved DMTs for progressive MS. DMTs work by reducing annual relapse rates (ARR) between 30 and 70 per cent, depending on the agent being used, slow disability progression and reduce the number or new or enhanced lesions (as seen on MRI). Many MS therapies have similar mechanisms of action; however, dosing and administration are not the same and therefore the options available to people are selected based on tolerance, known (expected) side-effects, lifestyle choices, disease course and cost. It is very common for one treatment to work well in one individual, and fail in another.

The originator drug, Copaxone 20mg was approved for relapsing remitting MS in 1997 and continues to be one of the more commonly prescribed DMTs due to its longstanding safety profile, relatively minimal side effects, limited monitoring and cost. Side-effects of Copaxone 20mg include injection site reactions (redness, pain, inflammation, itching, or a lump), immediate post-injection reaction (flushing, chest tightness or pain with heart palpitations, anxiety, and trouble breathing) and lipoatrophy. Over 89% of respondents reported that they are currently, or were previously treated with Copaxone 20mg. Of those, about half reported experiencing fewer relapses while taking Copaxone 20mg (as compared with no treatment). Approximately 27% reported not knowing if treatment with Copaxone 20mg was effective in managing their MS and 18% felt it did not manage their MS. Other respondents reported they had fewer hospitalizations, maintained stable EDSS scores, the ability to remain in the workforce, fewer lesions and symptom improvements while taking Copaxone 20mg. Close to 100% of respondents who take, or previously took Copaxone 20mg were aware of the patient support program offered by the pharmaceutical company and over half of those had used the program for information related to medication side-effects and 16% contacted the program for financial assistance. Eighty-four per cent of all respondents felt that the patient support program was helpful.

Other DMTs used by respondents included Tecfidera, Rebif, Aubagio, Avonex and Tysabri. Sixty per cent of respondents taking medications other than Copaxone 20mg felt that their medication was effective in managing their MS while 28% were unsure. The most common side-effects reported included flu-like symptoms, pain, headache, GI symptoms, and injection site reactions. Approximately 24% reported they did not experience any side-effects. More than half of those who experienced side-effects reported that their side-effects were managed effectively with OTC medications. Twenty-three per cent reported that the side-effects resolved on their own within several months of taking the medication. Medication side-effects were reported as the most important factor to consider when selecting a DMT, followed by the safety profile of the drug, advice given by their clinician, route of administration and cost, respectively. About 20% indicated that high cost, access to public drug plans, limited transportation to receive drug administration (i.e. infusion clinic) were issues in accessing their medication. Approximately 60% of respondents said they would switch medication from Copaxone 20mg to a different DMT. Many commented the desire to switch from Copaxone 20mg daily to Copaxone 40mg three times weekly. The other reason given for switching from Copaxone 20mg to another therapy was to avoid daily injections.

"Please approve the larger dosage for Copaxone after 5 years I hate injections and try each night to find a reason not to do it. Of course, I do the injection, but would be happier with doing the injection 3 days a week. Injection fatigue is real."

"Needles everyday are part of my life I hate. The ability to take 3 a week would make a huge difference in my life, if it didn't come with a hefty price. The pain is real, the dents are real, lipoatrophy is real and it sucks."

Impact on Caregivers

Caregivers play an instrumental role in the overall care management plan of people living with MS. 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. Regardless of the role caregivers play, most feel that providing care for a loved one living with multiple sclerosis impacts their day-to-day activities.

"Just overall, the general stress that is created by caring and being concerned for a loved one with MS. In the past, on occasion, I have helped administered medication when their symptoms were debilitating. You know that the person's level of wellness can

change day to day and minute by minute so you need to be flexible and empathetic. That sometimes means giving needles or being that annoying person who reminds them to take their needle."

Information About the SEB Being Reviewed

What are Patients' Expectations for the SEB?

Approximately 63% of respondents reported they would choose the originator drug over an SEB based on trust and comfort in taking the originator; due to length of time it has been on the market and its known safety and efficacy data. Fear of switching to a SEB was also reported because it is 'similar' rather than 'equivalent'.

"Originator would have more patient data and recommendations on usage, safety, monitoring etc. Originator also provided home training for giving self injections and follow up support."

Lower cost to the individual treated and payers was the main reason provided for choosing an SEB over the originator. Some respondents felt they didn't know enough about SEBs to comment, or make a decision about treatment with an SEB rather than the originator.

"If the same drug, then I would consider the cost to the province."

"I think it would be cheaper, and a lot of people with MS are on disability."

Key Messages

- The MS Society strongly advocates for individual choice of therapy based on lifestyle, perceived benefit vs risk and individual preference of administration.
- People living with MS generally lack knowledge and understanding about SEBs and relating to this new category subsequent entry glatiramer acetate.
- The MS Society recognizes that Health Canada approved SEBs, like Glatect 20mg offer additional treatment choices and access to medication for some people living with MS and should be made publicly available as all other Health Canada approved therapies.
- The needs of people living with MS need to be at the centre of health policy decisions. Cost and/or cost savings should not be the major and/or deciding factor for the listing of drugs on the public drug plans.
- The MS Society believes that the decision to use an originator or a SEB must be made jointly by people living with MS and their health care provider and that individuals should be provided with all relevant information to make an informed choice.

Additional Information

"I am thankful that we have more options for treating MS now then we did 10-15 years ago. Nobody should have to make a choice on what treatment to choose based on if they can afford it or not. The drugs should be accessible to all Canadians and choice of drug should be based on what's best for them and their disease. Never should someone not be able to choose a drug therapy because they can't afford it."

Comments on Potential Ways SEBs Can be Used

Briefly provide your comments on the following scenarios or you may wish to provide other comments.

The SEB will be used instead of the originator (reference/brand name) product with physician approval before patient receives any treatments.

- *The MS Society believes that the decision to use an originator or a SEB must be made jointly by people living with MS and their health care provider and that individuals should be provided with all relevant information to make an informed choice.*

The SEB would be replacing the originator product with physician approval once the patient has been on the originator product for a period of time, i.e. a one-time switch.

- *The MS Society believes that people living with MS should not be required to switch their treatment regimen given the lack of information on the effect of switching from an originator to a SEB.*

The SEB will be used instead of the originator product without physician approval before patient receives any treatments.

- *The MS Society recommends that a SEB should not be automatically considered as an appropriate substitute or interchangeable with the originator given insufficient data to confirm equivalence. The decision to use an originator or a SEB must be made jointly by people living with MS and their health care provider.*

The SEB would be replacing the originator product without physician approval once the patient has been on the originator product for a period of time.

- *The SEB should not replace the originator product without physician approval. Patient and physician should discuss replacement prior to switching.*

Back and forth replacement between SEB and originator product without physician consent.

- *It is unknown if switching between an SEB and the originator product has any risks. The benefit of back and forth replacement is also unknown. Patients should have the choice for back and forth replacement and receive proper education about the SEB as a periodic replacement.*