

CADTH COMMON DRUG REVIEW

Patient Input

SAFINAMIDE (Onstryv)

Valeo Pharma Inc.

Indication: Parkinson's disease

CADTH received patient input from:

Parkinson Canada

Parkinson Society BC

June 19, 2019

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.

CADTH 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.

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Safinamide (Onstryv)
Name of the Patient Group	Parkinson Canada
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	████████████████████
Telephone Number	██

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

Parkinson Canada provides support services and education to people living with Parkinson’s disease, their families, and the health care professionals who treat them.

Operating since 1965, the organization advocates on issues that concern the Parkinson’s community in Canada. The Parkinson Canada Research Program funds innovative research for better treatments and a cure.

A national registered charity, Parkinson Canada fulfils its mission through the generosity of donors and is an accredited organization under the Imagine Canada Standards Program.

www.parkinson.ca

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

Over the past two years, Parkinson Canada has gathered evidence and feedback from people diagnosed with Parkinson’s and care partners on their experience living with Parkinson’s. The findings from two surveys, as well as an interview conducted by Parkinson

Canada with a Movement Disorder Specialist who has previous experience prescribing safinamide in Italy, will be brought together for the purpose of this review.

In June-July 2017, Parkinson Canada conducted a survey and received responses from 863 people. The vast majority of responses were gathered from Canada with the following breakdown:

53 per cent from Ontario; 12 per cent from Quebec; 11 per cent from Manitoba; 9 per cent from British Columbia; 5 per cent from Atlantic Canada; 4 per cent from Alberta; 3 per cent from Saskatchewan; Less than 1 per cent from the territories; and less than 3 per cent of the responses were gathered internationally from people in the United States and Europe.

61 percent (526) of respondents are people with Parkinson’s disease and 39 per cent (337) are caregivers of people with Parkinson’s disease.

63 per cent of respondents are retired. This is followed by 16 per cent who are working full-time. Eight per cent are working part-time or on disability respectively. The remaining respondents are home full time, volunteers, students or looking for work.

In October 2017, Parkinson Canada partnered with Ipsos Reid to conduct a nationwide survey to determine areas of greatest concern for individuals diagnosed with Parkinson’s, care partners, and health care providers with regards to the experience of living with Parkinson’s, and access to care and treatment to manage the disease. The survey was completed by nearly 1500 people across Canada. The breakdown of the respondents is 45% people diagnosed with Parkinson’s; 30% care partners; 20% health care professionals; and 5% other stakeholders.

The regional breakdown for respondents diagnosed with Parkinson’s are as follows: 57% Ontario; Quebec 9%; Atlantic 9%; Manitoba 9%; BC 7%; Alberta 4%; Saskatchewan 4%. There was not enough respondents from the Territories to yield a statistically valid sample.

The regional breakdown for respondents who identify as care partners are as follows: 65% Ontario; Quebec 6%; Atlantic 6%; Manitoba 10%; BC 6%; Alberta 4%; Saskatchewan 4%. There was not enough respondents from the Territories to yield a statistically valid sample.

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient’s perspective. Describe how the disease impacts patients’ and caregivers’ day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

From Parkinson Canada’s June-July 2017 survey results, overwhelmingly people with Parkinson’s describe the “loss of confidence” that they have experienced since developing Parkinson’s disease and the impact that has on their daily life:

“It is increasingly more challenging to manage care of myself, dog, & home. Also attending the local Parkinson’s exercise group, and other activities is becoming more limited.

Because of my Parkinson's tremor, even with medication, I have lost my confidence in any social situations where food is served, and so no longer want to participate in these activities."

This "loss of confidence" reported is in large part due medication "wearing off". Medication "wearing off" also described as "off times". This is when the effectiveness of medication stops, causing a resurgence of motor and non-motor Parkinson's symptoms (e.g. freezing episodes, tremor, mood swings, panic attacks etc.). For some people there is a certain degree of predictability to "off times", but for many these fluctuations are unpredictable.

"My father's quality of life has been impacted and that's what has been most difficult. He has to plan his day and time out of the house based on his [sic] medication schedule because he can't be out when the meds start to wear off and he gets stiff. This makes it difficult for him to enjoy time with family"

Nearly 40 per cent of respondents specifically mentioned that Parkinson's has negatively impacted their ability to socialize and maintain relationships because they have had to stop engaging in recreational activities (e.g. sport) or family life:

"I have a hard time with all aspects of daily life (recreational, meal prep, have to cancel planned activities with family and friends) because of the following: very low energy, fall asleep unexpectedly, emotional, difficulty walking for prolong period, hard time moving my body at night in bed."

"Loss of independence in many areas including driving a car, relationships, social interactions, reading and writing."

Nearly 10 per cent of respondents discussed having to leave the workforce or reduce hours due to Parkinson's:

"I had to go on disability and stop working, which made me sad and also put more stress on my husband as he became the sole supporter of our family."

In addition to the ability to maintain relationships, many survey respondents also discussed their loss of independence citing challenges in doing household chores and getting dressed.

People with Parkinson's who report being able to maintain relationships and engage in daily activities often reported slowness and balance issues as being a challenge to their participation. It is important to understand that Parkinson's is a progressive disease causing abilities to change and making participation in daily activities increasingly more difficult overtime.

Survey respondents ranked the following symptoms of Parkinson's as most important to control: slowness and stiffness, impaired balance, cognitive changes and memory, and rigidity of the muscles.

Survey respondents who are caregivers most often reported a lack of time due to the demands of caring for a person with Parkinson's. This lack of time creates a challenge for maintaining social and/or recreational activities. Caregivers also discussed that the loss of confidence being experienced by the person they care for (due to "off times") as being a barrier to engaging in social or daily activities with the person they care for:

“The disease has a direct impact on every aspect of life for the caregiver. As the symptoms develop and increase in severity, everything becomes unpredictable. Managing household chores, planning for the day’s and week’s activities, etc. all become difficult. The stress takes its toll on the caregiver...”

The October 2017 survey Parkinson Canada conducted with Ipsos Reid asked for a ranking of symptoms. The most common symptoms of those diagnosed with Parkinson’s are reported as slowness, fatigue, tremors, stiffness and sleep disturbances. Care providers, report a higher incidence of all symptoms, particularly impaired balance and muscle rigidity. Roughly half of respondents with Parkinson’s report experiencing anxiety, pain and changes in thinking/memory, with one-third experiencing issues with intimacy, changes in mood and depression. Overall, anxiety, stress, loss of confidence and sadness are the most common emotional changes experienced.

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

There are a wide number of symptomatic treatments that are available for Parkinson’s disease. These include medications (e.g. levodopa carbidopa), surgical procedures (e.g. Deep Brain Stimulation), and other forms of therapy (e.g. physiotherapy, occupational therapy, speech therapy, exercise) and psychological follow up. All of these treatments can have a significant impact on improving an individual’s quality of life and should be available. However, an individual with Parkinson’s becomes more reliant on their medication to maintain their ability to function as the disease progresses, and dosage has to be increased over time, for as long as possible. A balance between the side effects of the medication and the benefit often becomes more difficult with time. Medication schedules become more complex and the timing of when medications are given becomes crucial.

The benefit to taking medications can be a return to regular daily living activities and functionality:

“Every morning it takes an hour for my multiple medications to take effect, so that I can perform activities at a comfortable pace such as dressing and meal preparation. The effect of my medications wears off within 2 1/2 hours, causing very painful foot dystonia two to three times a day.”

However, 67 per cent of survey respondents have experienced side effects when taking medications to manage their Parkinson’s. The most reported side effects, according to survey respondents, are disturbed sleep, nausea, constipation, dyskinesia, fatigue and hallucinations.

14 per cent of survey respondents have experienced difficulty in accessing treatments for Parkinson’s disease. The following challenges are reported: wait times to see a physician to have medication prescribed or adjusted; transportation and travel to receive treatment; insurance requirements to receive a branded medication over the generic; cost; and drug shortages.

“Cost, constantly traveling to drug store to pick up something as the insurance company only releases the coverage dependent of the individual cost. Very frustrating to have to drive back and forth 4 x to get the pills I need for my husband every month.”

The most common reported difficulties in receiving treatment from survey respondents are swallowing, remembering to take medication, and timing their medication with meals.

Swallowing

Difficulty in swallowing is present in many people with Parkinson’s. The reason for this difficulty is a prolongation of the triggering of the swallowing reflex, a reduced rate of swallowing, and slowness of sequential muscle movements.

Remembering to take medication

The daily medication regimen for individuals with Parkinson’s can be complicated. As Parkinson’s progresses many individuals have to take more types of medication, adjust dosing and increase the frequency of taking medication. In addition to this, the majority of people with Parkinson’s will experience some degree of cognitive changes with 30 per cent having dementia.

Medication and meals

The medication levodopa (currently the gold standard in treating Parkinson’s disease) is a protein building block, so it competes for absorption with other proteins. Eating a meal high in protein reduces the likelihood of effectively absorbing levodopa; therefore meals need to be timed and/or adjusted to ensure medication is properly absorbed.

“Frequency and timing in conjunction with meals. Nobody with Parkinson's moves quickly and many have difficulty swallowing . A half hour window in which to eat, so that protein does not interfere with the Levodopa is impossible to realize and causes stress for the person with Parkinson's and for the caregiver.”

5. Improved Outcomes

CADTH is interested in patients’ views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

Survey respondents indicated many improvements that they would like to see from new treatments that are not currently achieved. Frequently reported is the need for longer lasting medications that limit or eliminate “off times”. Limiting or eliminating “off times” would provide increased confidence and security for people, especially when they are leaving their home, participating in social outings, or staying engaged in the workforce.

“I am tired of the unpredictability of my current meds regime and having several times per day when I am not feeling well”.

There is also an expressed need for medications that provide overall better symptom control with less side effects:

“Control of hallucinations and elimination of off times. If these symptoms were controlled I would hope to have a much more normal lifestyle”.

The described improvements would restore quality of life by allowing the freedom to make plans without fear of an “off time” resulting in loss of ability to function:

“To be able to go out and stay out for awhile, that he would last a little longer on an outing. We do not go out on planned outings”

“Medication that takes more rapid effect, does not lose it's effectiveness before the next dose is due (effectiveness wears off), and is more effective in treating inertia (freezing) and inability to walk; also medication to permit intelligible and normal speech. These improvements would enable more normal mobility and communication with family and others.”

Overall, 70 per cent of survey respondents have experienced “off” periods with their medication regimen.

“Parkinson disease, even on the best of days, severely limits ones daily activity. Off-periods bring everything to a halt and are disorienting and uncomfortable. Adding extra functionality to a day makes a significant difference when one has only a few hours to begin with.”

Side effects are definitely a major consideration and concern for people with Parkinson’s and caregivers before starting a new treatment. Survey respondents indicated that the benefits versus potential side effects would need to be carefully weighed before starting any new medication.

Safinamide offers an option for people living with Parkinson’s to control motor symptoms and motor complications, and has a beneficial effect on the experience of “off times” without increasing the risk of developing dyskinesia (uncontrolled, involuntary movements), which is a troubling symptom experienced by some people with Parkinson’s due to the progression of the disease and/or use of other medications used to treat Parkinson’s.

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways?

Parkinson Canada interviewed a Movement Disorder Specialist who has previous experience prescribing safinamide in Italy. The following is a summary of his statements about safinamide and the experience of the patients he prescribed it to:

His opinion is that as an MAO-B inhibitor, safinamide is very good. He believes it may be stronger than other medications in its class for treating motor fluctuations and found it had a profound benefit for patients experiencing fluctuations (“off times”).

In his experience using safinamide as an adjunct he would reduce patients’ levodopa, which seemed to cause patients to experience dyskinesia.

He found that safinamide would typically be used by patients living with Parkinson’s around years 7-16 in the disease progression.

In conclusion, he believes having the drug available would be beneficial as long as costs are not too high for patients.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?

- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

N/A

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

People with Parkinson's need access to a variety of options to ensure they can be on a treatment regimen that offers the best possible control of their unique set of symptoms and an improved quality of life. The unpredictability of the disease as well as loss of confidence and independence that one experiences due to this unpredictability is forcing people with Parkinson's to withdraw from normal activities too soon (e.g. work, travel, daily chores, maintaining relationships etc.). Many people with Parkinson's report anxiety and excessive worry over the inability to appropriately control their symptoms on a continuous or predictable basis. Overall this causes a breakdown in relationships resulting in isolation.

Furthermore, survey respondents across both surveys report it would be a significant financial burden if they did not have coverage to help with their drug costs. As discussed earlier, many people with Parkinson's and caregivers report having to leave the workforce early or reduce hours due to the progression of the disease. This limit of incoming resources coupled with increasing expenses for travel to appointments for follow-up/treatment and any incurring drug costs causes a great amount of additional stress and strain on families. A report made public in partnership with the Public Health Agency of Canada and Neurological Health Charities Canada found that people with Parkinson's in Canada had one of the highest out-of-pocket expenses related to treating their disease compared to people in Canada managing other types of neurological conditions (Mapping Connections: An understanding of neurological conditions in Canada, 2014).

When a disease is as life limiting as Parkinson's it is essential coverage is provided to ensure treatments are affordable and accessible for all who need it.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

No.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

No.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
N/A				

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Jacquie Micallef
 Position: Sr. Manager, Public Affairs and Partnerships
 Patient Group: Parkinson Canada
 Date: June 19, 2019

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Safinamide
Name of the Patient Group	Parkinson Society BC
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	████████████████████
Telephone Number	██████████

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

Established in 1969, Parkinson Society British Columbia (PSBC) is a non-profit organization governed by a volunteer Board of Directors. The Society receives no government funding and is supported entirely by donations from individuals, members, corporations, foundations and the dedicated efforts of volunteers.

We believe that every person touched by Parkinson's deserves to know that they are not alone in their journey. We are here for the person with Parkinson's, their care partners, family and friends. Our friendly and knowledgeable staff is committed to offering support, sharing reliable information and raising funds for programs and research.

<https://www.parkinson.bc.ca/>

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

Safinamide is not yet available to patients in Canada. However, as it's action in inhibiting monoamine oxidase B (MAO-B) is the same or similar to other MAO-B inhibitors with the generic names Rasagiline (brand name Azilect) and Selegiline, One difference is that it does not appear to be effective as a monotherapy.

PSBC conducted an online survey in May 2019 asking patients for their experience if they had used either Rasagiline (brand name Azilect) and Selegiline.

Demographics of respondents are as follows:

- 82 people responded – 75 people with Parkinson’s disease and 7 care partners.
- 49 were male and 33 female.
- 85% had PD for 5 years plus
- 79% were 60 years old or older
- 100% experienced at least one ‘off’ period every day (significant time periods when their medication was not working and they were essentially ‘frozen’ in place, unable to move, speak and sometimes with difficulty breathing)
- 68% experienced 3 or more ‘off’ periods every day
- Of the ‘off’ periods experienced:
 - 81% said the ‘off’ period lasted 15 minutes or more
 - 45% said the ‘off’ period lasted 30 minutes or more
 - 17% said the ‘off’ period lasted 45 minutes or more
- 88% had used Rasagiline and 17% had used Selegiline
- 35% found either Rasagiline or Selegiline extremely helpful in symptom management
- 33% said Rasagiline or Selegiline were somewhat helpful in symptom management
- 19% were neutral
- 14% said neither medication helped in symptom management

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient’s perspective. Describe how the disease impacts patients’ and caregivers’ day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

Parkinson’s disease is one of the most common illnesses of the nervous system. It is mainly identified by a loss of the ability to move normally. These changes appear slowly. They gradually become worse over time.

For most people, controlling the progression of the disease is most important.

Symptoms vary quite a bit from person to person. Often changes start on one side of the body and eventually spread to the other side.

Tremor while at rest, rigidity, slowness of movement, and postural instability are the main problems people experience.

Other symptoms can include:

- **Hypomimia** – This means reduced facial expression which makes a person appear uninterested or sad when they are not.
- **Hypophonia** – A person’s voice may become very soft. Deterioration in the rhythm and quality of the voice is common.
- **Micrographia** – Handwriting may become small and cramped.

- **Changes in mind, mood and memory** – Depression and anxiety are very common. Forgetfulness and confusion can also occur.
- **Difficulties with sleep** – This can include insomnia, vivid dreams, nightmares and daytime sleepiness.
- **Constipation** – Approximately 50% of people with Parkinson’s experience cramps and/or constipation.
- **Pain** – Different kinds of pain are common.
- **Fatigue** – A person may feel tired or exhausted, and the capacity for normal work or activity is reduced.

All can worsen over time.

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

Some patients are prescribed MAO inhibitors to delay treatment with levodopa or to augment levodopa or to delay progression of the disease.

As the disease progresses, the window and duration of effectiveness of levodopa decreases and the side effects increase. Newer medications are often focussed on increasing the effectiveness of levodopa, delaying its use and delaying disease progression.

An unfortunate side effect of levodopa, over time, is dyskinesia or involuntary writhing movements, and people in an advanced state of Parkinson’s frequently experience these when they are ‘on’ to a severe extent. However, without levodopa, they are then reduced to an “off” state, an even more disabling, frightening stage where breathing and swallowing are at risk.

5. Improved Outcomes

CADTH is interested in patients’ views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

Patient priorities are finding a cure, stopping disease progression and effective symptom control so they can achieve best quality of life possible remaining “on” and free from disabling “off” periods or periods of severe dyskinesia when they are unable to do anything much because they are writhing about. The danger of falls and fractures increases tremendously with this side effect although dyskinesia is also a symptom of the disease and may worsen with disease progression.

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better

understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways?

As Safinamide is not yet available in Canada/BC, we could only ask about experience with medications in the same class – MAO inhibitors.

Although generally most people felt beneficial effects of taking either of the existing MAO inhibitors, there were variable impacts. Following are patient statements both positive and negative:

- I have not noticed any benefit or anything negative effects from the Azilect.
- I have been told that it “may” slow down the progression of the disease and may protect my brain. I continue to take Azilect in the hope that the drug does actually help me.
- the tremor disappeared and motor symptoms improved
- Best drug ever, I was starting to deteriorate and Azilect saved me!
- I don't seem to have 'off' periods at all. Perhaps that is due to Rasagiline. I take the drug daily and don't believe I have ever missed a dose.
- Wearing off periods are not as predictable as most people think. They can occur at any time and last for varying periods. Also I am finding that the drugs for wearing off are less effective as the disease progresses.
- I stopped taking Azilect after taking it for 9+years because of possible contraindications with meds and anaesthetics for another condition. In retrospect, I think that it did indeed slow the progress of my Parkinson's, the progression of which did appear to speed on discontinuing Azilect. My main concerns with Azilect were contraindications with so many other medications and the cost, which was so high, it was therefore not available to anyone who did not have a good third party insurance or extended benefits package.
- I do not yet take levodopa, just rasagiline, and my "off" periods are very variable and intermittent. They are quite minor, and I don't really think of them as "off." A mild tremor can occur at any time of day or night, and last anywhere from 5 to 45 minutes. My answers to the questions above are only estimates. As rasagiline is the only drug I've taken for my PD, it's impossible for me to say how "helpful" is it, as I have nothing to compare it to. Nor do I know what it would be like had I never taken the drug. All I can truthfully say is that the rasagiline appears to keep my tremor at a low level (but so does exercise). While it is encouraging that there may be a new drug becoming available that has similar effects to rasagiline, I would also like to see the PD society put some energy into getting rasagiline subsidized by the BC health ministry. It is outrageously expensive for those without extended-care health plans. I'm fortunate enough to be able to afford it, but many cannot. Thanks.
- I feel that without the MAOI I would not be doing as well as I am. I am for the most part I am leading a fairly normal life.
- When first introduced as a substitute for Mirapex (or was it Isobutane) my family almost instantly noticed a return of my facial expression. More recently it does not seem to have the same quick and dramatic effect but I still think it I has a role to play in my disease

management program. I have tried taking two 1mg pills daily but it does not serve me any better as my prescribed dosage of 1/day 6/1/2019 3:04 PM 15 I believe the rasagiline combined with levodopa & a lot of hard exercise has kept my pd symptoms from getting worse.

- started using Azilect 2014. Was hard to determine how effective it was. Due to the cost and the potential of medication conflicts, stopped taking it in 2016. No difference as far as OFF Times were concerned
- Azilect was expensive approximately \$10 per pill so I was on it for about 2 years. I could not justify the cost. Sinemet worked better. Now that is another matter.
- My pharmacological therapy for PD started with 1 mg azilect each day, which resulted in enormous improvement. After about 3 years I added sinemet to my therapy and have been doing fairly well.
- One time I stopped taking Selegiline, with doc's OK, and the negative effects were horrible extreme slow down in movements, unable to live my normal life. After only about 5 days I put myself back on the drug and have been my normal self since then.
- my response is an assumption because I have no other control measure. What I strongly believe is that it has delayed or slowed progression of PD.
- My answer of "extremely helpful (above) relates to the improvement in mood associated with Rasagiline, as I don't really experience "off periods", due, in my mind, to my exercising program.
- My husband was prescribed Azilect when he was first diagnosed with Parkinson's by his Neurologist. Although it was very expensive, we felt that it was very effective. 6 months ago he went off it because of our financial situation. I can see a big difference since he has not been taking Azilect., in disease progression and worsening symptoms. We both feel that he would benefit greatly by going back on it.
- I stop taking Azilect for a month at end of last year. My health went down and I got all kind of symptom. I started to taking Azilect again. After three months, my health almost back to normal.
- In 2011 I stopped taking it for a while. However soon I had major problems: A. Severe back pain. B. Mentally getting way less. After 5 month or so I started using it again. Due to the high cost I switched in 2018 to Selegiline. It appears to work as Rasagiline.
- It helped my apathy/anxiety
- The first time I used rasagiline, I felt so "drugged" that evening that I couldn't function for a couple hours. The same thing happened the next day.. I took the third day off, then tried again on the fourth day. Same drugged reaction so it was discontinued.
- Referring to the drug Selegiline, there were benefits as well as side effects. The benefits were more energy, improved talking, better balance...generally I felt stronger. The side effects were increased anxiety & difficulty sleeping. My wife said I was more aggressive.
- I stopped taking Azilect, partially due to cost and partially, because of the concerns re. interactions with other drugs.
- I was using Rasagiline for 8 1/2 years. Six months ago I stopped using because cost was too great. I would like to use it again.
- Rasagiline was my first prescription before taking levodopa. I noticed no benefits, just sleepiness.

- Azilect was prescribed initially by neurologist immediately following diagnosis. It caused a severe allergic reaction within 11 days of beginning the drug. PwP was hospitalized for three days as a result. Neurologist advised no MAO inhibitors for this patient in future.
- I have been on Azilect since 2007, when diagnosed with PD. In my case, I did not see any change in my tremor immediately. However, within several weeks after beginning Azilect, my tremors had disappeared! I am aware of people that tried Azilect for a short period and discontinued the medication, perhaps to soon to realize a potential benefit. I am also aware of individuals that have come off Azilect due to extended health plans discontinuing covering cost of drug; all have experienced a rapid decline in their health and an increase in PD symptoms that impacted the quality of life. Although I now have tremors in both hand and legs, the intensity of tremor in my hand is still less than it was prior to taking the Azilect in 2007. I am still able to walk without aid, manage stairs and all in all, have a very good quality of life which I feel, is a direct relation to access to Azilect (through Veterans Affairs). Thank you for this opportunity to share my experience.
- During the two month period I took Azilect I had several non-health-related high stress issues plus a sustained experience with freezing numerous times per day which had occurred only rarely prior to this period. I believe it also affected me mentally. Since stopping Azilect I have slowly been returning to my previous 'normal' PD experience.
- I was diagnosed in 2014 and put on Azilect. I am still taking Rasagiline today. I firmly believe that the Azilect was what made it possible to stay off Levodopa until 2017.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

none

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

no

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

No

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

No

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
none				

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Jean Blake
Position: CEO
Patient Group: Parkinson Society BC
Date: June 11, 2019