

CADTH COMMON DRUG REVIEW

Patient Input

Levodopa / Carbidopa (Duodopa)

(AbbVie Corporation)

Indication: Parkinson's Disease

CADTH received patient input for this review from:

Parkinson Association of Alberta

Parkinson Canada

Parkinson Society BC

March 2, 2018

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1. About Your Patient Group

Parkinson Association of Alberta (PAA) is the voice of Albertans and their families living with Parkinson disease (PD).

PAA provides direct support services (supportive counselling & support groups), education, information/resources, referrals, programs (physical, cognitive, speech/voice and social) to the over 10,000 Albertans with PD and/or a Parkinson Plus Syndrome, their families and care partners. We also provide education and information to health care professionals, community partners and the public at large.

PAA also funds innovative research for a better and brighter future for Parkinson's.

PAA is a stand-alone Alberta-based registered charitable organization. PAA relies on donations and fundraising initiatives to support the services, resources and programs offered.

www.parkinsonalberta.ca

2. Information Gathering

PAA gathered data and perspectives from the Parkinson's community by conducting an online survey that was distributed across Alberta and beyond.

41 responses were gathered between February 23, 2018 and March 1, 2018. All respondents, save 1 (from Ottawa) were from Alberta. Respondents identified that where they resided was defined as urban (49%), suburban (31%) and rural (20%).

68% of respondents are people with Parkinson disease; 32% are care partners of people with Parkinson disease.

In terms of gender 54% of respondents identified as female, 46% identified as male.

34% of respondents are between the ages of 55-64, 32% between the ages of 65-74, 24% between the ages of 75-84, and 5% between the ages of both 45-54 and over the age of 85.

63% of respondents are retired. This is followed by 12% at home full time, 10% who are working full time, 7% who are on disability, 5% who are working part time and 3% who are unemployed/looking for work.

Parkinson Association of Alberta has also gathered information from 10 clients (5 people with Parkinson disease and 5 care partners of people with Parkinson disease) who have experience using Duodopa. All 10 were gathered from telephone interviews with Parkinson Association of Alberta staff directly

3. Disease Experience

From Parkinson Association of Alberta's survey results, the following are areas respondents indicated as being most negatively impacted by Parkinson disease:

- Overall quality of life – 73%
- Participation in social activities – 63%
- Participation in recreational/exercise activities – 60%
- Managing family obligations – 53%
- Relationships – 50%
- Loss of confidence – 45%
- Loss of independence – 38%

- Work/employment – 30%

“Parkinson’s has changed the course of my life. I can’t keep up the intensity required to do my job and have the energy left to socialize with family and friends as much as I would like.”

“The inability to meet all of my personal needs has impacted my quality of life. I need home care which invades my privacy, travelling to see grand and great-grandchildren, friends and other family is virtually impossible. Shopping is generally a problem – can’t try on clothing, can’t reach items on shelves.”

“My life revolves totally around my spouse (who has PD); it leaves little time or interest in other activities.”

“We are dealing with the loss of hopes and dreams we had for retirement.”

“I have experienced frustration and helplessness and this also leads to feelings of hopelessness.”

Respondents ranked ten aspects/symptoms of Parkinson disease in terms of being most important to control and/or manage, they are listed below in order of indicated as most important to least important:

- Changes in Mood
- Sleep issues
- Speech and Swallowing Issues
- Tremors AND Rigidity (tied)
- Changes in cognition and memory AND bladder/bowel issues (tied)
- Impaired balance
- Fatigue
- Slowness and stiffness

4. Experiences with Currently Available Treatments

There are a wide number of symptomatic treatments available for Parkinson disease. These include medications, surgical/medical procedures (ie: DBS, Duodopa), other forms of rehabilitation therapy (physiotherapy, occupational therapy, speech therapy, exercise) and psychological follow-up (ie: counselling). All treatments can have a significant impact on improving quality of life, especially when a personalized combination is utilized as opposed to a one-size fits all approach.

“I am doing everything possible to manage and hopefully slow down the progression of PD.”

“Medications help with the rigidity and muscle stiffness and my daily exercise program keeps me healthy and plays an important role in slowing my PD.”

Medications

The majority of respondents (98%) are currently utilizing medications as part of their treatment options. The benefit to utilizing medications is maintaining day-to-day functioning by way of better management of symptoms.

“Medications are essential to maintain some comfort level.”

“Medications have reduced my tremors and helped improve my bladder control.”

In terms of medications being taken to manage Parkinson’s, 54% of respondents have reported that they or the person they are taking care of have experienced side effects. The most noted side effects that respondents indicated were most difficult to endure were: increasing dyskinesia (as medications increased), constipation, nausea and fatigue/drowsiness.

Other side effects noted as being difficult to endure were: pain, reduced impulse control and the form the medication comes in.

“Amantadine is currently not available in pill form – liquid only. The impact is that my husband can’t take medication on his own as he can’t measure out the dosage.”

When it comes to experiencing difficulties receiving/taking medication as a treatment for Parkinson’s respondents indicated the following:

- Difficulties with timing of and/or remembering to take medications – 48%
- Difficulties swallowing medications – 13%
- Portability issues of medications – 8%
- Storage of medications – 5%
- Difficulties with availability of medications/shortages – 3%

“I have problems remembering when to take the next dose or I get so busy at work that I will be late taking my meds. When this happens I have more PD symptoms throughout the day including dyskinesia.”

Rehabilitation

70% have included some form of rehabilitation (physio, occupational/speech therapy and/or exercise)

“Exercise is imperative for me both physically and mentally”

“Exercise is beneficial as it not only affects and helps physical aspects, but the mental and emotional aspects.”

When it comes to experiencing difficulties receiving rehabilitation as a treatment for Parkinson’s respondents indicated the following:

- Lack of motivation/apathy – 30%
- Wait lists/times to access rehabilitation opportunities – 3%

Psychological Follow-up

23% have included psychological follow-up.

“Counselling sessions have helped me deal with depression and feeling worthless and useless.”

When it comes to experiencing difficulties receiving psychological follow-up as a treatment for Parkinson’s respondents indicated the following:

- Difficulties communicating and/or expressing myself – 28%

Surgical /Medical Procedure

13% have included a surgical/medical procedure. Benefits include a reduction in the fluctuation of on/off times which helps alleviate some quality of life issues.

“Duodopa has provided freedom from the ups and downs of the pills and given me the ability to move more fluidly.”

“DBS has dramatically decreased my medication requirement.”

“The Duodopa pump has made a big difference in the absorption of the medication and on my spouse’s quality of life. He has more energy and less off times.”

When it comes to experiencing difficulties receiving a surgical/medical procedure as a treatment for Parkinson's respondents indicated the following:

- Technical difficulties with equipment/devices following procedure – 2%

In terms of accessing treatment for Parkinson disease respondents indicated difficulties with the following:

- Cost of medications (including insurance coverage issues) – 33%

"My med is not on the Alberta Health Formulary. I can manage, but perhaps others cannot. I've never been on a long-term medication before and I need this one to keep me a functioning individual who is still contributing to society. I was surprised it was not covered."

Doctors who have worked with me have had to contact my insurance company to explain the need of the prescribed medication in order for my medications to be covered."

- Access to appropriate healthcare professionals and/or service providers – 23%

"Waiting times/lists for healthcare professionals and programs are long – over 1 year to see a neurologist."

"No appropriate healthcare professionals outside of the cities – have to travel to see neurologist and or attend programs which is not always easy to do."

- Time off work for appointments/treatments – 3%

5. Improved Outcomes

Survey respondents indicated a variety of improvements that they would like to see that are currently not being achieved. The most reported improvement indicated was a treatment option that would not increase dyskinesia as time went on. This was followed by medications that would "last longer" (less fluctuations with on/off) and medications with "less side effects" – particularly constipation and hallucinations. A treatment to address sleep issues in Parkinson's and relief from dystonia was also noted.

"To know that I didn't have to worry about not being 'on' or having dyskinesia during work meetings or in social situations would increase my confidence, decrease my anxiety and stress levels and would let me feel more like myself."

"I would experience a more normal daily life."

"It would feel like I actually got my life back. I could make plans on a day-to-day basis and not worry about off times."

"I could go for walks with my husband, go to the movies, go back to work."

When considering the trade-offs between a treatment option and the side effects and/or risks involved respondents overwhelmingly indicated that as long as they could see and/or experience improvements (in movement and/or quality of life) they would seriously consider trying it.

"My main focus is on quality of life and I weigh the benefit of the treatment in terms of having less off periods and the ability to enjoy life as fully as possible."

"I am willing to experience difficulties in return for more energy and quality of life."

"As my disease progresses, I will certainly consider any and all options and weight the benefits against risks and side effects."

"I would not use a new treatment if the side effects were worse than the Parkinson's symptoms."

6. Experience with Drug Under Review

Parkinson Association of Alberta has connected with 10 clients (5 people with Parkinson disease (PWP) and 5 care partners of people with Parkinson disease) who are using or are caring for someone who is using Duodopa. The 5 people with Parkinson disease using Duodopa accessed it via through their neurologist.

- PWP #1
 - Using Duodopa for 3 years and 3 months
 - Side effects experienced: no side effects experienced
 - Benefits compared to previous treatment/therapies: the benefits were instantaneous, no more ups and downs, no need to deal with the complications of medication timing, less off times, walking and balance improved
 - Disadvantages compared to previous treatment/therapies: no real disadvantages
 - Indicated that Duodopa was “significantly easier to use than previous treatments/therapies.”

- PWP #2
 - Using Duodopa for 7 months
 - Side effects experienced: frequent freezing
 - Benefits compared to previous treatment/therapies: regular supply of medication, not worried about timing, not having to deal with the on/off fluctuations, don't feel as much stiffness
 - Disadvantages compared to previous treatment/therapies: have to wear the pump – finds it awkward and restrictive, but is able to deal with it or make changes necessary to make it work. Another disadvantage is the portability of the medication – cumbersome and the need for refrigeration makes travel more challenging.
 - Indicated that Duodopa was “significantly easier to use than previous treatments/therapies”

- PWP #3
 - Using Duodopa for 7 months
 - Side effects experienced: freezing, feel slow sometimes, keep upping the dosage
 - Benefits compared to previous treatment/therapies: doesn't get as tired as before
 - Disadvantages compared to previous treatment/therapies: It is taking a long time to get “used to”, equipment is bulky and heavy, feels they cannot dress up the way they used to, not sure if they want to continue.
 - Indicated that Duodopa was “slightly easier to use than previous treatments/therapies.”

- PWP #4
 - Using Duodopa for 5 months
 - Side effects experienced: no side effects experienced
 - Benefits compared to previous treatment/therapies: the ability to go out and about and live a “normal” life, haven't had to use walker as much, better quality of life
 - Disadvantages compared to previous treatment/therapies: device is heavy and awkward
 - Indicated that Duodopa was “slightly easier to use than previous treatments/therapies”

- PWP #5
 - Using Duodopa for 5 months
 - Side effects experienced: none experienced
 - Benefits compared to previous treatment/therapies: activity level increased, no longer have to deal with fluctuations, constipation improved
 - Disadvantages compared to previous treatment/therapies: having a tube and the pump took some getting used to but the independence is worth it – cassettes need to be refrigerated can be inconvenient especially when it comes to travel.
 - Indicated that Duodopa was “significantly easier to use than previous treatments/therapies”

From a Care Partner perspective

- CP #1
 - Benefits compared to previous treatment/therapies: the benefits were instantaneous, no more ups and downs, no need to deal with the complications of medication timing, less off times, walking and balance improved, loved one's independence increased
 - Disadvantages compared to previous treatment/therapies: incision sight has to be attended to at times
 - Indicated that Duodopa was "significantly easier to use than previous treatments/therapies."

- CP #2
 - Benefits compared to previous treatment/therapies: instances of freezing do not last as long, but feels they haven't been on it long enough yet to tell.
 - Disadvantages compared to previous treatment/therapies: not as much independence as first thought, PWP cannot re-hook up pump after showering, CP needs to be there. Travelling is challenging as cassettes need to be refrigerated. Felt there was not enough support
 - Indicated that Duodopa was "slightly more difficult to use than previous treatments/therapies"

- CP #3
 - Benefits compared to previous treatment/therapies: dealing with the timing has become a non-issue, not living life by an "alarm clock" (medication timing)
 - Disadvantages compared to previous treatment/therapies: inconvenient in terms of travel as the medication has to be refrigerated.
 - Indicated that Duodopa was "slightly easier to use than previous treatments/therapies."

- CP #4
 - Benefits compared to previous treatment/therapies: longer on times than oral meds, more freedom to get out of the house
 - Disadvantages compared to previous treatment/therapies: device is heavy and the tube could be longer. Incision sight needs to be attended to.
 - Indicated that Duodopa was "slightly easier to use than previous treatments/therapies"

- PWP #5
 - Benefits compared to previous treatment/therapies: too early to tell
 - Disadvantages compared to previous treatment/therapies: no real disadvantages, but there is a certain discomfort that comes with a wearable apparatus
 - Indicated that Duodopa was "slightly easier to use than previous treatments/therapies"

"16 hours of constant flow allowing us to go out and live our lives."

"Duodopa gave us our life back."

7. Anything Else?

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 and loss of quality of life is forcing people with Parkinson's to withdraw from normal activities too soon (e.g. day-to-day activities (including self-care and household chores) work, travel, maintaining relationships, etc.).

The inability to appropriately control their symptoms on a continuous or predictable basis causes undue stress, anxiety and can lead to depression and/or social isolation.

Furthermore, survey respondents reported it would be a significant financial burden if they did not have coverage to help with their drug costs. Many people with Parkinson's and care partners 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.

When a disease is not only life-long, but as life limiting as Parkinson's it is essential to provide coverage to ensure treatments are affordable and accessible for all who need it

Appendix: Patient Group Conflict of Interest Declaration

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
AbbVie Pharmaceutical			√	

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: Brandi La Bonte

Position: Communications

Patient Group: Parkinson Association of Alberta

Date: 2018-03-02

1. About Your Patient Group

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

Parkinson Canada is providing information and evidence for this submission by providing evidence gathered by a survey of people with Parkinson's and care partners conducted by Parkinson Canada in June-July 2017, as well as from interviews with patients using the product.

Survey

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.

In terms of gender, 52 per cent identified as female, 48 percent identified as male, and less than 1 percent identified as a gender other than female or male.

42 per cent of respondents are between the ages of 65-74. This is followed by 23 per cent between the ages of 55-64, 17 per cent between the ages of 75-84, and nearly 10 per cent are 45-54, nearly six per cent were under the age of 53, and three per cent were over the age of 85.

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.

Interviews

Parkinson Canada has gathered information from 11 patients who have experience using Duodopa. This evidence was gathered via phone interviews with Parkinson Canada staff.

3. Disease Experience

From Parkinson Canada's 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 loss 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) and 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 changes in abilities and making participation in daily activities increasingly more difficult over time.

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 for whom they provide care:

“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...”

4. Experiences With Currently Available Treatments

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

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".

"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 products 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 regime.

“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 verses potential side effects would need to be carefully weighed before starting any new medication.

6. Experience With Drug Under Review

Patient #1 – Female diagnosed in 2006 with Parkinson’s, received Duodopa in 2016

- Accessed Duodopa through the Ontario Drug Benefit Program after years of dose failure and experimenting with adjunct therapies that did not improve her condition.
- Before accessing Duodopa she was wheelchair-bound due to frequent falling.
- She reports that Duodopa was a “last resort” for her since other medications were not having an effect on her symptoms.
- Duodopa has improved her fluctuations or “off times” that she previously experienced with oral medications. She has also been able to lower her dose of levodopa/carbidopa and thus reduce the adverse side effects she experienced.
- Disadvantages to using Duodopa include: care and attention that’s required to maintain the system as a whole; size of the pump can be a challenge with certain clothing; protecting the pump from water (e.g. showering, swimming)
- Overall Duodopa is easier to use than oral medications at this stage in her disease progression. She and her care partner are able to readily manage the routines needed to use Duodopa.

Patient #2 – Female diagnosed with Parkinson’s 5-6 years ago, received Duodopa in 2017

- Accessed Duodopa through the Ontario Drug Benefit Program
- Before Duodopa she was on 12 different medications that were not effective and made her feel very “loopy”, and she often forgot to take her medication or took them twice.
- She expressed a great benefit in that she does not have to remember so many pills anymore and her speech is clearer. Her Dyskenia has reduced and almost stopped completely at times. She used to fall a lot due to the dyskenia’ however now that this symptom is controlled on Duodopa her falls have reduced in frequency.
- Disadvantages to using Duodopa is the inconvenience of the pump itself. For her, it is heavy, awkward when dressing, needs special consideration when going in water, and sometimes she gets itchy where the tubing is inserted. She indicated that the itching is a minor concern that can be remedied with polysporin.
- Duodopa is much less work than taking the oral medications she was on. She stated “it has changed my life”.

Patient #3 – Female diagnosed with Parkinson’s in 2008

- Accessed Duodopa through a provincial drug access program.
- She stated that there are many benefits, including it’s easier to use, it alleviates symptoms a lot more than her pills, she can walk again even if for short periods of time.
- She indicated that the only disadvantage is that the pump is heavy and pulls on her neck.
- She said that Duodopa has had a positive impact on her life. She couldn’t walk and now she can do things for herself such as make breakfast, which puts less pressure on her family. She can also walk a bit more which again it’s less work for others.
- Duodopa is easier to use for her. She was taking 24 pills a day which was very difficult to do and monitor to make sure no pills were forgotten.

Patient #4 – Male from Ontario, diagnosed with Parkinson’s in 2004

- He did not qualify for Deep Brain Stimulation. He waited for two years to have access to Duodopa through the provincial drug program.
- He stated “the benefit is life itself, it’s a miracle”. He was physically unable to function. He would stay in bed for days and could not pick up a weight. Duodopa has alleviated these physical symptoms. He now goes to the gym twice a week and can walk without difficulty.
- He did not have any disadvantages to using Duodopa. He said he got used to carrying the pump.
- He stated “*We are so much happier. We were given life back. My wife doesn’t have to worry anymore*”.
- It is also made easier since he no longer has to schedule his meals around oral medications.

Patient #5 – Male from Quebec, diagnosed in 2006

- Accessed Duodopa from the provincial drug coverage in Quebec
- He indicated that his situation has improved 75-80% since receiving Duodopa.
- He is now able to eat, walk, and participate in family activities that he previously could not be involved in due to his Parkinson's symptoms.
- Disadvantages include needing help to clean the tubing and bandage daily, and the weight of the pump.
- He expressed a huge improvement with the use of Duodopa verses taking pills on his symptoms and quality of life.

Patient #6 – Male from Quebec, diagnosed in 2012

- Accessed Duodopa from the provincial drug coverage in Quebec
- He used to take pills which were not having a positive effect on his situation. Now since being on Duodopa, he is more stable and can walk properly. He also finds that Duodopa is very fast acting. He reports feeling more confident and enjoys walking around his neighbourhood. He says “*it’s a huge improvement*” from where he was before receiving Duodopa.
- He does not report any disadvantages to using Duodopa, and has not experienced any side effects. He indicated that he does not have a problem with the machine’s weight.

Patient #7 – Female from Quebec, diagnosed in 2003

- Accessed Duodopa through a private insurance plan
- Compared to using other medications, the patient reports the following experience with Duodopa “*There have been big changes for me [before Duodopa] my muscles were not working anymore. I wasn’t feeling good, even if all of the disease is not gone, now it’s more pleasant*”.
- The biggest advantages to Duodopa treatment for her is that she feels better and more active and energetic overall.
- A disadvantage for her is having to change the battery every week.
- She reports constipation as being a side effect she has experienced since starting Duodopa.
- She indicated that the weight of the pump is not an issue for her since she wears it over her shoulder.
- She said that on Duodopa she is less tired than with other treatments she’s tried. She is able to do more activities with her husband like baking.

Patient #8 – Male from Quebec, diagnosed in 2006

- Accessed Duodopa through a private insurance plan
- He no longer has “off” times as he experienced with oral medications. He states that now using Duodopa *“I don’t need to plan when I’ll have to take my pill, I was taking 29 pills a day”*.
- He has a regular routine now that he’s on Duodopa. He no longer has to be concerned with his 29 pill a day schedule and fear of “off” times.
- Some disadvantages to Duodopa are that he has to clean it daily, the pump is heavy, and he experiences dizziness and headaches as a side effect.
- He indicates that even with the side effects and reported disadvantages, he still prefers Duodopa. It is much easier for him than trying to manage his oral medication schedule and the “off” times.

Patient #9 – Male from Ontario, diagnosed 1998

- Combination of provincial and private coverage
- His oral medications were becoming less effective for controlling his symptoms and he was not a candidate for Deep Brain Stimulation. Duodopa was his only option to improve his condition.
- He explained the following when asked to compare Duodopa to his past treatments: *“I’m always ‘on’ when I am plugged in to my pump! I have energy and motivation to try and live a reasonably normal life. It’s miraculous! My mood is much better knowing that the medication is infusing into me at a regular, constant rate; I don’t have to wonder if the next dosage of oral meds is going to get absorbed and work for me”*.
- He reports that some of the disadvantages to Duodopa is that the pumps gets in the way of some activities (e.g. playing tennis, tying shoes, exercises that require bending). He does add the following: *“The benefits far outweigh the disadvantages of life with Duodopa. I’ve been given a new lease on life with this regular infusion (every 30 seconds for 14 – 16 hours a day) of the medication to control the symptoms of Parkinson’s”*.
- He has had Duodopa for three years without any issues. He has recently had an issue with frequent infections related to the tube. He will be getting a new tube inserted in a different place, which he hopes will provide him with more years of a good quality of life. He states *“I would not trade this method of treatment for previous methods of treatment for anything. Yes, the pills taken 4 or 5 times a day is easier, but if they are ineffective and need to be taken every 2 hours, then Duodopa is the way to go for me. I wish more people could be given the opportunity to have a better quality of life with Duodopa for the treatment of Parkinson’s.”*

Patient #10 – Male from Ontario, diagnosed in 2014

- Received provincial coverage for Duodopa
- His oral medications were getting much more difficult to take due to the scheduling. He and his wife had to set alarms every 2-3 hours; however, they were finding it increasingly more difficult to keep track of when medications had to be taken.
- The pump can pose difficulty when dressing and had infections that were treated topically a couple of times at the site of the tube; however, according to his wife *“the benefits outweigh the minor challenges”*.
- His wife claims he is “brighter” since being on Duodopa. They can continue to have a very full and busy life without being concerned about “off” times and scheduling of medications. His wife can now go quilting for a few hours each week without being concerned that her husband has forgotten to take a dose of medication.
- They report no side effects.
- It has made life *“a little easier”* for them.

Patient #11 – Male from Ontario, diagnosed since 2008

- Before Duodopa he was taking 12-14 pills a day and was experiencing more frequent “off times” with constant shaking. He had limited mobility and was not able to do much for himself. He was not a candidate for Deep Brain Stimulation due to his age.
- According to his daughter, *“Duodopa is wonderful! He is a different person and is mobile again around his home. It is the greatest treatment for Parkinson’s that I have ever seen”*.
- He no longer takes any oral medication for Parkinson’s.
- He requires his daughter to clean the tube daily, and as a caregiver his daughter is worried about the tube being pulled out. Twice the tube pulled out and now his daughter pins the carrying case for the pump to his clothing to try and prevent it from being pulled out. He developed loose stool; however, they are unclear if that is related to the use of Duodopa or something else going on with him.
- Overall the advantages and benefits from Duodopa outweigh any minor disadvantages or possible side effects.

7. Anything Else?

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 and 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 reported 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.

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

In particular, the exceptional benefits that have been experienced by individuals who have had access to Duodopa cannot be overlooked. It has given individuals and their care partners their lives back in many instances. By providing a return to, or increased in, independence has allowed many people with Parkinson’s to remain in their homes and communities for longer and provided their care partners with an opportunity to get back to their activities and reduced their stress.

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.

We requested help from the AbbVie Cares program in order to identify the names and contact information for patients using Duodopa. The patients provided by AbbVie Cares were in addition to Parkinson Canada's list of patients using Duodopa.

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
AbbVie			X	

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: March 05, 2018

1. About Your Patient Group

We have registered: www.parkinson.bc.ca

2. Information Gathering

Personal interviews with the few people and their caregivers that have received Duodopa therapy in BC were conducted. As Duodopa therapy was only made available in BC February 14, 2017, on a case by case basis for up to 5 people, this provided only a small group to interview.

In addition, a provincial online survey was conducted, mainly with people with advanced Parkinson's disease and their care partners. We received 56 responses.

We conducted an awareness and advocacy campaign in 2016 through early 2017 asking the BC Ministry of Health to provide access to Duodopa therapy on at least a case by case basis for those people with advanced Parkinson's disease.

Numerous friends and family (750) supported the campaign telling compelling stories of the distress their friend or family member was enduring and the hope that Duodopa would give them back their quality of life.

(see <https://www.youtube.com/watch?v=wtYOF9XhQ0A&feature=youtu.be>)

3. Disease Experience

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. 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.

However, swallowing problems can be the most frightening and life threatening and can lead to choking and/or asphyxiation.

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.

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 as described in this eloquent description that follows:

My Issues in Living With Parkinson's Disease and Its Progression – [REDACTED], April, 2016

"I spend approximately 65% of my waking day in the "off" state when my medication is not working. This causes me to have difficulty moving independently, feeding myself, and performing basic tasks. The 35% I manage in the "on" state is with troublesome dyskinesia, very violent movements that again prevent me from doing most activities.

Overall my health and safety are concerning for the following reasons:

- I have lost approximately 100 lbs in the past few years largely due to dyskinesias, these violent movements that are a side effect of my medication.*
- I am at serious risk of aspiration and choking due to my inability to swallow properly when medication is not working.*
- I have frequent dose failures with my medication, possibly due to my stomach not emptying properly. Medications to assist with stomach emptying have had adverse effects and made me even more ill. This makes my off periods fairly unpredictable and makes it difficult to plan my day (and my husband's day).*
- Additionally, I am also at risk for malnutrition due to difficulties with swallowing as well as the increased caloric expenditure due to dyskinesia, and difficulty feeding myself while dyskinetic or in an 'off' state.*
- If the serious symptom of not swallowing properly continues, there is a chance I may need a PEG tube for feeding to eliminate the risk of choking and ensure proper nutrition.*
- I suffer from rigidity, bradykinesia, dystonia, tremor, and more recently freezing while off. I fell and hurt my hip recently due to a freezing episode in the night when I was up to the washroom. Due to my low weight and new freezing, there is a real concern of a serious fall resulting in a fracture which could lead to a further decline in my condition and the need for community support or an increased level of care*

These are the main safety concerns, although I have many severe symptoms that cause me to need help with my activities of daily living (such as dressing, getting to the toilet, eating)."

PSBC also conducted a survey February 2018 – asking "How Does Parkinson's disease affect your daily life?"

Following is a sample of responses from people with advanced Parkinson's and their caregivers:

- I live, breath, eat and sleep Parkinson's.
- Parkinson's disease impacts every area of daily life. It can be difficult to plan any activities if my symptoms are not manageable and pain are not manageable. The result is missing the enjoyment of many social activities. Something as simple as going out for coffee is too difficult. Meal preparation is difficult. There is a definite loss of confidence.
- Cannot write. Sleep interrupted 4-9 times with urination urgency. "Neanderthal" gait. "Lumbering" behaviour slows physical activity.
- Embarrassment is also a part of my life especially around my eating ability. My family is very supporting but my loss of some independence is hard
- was on disability till early retirement, lost some pensionable time, so finances are challenging, with extra costs for prescriptions, health practitioners, etc. Can't keep up with conversations at times. Losing strength, even with exercises.
- My tremor makes it difficult to take on many day to day task. My rigidity is painful and uncomfortable.
- I can only manage anything when my medication is working. When it is "off" I can hardly function.
- Parkinson disease changes your life! It interferes with everything that you do. It's symptoms cause uncertainty and loss of self confidence. As a husband and care giver for my wife there is nothing good to say about this wretched disease.

For further description of the disease and its' progression, please see:

<https://www.parkinson.bc.ca/media/30933/what-is-parkinsons-disease.pdf>

<https://www.parkinson.bc.ca/media/31548/progression-of-parkinsons.pdf>

4. Experiences with Currently Available Treatments

Difficulties:

Majority of survey responders were using oral medications. Most had issues with timing. Those with advanced Parkinson's were taking levodopa every 2 to 4 hours. This coupled with the need to take *without* protein leads to nutritional issues and massive loss of weight. Wearing off is an increasing factor as the disease progresses. In the 'off' state people are frozen, unable to move, sometimes unable to speak or swallow and feel as if they cannot breathe.

Swallowing of oral medication becomes an increasing issue as the disease advances. Nausea was also mentioned although some have found taking meds with apple sauce or crackers helps.

Survey respondents described difficulties as follows:

- Swallowing pills, managing "off" periods, and finding a good balance with what foods can be eaten that won't interfere with the pills being taken.
- some days take longer to kick in at the beginning
- finding the right times to take medications as needs vary through the day and not consistent
- high frequency (every 2 hrs) and amount of many medications through the day, does not always work to control symptoms and improve functioning
- Due to swallowing difficulties, swallowing pills & dosing liquids have become increasingly difficult.
- PD person sleeps more during the day; it is a challenge to regulate medication
- The high number of pills taken during the day, coupled with no pd pills being provided between 10pm and 7 am Then playing catch-up all morning. Taking with apple sauce or puddings does help.
- Making sure they actually reach the stomach *very often they stick on the way to stomach*
- wearing off is troublesome, vigorous exercise or intensive mental activity shortens effective period.
- Managing the timing of multiple medications in the activities of daily life- ie meals. Wearing off with long term PD.
- Occasionally swallowing pills. Planning meal times around drugs. Drugs need to be an hour before eating or an hour after eating. Food interferes with the usefulness of the drugs
- Currently, there are some challenges to using duodopa, such as the flushing of the tube each evening, care for the stoma (where the tube is placed into the stomach), keeping the cassettes in the fridge, the challenges of having to deal with carrying the pump close to your body all day affecting freedom of movement, as well as showering challenges, and clothing limitations.
- Amantine now only in liquid form. Picture a person with PD measuring it out, let alone the awkwardness of packing a bottle and dispenser around.
- When taking pills, the inconsistency and uncertainty of how and when the medications work . Often the pills will cause overdosing due to slowness of the gut and bring on hours of torturous dyskinesia rendering my wife unable to eat or do anything. On duodopa it has made life considerably more tolerable , but also has many disadvantages

Current regimes:

- I am using Duodopa now. It works much better than the oral medications.
- Levodopa and carbidopa, every 2 hrs, liquid Amantadine, botox every 3 months, anxiety and depression medications, sleep aids
- Levodopa/caridopa. Pramipexol, Amantadine, for movement & Venlafaxine, Nabilone, & Lorazepam, Quetiapine for mood, Zopiclone to sleep

- Levodopa/Carbidopa. Clonazepam and Ativan. Laxatives. CBD. Started with an agonist with poor results. Little benefit and lots of side effects.
- Synemet and a variety of meds to augment the synemet.NOTE THAT WAS FOR THE FIRST 15 YEARS. Currently she is using Duodopa
- Titrating and managing the Duodopa gel
- Psychological follow up
- duodopa, seeing therapist re: impulse control disorder
- taking multiple pills throughout the day, massage appointments, physio appointments, dietitian appointments , naturopathic remedies and appointments. There have been at least three instances of hospitalization as well.
- frequent oral medications - every 2 hrs in day and late and early daily schedule, home support, senior support phone calls, caregiver respite, neurological clinical follow-up, hospitalization, follow-up with pharmacy and GP, support from family members
- DBS Implant. Medication (Sinemet/Amantadine)
- I take pills every 2 hours. I visit a my neurologist 2 times per Year. I use medical marijuana as Needed to control pain and help with insomnia. I do regular exercise which seems to help. Also I do brain teasers and online brain games
- -Sinemet every 4 hours, CR at bedtime, Azilect at breakfast -massage therapy every 4-6 weeks -physio as needed from movement specialist -1-2 hours of exercise every day (1 hour walk 5/week, indoor rock climbing 2/week, PWR exercises 3/week, stretch yoga 4/week, 20 min. hand held weights program 5/week)
- I am 75 years old and live alone, close to the centre of town. I don't drive any more, can walk to doctor, shops, local bus. For the most part I can manage daily activities but at a reduced level, and with considerable fatigue. I have only four or five hours of productive time each day, reduced social activities, seldom able to attend evening events, am beginning to seek out support services. I sometimes travel (by bus) to visit friends or family but find that increasingly exhausting. Medication has been reasonably effective for the six years since diagnosis but I don't count on it to work this well forever.
- My walking is very slow, and I can't go for walks with my friends any more. I can walk a very short distance. I have trouble swallowing food and eating alone is easier. Friends worry about me when I stop eating and likely will need to get to the bathroom fast.
- I can only manage anything when my medication is working. When it is "off" I can hardly function.
- I need to be careful to take my meds (Sinemet) every 4 hours throughout the day and night to control my symptoms of PD--both motor and non-motor.
- I am having a hard time getting the dosage and timing of my medications right.

Parkinson's disease (PD) is one of the most treatable of all neurological conditions. Medical treatment increases longevity and allows most people with PD to remain active and productive for many years.

However, the medical treatment of PD, is not always simple. As you can see above, the choice of drug, dose and timing are crucial. Motor and non-motor symptoms must be treated and the need for specialist care increases with the advancing disease.

The difference between optimal versus ineffective therapy may be the difference between a nursing home and independent living.

Because of the complexity of this disease, general practitioners often find it difficult to diagnose and then to treat. They may refer patients to either a community neurologist who specializes in a variety of neurological conditions or to a neurologist who specializes in Movement Disorders.

Patients in a more advanced stage of the disease are likely on a 'cocktail' of oral medications averaging a cost of \$1000 per month.

Current barriers to the proper management of PD in BC:

- Lack of integration in the system; disconnect between PD specialists and general health care providers.
- Waitlists of up to 24 months to see a specialist.
- No PD specialists in senior populated centres such as Victoria and not enough in centres such as Kelowna (1/2 day per week with a waitlist of 1300 patients)
- Allied health professionals often lack knowledge of PD and its management, leading patients to often receive improper treatment in emergency rooms, hospitals, general practices, and care homes.
- Duodopa, the only therapy for advanced PD patients, is not funded in BC (funded in AB, ON, QB, MB, YK).
- Deep Brain Stimulation program is under resourced both for access to the procedure and follow up with those who have received it.

Why is the proper management of PD important?

The treatment of PD is *complex*. However, it is one of the *most treatable* neurological conditions; but the specific medication types, combinations, timing and dosage are all crucial for proper patient functioning and quality of life. There are no objective diagnostic criteria for PD, so a comprehensive neurological examination is required.

If treatment is inappropriate, patients are at higher risk of falls, hospitalization, increased length of hospital stays, slower recovery from illness or surgery, and faster disease progression. *The difference between optimal versus ineffective therapy may be the difference between hospitalization, a nursing home or independent living.*

More Complex Care

Deep brain stimulation (DBS) is a surgical procedure used to treat a variety of disabling neurological symptoms—most commonly the debilitating symptoms of Parkinson’s disease (PD), such as tremor, rigidity, stiffness, slowed movement, and walking problems.

At present, the procedure is used only for patients whose symptoms cannot be adequately controlled with medications. DBS uses a surgically implanted, battery-operated medical device called a neurostimulator—similar to a heart pacemaker and approximately the size of a stopwatch—to deliver electrical stimulation to targeted areas in the brain that control movement, blocking the abnormal nerve signals that cause tremor and PD symptoms.

In British Columbia, there is currently *a four to five year waitlist for DBS*. As Parkinson’s is a progressive disease, in five years a patient may no longer be eligible for DBS as the disease may have created symptoms that make them no longer a good candidate.

Patients with PD who have undergone DBS have been able to return to work and potentially reduce their dose of medication by approximately 75%, while many others have been able to come off their medication entirely.

As there is only one neurosurgeon in BC, located in Vancouver, patients must travel there from other parts of the province, initially for an assessment from a movement disorder specialist (waitlist up to two years), be referred to the neurosurgeon (waitlist up to another two years) and if they meet the criteria, be placed on another waitlist for up to another two years. They must travel to Vancouver for all of these appointments, have recovery time in Vancouver from the DBS surgery, travel home, recover, come back to Vancouver for day surgery for installation of a ‘pacemaker’ type battery, then stay for several more days to have electronic signals calibrated for their device. Any complications require travel back to Vancouver.

Batteries need to be replaced every 4 to 5 years. Patients must travel to Vancouver for this procedure.

DUODOPA® is a levodopa and carbidopa combination in the form of a gel that is delivered directly into the small intestine. This type of treatment is for use in patients with advanced Parkinson’s disease who have severe and disabling motor symptoms that cannot be well controlled with available combinations of medications for Parkinson’s disease.

The gel is delivered continuously throughout the day with a pump via a tube, directly into the small intestine to provide more constant amounts of levodopa and carbidopa in the body throughout the day.

The therapy is expensive, approximately \$60,000 a year, and although recently made available on a case by case basis for people with advanced Parkinson's disease in BC, still not easily accessible. Patients must travel to Vancouver for gastrointestinal surgery to place a stoma into the small intestine. After recovery of two to four weeks, patients again travel to Vancouver to the Movement Disorder clinic for titration of Duodopa appropriate to their needs. Titration takes 3 to 4 days as an outpatient process.

5. Improved Outcomes

Patients would like to see their symptoms controlled and to have an acceptable quality of life. Severe "off" periods are disabling to the point of life threatening as breathing becomes difficult, speech impossible and collapse immediate causing sudden falls with the risk of serious injuries. Note from a caregiver whose wife (**My Issues in Living With Parkinson's Disease and Its Progression – [REDACTED], April, 2016**) received Duodopa in spring 2017.

"My caregiving role has changed dramatically since my spouse started receiving the Duodopa treatment.. For several years it was a very demanding role, 24 hours a day, with extensive support that needed to be given, such as cooking, chopping up her food, cleaning, laundry, helping her get dressed, helping her get up from a chair or bed, keeping on top of meds, help with bathing, emotional support, wheeling her around the house when she could not walk. I had to stop going out with friends (including the local choir). I had no independent life. She needed me 24--7. But now with duodopa most of that no longer applies."

And from Gail Guise who received Duodopa therapy in 2015 prior to BC Ministry of Health funding the therapy:

"It's made a huge difference in my quality of life," said Guise from her Murrayville condo. "This doesn't fix Parkinson's, but because the medication goes directly into my brain in small doses every minute, it evens things out more, and I'm not tied to my watch."

A year ago, Guise had surgery to implant a tube directly into her small intestine. The tube is connected to a pump that she wears in a pack around her waist. The pump, much like an insulin pump, administers medication continuously. She also has the option to increase a dose if she is having a tremor or experiencing worsened symptoms.

Because the delivery of the drug is steady and regulated she can better manage her disease while experiencing an improved quality of life.

Before accessing this new treatment, Guise was required to take pills every three hours, but was still experiencing both tremors and dyskinesia, an involuntary muscle movement experienced by Parkinson's patients, as her medication began to wear off.

But Duodopa is not covered under B.C.'s medical system.

"It costs \$70,000 for the first year. Luckily for me, I still had BlueCross coverage from when I worked, so I could have it covered. Otherwise, I wouldn't have been able to do it either, said Guise"

<https://www.bclocalnews.com/life/langley-woman-only-parkinsons-patient-in-b-c-to-have-special-medicine/>

Cathy, Gail's care partner:

When Gail had to take pills every 3 hours we bought a watch to help us make sure she took her pills on time. If she got a tremor it was a long stressful time before it stopped. When she got dyskenisa continually for six hours,I did not know what to do and I took her to the hospital. No one could help us but gave her a shot but that was 4 hours later. Sometime Gail would have a tremor and then dyskenisa. It was a nightmare.

Now she has less dyskenisa and can press a button and the tremor goes away in 15-20 minutes. No more watch ,life is good. I spend 5 minutes in the morning getting a new cartridge and 5 minutes at night flushing the tubes. That' is it.

6. Experience with Drug Under Review

Please see response to number 5, above.

For people with advanced Parkinson's disease, the ability to receive 'liquid' levodopa directly into the small intestine avoids problems with swallowing, lack of gut mobility, and oral medications not dissolving in the stomach or intestine but being passed with the stool.

Timing issues get increasingly difficult especially as protein can prevent uptake of the drug and especially as frequency increases and shorter and shorter times between oral medications. Nutrition suffers and often large weight loss is experienced leading to increased frailty, increased danger of falling, increased fatigue, and increased depression and anxiety. Quality of life in these patients is very poor. If they are fortunate enough to live with a spouse or adult child, qol for the care partner suffers as well – it becomes a fulltime job caring for these people.

Testimonial from [REDACTED] (Issues with PD prior to Duodopa therapy described under Point 3.)

My name is [REDACTED] and after 16 years of living with Parkinson's disease, my oral medications were becoming less effective – at times causing debilitating dyskinesia and dystonia.

*In the advanced stages of Parkinson's disease, every day was a new unknown for me and my husband [REDACTED]. Could I make it to the grocery store, or would we get there and have to turn around because I couldn't get out of the car? We had no way of knowing what each day would bring. **Over the past five years, I lost almost 100 pounds due to swallowing issues. My symptoms prevented me from leaving home, and I felt very isolated.** I was no longer able to participate in hobbies such as crafts or reading due to my frequent dyskinesia. Caregiving became a 24 hour necessity.*

*Last year, at age 68, I became one of the first people in British Columbia to receive a treatment recently approved for public funding under BC PharmaCare. This treatment, specifically for those with advanced Parkinson's disease, called Duodopa, delivers a levodopa and carbidopa drug combination directly to my small intestine, allowing for a more constant "on" time. This treatment has dramatically improved my symptoms, giving me back my life. **There have been so many astonishing outcomes since receiving Duodopa, I can now eat without any swallowing issues and have gained 10 pounds. I have even gone back to crafting, sewing, singing and exercising. The best part is we have a social life again! Reconnecting with my friends and spending time with my family has brought me so much joy and happiness.***

This past summer something happened that I never thought would be possible. One day our son and his family stopped by for lunch and I was able to play soccer with my three grandchildren. Yes, me, who has had Parkinson's for 16 years played soccer with my grandchildren. I was told I did okay for being a nana! This was a momentous moment for me that would never have been possible prior to receiving Duodopa. Receiving this treatment has changed my life and my family members' lives too.

7. Anything Else?

Parkinson's is a tough disease but more manageable if people and their physicians have access to different medications and therapies. Duodopa therapy is life changing for those with advanced Parkinson's disease experiencing the sudden 'off' periods which can be not only disabling but life threatening as they involve 'freezing', sudden loss of balance, swallowing and breathing difficulties.

Appendix: Patient Group Conflict of Interest Declaration

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
AbbVie – sponsorship of provincial patient education conference June 2017. PSBC’s annual budget is \$1.4 million.		x		

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: March 2, 2018