From:

Volpiana, Elide <elidevol@mail.ubc.ca>

Sent:

September-04-15 8:30 AM

To:

Zimmerman, Janine M HLTH:EX

Cc:

McKeown, Martin

Subject:

Meeting with Mr. Lun

Attachments:

LCIG Pharmacare Meeting request.pdf

Dear Ms. Zimmerman,

Thank you very much for taking my call this morning. Attached is the letter that Dr. McKeown sent to Mr. Lun in May 2015.

Could a meeting be scheduled at Mr. Lun's convenience re the contents of the above letter? If so, can you please contact me to set this up. I am in the office next week Tuesday to Friday 8 a.m. to 4 p.m.

If it is more convenient for Mr. Lun to meet with Dr. McKeown in Victoria, this is to let you know that he will be there October 16<sup>th</sup> and 17<sup>th</sup>.

Thank you very much for now. Look forward to hearing from you.

Best regards,

Elide

Elide Volpiana
Clinical & Admin. Secretary
For Martin J. McKeown, B.Eng., M.D., F.R.C.P. (C)
Director, Pacific Parkinson's Research Centre
UBC Hospital, Purdy Pavilion
M34 - 2221 Wesbrook Mall
Vancouver, B.C. V6T 2B5

Phone: 604-827-5136 Fax: 604-822-7866





Consultant Neurologist & Director Pacific Parkinson's Research Centre

Faculty of Medicine Vancouver Hospital and Health Sciences Centre Purdy Pavilion 2221 Wesbrook Mall Vancouver, B.C. Canada, V6T 2B5

Martin J. McKeown, BEng, MD, FRCP(C)
UBC/PPRI Chair in Parkinson's Disease Research
Professor, Dept. of Medicine (Neurology)
Associate Member, Dept of Electrical and Computer Engineering

Eric Lun, PharmD

Executive Director, Drug Intelligence

Medical benefits and Pharmaceutical Services

303 - 960 Quayside

New Westminster BC V3M 6G2

Dear Mr. Lun,

I am writing to request a meeting with PharmaCare to discuss the opportunity to gain PharmaCare reimbursment for levodopa/carbidopa intestinal gel (ECIG) (trade name Duodopa) for a limited number of patients with late stage Parkinson's Disease who can longer be adequately managed with oral therapy. I have recently taken over as Director of the Pacific Parkinson's Research Centre, a National Parkinson Foundation Centre for Excellence, and the only tertiary movement disorders clinic in the province of British Columbia and the largest Parkinson's clinic in western Canada..

My predecessor, Dr. Jon Stoessl, had in the past requested approval for 2 patients last summer. However do to a number of reasons (including one patient who progressed to Deep Brain Stimulation (DBS) surgery) these patients were subsequently removed from cosideration by the UBC Movement Disorders Clinic. Dr. Stoessl informs me that you had written to him regarding these patients and described the reasons that LCIG had been declined for formulary coverage by PharmaCare and suggested that one of your staff would be willing to meet to discuss the opportunity for LCIG coverage further. An excerpt of that communication is reproduced below:

With this context and without any commitments at this time, we would still be interested to better understand the situation you described. For this, Dr. Sue Bouma, Director – Special Authority, would be pleased to meet with you to discuss further. Among other things, we would like to better understand the anticipated patient population, the unmet clinical need warranting use, evidence to support use in this population and the expected outcome for levodopa/carbidopa intestinal gel therapy. Please contact either Janine Zimmerman (250-952-2504 or Janine Zimmerman@gov.bc.ca) or Sandy Stevens (250-952-1757 or Sandy Stevens@gov.bc.ca) to arrange a meeting date and location.

I would be pleased to meet at the earliest convenience with you or your staff to discuss the LCIG re: unmet medical need; patient population; evidence to support LCIG efficacy; and expected outcomes. It is important for a restricted number of British Columbians sufering with late stage Parkinson Disease to





Consultant Neurologist & Director

#### Pacific Parkinson's Research Centre

Faculty of Medicine Vancouver Hospital and Health Sciences Centre Purdy Pavilion 2221 Wesbrook Mall Vancouver, B.C. Canada, V6T 2B5

Martin J. McKeown, BEng, MD, FRCP(C)
UBC/PPRI Chair in Parkinson's Disease Research
Professor, Dept. of Medicine (Neurology)
Associate Member, Dept of Electrical and Computer Engineering

have access to this medication as similar tertiary movement disorders programs in Ontario, Alberta and Quebec have access to LCIG though public reimbursment.

Thank you for confirming if the contacts above remain correct in ordert to schedule this meeting in Vancouver. As you may know, LCIG is a highly specialized treatment that Pacific Parkinson's Research Centre is one of 5 sites in Canada qualified to administer and monitor LCIG treatment. We started our first patient last month with favourable results.

Thank you for consideration of this request. I look forward to hearing from you.

Yours truly,

Martin J. McKeown, BEng, MD, FRCP(C)

PPRI/UBC Chair in Parkinson's Research

Director, Pacific Parkinson's Research Centre

Professor of Medicine (Neurology)

Martin J. Waliown.

Associate Member, Department of Electrical and Computer Engineering

Brain Research Centre

University of British Columbia (UBC)

M33, Purdy Pavilion 1

University Hospital, UBC Site

2221 Wesbrook Mall

Vancouver, British Columbia

V6T 2B5 Canada

Tel. (604) 827-5136

Fax. (604) 822-7865

martin.mckeown@ubc.ca

http://www.parkinsons.ubc.ca/McKeown/

From: Vandermolen, Kayla S HLTH:EX on behalf of Bouma, Susan HLTH:EX

Sent: February-24-16 10:28 AM

To: 'Martin.mckeown@ubc.ca'

Subject: 1048126 - Minisrty of Health response

#### Dear Dr. McKeown:

Thank you for your email of September 4, 2015, regarding your request for PharmaCare to consider providing reimbursement for levodopa/carbidopa intestinal gel (LCIG) (Duodopa®).

Further to our discussion on December 7, 2015, I wish to provide the following information regarding the rationale for PharmaCare's decision to not include levodopa/carbidopa intestinal gel (LCIG) in the British Columbia drug formulary for treatment of advanced stages of Parkinson's disease:

In 2009, levodopa/carbidopa intestinal gel was reviewed by the Common Drug Review (CDR). The Canadian Expert Drug Advisory Committee (CEDAC), part of the CDR, released its final recommendation on July 22, 2009, recommending that participating jurisdictions, including British Columbia's PharmaCare program, not list levodopa/carbidopa intestinal gel on the formularies of their public drug plans. The link to the final recommendation is http://www.cadth.ca/media/cdr/complete/cdr complete Duodopa July 24 2009.pdf.

The CEDAC gave this recommendation primarily due to the manufacturer's reported incremental cost per quality adjusted life year (QALY) estimate for Duodopa<sup>®</sup>. The manufacturer requested that specific results from the economic evaluation remain confidential pursuant to the CDR Confidentiality Guidelines; however other published cost per QALY estimates for levodopa/carbidopa were reported at approximately \$1 million compared to other conventional oral therapies. At the manufacturer's list price of \$166/day, the annual cost of therapy is over \$60,000 per patient per year. Also, CEDAC had concerns with the two evaluated trials being small and having design limitations.

Subsequently, the Ministry of Health (the Ministry) reviewed levodopa/carbidopa intestinal gel and decided to not list this drug on the PharmaCare formulary. PharmaCare must apply its policies consistently; therefore, we are unable to make an exception in providing coverage at this time.

If Abbvie, the manufacturer of this product, has new clinical or economic/pricing information for this drug, they can forward a resubmission to the CDR. We appreciate your insights on this matter, and the opportunity to respond to your concerns. As mentioned during our meeting, and above, the first step will be to approach Abbvie about re-submitting, which we have done previously. If CDR reviews and recommends coverage we can then re-look at potential criteria during our Ministry review process. To date, we have not received a resubmission from the manufacturer to review LCIG. I apologize if this is not the response you were hoping for.

Sincerely,

Susan Bouma, B.Sc. (Pharm), R.Ph, PharmD Director, Special Authority, Drug Intelligence and Optimization Branch Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health

From:

Jean Blake <jblake@parkinson.bc.ca>

Sent: To: April-01-16 5:45 PM Bouma, Susan HLTH:EX

Subject:

Duodopa therapy

Attachments:

01 - Provincial Strategy for PD - Briefing Sheet for MLA 2016-01-20.pdf; 03 - Provincial

Strategy for PD - Full for MLA 2016-01-20.pdf; PARKINSON

stats\_LHA\_HSDA\_HA\_Edit2013\_V2.xls

Importance:

High

Dear Ms. Bouma:

Dr. McKeown shared your Feb 24, 2016 letter, with me, indicating you would not consider coverage of Duodopa until AbbVie re-submits to CDR. I am writing to ask you to re-consider.

As in my e-mail to Emma Isaac from Primary Health that I copied to you, we have recently heard from a woman whose health is deteriorating daily and who would benefit greatly from this therapy.

I have been in touch with AbbVie and Lunderstand that if they do the resubmission to CDR, those provinces which provide coverage, mainly under exceptional coverage, will stop coverage until after the review process. This, of course, will harm people in these provinces so Lunderstand their decision not to do so.

AbbVie told me and as you may already know, Ontario independently reviewed DUODOPA and has listed on their formulary; Yukon also covers on Formulary. Alberta and Quebec routinely cover DUODOPA via special access programs on a case by case basis. Manitoba has recently completed their review and has agreed to cover DUODOPA on a case by case basis. Saskatchewan is considering the same.

So BC Pharmacare appears to be the outlier in not considering coverage even on a case by case basis. AbbVie indicated to me that it has a DUODOPA submission ready to send immediately for your review and that you are aware of this.

In BC, we have people who are increasingly in dire straits such as the one I have provided you details for and they would benefit greatly from access to this therapy. It is very difficult for us to stand by and see a person's life dissolve while these decisions are constrained by BC Pharmacare's need to apply policies consistently. It is also apparent that if this woman survives, she will soon be utilizing other costly aspects of the healthcare system. I have attached our current campaign which asks government to help us with crossing traditional health care barriers to build better integration across the system, improve patient outcomes and ultimately reduce costs.

So back to this poor lady. What else, if anything can we do for this patient and others like her? I understand that very few patients would qualify on an annual basis – perhaps ten? And some of those would have private coverage.

We would welcome your ideas on how to provide DUODOPA coverage in BC at least on a case by case basis and as this woman's situation is becoming more urgent daily, we ask you to respond urgently.

Thank you for your consideration and for assisting us and patients in this matter.

## Jean Blake

CEO
Parkinson Society British Columbia
600 - 890 West Pender Street | Vancouver, BC V6C 1J9
604 662 3240 | 800 668 3330 | www.parkinson.bc.ca

Connect with us!





You are not alone. We are here to help.



April is Parkinson's Awareness Month. Help spread the word.

Information provided by Parkinson Society British Columbia is intended to be used for general information only and should not replace consultation with healthcare professionals. Please speak with a qualified healthcare professional before making medical decisions.

From: Ray, Jessica L HLTH:EX on behalf of Lun, Eric HLTH:EX

Sent:April-22-16 2:34 PMTo:'jblake@parkinson.bc.ca'

Cc:Lun, Eric HLTH:EX; Ray, Jessica L HLTH:EXSubject:1051644 - Ministry of Health Response

Dear Ms. Blake:

Thank you for your email of April 1, 2016, regarding PharmaCare coverage of levodopa-carbidopa intestinal gel (Duodopa®).

I wish to provide the following information regarding the rationale for PharmaCare's decision to not include levodopa-carbidopa intestinal gel (LCIG) in the British Columbia drug formulary for treatment of advanced stages of Parkinson's disease:

As you are aware, levodopa-carbidopa intestinal gel (Duodopa®) is indicated for the treatment of patients with advanced levodopa-responsive Parkinson's disease: who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products, and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration.

In 2009, levodopa-carbidopa intestinal gel was reviewed by the Common Drug Review (CDR). The Canadian Expert Drug Advisory Committee (CEDAC), part of the CDR, released its final recommendation on July 22, 2009, recommending that participating jurisdictions, including British Columbia's PharmaCare program, not list levodopa-carbidopa intestinal gel on the formularies of their public drug plans. The link to the final recommendation is <a href="http://www.cadth.ca/media/cdr/complete/cdr">http://www.cadth.ca/media/cdr/complete/cdr</a> complete Duodopa July 24 2009.pdf.

The CEDAC gave this recommendation partly due to the manufacturer's reported incremental cost per quality adjusted life year (QALY) estimate for Duodopa®, and partly due to questions regarding the quality and applicability of the available clinical evidence. The manufacturer requested that specific results from the economic evaluation remain confidential pursuant to the CDR Confidentiality Guidelines; however other published cost per QALY estimates for levodopa-carbidopa were reported at approximately \$1 million per QALY compared to other conventional oral therapies. At the manufacturer's list price of \$166/day, the annual cost of therapy is over \$60,000 per patient per year, compared with \$3 per day for oral forms of levodopa-carbidopa.

CEDAC also had concerns with the quality of the two evaluated trials, which were open-label, of small size, had high proportions of withdrawals, and were in patient populations that did not represent those most likely to use Duodopa®. Importantly, given that the PEG-J tube administration route was the stated reason for the drug's high cost, in both studies levodopa-carbidopa was administered by a nasoduodenal tube rather than the PEG-J tube of the marketed Duodopa® product. The use of a different route of administration in the clinical trials and in the marketed product means the results of the clinical trials may not be generalizable to the patient population expected to benefit from this drug.

Subsequently, the Drug Benefit Council (DBC) reviewed levodopa-carbidopa intestinal gel and recommended to the Ministry to not list this drug on the PharmaCare formulary. The Ministry agreed with the CDR and the DBC's recommendation and decided not to list the drug.

If Abbvie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa® to the CDR. Abbvie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa® be listed, Abbvie has so far declined to provide this data to the CDR as a re-submission.

I hope this information clarifies PharmaCare policy on this matter.

Sincerely,

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization Branch
Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health

From: Jean Blake <jblake@parkinson.bc.ca>

 Sent:
 May-03-16 1:48 PM

 To:
 Lun, Eric HLTH:EX

Cc: Ray, Jessica L HLTH:EX; s.22 Bouma, Susan HLTH:EX

**Subject:** RE: 1051644 - Ministry of Health Response

Attachments: Duodopa therapy; My Issues in Living With Parkinson anon.docx; Lancet Neurology

2014 Duodopa.pdf

Follow Up Flag: Follow up Flag Status: Flagged

Thank you, Eric. I appreciate you taking the time to respond to me.

I have attached a further appeal (My issues in living with Parkinson's) from \$.22

s.22

I understand that AbbVie, the drug company has not followed procedure in getting the therapy reviewed by CDR. I met with some of their representatives and they are aware the Society is concerned about their lack of application to CDR with their newer evidence (Lancet Neurology 2014 attached) and the position it has placed people in BC in who are requiring the therapy.

Lasked them to please apply to CDR and they indicated their business office is considering this approach. If they would commit to this approach, could you perhaps negotiate a timeline with AbbVie for the application? And in the interim, would you consider providing this coverage on a case by case basis? Other provinces have reviewed the newer research and Lunderstand they have either placed it on formulary or it is available on a case by case basis.

I realize there may be many issues at play here but hope you can work to resolve them.

My concern is for people like s.22 s.22

Time may be of the essence for her,

Thank you for your reconsideration.

### Jean Blake

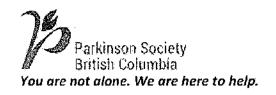
CEO

Parkinson Society British Columbia 600 - 890 West Pender Street | Vancouver, BC V6C 1J9

604 662 3240 | 800 668 3330 | www.parkinson.bc.ca

Connect with us!







April is Parkinson's Awareness Month. Help spread the word.

Information provided by Parkinson Society British Columbia is intended to be used for general information only and should not replace consultation with healthcare professionals. Please speak with a qualified healthcare professional before making medical decisions.

From: Ray, Jessica L HLTH:EX [mailto:Jessica.Ray@gov.bc.ca] On Behalf Of Lun, Eric HLTH:EX

Sent: Friday, April 22, 2016 2:34 PM

To: Jean Blake

Cc: Lun, Eric HLTH:EX; Ray, Jessica L HLTH:EX Subject: 1051644 - Ministry of Health Response

Dear Ms. Blake:

Thank you for your email of April 1, 2016, regarding PharmaCare coverage of levodopa-carbidopa intestinal gel (Duodopa®).

I wish to provide the following information regarding the rationale for PharmaCare's decision to not include levodopacarbidopa intestinal gel (LCIG) in the British Columbia drug formulary for treatment of advanced stages of Parkinson's disease:

As you are aware, levodopa-carbidopa intestinal gel (Duodopa®) is indicated for the treatment of patients with advanced levodopa-responsive Parkinson's disease: who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products, and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration.

In 2009, levodopa-carbidopa intestinal gel was reviewed by the Common Drug Review (CDR). The Canadian Expert Drug Advisory Committee (CEDAC), part of the CDR, released its final recommendation on July 22, 2009, recommending that participating jurisdictions, including British Columbia's PharmaCare program, not list levodopa-carbidopa intestinal gel on the formularies of their public drug plans. The link to the final recommendation is <a href="http://www.cadth.ca/media/cdr/complete/cdr">http://www.cadth.ca/media/cdr/complete/cdr</a> complete <a href="http://www.cadth.ca/media/cdr/complete/cdr">Duodopa July 24 2009.pdf</a>.

The CEDAC gave this recommendation partly due to the manufacturer's reported incremental cost per quality adjusted life year (QALY) estimate for Duodopa®, and partly due to questions regarding the quality and applicability of the available clinical evidence. The manufacturer requested that specific results from the economic evaluation remain confidential pursuant to the CDR Confidentiality Guidelines; however other published cost per QALY estimates for levodopa-carbidopa were reported at approximately \$1 million per QALY compared to other conventional oral therapies. At the manufacturer's list price of \$166/day, the annual cost of therapy is over \$60,000 per patient per year, compared with \$3 per day for oral forms of levodopa-carbidopa.

CEDAC also had concerns with the quality of the two evaluated trials, which were open-label, of small size, had high proportions of withdrawals, and were in patient populations that did not represent those most likely to use Duodopa®. Importantly, given that the PEG-J tube administration route was the stated reason for the drug's high cost, in both studies levodopa-carbidopa was administered by a nasoduodenal tube rather than the PEG-J tube of the marketed Duodopa® product. The use of a different route of administration in the clinical trials and in the marketed product means the results of the clinical trials may not be generalizable to the patient population expected to benefit from this drug.

Subsequently, the Drug Benefit Council (DBC) reviewed levodopa-carbidopa intestinal gel and recommended to the Ministry to not list this drug on the PharmaCare formulary. The Ministry agreed with the CDR and the DBC's recommendation and decided not to list the drug.

If Abbvie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa® to the CDR. Abbvie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa® be listed, Abbvie has so far declined to provide this data to the CDR as a re-submission.

I hope this information clarifies PharmaCare policy on this matter.

Sincerely,

Eric Lun, PharmD

Executive Director, Drug Intelligence & Optimization Branch

Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health

Page 13 to/à Page 23

Withheld pursuant to/removed as

Copyright

s.22

What Could Help

s.22

Page 25

Withheld pursuant to/removed as

s.22

From:

Ray, Jessica L HLTH:EX on behalf of Lun, Eric HLTH:EX

Sent:

May-09-16 9:16 AM

To:

'jblake@parkinson.bc.ca'

Cc: Subject: Lun, Eric HLTH:EX; Ray, Jessica L HLTH:EX 1054489 - Ministry of Health Response

Dear Ms. Blake:

Thank you for your email of May 3, 2016, in response to our email of April 22, 2016, regarding PharmaCare coverage of levodopa-carbidopa intestinal gel (Duodopa<sup>®</sup>).

I also appreciate receiving the information you forwarded from \$.22

In keeping with the health needs of British Columbians and within available resources, PharmaCare has significantly expanded the number of benefits covered since its establishment. However, PharmaCare is unable to provide reimbursement for all medications available to assist individuals with their health needs. Given the fiscal pressures affecting PharmaCare and the broader health system, the program has limited capacity to expand coverage for new benefits and must be very selective in that regard.

Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases.

As before, because the manufacturer has new research to present on the drug's efficacy, safety, or cost effectiveness, they are welcome to resubmit to the national CDR for reassessment. Approving coverage requests Duodopa<sup>®</sup> on exceptional basis without conducting a proper review or reassessment would also be unfair to the vast majority of drug manufacturers who do respect the established drug review process, and also other patients who may also be seeking coverage.

I realize that this may not be the response you were hoping for but I hope you understand the rationale for this approach.

Thank you for the opportunity to respond.

Sincerely,

Eric Lun, PharmD

Executive Director, Drug Intelligence & Optimization Branch

Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health

From:

McCormick, Erika HLTH:EX

Sent:

June-09-16 9:23 AM

To:

Minister, HLTH HLTH:EX

Subject:

FW s.22

& Duodopa therapy

Attachments:

Appeal to Minister Lake...22

pdf; Lancet Neurology 2014 Duodopa.pdf

Importance:

High

Categories:

Assign

From: Morris, Kirsty L [mailto:Kirsty.Morris@leq.bc.ca]

**Sent:** Thursday, June 9, 2016 9:21 AM

To: McCormick, Erika HLTH:EX

Subject: FW s.22

& Duodopa therapy

Importance: High

From: Jean Blake [mailto:jblake@parkinson.bc.ca]

Sent: June 8, 2016 4:41 PM

To: Lake.MLA, Terry < Terry.Lake.MLA@leg.bc.ca>

Cc: Walman, Barbara J HLTH: EX < Barbara, Walman@gov.bc.ca >; \$.22

McKeown, Martin

(martin.mckeown@ubc.ca) < martin.mckeown@ubc.ca>

Subject: s.22

& Duodopa therapy

Importance: High

Dear Honorable Lake – thank you again for meeting with PSBC representatives on April 11 regarding a provincial strategy for the management of Parkinson's disease. At the time, ‡ also provided a letter to you on behalf of S.22 Further to that letter, please see the attached special request.

#### Jean Blake

CEO

Parkinson Society British Columbia 600 - 890 West Pender Street | Vancouver, BC V6C 1J9 604 662 3240 | 800 668 3330 | www.parkinson.bc.ca

Connect with us!



Parkinson Society British Columbia

You are not alone. We are here to help.



Register now for <u>Parkinson SuperWalk!</u> You can help make a difference for 13,300 British Columbians, and their loved ones, affected by Parkinson's disease.

Information provided by Parkinson Society British Columbia is intended to be used for general information only and should not replace consultation with healthcare professionals. Please speak with a qualified healthcare professional before making medical decisions.

www.parkinson.bc.ca

890 West Pender Street, Suite 500, Vançouwer, 90 V00 1.19 + Tel-604 562,3240 + Fax: 504,687,1327 + Toll-free (Canada and US): 1-800 568 3330

June 8, 2016

The Honorable Terry Lake BC Minister of Health

Dear Honorable Lake:

Re;s.22 and Duodopa therapy

Sir, we met with you on April 11 (International Parkinson's Awareness Day). Thank you again for this opportunity to present our request for the development of a provincial strategy for the management of Parkinson's disease.

We left with you a note from s.22 s.22

The recommended therapy for her is Duodopa therapy which, although medically available in BC, is not covered by BC Pharmacare. One patient to date has had the procedure and has coverage under a private health care plan. Unfortunately, \$.22 s 22.

BC Pharmacare has indicated they will not consider new evidence that AbbVie, the drug company has offered to them. As is accepted practice, they have indicated that AbbVie needs to make a submission through the Common Drug Review (CDR) process for consideration. AbbVie has indicated they will not do this as they have already made successful submissions to other provinces and obtained coverage of the therapy in Ontario, Quebec, Alberta and Manitoba. As there are very few patients in BC that will require this therapy (Dr. McKeown, Director of the UBC Movement Disorder Clinic estimates 10 to 12 patients per year, some of whom will have private plans that cover the cost), I understand from AbbVie they feel there is not a good business reason for them to submit to CDR.

While we support the need for process, in the meantime <sup>s.22</sup> is caught in between BC. Pharmacare's request that AbbVie follow accepted process and AbbVie having gained approval in other provinces through a direct review of their new evidence (see attached).

The Society requested that BC Pharmacare review this evidence and at least, on a case by case approach, review and approve Duodopa therapy for patients in need of this life changing and/or life saving therapy.s.22 s.22

Although Duodopa will 'cost' PharmaCare, it will save money in other parts of healthcare. As integrating the system is part of the Ministry's strategic plan, we hope you will consider the following in making a decision.

s.22

You are not alone. We are here to help.

Thank you for your kind consideration.

Sincerely,

Jean Blake, CEO

cc. Barbara Walman, Pharmacare s.22

Dr. Martin McKeown, UBC Movement Disorder Clinic

From:

Stevens, Sandy HLTH:EX on behalf of hith Med Ben & Pharm Services Correspondence

Unit HLTH:EX

Sent:

June-30-16 1:52 PM

To:

'jblake@parkinson.bc.ca'

Subject:

Ministry of Health Response 1057244

Importance:

High.

1057244

Ms. Jean Blake jblake@parkinson.bc.ca

Dear Ms. Blake:

Thank you for your email and attached letter of June 8, 2016, regarding PharmaCare coverage of levodopa-carbidopa intestinal gel (Duodopa®). Honourable Terry Lake, Minister of Health, has asked me to respond on his behalf. It was also a pleasure to meet with you as part of the BC PharmaCare Coalition last week.

As per Eric Lun's prior response to you of May 9, 2016, in keeping with the health needs of British Columbians and within available resources, PharmaCare has significantly expanded the number of benefits covered since its establishment. However, PharmaCare is unable to provide reimbursement for all medications available to assist individuals with their health needs. Given the fiscal pressures affecting PharmaCare and the broader health system, the program has limited capacity to expand coverage for new benefits and must be very selective in that regard.

Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases.

As before, if Abbvie has new research to present on the drug's efficacy, safety, or cost effectiveness, I would strongly encourage them to resubmit to the national Common Drug Review for reassessment. This would benefit our decision making in BC and I understand that this has also been requested by other jurisdictions.

Approving coverage requests for Duodopa® on exceptional basis without conducting a proper review or reassessment would be unfair to the drug manufacturers who do respect the established drug review process, and to other patients who may also be seeking coverage.

I am sure that this is not the response you were hoping for, and I appreciate your bringing this to my attention.

Sincerely,

Barbara Walman Assistant Deputy Minister Medical Beneficiary and Pharmaceutical Services

pc: Honourable Terry Lake

From: Jean Blake [mailto:jblake@parkinson.bc.ca]

Sent: June 8, 2016 4:41 PM

To: Lake.MLA, Terry < Terry.Lake.MLA@leg.bc.ca>

Cc: Walman, Barbara J HLTH:EX <Barbara.Walman@gov.bc.ca>\$.22

(martin.mckeown@ubc.ca) <martin.mckeown@ubc.ca>

Subject: s.22

.& Duodopa therapy

Importance: High

Dear Honorable Lake – thank you again for meeting with PSBC representatives on April 11 regarding a provincial strategy for the management of Parkinson's disease. At the time, I also provided a letter to you on behalf of Further to that letter, please see the attached special request.

McKeown, Martin

#### Jean Blake

CEO

Parkinson Society British Columbia 600 - 890 West Pender Street | Vancouver, BC V6C 1J9 604 662 3240 | 800 668 3330 | www.parkinson.bc.ca

Connect with us!





You are not alone. We are here to help.



Register now for <u>Parkinson SuperWalk!</u> You can help make a difference for 13,300 British Columbians, and their loved ones, affected by Parkinson's disease.

Information provided by Parkinson Society British Columbia is intended to be used for general information only and should not replace consultation with healthcare professionals. Please speak with a qualified healthcare professional before making medical decisions.







1057084

Director

Pacific Parkinson's Research Centre

Faculty of Medicine

Vancouver Hospital and Health Sciences Centre

Purdy Pavilian 2221 Wesbrook Mall

Vancouver, B.C. Canada, V6T 285

Martin J. McKeown, BEng, MD, FRCP(C) PPRI/UBC Chair in Parkinson's Disease Research Professor, Dept. of Medicine (Neurology) Associate Member, Dept of ECE, UBC University of British Columbia

June 3, 2016

#### Ms. Susan Bouma

Director, Special Authority, Drug Intelligence and Optimization Branch
Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health
3-1, 1515 Blanshard St.
Victoria BC V8W3C8
Susan.Bouma@gov.bc.ca

Dear Ms. Bouma,

JUN 0 / 2016

MINISTRY OF HEALTH
PHARMACARE (VICTORIA)
BPECIAL AUTHORITY

I am writing to request PharmaCare approval for levodopa/carbidopa intestinal gel ("LCIG" brand name "Duodopa") for our patient \$.22 s.22

Page 1 of 3
Tel.(604)822-7516 Fax. (604)822-7866 Email: martin.mckeown@ubc.ca



s.22

Page 2 of 3
Tel.(604)822-7516 Fax. (604)822-7866 Email: martin.mckeown@ubc.ca



s.22

As per our meeting with yourself and Mr. Lun on December 7, 2015 I would like to reassure PharmaCare that the use of LCIG managed by the Movement Disorders Clinic at UBC will be *strictly limited to a very small number of patients that have no other therapeutic options*. Recommendation for LCIG therapy is not made solely on the patient's clinical presentation. The UBC/VCH Duodopa program further assesses and evaluates all patients on a number of factors that will affect the patient's success with the therapy. For example, the patient needs to have a supportive partner/person in their life that is willing and able to learn and aid in the use of the therapy. Additionally, the patient and support person's commitment are assessed during a trial period with the pump before a referral to a gastroenterologist is made. There a number of assessments made that will further reduce the number of qualified applications for this therapy. I would also like to remind PharmaCare that a pivotal double-blind RCT was published in the *Lancet Neurology* on December 20, 2013 confirming that "Continuous delivery of levodopa-carbidopa with an intestinal gel offers a promising option for control of advanced Parkinson's disease with motor complications. Benefits noted with intestinal gel delivery were of a greater magnitude than were those obtained with medical therapies to date..." and are "in a similar range as reported with deep brain stimulation."

Thank you for your time to meet with Dr. Hinnell and me on December 7, 2015. We were disappointed that Pharmacare has made the decision to decline approval for LCIG Formulary coverage or at a minimum to accept a submission from the manufacturer for review (unlike Ontario). However we expect that BC should reimburse LCIG on an exceptional basis as other provinces do where Movement Disorder Clinics have expertise with LCIG. If our patient were a resident of Alberta, Manitoba, Ontario, Quebec or Yukon my patient would successfully gain public reimbursement for LCIG.

Thank you for consideration of this request and I would appreciate hearing back from you within 7-10 business days as there is urgency to this request.

Sincerely yours,

Martin J. Walson.

Cc: Honourable Terry Lake, Minister of Health <patient identifiers redacted>

<sup>1</sup> C Warren Olanow et al "Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomised, controlled, double-blind, double-dummy study." The Lancet Neurology, 2014 Feb;13(2):141-9. doi: 10.1016/S1474-4422(13)70293-X

Page 3 of 3

Tel.(604)822-7516 Fax. (604)822-7866 Email: martin.mekeown@ubc.ca



June 27, 2016 1057084

Dr. Martin J. McKeown
Director, Pacific Parkinson's Research Centre
Faculty of Medicine
Vancouver Hospital and Health Sciences Centre
Purdy Pavilion 2221 Wesbrook Mali
Vancouver BC V6T 2B5

Dear Dr. McKeown:

Thank you for your letter of June 3, 2016, regarding PharmaCare coverage of levodopa-carbidopa intestinal gel (Duodopa<sup>®</sup>).

I also appreciate receiving the information you forwarded regarding \$.22 s.22

In keeping with the health needs of British Columbians and within available resources, PharmaCare has significantly expanded the number of benefits covered since its establishment. However, PharmaCare is unable to provide reimbursement for all medications available to assist individuals with their health needs. Given the fiscal pressures affecting PharmaCare and the broader health system, the program has limited capacity to expand coverage for new benefits and must be very selective in that regard. At the manufacturer's list price of \$166/day, the annual cost of therapy with Duodopa® is over \$60,000 per patient per year, compared with \$3 per day for other drug therapies or \$1433.86 for a deep brain stimulation procedure.

Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases.

As per our previous correspondence, if the manufacturer has new research to present on the drug's efficacy, safety, or cost-effectiveness, they are welcome to resubmit to the national CDR for reassessment. Approving coverage requests for Duodopa® on exceptional basis without conducting a proper review or reassessment would be unfair to the vast majority of drug manufacturers who do respect the established drug review process, and also to other patients who may also be seeking coverage.

...2

Ministry of Health

Telephone: 250 952-3234

Page 36 of 77 HTH-2016-65265

I realize that this may not be the response you were hoping for but I hope you understand the rationale for this approach.

Thank you for the opportunity to respond.

Sincerely,

Susan Bouma, B.Sc. (Pharm), R.Ph, PharmD Director, Special Authority, Drug Intelligence and Optimization Branch Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health

From:

Will, Jordan HLTH:EX

Sent:

July-19-16 4:52 PM

To:

**Docs Processing HLTH:EX** 

Subject:

INCOMING URGENT: Injectable Duodopa

Ηi,

Could we please assign to MBPSD a request for an update on injectable duodopa (Parkinson's medication) and the availability of any special exemptions for the drug.

The MO has asked for the update by tomorrow midday.

Thank you,

JORDAN WILL

a/Manager, Executive Program Operations Office of the Deputy Minister Ministry of Health

P: 250.952.1908 [C: 250.217.3655 | Jordan, will@gov.bc.ca

### INFORMATION BULLETS

Cliff# 1059192 – Honourable Terry Lake, Minister re: request for updated information about PharmaCare coverage of levodopa-carbidopa intestinal gel (Duodopa®) and policy for providing exceptional Special Authority (SA) coverage of this medication.

## REQUEST:

Request for information bullets re updated information about PharmaCare coverage of levodopa-carbidopa intestinal gel (Duodopa<sup>®</sup>), and policy for providing exceptional Special Authority (SA) coverage of this medication.

## BACKGROUND:

- Levodopa-carbidopa intestinal gel (Duodopa<sup>®</sup>) is indicated for the treatment of patients with advanced levodopa-responsive Parkinson's disease:
  - whom do not have satisfactory control of severe, debilitating motor fluctuations and hyper-dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products: and
  - o for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration.

#### FINDINGS:

- In 2009, levodopa-carbidopa intestinal gel was reviewed for the treatment of Parkinson's disease by the Common Drug Review (CDR). The Canadian Expert Drug Advisory Committee (CEDAC), part of the CDR, released its final recommendation on July 22, 2009, recommending that participating jurisdictions, including British Columbia's PharmaCare program, not list levodopa-carbidopa intestinal gel on the formularies of their public drug plans. The link to the final recommendation is <a href="http://www.cadth.ca/media/cdr/complete/cdr">http://www.cadth.ca/media/cdr/complete/cdr</a> complete Duodopa July 24 2009.pdf.
- The CEDAC gave this recommendation due to the manufacturer's reported incremental cost per quality adjusted life year (QALY) estimate for Duodopa®, and also due to questions regarding the quality and applicability of the available clinical evidence.
- The manufacturer requested that specific results from the economic evaluation remain confidential pursuant to the CDR Confidentiality Guidelines; however other published cost per QALY estimates for levodopa-carbidopa were reported at approximately \$1 million per QALY compared to other conventional oral therapies. At the manufacturer's list price of \$166/day, the annual cost of therapy is over \$60,000 per patient per year, compared with \$3 per day for oral forms of levodopa-carbidopa.
- CEDAC also had concern with the quality of the two evaluated trials. Which were openlabel, of a small size, had high proportions of withdrawals and were in patient populations that did not represent those most likely to use Duodopa<sup>®</sup>.

- It is important to note that given the PEG-J tube administration route was stated as the reason for the drug's high cost, in both studies the levodopa-carbidopa was administered by a nasoduodenal tube not the PEG-J tube. The use of a different route of administration in the clinical trials and in the marketed product means the results of the clinical trials may not be generalizable to the patient population expected to benefit from this drug.
- Subsequently, the Drug Benefit Council (DBC) reviewed levodopa-carbidopa intestinal gel and recommended to the Ministry to not list this drug on the PharmaCare formulary. The Ministry agreed with the CDR and the DBC's recommendation and decided not to list the drug.
- If Abbvie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa® to the CDR. Abbvie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa® be listed, Abbvie has so far declined to provide this data to the CDR as a re-submission.
- Given the fiscal pressures affecting PharmaCare and the broader health system, the
  program has limited capacity to expand coverage for new benefits and must be very
  selective in that regard.
- Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases. Therefore, approving coverage requests for Duodopa<sup>®</sup> on exceptional basis without conducting a proper review or reassessment would be unfair to the drug manufacturers who do respect the established drug review process, and to other patients who may also be seeking coverage.

### SUGGESTED MLA RESPONSE:

- In 2009, levodopa-carbidopa intestinal gel was reviewed for the treatment of Parkinson's
  disease by the Common Drug Review (CDR). The Canadian Expert Drug Advisory
  Committee (CEDAC) as a part of the CDR, released its final recommendation on
  July 22, 2009, recommending that participating jurisdictions, including
  British Columbia's PharmaCare program, not list levodopa-carbidopa intestinal gel on
  the formularies of their public drug plans.
- The link to the final recommendation is <a href="http://www.cadth.ca/media/edr/complete/cdr">http://www.cadth.ca/media/edr/complete/cdr</a> complete Duodopa July 24 2009.pdf.
- For further details about the rationale of the CDR recommendation to not list this medication, please see the background information above.
- Subsequently, the Drug Benefit Council (DBC) reviewed levodopa-carbidopa intestinal gel and recommended to the Ministry to not list this drug on the PharmaCare formulary. The Ministry agreed with the CDR and the DBC's recommendation and decided not to list the drug.
- If Abbvie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa® to

- the CDR. Abbvie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa<sup>®</sup> be listed, Abbvie has so far declined to provide this data to the CDR as a re-submission.
- I wish to advise that PharmaCare has significantly expanded the number of benefits covered since its establishment. However, PharmaCare is unable to provide reimbursement for all medications available to assist individuals with their health needs.
- Given the fiscal pressures affecting PharmaCare and the broader health system, the
  program has limited capacity to expand coverage for new benefits and must be very
  selective in that regard.
- Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases. Therefore, approving coverage requests for Duodopa<sup>®</sup> on exceptional basis without conducting a proper review or reassessment would be unfair to the drug manufacturers who do respect the established drug review process, and to other patients who may also be seeking coverage.

**Program ED/Branch/Division:** Eric Lun/Drug Intelligence and Optimization Branch/Medical Beneficiary and Pharmaceutical Services Division

Date: July 20, 2016

From:

McClymont, Brenda HLTH:EX

Sent:

November-15-16 10:44 AM

To: Cc: Docs Processing HLTH:EX Stevens, Sandy HLTH:EX

Subject:

1073945 - MLA Laurie Throness - Duodopa/ Parkinson's and what BC currently does for

Parkinson's x ref 1059192

Attachments:

RE: ETA??? Parkinsons stuff; 1059192 Info Bullets re update on PharmaCare coverage of

Duodopa.docx

The attached does not address what the province currently does for Parkinson's. Would you like to assign formally?

From: Docs Processing HLTH:EX

Sent: Tuesday, November 15, 2016 10:14 AM

To: Stevens, Sandy HLTH:EX; McClymont, Brenda HLTH:EX

Cc: Docs Processing HLTH:EX

Subject: MLA Throness - Duodopa/ Parkinson's x ref 1059192

Just one more thing, please. Do the bullets address the 2<sup>nd</sup> part of the MO's request: what the province currently does for Parkinson's?

Thanks so much,

Kathy Simonson Program Coordinator / Executive Operations / DMO / Ministry of Health 5-3 4515 Blanshard St. Victoria BC V8W 3C8 Telephone 250 952-0998

### kathy.simonson@gov.bc.ca

Warning: This email is intended only for the use of the individual or organization to other it is addressed. If may contain information that is privileged or confidential. Any distribution, disclosure, copying, or other use by anyone else is strictly prohibited. If you more received this in error, please telephone or e-mail the sender incondingly and delete the mossage.

From: Stevens, Sandy HLTH:EX

**Sent:** Tuesday, November 15, 2016 10:06 AM

To: Docs Processing HLTH: EX

Cc: McClymont, Brenda HLTH:EX; Stevens, Sandy HLTH:EX

Subject: FW: MLA Throness - Duodopa/ Parkinson's x ref 1059192

Hi Kathy:

Tijana confirmed that they are fine as it @

Cheers Sandy

From: Docs Processing HLTH:EX

Sent: Tuesday, November 15, 2016 9:42 AM

To: McClymont, Brenda HLTH:EX; Stevens, Sandy HLTH:EX

Cc: Docs Processing HLTH: EX

Subject: MLA Throness - Duodopa/ Parkinson's x ref 1059192

Do they need to be fine-tuned for MLA Throness?

Thanks so much,

Kathy Simonson Program Coordinator / Executive Operations / DMO / Ministry of Health 5-3 1515 Blanshard St. Victoria BC V8W-3C8 Telephone 250 952-0998

#### kathy.simonson@gov.bc.ca

Warning: This email is intended only for the use of the initividual or organization to adjount it is addressed. If may contain information that is privileged or confidential. Any distribution, disclosure, copying, or other use by anyone else is strictly prohibited. If you have received this in error, place telephone or a mail the sender immediately and delete the message.

From: Stevens, Sandy HLTH: EX

Sent: Tuesday, November 15, 2016 9:38 AM

To: Docs Processing HLTH:EX

Cc: McClymont, Brenda HLTH:EX; Stevens, Sandy HLTH:EX

Subject: FW: MLA Throness - Duodopa/ Parkinson's x ref 1059192

Hi Kathy:

Tijana Fazlagic has confirmed that this attached bullets are still up to date.

Cheers Sandy

From: Docs Processing HLTH:EX

Sent: Monday, November 14, 2016 4:26 PM

To: McClymont, Brenda HLTH: EX; Stevens, Sandy HLTH: EX

Cc: Docs Processing HLTH:EX

**Subject:** MLA Throness - Duodopa/ Parkinson's x ref 1059192

Back in July, MBPSD staff created the attached document regarding Doodopa and Parkinson's Disease. Our MO has asked staff to review the attached and make sure it is still up to date.

Please confirm updates and I will create a new assignment.

Thanks so much,

Kathy Simonson Program Coordinator / Executive Operations / DMO / Ministry of Health 5-3 1515 Blanshard St, Victoria BC V8W 3C8 Telephone 250 952-0998

#### kathy.simonson@gov.bc.ca

Warning: This email is burneded only for the use of the individual or organization to whom it is addressed. It may contain information that is privileged or confidential. Any distribution, disclosure, copying, or other use by anyone else is strictly probabiled. If you have received this in error, please telephone or esmall the sender immediately and delete the missiage.

From: Robertson, Derek HLTH:EX

Sent: Monday, November 14, 2016 4:21 PM

**To:** Docs Processing HLTH:EX **Cc:** Will, Jordan HLTH:EX

Subject: MLA Throness - Duodopa/ Parkinson's x ref 1059192

This is the one.

Can we go back and review this document to make sure it is still up-to-date? Also, Can we prepare bullets on what the province currently does for Parkinson's for MEA Throness?

Thanks,

Derek

From: Docs Processing HLTH:EX

Sent: Monday, November 14, 2016 3:42 PM

To: Robertson, Derek HLTH:EX

Cc: Will, Jordan HLTH:EX; Docs Processing HLTH:EX

Subject: RE: Duodopa

Is this the one?

Thanks so much,

Kathy Simonson
Program Coordinator / Executive Operations / DMO / Ministry of Health
5-3 1515 Blanshard St, Victoria BC V8W 3C8
Telephone 250 952-0998

#### kathy.simonson@gov.bc.ca

Warning: This email is intended only for the use of the individual or organization to whom it is addressed. It may contain information that is provileged or confidential, Any distribution, disclosure, copying, or other use by anyone also is strictly prohibited, if you have received this in error, please telephone or e-mail the sender immediately and delete the message.

From: Robertson, Derek HLTH:EX

Sent: Monday, November 14, 2016 3:37 PM

To: Docs Processing HLTH:EX
Cc: Will, Jordan HLTH:EX
Subject: Duodopa

Hey Docs,

I know a couple months ago we dealt with a request from MLA Dalton in regards to duodopa. Can you find this information and send it to me?

Thanks,

Derek

#### Derek Robertson

Executive Assistant to the Honourable Terry Lake Minister of Health Office: (250) 953-3547

Derek.Robertson@gov.bc.ca

### INFORMATION BULLETS

### Cliff# 1073945

## REQUEST:

• Mr. Laurie Throness, MLA, Chilliwack-Hope, requested information regarding what coverage PharmaCare currently provides for treatments for Parkinson's disease.

## BACKGROUND:

- PharmaCare provides coverage for the following medications commonly used for treatment of Parkinson's disease as Regular Benefits:
  - o levodopa-benserazide (Prolopa®);
  - o levodopa-carbidopa (Sinemet® and generics);
  - o bromocriptine (generic versions);
  - o rasagiline (generics);
  - o selegiline (generics);
  - o amantadine (PMS-amantadine capsules and syrup);
  - o benztropine (generics); and
  - o trihexyphenidyl (generics).
- PharmaCare provides coverage for the following medications for treatment of Parkinson's disease as Limited Coverage benefits:
  - o levodopa-carbidopa-entacapone (Stalevo®);
  - o entacapone (Comtan®);
  - o pramipexolc (Mirapex® and generics); and
  - o ropinirole (Requip® and generics).
- Levodopa-carbidopa intestinal gel (Duodopa<sup>®</sup>) is indicated for the treatment of patients with advanced levodopa-responsive Parkinson's disease:
  - Those who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products; and
  - Those who the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration.

### FINDINGS:

- In 2009, levodopa-carbidopa intestinal gel was reviewed for the treatment of Parkinson's
  disease by the Common Drug Review (CDR). The Canadian Expert Drug Advisory
  Committee (CEDAC), part of the CDR, released its final recommendation on July 22, 2009,
  recommending that participating jurisdictions, including BC's PharmaCare program, not list
  levodopa-carbidopa intestinal gel on the formularies of their public drug plans. The link to
  the final recommendation is
  - http://www.cadth.ca/media/cdr/complete/cdr\_complete\_Duodopa\_July\_24\_2009.pdf.
- The CEDAC gave this recommendation due to the manufacturer's reported incremental cost per quality adjusted life year (QALY) estimate for Duodopa®, and also due to questions regarding the quality and applicability of the available clinical evidence.

- The manufacturer requested that specific results from the economic evaluation remain confidential pursuant to the CDR Confidentiality Guidelines; however other published cost per QALY estimates for levodopa-carbidopa were reported at approximately \$1 million per QALY compared to other conventional oral therapies. At the manufacturer's list price of \$166/day, the annual cost of therapy is over \$60,000 per patient per year, compared with \$3 per day for oral forms of levodopa-carbidopa.
- CEDAC also had concern with the quality of the two evaluated trials. Which were open-label, of a small size, had high proportions of withdrawals and were in patient populations that did not represent those most likely to use Duodopa®.
- It is important to note that given the PEG-J tube administration route was stated as the reason for the drug's high cost, in both studies the levodopa-carbidopa was administered by a nasoduodenal tube not the PEG-J tube. The use of a different route of administration in the clinical trials and in the marketed product means the results of the clinical trials may not be generalizable to the patient population expected to benefit from this drug.
- Subsequently, the Drug Benefit Council (DBC) reviewed levodopa-carbidopa intestinal gel
  and recommended to the Ministry to not list this drug on the PharmaCarc formulary. The
  Ministry agreed with the CDR and the DBC's recommendation and decided not to list the
  drug.
- If Abbvie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa<sup>®</sup> to the CDR. Abbvie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa<sup>®</sup> be listed, Abbvie has so far declined to provide this data to the CDR as a re-submission.
- Given the fiscal pressures affecting PharmaCare and the broader health system, the program
  has limited capacity to expand coverage for new benefits and must be very selective in that
  regard.
- Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases. Therefore, approving coverage requests for Duodopa<sup>®</sup> on exceptional basis without conducting a proper review or reassessment would be unfair to the drug manufacturers who do respect the established drug review process, and to other patients who may also be seeking coverage.

## SUGGESTED MLA RESPONSE:

- In 2009, levodopa-carbidopa intestinal gel was reviewed for the treatment of Parkinson's
  disease by the CDR. CEDAC as a part of the CDR, released its final recommendation on
  July 22, 2009, recommending that participating jurisdictions, including British Columbia's
  PharmaCare program, not list levodopa-carbidopa intestinal gel on the formularies of their
  public drug plans.
- The link to the final recommendation is http://www.cadth.ca/media/cdr/complete/cdr\_complete\_Duodopa\_July\_24\_2009.pdf.
- For further details about the rationale of the CDR recommendation to not list this medication, please see the background information above.
- Subsequently, the DBC reviewed levodopa-carbidopa intestinal gel and recommended to the Ministry to not list this drug on the PharmaCare formulary. The Ministry agreed with the CDR and the DBC's recommendation and decided not to list the drug.

- If Abbvie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa<sup>®</sup> to the CDR. Abbvie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa<sup>®</sup> be listed, Abbvie has so far declined to provide this data to the CDR as a re-submission.
- I wish to advise that PharmaCare has significantly expanded the number of benefits covered since its establishment. However, PharmaCare is unable to provide reimbursement for all medications available to assist individuals with their health needs.
- Given the fiscal pressures affecting PharmaCare and the broader health system, the program
  has limited capacity to expand coverage for new benefits and must be very selective in that
  regard.
- Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases. Therefore, approving coverage requests for Duodopa® on exceptional basis without conducting a proper review or reassessment would be unfair to the drug manufacturers who do respect the established drug review process, and to other patients who may also be seeking coverage.
- PharmaCare provides coverage for the following medications commonly used for treatment of Parkinson's disease as Regular Benefits:
  - o levodopa/benserazide (Prolopa®);
  - o levodopa/carbidopa (Sinemet® and generics);
  - o bromocriptine (generic versions);
  - o rasagiline (generics);
  - o selegiline (generics);
  - o amantadine (PMS-amantadine capsules and syrup);
  - o benztropine (generics); and
  - o trihexyphenidyl (generics).
- PharmaCare provides coverage for the following medications for treatment of Parkinson's disease as Limited Coverage benefits:
  - o levodopa/carbidopa/entacapone (Stalevo®);
  - o entacapone (Comtan®);
  - o pramipexole (Mirapex® and generics); and
  - o ropinirole (Requip® and generics).

Program ED/Branch/Division: Eric Lun/Drug Intelligence and Optimization /

Medical Beneficiary & Pharmaceutical Services Division

Date: November 23, 2016

From: Docs Processing HLTH:EX

Sent: December-20-16 8:31 AM
To: Robertson: Derek HLTH:EX

Cc: Docs Processing HLTH:EX; Fougere, Brianna HLTH:EX

Subject: URGENT Answer needed: 1073945 - MLA Laurie Throness - Duodopa/ Parkinson's and

what BC currently does for Parkinson's x ref 1059192

#### Good morning Derek,

Here is the information prepared by MBPSD for you inquiry below.

Below is a table that Kim Graff provided, that shows which provinces provide Duodopa as a benefit.

Benefit	Non-Bénefit
Ontario (Exceptional Access Program)	Alberta
Yukon (Exceptional)	Saskatchewan
	Manitoba
	Quebec
	New Brunswick
	Nova Scotia
	Newfoundland and Labrador
	PEI
	NIHB

#### Thank you!

#### Debra Hartien

Team Assistant, Docs Processing, Executive Operations, Deputy Minister's Office.

1515 Blanshard Street, Victoria, BC, V8W 3C8 | Phone: 250.952,1040

Warning: This email is intended only for the use of the indicidual or organization to adams it is addressed, it may contain information that is privileged or confidential. Any distribution, disclosure, copying, or other use by anyone clse is strictly prohibited. If you have received this in error, please telephone or e-mail the sender immediately and actete the message.

From: Robertson, Derek HLTH:EX

**Sent:** Monday, December 19, 2016 12:37 PM

To: Docs Processing HLTH:EX

Cc: Will, Jordan HLTH:EX; Stearn, Anne HLTH:EX; Michell, Jennifer HLTH:EX; Fougere, Brianna HLTH:EX

**Subject:** RE: 1073945 - MLA Laurie Throness - Duodopą/ Parkinson's and what BC currently does for Parkinson's x ref 1059192

Hey Docs,

Can we get ASAP confirmation on whether any other provinces/territories currently cover Duodopa? Need by the end of the day,

#### Derek

From: Docs Processing HLTH:EX

Sent: Thursday, November 24, 2016 11:18 AM

To: Robertson, Derek HLTH:EX

Cc: Docs Processing HLTH:EX; Will, Jordan HLTH:EX; Steam, Anne HLTH:EX; Michell, Jennifer HLTH:EX

**Subject:** 1073945 - MLA Laurie Throness - Duodopa/ Parkinson's and what BC currently does for Parkinson's x ref 1059192

Hi Derek:

MBPSD has provided the attached updated information in response to your request below. This has been approved by Barbara Walman, ADM.

Thanks so much,

Kathy Simonson Program Coordinator / Executive Operations / DMO / Ministry of Health 5-3 1515 Blanshard St, Victoria BC V8W 3CB Telephone 250 952-0998

#### kathy.simonson@gov.bc.ca

Warning: This email is intended only for the use of the individual or organization to schom it is addressed. It may contain information that is provileged or confidential. Any distribution, disclusive, copyring, or other use by anyone else is strictly prohibited. If you tune received this in error, please telephone or a mail the sender immédiafely and delete the mossage.

From: Robertson, Derek HLTH:EX

Sent: Monday, November 14, 2016 4:21 PM

To: Docs Processing HLTH: EX Cc: Will, Jordan HLTH:EX

Subject: MLA Throness - Duodopa/ Parkinson's x ref 1059192

grand process of the contract of the contract

This is the one.

Can we go back and review this document to make sure it is still up-to-date? Also, Can we prepare bullets on what the province currently does for Parkinson's for MLA Throness?

Thanks. Derek

From: Docs Processing HLTH:EX

Sent: Monday, November 14, 2016 3:42 PM

To: Robertson, Derek HLTH:EX

Cc: Will, Jordan HLTH:EX; Docs Processing HLTH:EX

Subject: RE: Duodopa

Is this the one?

Thanks so much.

Kathy Simonson Program Coordinator / Executive Operations / DMO / Ministry of Health 5-3 1515 Blanshard St. Victoria BC V8W 3C8 Telephone 250 952-0998

#### kathy.simonson@gov.bc.ca

Warning: This email is intended only for the use of the individual or organization to whom it is addressed. It may contain information that is privileged or confidential. Any distribution, disclosure, copying, or other use by anyone else is strictly prohibited. If you have received this in error, please telephone or e-mad the sonder framediately and delete the message.

From: Robertson, Derek HLTH:EX

Sent: Monday, November 14, 2016 3:37 PM

To: Docs Processing HLTH: EX Cc: Will, Jordan HLTH: EX. Subject: Duodopa

Hey Docs,

I know a couple months ago we dealt with a request from MLA Dalton in regards to duodopa. Can you find this information and send it to me?

Thanks.

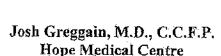
Derek

Derek Robertson

Executive Assistant to the Honourable Terry Lake

Minister of Health Office: (250) 953-3547

Derek.Robertson@gov.bc.ca



735 - 4TH AVENUE PO BOX 1000 HOPE, BC VOX (LO

PHONE: 604-869-5648 FAX: 604-869-2459

Laurie Throness
Chilliwack-Hope
British Columbia Liberal Party
laurie throness MLA@leg.bc.ca
East Annex, Parliament Buildings
Victoria, BC
V8V 1X4

30 Nov 2016

Dear Mr. Laurie Throness,

Re: DUODOPA® therapy for advanced Parkinson's disease

I am writing to ask for your support in the public funding of DUODOPA® therapy for people with advanced Parkinson's disease. The drug is publicly funded in most Canadian provinces, putting British Columbians living with this condition at a detrimental disadvantage by denying them access to a life-changing therapy.

I am aware that , DUODOPA® is expensive. It is offered at a cost of \$60,000 per year per patient; however, there are very few patients in British Columbia requiring the therapy. The Movement Disorders Clinic at the Diavad Mowafaghian Centre for Brain Health, University of British Columbia, estimates there are currently 10 to 12 patients requiring urgent access to this drug. I am currently looking after one such patient in my practice in Hope; BC.

In receiving the DUODOPA® therapy, patients will experience considerable relief of pain; have better control over severe and dangerous balance issues; be removed from the fear of breathing and swallowing issues; and be provided with support with other non-movement (non-motor) problems.

The payoff for the health care system will be fewer hospitalizations, fewer emergency visits and avoidance of early admissions to long term care.

For a number of these patients, access to DUODOPA® therapy has become a life or death issue and a palliative measure. I urge you to work with BC Pharma Care to fund this therapy at least on a case by case basis.

As a family physician in Hope, BC, I have<sup>8.22</sup> s.22

s.22

. I would therefore implore you to advocate at the Ministry of Health level, to add

DUODOPA therapy for qualified Parkinson's patient.

Dr. Josh Greggain, B.Sf. M.D., C.C.F.P.

Médical Director, Hope Medical Centre Site Medical Director, Fraser Canyon Hospital

Hope, BC

Page 51

Withheld pursuant to/removed as

From:

Walman, Barbara J. HLTH:EX

Sent: To: November-24-16 8:26 AM McClymont, Brenda HLTH:EX

Subject:

1074892: DUODOPA® therapy for advanced Parkinson's disease

From: s.22

Sent: Wednesday, November 23, 2016 6:15 PM

To: Walman, Barbara J. HLTH:EX

Subject: DUODOPA® therapy for advanced Parkinson's disease

Barbara Walman

Re: DUODOPA® Therapy for Advanced Parkinson's Disease

I encourage you to take 5 minutes to watch this video demonstrating the difficulties encountered by two patients who are in desperate need of relief: <a href="https://youtu.be/wtyOF9XhQ0A">https://youtu.be/wtyOF9XhQ0A</a>

Yes, DUODOPA® is expensive. It is offered at a cost of \$60,000 per year per patient; however, there are very few patients in British Columbia requiring the therapy. In receiving the DUODOPA® therapy, patients will experience considerable relief of pain; have better control over severe and dangerous balance issues; be removed from the fear of breathing and swallowing issues; and be provided with support with other non-movement (non-motor) problems.

For a number of these patients, access to DUODOPA® therapy has become a life or death issue and a palliative measure. I urge you to work with BC PharmaCare to fund this therapy at least on a case by case basis.

Thank you for your kind consideration,

From:

Walman, Barbara J. HLTH:EX

Sent:

November-27-16 10:43 AM

To:

McClymont, Brenda HLTH;EX

Subject:

1075215: Parkinson's Disease Treatment

Barbara Walman

ADM

## Begin forwarded message:

From: s.22

Date: November 26, 2016 at 4:07:09 PM MST

To: Barbara. Walman@gov.bc.ca

Subject: Parkinson's Disease Treatment

November 25, 2016

Dear Barbara Walman

My name is \$.22

s.22

I encourage you to take 5 minutes to watch this video demonstrating the difficulties encountered by two patients who are in desperate need of this therapy.

# https://youtu.be/wtyOF9XhO0A

Thank you for your kind consideration.

Page 55

Withheld pursuant to/removed as

From:

McClymont, Brenda HLTH:EX on behalf of hlth Med Ben & Pharm Services

Correspondence Unit HLTH:EX

Sent:

December-06-16 2:54 PM

To:

s.22

Subject:

Ministry of Health Response - 1075215

s.22

Dear s.22

Thank you for your email of November 26, 2016, regarding PharmaCare coverage of levodopa-carbidopa intestinal gel (Duodopa®). Barbara Walman, Assistant Deputy Minister, Medical Beneficiary and Pharmaceutical Services, has asked me to respond on her behalf.

I wish to provide the following information regarding the rationale for PharmaCare's decision to not include Duodopa in the British Columbia drug formulary for treatment of advanced stages of Parkinson's disease.

As you may be aware, Duodopa is approved by Health Canada for the treatment of patients with advanced levodopa-responsive Parkinson's disease: who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products, and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration.

In 2009, Duodopa was reviewed by the Common Drug Review (CDR). The Canadian Expert Drug Advisory Committee (CEDAC), part of the CDR, released its final recommendation on July 22, 2009, recommending that participating jurisdictions, including BC's PharmaCare program, not list Duodopa on the formularies of their public drug plans. The link to the final recommendation is <a href="http://www.cadth.ca/media/cdr/complete/cdr\_complete\_Duodopa\_July\_24\_2009.pdf">http://www.cadth.ca/media/cdr/complete/cdr\_complete\_Duodopa\_July\_24\_2009.pdf</a>.

The CEDAC gave this recommendation partly due to the cost of Duodopa, and partly due to questions regarding the quality and applicability of the available clinical evidence. At the manufacturer's list price of \$166/day, the annual cost of therapy with Duodopa is over \$60,000 per patient per year, compared with \$3 per day or approximately \$1,095 for the oral forms of the same drug. This represents a 5,379 percent increase in the price of levodopa-carbidopa from the oral form to the Duodopa® form of the drug.

CEDAC also had concerns with the quality of the two evaluated trials, which were open-label, of small size, had high proportions of withdrawals, and were in patient populations that did not represent those most likely to use Duodopa.

Importantly, given that the PEG-J tube administration route was the manufacturer's stated reason for the drug's high cost, in both studies levodopa-carbidopa was administered by a nasoduodenal tube rather than the PEG-J tube of the marketed Duodopa product. The use of a different route of administration in the clinical trials and in the marketed product means the results of the clinical trials may not be generalizable to the patient population expected to benefit from this drug.

Subsequently, the Drug Benefit Council (the DBC) reviewed Duodopa and recommended to the Ministry to not list this drug on the PharmaCare formulary. The Ministry agreed with the CDR and the DBC's recommendation and decided not to list the drug.

Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases. Approving coverage requests for Duodopa on exceptional basis without conducting a proper review or reassessment would be unfair to the vast majority of drug manufacturers who do respect the established drug review process, and also to other patients who may also be seeking coverage.

If Abbvie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa to the CDR. Abbvie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa be listed. Abbvie has so far declined to provide this data to the CDR as a resubmission.

I realize that this is not the response you were hoping for but I hope you understand the rationale for the Ministry's current position on this drug.

Sincerely,

Eric Lun, PharmD

Executive Director, Drug Intelligence & Optimization Branch

Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health

pc: Barbara Walman

From:

s.22

Sent:

December-09-16 2:45 PM

To:

Weaver.MLA, Andrew LASS:EX

Cc:

Minister, HLTH HLTH:EX; Walman, Barbara J. HLTH:EX; Jean Blake

Subject:

MBPSD - Re: Pharmacare coverage urgently needed for Duodopa pump therapy

Categories:

FYI

Dear Dr Andrew Weaver,

re Duodopa pump therapy for severe Parkinson's disease

Further to my emailed letter written yesterday, please read the excellent summary

http://www.parkinson.bc.ca/media/69852/psbc-duodopa-issue-summary.pdf

on Parkinson Society BC's website which explains the great difficulty in getting Pharmacare approval via the usual procedure as this would put at risk reimbursement programs in Quebec & Alberta. DuoDopa pump therapy is already covered in Ontario, Manitoba & the Yukon Territory.

Again, thank you for your time & help.

Best wishes for Christmas & the holiday season. sincerely,

s.22

On Fri, Dec 9, 2016 at 12:29 AM<sup>s.22</sup>

wrote:

Dear Dr Andrew Weaver, MLA

At present, Pharmacare does not cover Duodopa pump therapy that is urgently needed for the small number of people living in BC with severe Parkinson's disease. I urge you to read my letter in the attachment & watch the short video that will make clear to you why this treatment, covered in most other provinces, is urgently needed by a small number of people living in BC. Please do all you can to bring this life saving treatment into Pharmacare coverage.

Thank you for your help. Sincerely,

s.22

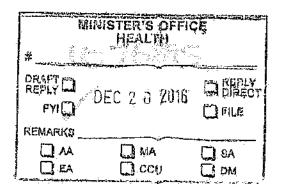
Dear

s.22

Thank you for your consideration concerning this matter.

Sincerely s.22

Cc Barbara Walman Hon. Dr. Terry Lake



From:

Morris, Kirsty L <Kirsty.Morris@leg.bc.ca>

Sent: To:

November-30-16 9:31 AM Minister, HLTH HLTH:EX

Subject:

FWs.22

From: s.22

Sent: November 29, 2016 10:18 PM

To: Lake MLA. Terrv Subject: \$.22

Dear Dr Lake,

My name is \$.22

s.22

I have included a video about the pump below. I hope you will share it with your colleagues, and bring this matter to light as quickly as possible.

Sincerely,

https://www.youtube.com/watch?v=wtyOF9XhQ0A

From:

Stone,MLA, Todd <Todd.Stone.MLA@leg.bc.ca>

Sent:

November-30-16 3:15 PM Minister, HLTH HLTH:EX

To: Cc:

Robertson, Derek HLTH:EX

Subject:

MBPSD - FW s.22

Categories:

Assign

Response is underway/add pc to MLA Stone

Good Afternoon,

Please have MoH respond to this email as these residents are not our constituents.

Much thanks,

Becky

From: s.22

Sent: November 29, 2016 10:18 PM

To: Stone.MLA, Todd < Todd.Stone.MLA@leg.bc.ca >

Subject: s.22

Dear Mr. Stone,

My name is \$.22

I have included a video about the pump below. I hope you will share it with your colleagues, and bring this matter to light as quickly as possible.

Sincerely,

s.22

https://www.youtube.com/watch?v=wtyOF9XhQ0A

From: Stevens, Sandy HLTH:EX on behalf of hith Med Ben & Pharm Services Correspondence

Unit HLTH:EX

Sent: December-13-16 9:05 AM

To: \$.7

Cc: 'OfficeofthePremier, Office PREM:EX (Premier@gov.bc.ca)'; 'Todd.Stone.MLA@leg.bc.ca'

**Subject:** Ministry of Health response 1075515

1075515

s.22

Dear s.22

Thank you for your email of November 29, 2016, regarding Pharmacare coverage of levodopa-carbidopa intestinal gel (Duodopa®). The Honourable Terry Lake, Minister of Health, has asked me to respond on his behalf.

I wish to provide the following information regarding the rationale for PharmaCarc's decision to not include Duodopa in the British Columbia drug formulary for treatment of advanced stages of Parkinson's disease.

As you may be aware, Duodopa is approved by Health Canada for the treatment of patients with advanced levodopa-responsive Parkinson's disease: who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products, and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration.

In 2009, Duodopa was reviewed by the Common Drug Review (CDR). The Canadian Expert Drug Advisory Committee (CEDAC), part of the CDR, released its final recommendation on July 22, 2009, recommending that participating jurisdictions, including BC's PharmaCare program, not list Duodopa on the formularies of their public drug plans. The link to the final recommendation is: <a href="http://www.cadth.ca/media/cdr/complete/cdr">http://www.cadth.ca/media/cdr/complete/cdr</a> complete Duodopa July 24 2009.pdf.

The CEDAC gave this recommendation partly due to the cost of Duodopa, and partly due to questions regarding the quality and applicability of the available clinical evidence. At the manufacturer's list price of \$166/day, the annual cost of therapy with Duodopa is over \$60,000 per patient per year, compared with three dollars per day or approximately \$1,095 for the oral forms of the same drug. This represents a 5,379 percent increase in the price of levodopa-carbidopa from the oral form to the Duodopa form of the drug.

CEDAC also had concerns with the quality of the two evaluated trials, which were open-label, of small size, had high proportions of withdrawals, and were in patient populations that did not represent those most likely to use Duodopa.

Importantly, given that the PEG-J tube administration route was the manufacturer's stated reason for the drug's high cost, in both studies levodopa-carbidopa was administered by a nasoduodenal tube rather than the PEG-J tube of the marketed Duodopa product. The use of a different route of administration in the clinical trials and in

the marketed product means the results of the clinical trials may not be generalizable to the patient population expected to benefit from this drug.

Subsequently, the Drug Benefit Council (the DBC) reviewed Duodopa and recommended to the Ministry to not list this drug on the PharmaCare formulary. The Ministry agreed with the CDR and the DBC's recommendation and decided not to list the drug.

Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases. Approving coverage requests for Duodopa on exceptional basis without conducting a proper review or reassessment would be unfair to the vast majority of drug manufacturers who do respect the established drug review process, and also to other patients who may also be seeking coverage.

I appreciate your comments about the coverage some provinces provide for this drug but must note that, because coverage of pharmaceuticals is not included in the Canada Health Act, drug coverage may vary considerably from province to province. While there are cases in which other provinces cover a drug not included in PharmaCare's benefit list, there are also cases in which PharmaCare covers a drug that other provinces do not. Overall, BC provides one of the most generous drug coverage programs in Canada.

If Abbvie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa to the CDR. Abbvie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa be listed, Abbvie has so far declined to provide this data to the CDR as a resubmission.

I realize that this is not the response you were hoping for but I hope you understand the rationale for the Ministry's current position on this drug.

Sincerely,

Eric Lun, PharmD

Executive Director, Drug Intelligence & Optimization Branch

Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health

pe: Honourable Christy Clark, Premier Honourable Terry Lake Honourable Todd Stone, MLA, Kamloops-South Thompson

From: s.22

Sent: November 29, 2016 10:18 PM

To: Lake.MLA, Terry

Subject: 5.22

Dear Dr Lake,

My name is s.22

Gary Holman, M.L.A.
Saanich North and the Islands
Room 201 – Parliament Buildings
Victoria, B.C. V8V 1X4
P: 250-387-3655
F: 250-387-4680

Community Office

2393 Beacon Ave Sidney, B.C. V8L 1W9 P: 250-655-5711 or 1-855-955-5711 F: 250-655-7398



Province of British Columbia Legislative Assembly



Gary Holman, MLA Saanich North and the Islands

December 12, 2016

Honorable Terry Lake Minister of Health PO Box 9050 Stn Prov Gov't Victoria, B.C. V8W 9E2

Dear Minister Lake, s.22

s.22

I understand that DUODOPA® has been approved by Health Canada and is funded by a number of provinces, but not British Columbia. DUODOPA is costly, but only 10-12 patients in British Columbia would be candidates for this therapy. It is also my understanding that despite a presentation by the Parkinson's Society of British Columbia to the Select Standing Committees on Health and on Finance and Government Services, you have turned down the request for funding.

As a matter of compassion and prudent management of a \$17 billion health care budget, I urge you to immediately review this life changing therapy and the BC PharmaCare funding of it.

I look forward to your response.

Sincerely,

Gary Holman, MLA

Saanich North and the Islands

Cc: Barbara Walman, Assistant Deputy Minister

Medical Beneficiary and Pharmaceutical Services, PharmaCare

Dr. Brendan Carr, Vancouver Island Health Authority

s.22

Diana Satok, ParkinGo

Jack Knox, Times Colonist

Steven Heywood, Peninsula News Review

Judy Darcy, Official Opposition Spokesperson for Health



1076303

Mr. Gary Holman MLA, Saanich North and the Islands 2393 Beacon Ave Sidney BC V8L 1W9

Dear Mr. Holman:

Thank you for your letter of December 12, 2016, written on behalf of \$22

I wish to provide the following information regarding the rationale for PharmaCare's decision to not include Duodopa in the British Columbia drug formulary for treatment of advanced stages of Parkinson's disease.

As you may be aware, Duodopa is approved by Health Canada for the treatment of patients with advanced levodopa-responsive Parkinson's disease: who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products, and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration.

In 2009, Duodopa was reviewed by the Common Drug Review (CDR). The Canadian Expert Drug Advisory Committee (CEDAC), part of the CDR, released its final recommendation on July 22, 2009, recommending that participating jurisdictions, including BC's PharmaCare program, not list Duodopa on the formularies of their public drug plans. The link to the final recommendation can be found at:

http://www.cadth.ca/media/cdr/complete/cdr\_complete\_Duodopa\_July\_24\_2009.pdf.

The CEDAC gave this recommendation partly due to the cost of Duodopa, and partly due to limitations regarding the quality and applicability of the available clinical evidence. At the manufacturer's list price of \$166/day, the annual cost of therapy with Duodopa is over \$60,000 per patient per year, compared with three dollars per day or approximately \$1,095 for the oral forms of the same drug. This represents more than a 5,000 percent increase in the price of levodopa-carbidopa from the oral form to the Duodopa form of the drug.

CEDAC also expressed concerns with the quality of the two evaluated trials, which were open-label, of small size, had high proportions of withdrawals, and were in patient populations that did not represent those most likely to use Duodopa.

...2

Importantly, given that the PEG-I tube administration route was the manufacturer's stated reason for the drug's high cost, in both studies levodopa-carbidopa was administered by a nasoduodenal tube rather than the PEG-I tube of the marketed Duodopa product. The use of a different route of administration in the clinical trials and in the marketed product means the results of the clinical trials may not be generalizable to the patient population expected to benefit from this drug.

Subsequently, in September 2009, the Drug Benefit Council (the DBC) reviewed Duodopa and recommended to the Ministry of Health (the Ministry) to not list this drug on the PharmaCare formulary. The Ministry agreed with the CDR and the DBC's recommendation and decided not to list the drug.

Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases. Approving coverage requests for Duodopa on exceptional basis without conducting a proper review or reassessment would be unfair to the vast majority of drug manufacturers who do respect the established drug review process, and also to other patients who may also be seeking coverage.

I appreciate your comments about the coverage some provinces provide for this drug but must note that, because coverage of pharmaceuticals is not included in the Canada Health Act, drug coverage may vary considerably from province to province. While there are cases in which other provinces cover a drug not included in PharmaCare's benefit list, there are also cases in which PharmaCare covers a drug that other provinces do not. Overall, BC provides one of the most generous drug coverage programs in Canada.

If Abbyie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa to the CDR. Abbyie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa be listed; Abbyie has so far declined to provide this data to the CDR as a resubmission.

I realize that this is not the response you were hoping for but I hope you understand the rationale for the Ministry's current position on this drug.

Sincerely,

Take

Terry Lake Minister

pe: Ms. Judy Darcy, Official Opposition Spokesperson for Health

Dr. Brendan Carr, Vancouver Island Health Authority



From:

Morris, Kirsty L < Kirsty. Morris@leg.bc.ca>

Sent:

December-23-16 9:46 AM Minister, HLTH HLTH:EX

To: Subject:

FW: s.22

and Duodopa

Importance:

High

----Original Message-----

From: Jean Blake [mailto:jblake@parkinson.bc.ca]

Sent: December 22, 2016 11:22 AM

To: Lake.MLA, Terry < Terry.Lake.MLA@leg.bc.ca>; Walman, Barbara J HLTH:EX < Barbara.Walman@gov.bc.ca>

Cc: s.22

Subject: FW s.22

and Duodopa

Importance: High

Hello Minister Lake and Ms.Walman - please read the e-mail below s. .22

s.22

Jean Blake CEO

Parkinson Society British Columbia 600 - 890 West Pender Street | Vancouver, BC V6C 1J9 604 662 3240 | 800 668 3330 | www.parkinson.bc.ca

Connect with us!

You are not alone. We are here to help.

Membership Renewal 

■ Education Events 

■ Fundraising Events 

■ Support & Resources

Information provided by Parkinson Society British Columbia is intended to be used for general information only and should not replace consultation with healthcare professionals. Please speak with a qualified healthcare professional before making medical decisions.

----Original Message-----

From: s.22

Sent: Thursday, December 22, 2016 8:36 AM

To: Diana Satok; Jean Blake

Subject: s.22

Hi Diana and Jean,

From:

Morris, Kirsty L «Kirsty.Morris@leg.bc.ca»

Sent:

December-15-16 9:40 AM Minister, HLTH HLTH:EX

Subject:

MBPSD - FW:s.22

Attachments:

Lancet Neurology 2014 Duodopa.pdf

Categories:

Assign

From: Jean Blake [mailto:jblake@parkinson,bc.ca]

Sent: December 14, 2016 4:37 PM

To: Lun, Eric HLTH:EX

Cc:<sup>s.22</sup>

; Holman.MLA, Gary; Walman, Barbara J HLTH:EX; Lake.MLA, Terry

Subject: FW s.22

Dear Eric – I am sorry to be writing to you once again with the following circumstances.

s.22

We ask you once again to consider reviewing the new 2014 evidence as your colleagues in Quebec, Ontario, Alberta, Manitoba and the Yukon have done. It is just not right that because these people live in BC they cannot receive this life saving therapy.

Thank you for giving this a reasonable and ethical review.

#### Jean Blake CEO

Parkinson Society British Columbia 600 - 890 West Pender Street | Vancouver, BC V6C 1J9 604 662 3240 | 800 668 3330 | www.parkinson.bc.ca

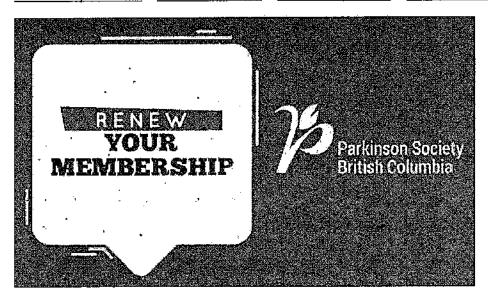
Connect with us!





You are not alone. We are here to help.

# Membership Renewal ■ Education Events ■ Fundraising Events ■ Support & Resources



Information provided by Parkinson Society British Columbia is intended to be used for general information only and should not replace consultation with healthcare professionals. Please speak with a qualified healthcare professional before making medical decisions.

From s.22

Sent: Tuesday, November 29, 2016 10:12 PM

To: gary.holman.MLA@leg.bc.ca

Cc: Jean Blake Subject: s.22

Dear Mr. Holman,

My name is s.22

I have included a video about the pump below. I hope you will share it with your colleagues, an	id bring this
matter to light as quickly as possible.	

Sincerely,

s.22

https://www.youtube.com/watch?v=wtyOF9XhQ0A

From:

s.22

Sent:

December-24-16 10:54 PM

To:

hith Med Ben & Pharm Services Correspondence Unit HLTH:EX

Cc:

Nadia Stewart; Megan Thomas; Jean Blake; Alicia Wrobel; Diana Bennett-Satok;

OfficeofthePremier, Office PREM:EX; Lake.MLA, Terry LASS:EX; Minister, HLTH HLTH:EX;

ceharnett@timescolonist.com

Subject:

will include in 1076557 MBPSD - Re: Ministry of Health Response 1075515

Categories:

FYI

Dear Mr Lun,

s.22

On Dec 13, 2016, at 9:05 AM, hith Med Ben & Pharm Services Correspondence Unit HLTH:EX <HIthMBPSDCorr@gov.bc.ca> wrote:

1075515

#### Dear s.22

Thank you for your email of November 29, 2016, regarding Pharmacare coverage of levodopa-carbidopa intestinal gel (Duodopa®). The Honourable Terry Lake, Minister of Health, has asked me to respond on his behalf.

I wish to provide the following information regarding the rationale for PharmaCare's decision to not include Duodopa in the British Columbia drug formulary for treatment of advanced stages of Parkinson's disease.

As you may be aware, Duodopa is approved by Health Canada for the treatment of patients with advanced levodopa-responsive Parkinson's disease: who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products, and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration. In 2009, Duodopa was reviewed by the Common Drug Review (CDR). The Canadian Expert Drug Advisory Committee (CEDAC), part of the CDR, released its final recommendation on

July 22, 2009, recommending that participating jurisdictions, including BC's PharmaCare program, not list Duodopa on the formularies of their public drug plans. The link to the final recommendation

is: http://www.cadth.ca/media/cdr/complete/cdr\_complete Duodopa July 24 2009.pdf. The CEDAC gave this recommendation partly due to the cost of Duodopa, and partly due to questions regarding the quality and applicability of the available clinical evidence. At the manufacturer's list price of \$166/day, the annual cost of therapy with Duodopa is over \$60,000 per patient per year, compared with three dollars per day or approximately \$1,095 for the oral forms of the same drug. This represents a 5,379 percent increase in the price of levodopa-carbidopa from the oral form to the Duodopa form of the drug.

CEDAC also had concerns with the quality of the two evaluated trials, which were open-label, of small size, had high proportions of withdrawals, and were in patient populations that did not represent those most likely to use Duodopa.

Importantly, given that the PEG-J tube administration route was the manufacturer's stated reason for the drug's high cost, in both studies levodopa-carbidopa was administered by a nasoduodenal tube rather than the PEG-J tube of the marketed Duodopa product. The use of a different route of administration in the clinical trials and in the marketed product means the results of the clinical trials may not be generalizable to the patient population expected to benefit from this drug. Subsequently, the Drug Benefit Council (the DBC) reviewed Duodopa and recommended to the Ministry to not list this drug on the PharmaCare formulary. The Ministry agreed with the CDR and the DBC's recommendation and decided not to list the drug.

Due to the extremely high cost of this product, coverage requests are not being considered, including exceptional cases. Approving coverage requests for Duodopa on exceptional basis without conducting a proper review or reassessment would be unfair to the vast majority of drug manufacturers who do respect the established drug review process, and also to other patients who may also be seeking coverage.

I appreciate your comments about the coverage some provinces provide for this drug but must note that, because coverage of pharmaceuticals is not included in the Canada Health Act, drug coverage may vary considerably from province to province. While there are cases in which other provinces cover a drug not included in PharmaCare's benefit list, there are also cases in which PharmaCare covers a drug that other provinces do not. Overall, BC provides one of the most generous drug coverage programs in Canada.

If Abbvie, the manufacturer of this product, has new clinical or economic pricing information for this drug, they are welcome to forward a resubmission for Duodopa to the CDR. Abbvie has approached individual jurisdictions claiming it has new clinical trial information and requesting Duodopa be listed, Abbvie has so far declined to provide this data to the CDR as a resubmission. I realize that this is not the response you were hoping for but I hope you understand the rationale for the Ministry's current position on this drug.

Sincerely,

Eric Lun, PharmD

Executive Director, Drug Intelligence & Optimization Branch

Medical Beneficiary and Pharmaccutical Services Division, Ministry of Health

pc: Honourable Christy Clark, Premier

Honourable Terry Lake

Honourable Todd Stone, MLA, Kamloops-South Thompson

Sent: November 29, 2016 10:18 PM

To: Lake.MLA, Terry

Subject: s.22

Dear Dr Lake

My name is s.22

I have included a video about the pump below. I hope you will share it with your colleagues, and bring this matter to light as quickly as possible. Sincerely, s.22