

MBPSD



Annie Chou, MD, FRCPC
Cardiologist

400 - 1133 Lonsdale Avenue
North Vancouver, BC, V7M 2H4

www.anniechou.ca

T: 604-980-1031

F: 604-980-1032

E: scheduling@anniechou.ca



March 22, 2017

Dear Honourable Terry Lake,

I am writing to you today with a request that will lower hospitalizations in patients with Heart Failure by simply reimbursing a medication by Pharmacare. The medication is called LCZ696 or Entresto.

The Paradigm trial was published in the New England Journal of Medicine in 2014 and showed a significant improvement in hospitalizations and mortality. The study was stopped early as this new medication met the criteria for "overwhelming benefit". These types of results are relatively rare and can significantly and positively impact our patients.

Unfortunately 50% of patients with Heart Failure die within 5 years of diagnosis. In many cases, this is due to Sudden Cardiac Death. As the name implies, the patient dies suddenly and without warning. There is a misconception that this occurs only in the sickest of patients but in fact, most patients that have a Sudden Cardiac Death have only mild symptoms. (classified as NYHA II symptoms).

In our clinic, we have a few dozen patients on LCZ696 and we have had good results. Entresto is prescribed because it is proven to lower hospitalizations and death but many patients also feel significantly better. These improvements in quality of life cannot be underscored enough and will have many significant benefits to society as a whole.

The life expectancy for patients with heart failure is worse than for most cancers and for every month that Pharmacare delays the approval of LCZ696, there will be significantly more hospitalizations and premature deaths.

Sincerely,

Annie Y. Chou, MD, FRCPC



APR 18 2017

1082823

Dr. Annie Y. Chou
400 – 1133 Lonsdale Ave
North Vancouver BC V7M 2H4

Dear Dr. Chou:

Thank you for your letter of March 22, 2017, regarding PharmaCare coverage of sacubitril-valsartan (Entresto™). I am pleased to respond on behalf of the Ministry of Health (the Ministry).

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost-effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary.

The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence-informed recommendations of an independent advisory body called the Drug Benefit Council (DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence; clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's *Your Voice* web page; and the recommendations of the national Common Drug Review (CDR).

The Ministry may also participate in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer if applicable and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug.

The CDR reviewed sacubitril-valsartan for the treatment of heart failure (HF) with reduced ejection fraction in patients with New York Heart Association class II or III, to reduce the incidence of cardiovascular death and HF hospitalization. On March 18, 2016, the CDR recommended that the participating provinces and territories should list it as a benefit for treatment of heart failure with specific clinical criteria.

British Columbia participated in the pCPA negotiations which are now completed.

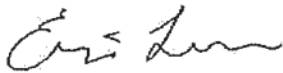
...2

- 2 -

At this time, it is not known when the Ministry will be able to complete this review. BC PharmaCare is currently facing significant budget pressures, in part due to the large number of other drugs presently under review and the existing demands from already covered products and services.

Thank you for the opportunity to respond.

Sincerely,

A handwritten signature in cursive script, appearing to read "Eric Lun".

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

Dear Eric Lund and Honourable Health Minister,

I very much appreciate your quick response. Life expectancy for patients with Heart Failure is quite short and speed is of the utmost importance. Thus I'm requesting that you expedite a Pharmacare approval for Entresto as other provinces have. Every province has budget constraints of course but some health care advancements offer a more substantial improvement than others.

The beauty of this medication, Entresto, is that it will help with other ends of the budget. How? It reduces Hospitalizations. The largest trial ever published in Heart Failure showed a 20% reduction in Hospitalizations. (New England Journal of Medicine 2014) Since HF is responsible for more hospitalizations than all forms of cancer combined, it should be made a top priority (Adams et al, AHA 2006) In 2009, the cost of hospitalizations related to HF in BC topped out at over \$300 million dollars per year. (BC Ministry of Health Services, 2010). Since the reductions in the hospitalizations were shown to be significant within only 30 days of switching medications the budget impact could be almost immediate.

Obviously it is the overall Health Care Budget that matters to tax payers and not the Pharmacare piece of the budget. Health Canada, the FDA and Europe all expedited Entresto approvals but it can't reduce hospitalizations if we don't make it available to our patients. Every Hospitalization costs tax payers thousands of dollars per day. Every day on a medication does not. Deductibles in BC are quite high and many private insurers will only insure products that BC Pharmacare approves. Thus approving Entresto allows more patients to receive the medication and the tax payer only pays a portion of the medication cost.

My patients really appreciate all of your hard work on this file. I know that you have a difficult role as there are constant improvements in other areas of Healthcare. This one is different however as it reduces hospitalizations. Yes it improves symptoms and yes it lowers sudden cardiac death but it is the hospitalizations that should matter most to the health authorities. I've included the Health Minister as you had mentioned in your previous letter that your budget is constrained and it is important that the province knows how cost effective this medication is. Large provinces like Ontario and Quebec have approved Entresto. Small budgets like Saskatchewan and the Yukon have also worked it into the budget. There must be a way for a prosperous province like BC.

To summarize, Pharmacare only partially pays for medications but BC Taxpayers pay for 100% of days in Hospital. I look forward to hearing where in the cue Entresto is and how it compares for reducing days and stays in hospital with other medications that you are evaluating.

Sincerely,



Annie Chou, MD, FRCPC Cardiology

MINISTER'S OFFICE HEALTH		
<input type="checkbox"/> DRAFT <input type="checkbox"/> REPLY	AUG 31 2017	<input type="checkbox"/> REPLY <input type="checkbox"/> DIRECT
<input type="checkbox"/> FYI		<input type="checkbox"/> FILE
REMARKS		
<input type="checkbox"/> AA	<input type="checkbox"/> MA	<input type="checkbox"/> SA
<input type="checkbox"/> EA	<input type="checkbox"/> CCU	<input type="checkbox"/> DM

Hello Honourable Adrian Dix and Bowinn Ma,

I am writing you today to request an addition to Pharmacare. Please add Entresto (LCZ696) to Pharmacare as soon as possible for Heart Failure patients.

Three years ago the New England Journal of Medicine published the Paradigm Trial. "The trial was stopped early, according to prespecified rules, after a median follow-up of 27 months, because the boundary for an overwhelming benefit with LCZ696 had been crossed." (Page 993, NEJM Sept 11, 2014) Because of this "Overwhelming Benefit", Health Canada, the FDA and the European regulators all fast tracked the product to make it available as soon as possible to patients in need.

It has been two years since LCZ696 was approved by Health Canada and most other provinces have made it available. Unfortunately Pharmacare has not. BC is not a poor province. What is a little perplexing in this case is that LCZ696 has a clear benefit for reducing hospitalizations. Since HF is a leading cause of hospitalizations in BC it should be a top priority and adding one medication for outpatients is an easy and quick improvement. The average stay for a patient with HF is 8-10 days. Thus one reduced HF hospitalization can open up a few days for other conditions. HF patients are also repeat customers ending up in hospital numerous times. Obviously LCZ696 comes with a cost but at approximately \$7 per day it doesn't seem unreasonable in comparison to the cost of hospitalizations. It is also important to highlight that the high deductibles in BC means the government pays for only a portion of the medication costs. However the government pays for 100% of hospital stays.

Patients living with Heart Failure have a life expectancy of 5 years from diagnosis. Making this product available quickly is important. Literally every day could be their last and Sudden Cardiac Death is common. As the name implies, the patient passes away suddenly and without warning.

This is a simple change that would Make Life More Affordable for patients with Heart Failure. I look forward to hearing back from you.

Sincerely,



Dr. Benny Lau, MD, FRCPC, Cardiology

North Shore Heart Centre and Lion's Gate Hospital



September 22, 2017

1092491

Dr. Benny Lau
North Shore Heart Centre and Lion's Gate Hospital
400 - 1133 Lonsdale Ave
North Vancouver BC V7M 2H4

Dear Dr. Lau:

Thank you for your letter, received August 31, 2017, regarding PharmaCare coverage for sacubitril-valsartan (Entresto™) for the treatment of heart failure (HF). The Honourable Adrian Dix, Minister of Health, has asked me to respond on his behalf.

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost-effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary.

The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence-informed recommendations of an independent advisory body called the Drug Benefit Council (DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence; clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's *Your Voice* web page; and the recommendations of the national Common Drug Review (CDR). The Ministry may also participate in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer if applicable and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug.

As I stated in my previous letters to your colleagues at the North Shore Heart Centre and Lion's Gate Hospital, the CDR reviewed sacubitril-valsartan for the treatment of HF with reduced ejection fraction in patients with New York Heart Association class II or III, to reduce the incidence of cardiovascular death and HF hospitalization. On March 18, 2016, the Canadian Drug Expert Committee, part of the CDR, recommended that the provinces and territories participating in the CDR should list sacubitril-valsartan as a benefit for treatment of heart failure with specific clinical criteria.

British Columbia participated in the pCPA negotiations which are now completed.

...2

At this time, it is not known when the Ministry will be able to complete its review of sacubitril-valsartan. However, note that your input provided from your letter will be considered in the product review. BC PharmaCare is currently facing significant budget pressures, in part due to the large number of other drugs presently under review and the existing demands from already covered products and services. BC PharmaCare currently does provide coverage for several other medications used for heart failure.

Thank you for the opportunity to respond.

Sincerely,

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

pc: Honourable Adrian Dix
Ms. Bowinn Ma, MLA, North Vancouver-Lonsdale

Mitchell, Emma D HLTH:EX

From: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>
Sent: Wednesday, December 13, 2017 2:27 PM
To: Minister, HLTH HLTH:EX
Subject: FW: Heart Failure is Getting Left Behind...

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Assign, PRIORITY

HLTH MO to PSD – dd

s.22

Page 09

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s.22



Kapil M. Bhagirath, MD, FRCP(C), FACC, FASE
Cardiology & Echocardiography
 Clinical Assistant Professor of Medicine
 Consultant Surrey Memorial Hospital/Peach Arch Hospital



West Coast Cardiology
 Suite 1105 13737 - 96 Avenue
 Surrey BC V3V 0C6

Office: (604) 593-5288
 Fax: (604) 593-5289

December 18, 2017

Hon. Adrian Dix

s.22

MINISTER'S OFFICE HEALTH		
<input type="checkbox"/> DRAFT <input type="checkbox"/> REPLY	DEC 19 2017	<input checked="" type="checkbox"/> REPLY DIRECT
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REMARKS		
<input type="checkbox"/> AA <input type="checkbox"/> EA	<input type="checkbox"/> MA <input type="checkbox"/> CCU	<input type="checkbox"/> SA <input type="checkbox"/> DM


Dear Hon. Adrian Dix,

As a practicing Cardiologist at Surrey Memorial Hospital, I am actively involved in looking after patients with congestive heart failure. As you may already know, there is a landmark medication called Entresto (Sacubitril-Valsartan) with very important long-term benefits including mortality reduction. This was studied in the PARADIGM clinical trial in 2014 and was published in the New England Journal of Medicine. The results have been excellent. Unfortunately, it is still not covered in British Columbia, and I kindly ask you to please consider covering this medication. Other provinces in Canada do offer coverage.

In particular, I am writing this letter on behalf of my patient s.22 although there are many patients very similar to s.22 in my practice. This medication has greatly helped s.22 but the costs are very high and that s.22 is having trouble affording this extremely valuable heart failure medication.

Thank you in advance for your consideration.

Yours Sincerely,


 Dr. Kapil M. Bhagirath
 M.D., FRCP(C), FACC, FASE

1/1
 0001/0001
 6045935289-5551212
 2017/Dec/19 10:52:34 AM
 12/19/2017 10:50AM FAX 6045935289

Mitchell, Emma D HLTH:EX

From: Hampson, Ashley PREM:EX
Sent: Wednesday, January 3, 2018 11:53 AM
To: Health, HLTH HLTH:EX
Subject: 1101425^{s.22} incoming -FW: Entresto

Categories: Assign

HLTH MO to PSD - pc Premier - dd

Hello!

Could Health provide a response please?

Thanks,

Ashley Hampson
Correspondence Officer
Office of the Premier
(250) 387-3539

-----Original Message-----

From^{s.22}
Sent: Wednesday, January 3, 2018 6:55 AM
To: OfficeofthePremier, Office PREM:EX
Subject: Entresto

Good Morning,
s.22

Page 12

Withheld pursuant to/removed as

s.22

Mitchell, Emma D HLTH:EX

From: Stevens, Sandy HLTH:EX on behalf of hlth Pharmaceutical Services Correspondence Unit HLTH:EX
Sent: Thursday, January 4, 2018 6:58 AM
To: s.22
Subject: Ministry of Health Response 1099758

1099758
s.22

Dear s.22

Thank you for your email of December 13, 2017, regarding PharmaCare coverage for sacubitril-valsartan (Entresto™) for the treatment of heart failure with reduced ejection fraction in patients with New York Heart Association (NYHA) Class II or III heart failure. The Honourable Adrian Dix, Minister of Health, has asked me to respond on his behalf.

s.22

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost-effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).

The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence informed recommendations of an independent advisory body called the Drug Benefit Council (the DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence (pharmacoeconomics is the branch of economics that compares the value of drugs); clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's *Your Voice* web page; and the recommendations of the national Common Drug Review (CDR). The Ministry may also participate in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer, if applicable, and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug.

As you stated in your letter, the CDR began to review sacubitril-valsartan in 2015. On March 18, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released its recommendation for sacubitril-valsartan, advising that participating jurisdictions, including PharmaCare list this drug on their formularies, with clinical criteria.

Subsequently, the DBC reviewed sacubitril-valsartan and also recommended that it be listed on the PharmaCare formulary, with the same clinical criteria specified by the CDEC and the additional recommendation that patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow-up, and monitoring.

The pCPA has concluded successful negotiations with Novartis Pharmaceuticals, the manufacturer of sacubitril-valsartan. British Columbia participated in these negotiations.

At this time, it is not known when the Ministry will be able to complete its review of sacubitril-valsartan. BC PharmaCare is currently facing significant budget pressures, in part due to the large number of other drugs presently under review and the existing demands from already covered products and services.

I realize this is not the response you were seeking; however, I trust it serves to clarify the Ministry's position.

Sincerely,

Mitch Moneo

Assistant Deputy Minister

Pharmaceutical Services Division

pc: Honourable Adrian Dix

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s.22

Page 15

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s.22

EMAIL RESPONSE

1099758

s.22

Dear ^{s.22}

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s.22

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As you stated in your letter, the CDR began to review sacubitril-valsartan in 2015. On March 18, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released its recommendation for sacubitril-valsartan, advising that participating jurisdictions, including PharmaCare list this drug on their formularies, with clinical criteria.

Subsequently, the DBC reviewed sacubitril-valsartan and also recommended that it be listed on the PharmaCare formulary, with the same clinical criteria specified by the CDEC and the additional recommendation that patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow-up, and monitoring.

The pCPA has concluded successful negotiations with Novartis Pharmaceuticals, the manufacturer of sacubitril-valsartan. British Columbia participated in these negotiations.

At this time, it is not known when the Ministry will be able to complete its review of sacubitril-valsartan. BC PharmaCare is currently facing significant budget pressures, in part due to the large number of other drugs presently under review and the existing demands from already covered products and services.

I realize this is not the response you were seeking; however, I trust it serves to clarify the Ministry's position.

Sincerely,

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical Services Division

pc: Honourable Adrian Dix

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Honourable Adrian Dix
Health Minister BC
Room 337 Parliament Buildings
Victoria, BC, V8X-1X4

MINISTER'S OFFICE HEALTH		
#		
DRAFT <input type="checkbox"/>	JAN 08 2017	REPLY <input type="checkbox"/>
REPLY <input type="checkbox"/>		DIRECT <input type="checkbox"/>
FYI <input type="checkbox"/>		<input checked="" type="checkbox"/> FILE
REMARKS <i>WC</i>		
<input type="checkbox"/> AA	<input type="checkbox"/> MA	<input type="checkbox"/> SA
<input type="checkbox"/> EA	<input type="checkbox"/> CCU	<input type="checkbox"/> DM

Dear Health Minister,

I am currently:

- ☒ A Person living with Heart Failure in British Columbia
- ☐ A Caregiver for a person living with Heart Failure in British Columbia

My physician would like to follow the Canadian Cardiovascular Society Heart Failure Guidelines. The guidelines recommend a medication called Sacubitril/Valsartan for a patient in my situation, yet Pharmacare doesn't fund the medicine.

I've been informed that virtually every province in Canada covers this medication. Every province but BC. I've also been informed that many private insurance companies cover it and that the medication could be purchased for approximately \$250/month.

Could you ensure Pharmacare adds this medication soon so that patients can count the costs towards our yearly deductible?

Sincerely

s.22

Mitchell, Emma D HLTH:EX

From: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>
Sent: Thursday, January 11, 2018 11:48 AM
To: Minister, HLTH HLTH:EX
Subject: FW: letters.22
Attachments: 20180111113523.pdf

Categories: FYI

HLTH MO fyi to PSD - jp

From: ricohmfd@leg.bc.ca [<mailto:ricohmfd@leg.bc.ca>]
Sent: Thursday, January 11, 2018 11:35 AM
To: Dix.MLA, Adrian
Subject: letter s.22

Mr. Adrian Dix, MLA
5022 Joyce St
Vancouver, BC, V5R 4G6

Dear BC Health Minister,

Could you ensure that Entresto (Sacubitril/Valsartan) is added to Pharmacare?

My Cardiologist informs me that a person in my particular situation should be prescribed this medication. They tell me that the Canadian, European and American guidelines all make the same recommendation.

I am told that private insurance companies may cover the medicine or I can buy the medication for between \$240 and \$290 per month.

Please add this medicine to Pharmacare so that people living with Heart Failure in BC can benefit like citizens living in other provinces.

Sincerely,

s.22



1100498

Dr. Kapil M. Bhagirath
West Coast Cardiology
1105 - 13737 96 Ave
Surrey BC V3V 0C6

Dear Dr. Bhagirath:

Thank you for your letter dated December 18, 2017, regarding PharmaCare coverage for sacubitril/valsartan (Entresto™) for the treatment of heart failure with reduced ejection fraction in patients with New York Heart Association (NYHA) class II or III heart failure. The Honourable Adrian Dix has asked me to respond on his behalf.

As you probably know, PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost-effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).

The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence-informed recommendations of an independent advisory body called the Drug Benefit Council (DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence (pharmacoeconomics is the branch of economics which compares the value of drugs); clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's *Your Voice* web page; and the recommendations of the national Common Drug Review (CDR). The Ministry may also participate in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer if applicable and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug.

The CDR began to review sacubitril/valsartan in 2015. On March 18, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released its recommendation for sacubitril/valsartan, advising that participating jurisdictions, including PharmaCare list this drug on their formularies, with clinical criteria.

...2

Subsequently, the DBC reviewed sacubitril/valsartan and also recommended that it be listed on the PharmaCare formulary, with the same clinical criteria specified by the CDEC and the additional recommendation that patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow-up and monitoring.

The pCPA has concluded successful negotiations with Novartis Pharmaceuticals, the manufacturer of sacubitril/valsartan. British Columbia participated in these negotiations.

At this time, it is not known when the Ministry will be able to complete its review of sacubitril/valsartan. BC PharmaCare is currently facing significant budget pressures, in part due to the large number of other drugs presently under review and the existing demands from already covered products and services.

I realize this is not the response you were seeking; however, I trust it serves to clarify the Ministry's position.

Sincerely,

A handwritten signature in black ink, appearing to read 'Eric Lun', with a stylized, cursive script.

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

pc: Honourable Adrian Dix

Mitchell, Emma D HLTH:EX

From: hlth Pharmaceutical Services Correspondence Unit HLTH:EX
Sent: Friday, January 26, 2018 12:59 PM
To: s.22
Subject: Ministry of Health Response 1101425

1101425

s.22

Dear s.22

Thank you for your email of January 3, 2018, regarding PharmaCare coverage for sacubitril-valsartan (Entresto®) for the treatment of heart failure with reduced ejection fraction in patients with New York Heart Association Class II or III heart failure. The Honourable John Horgan, Premier, and the Honourable Adrian Dix, Minister of Health, have asked me to respond on their behalf.

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).

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Sacubitril-valsartan was reviewed by the CDR and on March 18, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released its recommendation for sacubitril valsartan, advising that participating jurisdictions, including PharmaCare list this drug on their formularies, with clinical criteria.

Subsequently, the DBC reviewed sacubitril-valsartan and also recommended that it be listed on the PharmaCare formulary, with the same clinical criteria specified by the CDEC and the additional recommendation that patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow up, and monitoring.

The pCPA has concluded successful negotiations with Novartis Pharmaceuticals, the manufacturer of sacubitril-valsartan. British Columbia participated in these negotiations.

The coverage decision for sacubitril-valsartan is delayed due to significant budget pressures BC PharmaCare is facing due, in part, to the large number of other drugs presently under review and the existing demands from already covered products and services. The coverage decision for sacubitril-valsartan is expected in the spring of 2018.

I appreciate your comments that other provinces provide coverage for some drugs that BC does not, but must note that, because coverage of pharmaceuticals is not included in the *Canada Health Act*, which drugs are covered and the extent to how much coverage is provided may vary from province to province. While there are cases in which other provinces cover a drug not included in BC PharmaCare's benefit list, there are also cases in which PharmaCare covers a drug that other provinces do not.

Overall, among the provinces, there is a relatively high degree of consistency in terms of which drug are covered. In cases where a particular drug is not covered by a province, the province may in fact cover a clinically equivalent alternative drug within the same drug class. In terms of the extent of coverage, BC provides one of the most generous drug coverage programs in Canada with many plans providing 100 percent coverage and Fair PharmaCare providing universal, income-based coverage.

I trust that this response helps to provide some background around the Ministry's review process and to clarify where the Ministry is at with its review of Entresto which, as mentioned, we expect to complete in the Spring of 2018.

Sincerely,

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

pc: Honourable John Horgan
Honourable Adrian Dix

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-----Original Message-----

Page 25

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s.22

EMAIL RESPONSE

1101425

s.22

Dear s.22

Thank you for your email of January 3, 2018, regarding PharmaCare coverage for sacubitril-valsartan (Entresto®) for the treatment of heart failure with reduced ejection fraction in patients with New York Heart Association Class II or III heart failure. The Honourable John Horgan, Premier, and the Honourable Adrian Dix, Minister of Health, have asked me to respond on their behalf.

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).

The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence informed recommendations of an independent advisory body called the Drug Benefit Council (the DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence (pharmacoeconomics is the branch of economics that compares the value of drugs); clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's *Your Voice* webpage; and the recommendations of the national Common Drug Review (CDR). The Ministry may also participate in the pan Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer if applicable and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug. Sacubitril-valsartan was reviewed by the CDR and on March 18, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released its recommendation for sacubitril valsartan, advising that participating jurisdictions, including PharmaCare list this drug on their formularies, with clinical criteria.

Subsequently, the DBC reviewed sacubitril-valsartan and also recommended that it be listed on the PharmaCare formulary, with the same clinical criteria specified by the CDEC and the additional recommendation that patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow up, and monitoring.

The pCPA has concluded successful negotiations with Novartis Pharmaceuticals, the manufacturer of sacubitril-valsartan. British Columbia participated in these negotiations.

The coverage decision for sacubitril-valsartan is delayed due to significant budget pressures BC PharmaCare is facing due, in part, to the large number of other drugs presently under review and

the existing demands from already covered products and services. The coverage decision for sacubitril-valsartan is expected in the spring of 2018.

I appreciate your comments that other provinces provide coverage for some drugs that BC does not, but must note that, because coverage of pharmaceuticals is not included in the *Canada Health Act*, which drugs are covered and the extent to how much coverage is provided may vary from province to province. While there are cases in which other provinces cover a drug not included in BC PharmaCare's benefit list, there are also cases in which PharmaCare covers a drug that other provinces do not.

Overall, among the provinces, there is a relatively high degree of consistency in terms of which drug are covered. In cases where a particular drug is not covered by a province, the province may in fact cover a clinically equivalent alternative drug within the same drug class. In terms of the extent of coverage, BC provides one of the most generous drug coverage programs in Canada with many plans providing 100 percent coverage and Fair PharmaCare providing universal, income-based coverage.

I trust that this response helps to provide some background around the Ministry's review process and to clarify where the Ministry is at with its review of Entresto which, as mentioned, we expect to complete in the Spring of 2018.

Sincerely,

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

pc: Honourable John Horgan
Honourable Adrian Dix

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Mitchell, Emma D HLTH:EX

From: Fazlagic, Tijana HLTH:EX
Sent: Tuesday, January 30, 2018 10:12 AM
To: Barry, Brittany JR HLTH:EX
Subject: RE: Reply to Ministry of Health Response 1099758

Follow Up Flag: Follow up
Flag Status: Flagged

Yes, FM. I am seeking clarification from Eric how much we can share with this person regarding our coverage plans.

From: Barry, Brittany JR HLTH:EX
Sent: Tuesday, January 30, 2018 10:08 AM
To: Fazlagic, Tijana HLTH:EX
Subject: FW: Reply to Ministry of Health Response 1099758

Andrea popped over and said that this seemed like more of an FM issue than an SA one. Can you please advise on whether we need to take further action?

Thank you!

BB

From: hlth Pharmaceutical Services Correspondence Unit HLTH:EX
Sent: Tuesday, January 30, 2018 10:00 AM
To: Raine, Andrea L HLTH:EX; Barry, Brittany JR HLTH:EX
Cc: Stevens, Sandy HLTH:EX
Subject: Reply to Ministry of Health Response 1099758

Please see reply to Mitch's response below. I have added to the Cliff log.
Please advise if further action (phone call) is required. If so please Cliff and advise us of the number.

Thanks
Brenda

From: s.22
Sent: Sunday, January 28, 2018 9:11 PM

Page 29

Withheld pursuant to/removed as

s.22

PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost-effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).

The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence informed recommendations of an independent advisory body called the Drug Benefit Council (the DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence (pharmacoeconomics is the branch of economics that compares the value of drugs); clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's *Your Voice* web page; and the recommendations of the national Common Drug Review (CDR). The Ministry may also participate in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer, if applicable, and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug.

As you stated in your letter, the CDR began to review sacubitril-valsartan in 2015. On March 18, 2016, the Canadian Drug Expert Committee (CDEC), part of the CDR, released its recommendation for sacubitril-valsartan, advising that participating jurisdictions, including PharmaCare list this drug on their formularies, with clinical criteria.

Subsequently, the DBC reviewed sacubitril-valsartan and also recommended that it be listed on the PharmaCare formulary, with the same clinical criteria specified by the CDEC and the additional recommendation that patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow-up, and monitoring.

The pCPA has concluded successful negotiations with Novartis Pharmaceuticals, the manufacturer of sacubitril-valsartan. British Columbia participated in these negotiations.

At this time, it is not known when the Ministry will be able to complete its review of sacubitril-valsartan. BC PharmaCare is currently facing significant budget pressures, in part due to the large number of other drugs presently under review and the existing demands from already covered products and services.

I realize this is not the response you were seeking; however, I trust it serves to clarify the Ministry's position.

Sincerely,

Mitch Moneo

Assistant Deputy Minister

Pharmaceutical Services Division

pc: Honourable Adrian Dix

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Page 32 to/à Page 34

Withheld pursuant to/removed as

s.22

Mitchell, Emma D HLTH:EX

From: HLTH Corporate Operations HLTH:EX
Sent: Wednesday, February 7, 2018 1:19 PM
To: van Baarsen, Amanda HLTH:EX
Cc: HLTH Corporate Operations HLTH:EX; Will, Jordan HLTH:EX; Stearn, Anne HLTH:EX; Fougere, Brianna HLTH:EX; Andrachuk, Andrea HLTH:EX; Moulton, Holly HLTH:EX; McCormick, Erika HLTH:EX; Singh, Jasmyn HLTH:EX
Subject: MO info request re Sacubitril-Valsartan batch letters
Attachments: 1102019 - MO Information Bullets.docx; 1102019 - MO info request re Sacubitril-Valsartan batch letters.pdf

Good afternoon,

Attached you will find bullets for your request for information on the attached PDF regarding the Sacubitril-Valsartan batch letters. This has been prepared by Pharmaceutical Services Division and approved by Mitch Moneo, ADM and Sabine Feulgen, Assoc. DM.

Thank you!

Debra Hartlen

Team Assistant, Corporate Operations, Deputy Minister's Office, Ministry of Health
1515 Blanshard Street, Victoria, BC, V8W 3C8 | Phone: 250.952.1040

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Page 36 to/à Page 37

Withheld pursuant to/removed as

s.22;s.13

Mitchell, Emma D HLTH:EX

From: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>
Sent: Friday, February 9, 2018 11:02 AM
To: Minister, HLTH HLTH:EX
Subject: FW: RicohScan
Attachments: Letter - s.22

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: PRIORITY, Assign

HLTH MO to PSD – jp

From: ricohmfd@leg.bc.ca [mailto:ricohmfd@leg.bc.ca]
Sent: Thursday, February 8, 2018 10:41 AM
To: Dix.MLA, Adrian
Subject: RicohScan

Mr. Adrian Dix, MLA
5022 Joyce St
Vancouver, BC, V5R 4G6

Dear BC Health Minister,

Could you ensure that Entresto (Sacubitril/Valsartan) is added to Pharmacare?

My Cardiologist informs me that a person in my particular situation should be prescribed this medication. They tell me that the Canadian, European and American guidelines all make the same recommendation.

I am told that private insurance companies may cover the medicine or I can buy the medication for between \$240 and \$290 per month.

Please add this medicine to Pharmacare so that people living with Heart Failure in BC can benefit like citizens living in other provinces.

Sincerely,
s.22

Page 40

Withheld pursuant to/removed as

s.22

Traverse, Chantal HLTH:EX

From: Fazlagic, Tijana HLTH:EX
Sent: Tuesday, November 14, 2017 12:41 PM
To: Bouma, Susan HLTH:EX
Subject: RE: Status update on sacubitril/valsartan and ivabradine?

No estimated time yet. Ivabradin is still early in the process, no pCPA negotiations yet and Entresto – we are still not funding due to budgetary constraints.

From: Bouma, Susan HLTH:EX
Sent: Tuesday, November 14, 2017 12:35 PM
To: Fazlagic, Tijana HLTH:EX
Subject: FW: Status update on sacubitril/valsartan and ivabradine?

Hi T:

Do you have an estimate?

S

From: Chua, Doson [PH] [<mailto:DChua@providencehealth.bc.ca>]
Sent: Friday, November 10, 2017 4:30 PM
To: Bouma, Susan HLTH:EX
Subject: Status update on sacubitril/valsartan and ivabradine?

Hi Su.

Hope life is going well for you!

I know you are very busy and that the sacubitril/valsartan and ivabradine review is in the works.

I am getting questions from cardiologists asking me how far along the review is.

Do you have an idea of when a Pharmacare decision for sacubitril/valsartan and ivabradine will come out?

Thanks!
Doson

Traverse, Chantal HLTH:EX

From: Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>
Sent: Thursday, November 16, 2017 2:16 PM
To: Minister, HLTH HLTH:EX
Subject: 1098215-Davis-Plan W coverage of Entresto

Categories: Suzanne, Assign

HLTH MO to PSD – dd

Please address as casework – cc MO office ly

From: Davis, Margot [<mailto:margot.davis@ubc.ca>]
Sent: Thursday, November 16, 2017 2:15 PM
To: ann.johnston@bcpharmacy.ca; Ross.MLA, Ellis <Ellis.Ross.MLA@leg.bc.ca>; Dix.MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>; HealthBenefits@fnha.ca
Cc: Mustafa Toma <MToma@providencehealth.bc.ca>; Szewski, Aigna (providencehealth.bc.ca) <aignaszewski@providencehealth.bc.ca>; Sean Virani <svirani@telus.net>; Munt, Brad [PH] <bmunt@providencehealth.bc.ca>; Tania Alia <talia@providencehealth.bc.ca>
Subject: Plan W coverage of Entresto

Dear First Nations Health, Ellis Ross (MLA), Ann Johnston (BC Pharmacy Assoc), and Adrian Dix (Health Minister),

I am a heart failure cardiologist and write to you on behalf of the Heart Function Clinic at St. Paul's Hospital in Vancouver. We need your help urgently.

We have a patient that was started on an important new medication called Entresto (Sacubitril/Valsartan) for her heart failure. She was started on the medication prior to October 1st and was covered by NIHB/FNHA like every other First Nations patient across Canada and in accordance with national guidelines. There is no substitute for this medication, which was demonstrated to be superior to ACE inhibitor medications in a large clinical trial, reducing the risk of death and heart failure hospitalization by ~20%. Major society guidelines worldwide recommend that this type of patient be prescribed a drug of this class (angiotensin receptor/neprilysin inhibitor).

Pharmacare Plan W has recently told her retail pharmacist that they will no longer fund her medication. She was given 4 weeks based on the "FNHA Transitional Coverage Request Form". Now the transition from FNHA to Plan W has broken down when it has come time for Pharmacare Plan W to pay. The patient only has enough supply to last her until the end of November 2017.

Changing a medication in this fashion is inappropriate. Heart failure treatment is based on the needs of individual patients. Medication changes can affect kidney function, heart function, blood pressure and potassium levels. Inappropriate medication changes can result in clinical decompensation, hospitalization or worse.

Please help this patient immediately and fix Plan W to allow "Grandfathered" patients their life saving

medicine. It is unacceptable that BC First Nations members would suddenly have coverage that is inferior to members in every other jurisdiction in Canada and that medication would be taken away from patients in need.

I look forward to hearing from you soon.

Sincerely,

Margot Davis, MD SM FRCPC
Clinical Assistant Professor, UBC Cardiology
Director, UBC Cardiology-Oncology Program
margot.davis@ubc.ca

Traverse, Chantal HLTH:EX

From: Darren McKnight <Darren.McKnight@fnha.ca>
Sent: Monday, November 20, 2017 1:59 PM
To: Bouma, Susan HLTH:EX; Capelli, John HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Cindy Preston; Bradley Leong
Subject: RE: Plan W coverage of Entresto
Attachments: RE: Plan W coverage of Entresto

Hi Sue,

Thanks for your reply.

For reference, attached is my reply to Dr. Davis. I can keep you in the loop with any follow-up contact. .

dm

Darren McKnight
Director, Benefit Management
First Nations Health Authority
Phone (604) 699-3175 | Mobile: (604) 789-6143

From: Bouma, Susan HLTH:EX [mailto:Susan.Bouma@gov.bc.ca]
Sent: November 17, 2017 12:26 PM
To: Darren McKnight; Capelli, John HLTH:EX
Cc: Fazlagic, Tijana HLTH:EX; Cindy Preston
Subject: RE: Plan W coverage of Entresto

Thanks Darren:

We had discussed this drug previously and it had been decided a switch was appropriate (but would "depend"). This drug is still technically under review with us and not likely to be considered for listing in this fiscal year. We did not provide the transitional coverage mentioned here (perhaps NIHB did).

That all said, we may be willing to provide coverage for individual patients (I believe there was only one on this with NIHB) exceptionally if we receive more detailed patient specific information. The response I would suggest is to have the prescriber send in a request in writing with detailed patient specific reasons for this product and why other products are not appropriate.

Let me know if you would like any further info or support,

Sue

From: Darren McKnight [mailto:Darren.McKnight@fnha.ca]
Sent: Friday, November 17, 2017 12:08 PM
To: Capelli, John HLTH:EX; Bouma, Susan HLTH:EX
Subject: FW: Plan W coverage of Entresto

Sue & John,

I am looping you into this as it has been copied at a high-level at your end.

I am looking into it from our perspective. Cindy is off today so I don't expect to get far this afternoon.

dm

Darren McKnight
Director, Benefit Management
First Nations Health Authority
Phone (604) 699-3175 | Mobile: (604) 789-6143

From: Davis, Margot [mailto:margot.davis@ubc.ca]

Sent: Thursday, November 16, 2017 2:15 PM

To: Ann Johnston (BCPhA) <Ann.Johnston@bcpharmacy.ca>; ellis.ross.MLA@leg.bc.ca; adrian.dix.MLA@leg.bc.ca; HealthBenefits@fnha.ca

Cc: Mustafa Toma <MToma@providencehealth.bc.ca>; Szewski, Aigna (providencehealth.bc.ca)

<aignaszewski@providencehealth.bc.ca>; Sean Virani <svirani@telus.net>; Munt, Brad [PH]

<bmunt@providencehealth.bc.ca>; Tania Alia <talialia@providencehealth.bc.ca>

Subject: Plan W coverage of Entresto

Dear First Nations Health, Ellis Ross (MLA), Ann Johnston (BC Pharmacy Assoc), and Adrian Dix (Health Minister),

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Pharmacare Plan W has recently told her retail pharmacist that they will no longer fund her medication. She was given 4 weeks based on the "FNHA Transitional Coverage Request Form". Now the transition from FNHA to Plan W has broken down when it has come time for Pharmacare Plan W to pay. The patient only has enough supply to last her until the end of November 2017.

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Please help this patient immediately and fix Plan W to allow "Grandfathered" patients their life saving medicine. It is unacceptable that BC First Nations members would suddenly have coverage that is inferior to members in every other jurisdiction in Canada and that medication would be taken away from patients in need.

I look forward to hearing from you soon.

Sincerely,

Margot Davis, MD SM FRCPC
Clinical Assistant Professor, UBC Cardiology

Director, UBC Cardiology-Oncology Program
margot.davis@ubc.ca

Traverse, Chantal HLTH:EX

From: Darren McKnight <Darren.McKnight@fnha.ca>
Sent: Monday, November 20, 2017 1:49 PM
To: margot.davis@ubc.ca
Subject: RE: Plan W coverage of Entresto

Hello Dr. Davis

Your message was forwarded to me for follow-up.

Thank you for raising this concern. As part of the October 1, 2017, transition of coverage for FNHA clients from the NIHB program BC PharmaCare Plan W we have placed a significant focus on both client safety and continuity of care.

In follow-up with PharmaCare on this case we've confirmed a review for exceptional coverage should occur. As a next step for this patient it would be appropriate for the patient's prescriber to send in a request in writing with detailed patient specific reasons for this product and why other products are not appropriate.

I trust this information is helpful. Please don't hesitate to reach out to let me know if you would like any further information or support.

Regards,

Darren

Darren McKnight
Director, Benefit Management
First Nations Health Authority
Phone (604) 699-3175 | Mobile: (604) 789-6143

From: Davis, Margot [<mailto:margot.davis@ubc.ca>]
Sent: Thursday, November 16, 2017 2:15 PM
To: Ann Johnston (BCPhA) <Ann.Johnston@bcpharmacy.ca>; ellis.ross.MLA@leg.bc.ca; adrian.dix.MLA@leg.bc.ca; HealthBenefits@fnha.ca
Cc: Mustafa Toma <MToma@providencehealth.bc.ca>; Szewski, Aigna (providencehealth.bc.ca) <aignaszewski@providencehealth.bc.ca>; Sean Virani <svirani@telus.net>; Munt, Brad [PH] <bmunt@providencehealth.bc.ca>; Tania Alia <talialia@providencehealth.bc.ca>
Subject: Plan W coverage of Entresto

Dear First Nations Health, Ellis Ross (MLA), Ann Johnston (BC Pharmacy Assoc), and Adrian Dix (Health Minister),

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and heart failure hospitalization by ~20%. Major society guidelines worldwide recommend that this type of patient be prescribed a drug of this class (angiotensin receptor/neprilysin inhibitor).

Pharmacare Plan W has recently told her retail pharmacist that they will no longer fund her medication. She was given 4 weeks based on the "FNHA Transitional Coverage Request Form". Now the transition from FNHA to Plan W has broken down when it has come time for Pharmacare Plan W to pay. The patient only has enough supply to last her until the end of November 2017.

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Please help this patient immediately and fix Plan W to allow "Grandfathered" patients their life saving medicine. It is unacceptable that BC First Nations members would suddenly have coverage that is inferior to members in every other jurisdiction in Canada and that medication would be taken away from patients in need.

I look forward to hearing from you soon.

Sincerely,

Margot Davis, MD SM FRCPC
Clinical Assistant Professor, UBC Cardiology
Director, UBC Cardiology-Oncology Program
margot.davis@ubc.ca

Traverse, Chantal HLTH:EX

From: Weston, Megan D HLTH:EX
Sent: Thursday, November 30, 2017 1:18 PM
To: Cindy Preston
Cc: Pitt, Katherine L HLTH:EX; Bouma, Susan HLTH:EX
Subject: Jardiance and Entresto

Hi Cindy

I have a request for further coverage of empagliflozin. Is NIHB continuing to cover?

And Entresto:

I have now 3 requests, and do not match up with the email from Dr. Davis. (Dr. Davis refers to a female patient, and we received a request from s.22 for a male patient, submitted by a different doctor – though probably a colleague).

In fact, 2 have been sent in with s.22 name on them. Are either of those the client we have heard about? (Also, the Limited Use request form attached is not complete, so if approved by NIHB they were missing some info).

We had initially received only one patient for Entresto (and did not grandfather at that time), and these are three new people.

Let me know how I should proceed.

Thanks

Megan Weston | Pharmacist, Special Authority

Drug Intelligence and Optimization, Pharmaceutical Services Division
BC Ministry of Health
1515 Blanshard St PO BOX 9652 STN PROV GOVT Victoria BC V8W 9P4
ph: 250 952 2883

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Traverse, Chantal HLTH:EX

From: Weston, Megan D HLTH:EX
Sent: Tuesday, December 12, 2017 1:01 PM
To: 'Cindy Preston'; Bradley Leong
Cc: Bouma, Susan HLTH:EX
Subject: RE: Entresto

Just something that says "yes, we'll cover that"

Thanks

Megan

From: Cindy Preston [<mailto:Cindy.Preston@fnha.ca>]
Sent: Tuesday, December 12, 2017 12:52 PM
To: Weston, Megan D HLTH:EX; Bradley Leong
Cc: Bouma, Susan HLTH:EX
Subject: RE: Entresto

Hi Megan,

NIHB would have a letter for an item granted coverage via appeal. But since NIHB lists Entresto as a limited use item that requires Prior Approval - which is pretty much the same as LCD that requires SA, NIHB wouldn't provide an approval letter for Entresto (only a Prior approval billing number based on the quantity (up to max one yr supply) prescribed by the physician). Do you want a copy of the NIHB prior approval information (quant/price) sent to the pharmacy? We can get that.

Cindy

From: Weston, Megan D HLTH:EX [<mailto:Megan.D.Weston@gov.bc.ca>]
Sent: Tuesday, December 12, 2017 11:14 AM
To: Bradley Leong <Bradley.Leong@fnha.ca>
Cc: Cindy Preston <Cindy.Preston@fnha.ca>; Bouma, Susan HLTH:EX <Susan.Bouma@gov.bc.ca>
Subject: Entresto

Hi Bradley

I have two clients with grandfather requests for Entresto (ND and BA). Each of them have an attached NIHB request form, but could you also forward the approval letter?

Thanks

Megan Weston | Pharmacist, Special Authority

Drug Intelligence and Optimization, Pharmaceutical Services Division

BC Ministry of Health

1515 Blanshard St PO BOX 9652 STN PROV GOVT Victoria BC V8W 9P4

ph: 250 952 2883

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EMAIL RESPONSE

1098215

Margot Davis
margot.davis@ubc.ca

Dear Dr. Davis:

Thank you for your email of November 16, 2017, inquiring about obtaining PharmaCare coverage of sacubitril-valsartan (Entresto®) on behalf of your patient. The Honourable Adrian Dix, Minister of Health has asked me to respond on his behalf.

Please note that sacubitril-valsartan is currently under review for treatment of heart failure, and therefore not eligible for coverage at this time. However, PharmaCare will consider providing exceptional coverage of this medication, on a case-by-case basis, only for patients who were previously approved by Non-Insured Health Benefits (NIHB). For consideration of exceptional coverage, submit a written letter to PharmaCare requesting Special Authority (SA) coverage and include the following clinical information:

- Details of diagnosis;
- Past medications tried; and/or
- Patient-specific rationale to avoid alternative options that are eligible for PharmaCare coverage and appropriate for the patient's diagnosis.

Please mail or fax the letter with the above information to the attention of:

Director, Special Authority
Pharmaceutical Services Division
Ministry of Health
PO BOX 9652 STN PROV GOVT
Victoria BC V8W 9P4

Fax: 1 800 609-4884

The actual coverage, if an SA approval is granted, is based on the patient's usual PharmaCare plan rules, including any deductible requirement. In addition, if a patient receives SA coverage for a drug, it may still be subject to the rules of the Low Cost Alternative Drug Program and the Reference Drug Program. Also, the PharmaCare Maximum Days' Supply and Maximum Pricing Policy still apply.

I appreciate the opportunity to respond, and trust this information is helpful.

Sincerely,

Mitch Moneo
Assistant Deputy Minister
Pharmaceutical Services Division

pc: Honourable Adrian Dix

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Traverse, Chantal HLTH:EX

From: Stevens, Sandy HLTH:EX on behalf of hlth Pharmaceutical Services Correspondence Unit
HLTH:EX
Sent: Wednesday, December 13, 2017 2:56 PM
To: 'margot.davis@ubc.ca'
Subject: Ministry of Health Response 1098215

1098215

Margot Davis
margot.davis@ubc.ca

Dear Dr. Davis:

Thank you for your email of November 16, 2017, inquiring about obtaining PharmaCare coverage of sacubitril-valsartan (Entresto®) on behalf of your patient. The Honourable Adrian Dix, Minister of Health has asked me to respond on his behalf.

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Pharmaceutical Services Division
Ministry of Health
PO BOX 9652 STN PROV GOVT
Victoria BC V8W 9P4

Fax: 1 800 609-4884

The actual coverage, if an SA approval is granted, is based on the patient's usual PharmaCare plan rules, including any deductible requirement. In addition, if a patient receives SA coverage for a drug, it may still be subject to the rules of the Low Cost Alternative Drug Program and the Reference Drug Program. Also, the PharmaCare Maximum Days' Supply and Maximum Pricing Policy still apply.

I appreciate the opportunity to respond, and trust this information is helpful.

Sincerely,

Mitch Moneo

Assistant Deputy Minister
Pharmaceutical Services Division

pc: Honourable Adrian Dix

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From: Davis, Margot [<mailto:margot.davis@ubc.ca>]
Sent: Thursday, November 16, 2017 2:15 PM
To: ann.johnston@bcpharmacy.ca; Ross, MLA, Ellis <Ellis.Ross.MLA@leg.bc.ca>; Dix, MLA, Adrian <Adrian.Dix.MLA@leg.bc.ca>; HealthBenefits@fnha.ca
Cc: Mustafa Toma <MToma@providencehealth.bc.ca>; Szewski, Aigna (providencehealth.bc.ca) <aignaszewski@providencehealth.bc.ca>; Sean Virani <svirani@telus.net>; Munt, Brad [PH] <bmunt@providencehealth.bc.ca>; Tania Alia <talia@providencehealth.bc.ca>
Subject: Plan W coverage of Entresto

Dear First Nations Health, Ellis Ross (MLA), Ann Johnston (BC Pharmacy Assoc), and Adrian Dix (Health Minister),

I am a heart failure cardiologist and write to you on behalf of the Heart Function Clinic at St. Paul's Hospital in Vancouver. We need your help urgently.

We have a patient that was started on an important new medication called Entresto (Sacubitril/Valsartan) for her heart failure. She was started on the medication prior to October 1st and was covered by NIHB/FNHA like every other First Nations patient across Canada and in accordance with national guidelines. There is no substitute for this medication, which was demonstrated to be superior to ACE inhibitor medications in a large clinical trial, reducing the risk of death and heart failure hospitalization by ~20%. Major society guidelines worldwide recommend that this type of patient be prescribed a drug of this class (angiotensin receptor/neprilysin inhibitor).

Pharmacare Plan W has recently told her retail pharmacist that they will no longer fund her medication. She was given 4 weeks based on the "FNHA Transitional Coverage Request Form". Now the transition from FNHA to Plan W has broken down when it has come time for Pharmacare Plan W to pay. The patient only has enough supply to last her until the end of November 2017.

Changing a medication in this fashion is inappropriate. Heart failure treatment is based on the needs of individual patients. Medication changes can affect kidney function, heart function, blood pressure and potassium levels. Inappropriate medication changes can result in clinical decompensation, hospitalization or worse.

Please help this patient immediately and fix Plan W to allow "Grandfathered" patients their life saving medicine. It is unacceptable that BC First Nations members would suddenly have coverage that is inferior to members in every other jurisdiction in Canada and that medication would be taken away from patients in need.

I look forward to hearing from you soon.

Sincerely,

Margot Davis, MD SM FRCPC
Clinical Assistant Professor, UBC Cardiology
Director, UBC Cardiology-Oncology Program
margot.davis@ubc.ca

Traverse, Chantal HLTH:EX

From: Gordon, Jason HLTH:EX
Sent: Wednesday, January 17, 2018 12:05 PM
To: Bolzonello, Joanne HLTH:EX; Bouma, Susan HLTH:EX; Gordon, Jason HLTH:EX; Ma, Michael B HLTH:EX; Oetomo, Enny HLTH:EX; Pollock, Lynn L HLTH:EX; Weston, Megan D HLTH:EX; Wilkinson, Stephanie HLTH:EX; Woo, Dustin HLTH:EX
Subject: FW: Entresto criteria - SA Pharmacist Lead

Hello, I am not sure if anybody is confirmed to be the SA lead for Entresto (sacubitril / valsartan combination). Is anybody already working on this and can touch base with Marie-Helene, or is this up for grabs to be volunteered for or ?

Jason

From: Giguere, Marie-Helene HLTH:EX
Sent: Wednesday, January 17, 2018 11:57 AM
To: Gordon, Jason HLTH:EX
Subject: Entresto criteria

Hi Jason,

Entresto might be listed in March 2018.

I am starting to draft the criteria. To which pharmacist in SA should I talk to?

Thank you!

Marie-Hélène Giguère, B. Pharm., M.B.A., RPh

Pharmacist

Formulary Management | Drug Intelligence and Optimization

Pharmaceutical Services Division | BC Ministry of Health

303-960 Quayside Drive, New Westminster, BC. V3M 6G2

t 604-660-5174 | f 604-660-2108

e MarieHelene.Giguere@gov.bc.ca

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Traverse, Chantal HLTH:EX

From: Fazlagic, Tijana HLTH:EX
Sent: Thursday, January 18, 2018 2:43 PM
To: Margawang, Edmond HLTH:EX; Lee, Diane HLTH:EX; Giguere, Marie-Helene HLTH:EX; Treacher, Noah HLTH:EX; Tan, Dominic HLTH:EX; Ingram, Chris HLTH:EX; Biserovic, Jesmina HLTH:EX; Bouma, Susan HLTH:EX; Pang, Walton HLTH:EX; Pugh, Sarah HLTH:EX; Gordon, Jason HLTH:EX; Chong, Elaine HLTH:EX
Cc: Lun, Eric HLTH:EX
Subject: Drugs that we can move forward with implementation

Hi everyone,

Good news! We just received confirmation from Eric that we can proceed with the following drug listings:

s.13

iva

Tijana

Tijana Fazlagic PharmD, BSP, MSc.
Director, Formulary Management
Pharmaceutical Services Division
604 374-2609
tijana.fazlagic@gov.bc.ca

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- * delete it and advise me by return email or telephone.

Traverse, Chantal HLTH:EX

From: Chua, Doson [PH] <DChua@providencehealth.bc.ca>
Sent: Thursday, February 1, 2018 4:54 PM
To: Bouma, Susan HLTH:EX
Subject: RE: Wishing to Touch Base with you Re: Proposed PharmaCare criteria for Entresto (sacubitril / valsartan)

THANK YOU so much Su, for letting us have some input into this!

:)

-----Original Message-----

From: Bouma, Susan HLTH:EX [<mailto:Susan.Bouma@gov.bc.ca>]
Sent: Thursday, February 01, 2018 4:51 PM
To: Chua, Doson [PH]
Subject: RE: Wishing to Touch Base with you Re: Proposed PharmaCare criteria for Entresto (sacubitril / valsartan)

Thanks Doson!

-----Original Message-----

From: Chua, Doson [PH] [<mailto:DChua@providencehealth.bc.ca>]
Sent: Thursday, February 1, 2018 4:49 PM
To: Gordon, Jason HLTH:EX; 'Wong, Graham'; Ignaszewski, Andrew [PH]
Cc: Giguere, Marie-Helene HLTH:EX; Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX; XT:Virani, Sean HLTH:IN; Toma, Mustafa [PH]
Subject: RE: Wishing to Touch Base with you Re: Proposed PharmaCare criteria for Entresto (sacubitril / valsartan)

I am very happy and pleased to attend.

To keep the number of participants manageable - I can be the point person in this group for the various cardiac pharmacists in the Vancouver region (eg. Elaine Lum at VGH, RCH and etc).

Thanks Jason!
Doson

-----Original Message-----

From: Gordon, Jason HLTH:EX [<mailto:Jason.Gordon@gov.bc.ca>]
Sent: Thursday, February 01, 2018 8:31 AM
To: 'Wong, Graham'; Ignaszewski, Andrew [PH]
Cc: Chua, Doson [PH]; Giguere, Marie-Helene HLTH:EX; Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX; XT:Virani, Sean HLTH:IN; Toma, Mustafa [PH]; Gordon, Jason HLTH:EX
Subject: RE: Wishing to Touch Base with you Re: Proposed PharmaCare criteria for Entresto (sacubitril / valsartan)

Thank you everybody for the quick replies!

I will forward everybody's contact information to Chantal Traverse who helps me find a good time for everybody to meet; she will be in touch soon!

Jason

-----Original Message-----

From: Wong, Graham [<mailto:gcwong@mail.ubc.ca>]

Sent: Wednesday, January 31, 2018 9:44 PM

To: Szewski, Aigna (providencehealth.bc.ca)

Cc: Gordon, Jason HLTH:EX; Chua, Doson [PH]; Giguere, Marie-Helene HLTH:EX; Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX; XT:Virani, Sean HLTH:IN; mtoma@providencehealth.bc.ca

Subject: Re: Wishing to Touch Base with you Re: Proposed PharmaCare criteria for Entresto (sacubitril / valsartan)

I agree with Andy that Dr. Sean Virani and Dr. Mustafa Toma are two key individuals that you would want on this discussion. I have copied them on this reply.

I am happy to help as well.

Best

Graham

Sent from my iPhone

> On Jan 31, 2018, at 18:58, Ignaszewski, Andrew [PH] <Algnaszewski@providencehealth.bc.ca> wrote:

>

> Thank you Jason. Happy to help. The other people should be Sean Virani and Mustafa Toma. Do you have their emails?

> A

>

> Sent from my iPhone

>

> On Jan 31, 2018, at 2:59 PM, Gordon, Jason HLTH:EX <Jason.Gordon@gov.bc.ca<<mailto:Jason.Gordon@gov.bc.ca>>> wrote:

>

> Good afternoon!

>

> As you are probably aware Entresto is currently under review for possible PharmaCare coverage.

>

> We are hoping to meet with you if you are interested in providing feedback on our proposed criteria, and helping shape how we end up rolling out coverage in the event of a listing. As usual, this would all be confidential until a public announcement is made.

>

> Confidentially, we are hoping to actually list Entresto in early March, so based on all the things that need doing we are already a bit behind. That being said, I am also aware plans can change based on unexpected things so I don't want to be too overconfident that Entresto will for sure be listed, but I want to be transparent with you about where things are likely heading.

>

> So today I have two questions:

>

> - Are you interested / able to meet in the next week or two for a 30 to 45 minute teleconference to discuss or proposed criteria and plans?

>

> - Are there other prescribers or representatives from prescriber groups who you feel should really be at such a meeting? I don't want to make this particularly exclusive, but don't necessarily want to engage a huge group at this point in the process either.

>
> Please let us know what you think, and if you have any questions please let me know!
>
> Once I have a list of potential attendees we will work to set up a time that works for as many people as we can.
>
> Jason Gordon
> Pharmacist
> Special Authority, Drug Intelligence and Optimization Branch
> Pharmaceutical Services Division, Ministry of Health
> 1515 Blanshard St|PO BOX 9652 STN PROV GOVT|Victoria BC |V8W 9P4
> Phone: 250-952-2975
>
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>

Traverse, Chantal HLTH:EX

From: Giguere, Marie-Helene HLTH:EX
Sent: Wednesday, February 14, 2018 9:01 AM
To: Fazlagic, Tijana HLTH:EX; Gordon, Jason HLTH:EX
Cc: Bouma, Susan HLTH:EX; Weston, Megan D HLTH:EX
Subject: RE: Entresto Feedback From Cardiologists (brief summary of Thursday Feb. 8th teleconference)

Thank you Jason and Tijana,
The changes I made in the criteria located on the Sharepoint are reflective of your summary.
It will soon be running in eApprovals.
MarieH

From: Fazlagic, Tijana HLTH:EX
Sent: Wednesday, February 14, 2018 7:24 AM
To: Gordon, Jason HLTH:EX
Cc: Giguere, Marie-Helene HLTH:EX; Bouma, Susan HLTH:EX; Weston, Megan D HLTH:EX
Subject: Re: Entresto Feedback From Cardiologists (brief summary of Thursday Feb. 8th teleconference)

Thank you for summarizing Jason and thanks to you and Marie-Helene for getting this input.

Here are my initial thoughts:

s.13

Tijana

Sent from my iPad

On Feb 13, 2018, at 4:37 PM, Gordon, Jason HLTH:EX <Jason.Gordon@gov.bc.ca> wrote:

Good afternoon!

I wanted to quickly document the points below for future reference and discussion. I still need to review the revised criteria, and update the draft sacubitril – valsartan form with some of the suggestions below.

Everybody was able to make it to our call (four cardiologists and one cardiac specialized pharmacist, exact attendees below).

Overall comments:

s.13

s.13

Suggestions I suggest we accept:

s.13

Suggestions to Discuss:

s.13

Marie-Helene, please let me know if I missed anything critical, easily possible given I was talking as much as I was taking notes...

Attendees:

Doson Chua (cardiology focused Pharmacist).

Cardiologists:

Dr. Graham Wong

Dr. Mustafa Toma

Dr. Sean Virani

Dr. Andrew Ignaszewski

Jason Gordon

Pharmacist

Special Authority, PharmaCare Benefits Branch

Pharmaceutical Services Division, Ministry of Health

1515 Blanshard St | PO BOX 9652 STN PROV GOVT | Victoria BC | V8W 9P4

Phone: 250-952-2975

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Page 01 to/à Page 28

Withheld pursuant to/removed as

s.16;s.13;s.17

Page 01 to/à Page 11

Withheld pursuant to/removed as

s.16;s.13;s.17

**Appendix: List of cardiologists who support expedited Pharmacare coverage
for sacubitril-valsartan**

Dr. Eve Aymong	Dr. Tara Sedlak
Dr. Zach Laksman	Dr. Michael Tsang
Dr. Marc Deyell	Dr. John Mancini
Dr. Andy Ignaszewski	Dr. Daniel Wong
Dr. Sean Virani	Dr. Christopher Fordyce
Dr. Nathaniel Hawkins	Dr. Vicki Bernstein
Dr. Margot Davis	Dr. Sandra Baker
Dr. Krishnan Ramanathan	Dr. Marg Blackwell
Dr. Simone Cowan	Dr. Ian Billingsley
Dr. Chirs Thompson	Dr. Daniel Patton
Dr. Brad Munt	Dr. Petr Polasek
Dr. Jasmine Grewal	Dr. Kathryn brown
Dr. John Webb	Dr. Frank Halperin
Dr. Ken Gin	Dr. Jonathon Keith Todd
Dr. John Yeung	Dr. Tycho Vuurmans
Dr. Brett Heilbron	Dr. Roger Philipp
Dr. Kevin Ong	Dr. Sam Doe
Dr. Carolyn Taylor	Dr. John Imrie
Dr. Ken Kaila	Dr. Annie Chou
Dr. Andrew Krahn	Dr. Teddi Orenstein Lyall
Dr. Sammy Chan	Dr. Elizabeth Swiggum
Dr. Vic Huckell	Dr. Benny Lau
Dr. Nathan Brunner	Dr. John Vyselaar
Dr. Matthew Bennett	Dr. Richard Vandegriend
Dr. Lynn Straatman	



Mustafa Toma
THE UNIVERSITY OF BRITISH COLUMBIA
DIVISION OF CARDIOLOGY



How you want to be treated.

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Clinical Associate Professor, UBC
Advanced Heart Failure and
Cardiac Transplantation
475 – 1081 Burrard Street
Vancouver, BC V6Z 1Y6

Ph: 604-806-9986 Fx: 604-806-9927

December 13, 2017

Honorable Mr. Adrian Dix
Minister of Health
PO Box 9050 Stn Prov Govt
Victoria, BC, V8W 9E2
Hlth.minister@gov.bc.ca

Dear Honorable Adrian Dix,

As you know Heart Failure is the most common cause of hospitalization for patients over 65 years of age in the province of British Columbia. Approximately one-half of patients with Heart Failure will die within 5 years of diagnosis. Often this occurs after recurrent hospitalizations. These hospitalizations are a major contributor to why Heart Failure is one of the **most expensive** chronic diseases in British Columbia. The first time a patient is hospitalized survival drops to 2.4 years on average. If the patient is hospitalized again survival drops to 1.2 years. By the fourth hospitalization the mean survival is 6 months. The scope and impact of heart failure on patients and the healthcare system is outlined in the Heart and Stroke Foundation of Canada's Annual Report on the Health of Canadians (see attached).

In 2014, the New England Journal of Medicine published results of the PARADIGM-HF trial. The primary outcome was a highly significant reduction in both hospitalizations and death. The trial was stopped early due to "overwhelming benefit" as LCZ696, or sacubitril-valsartan (Entresto), was superior to the current gold standard of an ACE-inhibitor. There are very few breakthroughs in heart failure care and to have a new therapy improve outcomes so quickly is truly remarkable.

Sacubitril-valsartan, was granted priority review by Health Canada and approved in October 2015. The Canadian Cardiovascular Society, the American College of Cardiology and the European Society of Cardiology have all updated their guidelines

to include sacubitril-valsartan as the new standard of care in patients with symptomatic Heart Failure and Reduced Ejection Fraction, recommending sacubitril-valsartan as superior over ACEI inhibitors. Thus Canadian and other international heart failure guidelines are now recommending sacubitril-valsartan be prescribed in all eligible HF patients. This medication isn't for every patient but it needs to be available to patients in a timely manner. Recently published data collected by Cardiac Services BC (An Agency of the Provincial Health Services Authority) shows high prescriber adherence with guideline recommendations for British Columbians initiated on sacubitril-valsartan.

The Canadian Common Drug Review by CADTH recommended that sacubitril-valsartan be listed on provincial formularies in March 2016. Sacubitril-valsartan is included in the GPAC Heart Failure Guideline available at [BC guidelines.ca](http://BCguidelines.ca).

The majority of provinces/territories in Canada (Alberta, Ontario, Manitoba, Quebec, and NWT) currently list sacubitril-valsartan on their provincial formularies. Coverage in BC is still lacking and there does not appear to be a time course outlined for the approval process. Moreover, there is clear inequity among indigenous peoples in Canada, as this medication is covered under NIHB benefits in all other jurisdictions.

On behalf of my cardiology colleagues working across the British Columbia (list attached in Appendix) as well as British Columbians living with heart failure, I am asking the Minister to ensure sacubitril-valsartan receives a priority for listing within BC Pharmacare to allow affordable coverage for this life saving drug.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mustafa Toma', with a long horizontal flourish extending to the right.

Mustafa Toma MD, FRCPC
Clinical Associate Professor, UBC
Medical Director, Heart Transplant and MCS

Cc:

Dr. Sue Bouman, PharmD - Director of Special Authority, Ministry of Health
Dr. Eric Lun, PharmD - Executive Director of Drug Intelligence, Pharmacare
Honourable John Horgan - Premier, Province of British Columbia
Darren McKnight - Director, Benefit Management, First Nations Health Authority