No. C965349
Vancouver Registry

In the Supreme Court of British Columbia

Between

Anita Endean, as representative plaintiff

Plaintiff

and

**The Canadian Red Cross Society
Her Majesty the Queen in Right of the Province of British Columbia, and The Attorney General of Canada**

Defendants

and

Prince George Regional Hospital, Dr. William Galliford, Dr. Robert Hart Dykes, Dr. Peter Houghton, Dr. John Doe, Her Majesty the Queen in Right of Canada, and Her Majesty the Queen in Right of the Province of British Columbia

Third Parties

Proceeding under the *Class Proceedings Act*, R.S.B.C. 1996, C. 50

NOTICE OF APPLICATION
(Compensable HCV Drug Therapy)

Name of Applicant: **British Columbia Joint Committee Member**

TO: The Attorney General of Canada

AND TO: Her Majesty the Queen in Right of the Province of British Columbia

AND TO: Fund Counsel

TAKE NOTICE that an application will be made by the British Columbia Joint Committee Member to the Honourable Chief Justice Hinkson on November 22 and 23, 2017 in Toronto, Ontario at a place and time be provided for the order(s) set out in Part 1 below.

PART 1: ORDERS SOUGHT

1. An order approving treatment with direct-acting antiviral agents ("DAA") that have been approved by Health Canada, as Compensable HCV Drug Therapy pursuant to s.1.01 of the Transfused HCV Plan, the Hemophiliac HCV Plan and the proposed HCV Late Claims Benefit Plan where the Treating Physician certifies a HCV Infected Person suffered adverse side effects as a result of the DAA treatment.

2. An order approving amendments to the Court Approved Protocol For Medical Evidence in the form attached as **Schedule "A".**

3. An order that the orders requested shall not be effective unless and until parallel orders are approved by the Superior Court of Québec and the Ontario Superior Court of Justice.

4. Such further and other relief as counsel may request and this Honourable Court may permit.

PART 2: FACTUAL BASIS

Background

5. The Transfused HCV Plan and the Hemophiliac HCV Plan of the 1986-1990 Hepatitis C Agreement (the "Agreement") and the proposed HCV Late Claims Benefit Plan (together, the "Plans") each provide in section 4 for compensation triggered by class members reaching certain disease levels. Compensation is progressive in nature in the sense that a class member can receive additional compensation if he or she progresses from one disease level to a higher disease level.

   Plans, s. 4.
   Affidavit #17 of Heather Rumble Peterson, made October 13, 2017 ("Peterson #17'), at para 7.

6. One of the ways that the Disease Level 3 requirement in section 4.01(1)(c) of the Plans is triggered relates to Compensable HCV Drug Therapy as it is defined in

section 1.01 of the Plans. Where class members have been treated with Compensable HCV Drug Therapy within the meaning of the Plans or have met or meet a protocol for Compensable HCV Drug Therapy (regardless of whether that treatment is recommended or taken) they are classified at Disease Level 3 and are eligible for a payment of $30,000 (indexed) under the Plans.

Plans, s. 4.01(1)(c).
Peterson #17 at para 8.

7. In addition, pursuant to section 4.05 of the Plans, class members who receive Compensable HCV Drug Therapy are entitled to be paid $1,000/month (indexed) for each completed month of such treatment.

Plans, s. 4.05.
Peterson #17 at para 9.

Events Leading Up to this Motion

8. Prior to the June 2016 joint hearings of the courts on allocating excess capital, the Joint Committee recognized that the 2013 medical model indicated a large number of class members would undergo treatment with DAAs (with or without ribavirin or interferon), including those at Disease Level 2. The Joint Committee also recognized that, while the medical model provided for Disease Level 2 to Disease Level 3 transition based on disease progression, it did not account for Disease Level 2 to Disease Level 3 transition based on having taken or met a protocol for treatment with Compensable HCV Drug Therapy as provided for in the Plans.

Peterson #17 at para 2.

9. Accordingly, the Joint Committee sought to ensure that the liabilities accounted for this liability and served motions/applications requesting that the Courts declare that the amount of excess capital available for allocation was a lesser amount than originally determined, namely, $206,920,000.

Peterson #17 at para 3.

10. The basis for the request for a reduction in excess capital was a belief on the part of the Joint Committee that an additional sufficiency liability in respect of Disease Level 2 claimants who are reclassified as Disease Level 3 claimants and become eligible for the $30,000 (1999 dollars) Disease Level 3 fixed payment based on taking or meeting a protocol for taking Compensable HCV Drug Therapy should be reflected in the financial position of the Trust.

    Peterson #17 at para 4.

11. The responding material served by the federal government included affidavit #4 of Peter Gorham attaching the Morneau Shepell *Actuarial Report on Proposed Allocation of the Actuarially Unallocated Funds as of 31 December 2013*. In that report, Mr. Gorham raised the issue of the appropriateness of Disease Level 2 to Disease Level 3 transition "by reason only of taking the new treatment..." Mr. Gorham suggested in his report that "the situation be reviewed to determine whether the court approved protocol regarding these payments should be revised."

    Peterson #17 at para 5.

12. The current applications seeks to address this outstanding issue and one further issue relating to Compensable HCV Therapy.

    Peterson #17 at para 6.

The Relevant Provisions of the Plans and the Medical Evidence Protocol

13. Compensable HCV Drug Therapy is defined under the Plans as follows:

> "Compensable HCV Drug Therapy" means interferon or ribavirin, used alone or in combination, or any other treatment that has a propensity to cause adverse side effects and that has been approved by the courts for compensation.
>
> **« médication indemnisable au titre du VHC »**, l'interféron ou la ribavirine, utilisé seul ou en combinaison, ou tout autre traitement qui est susceptible d'avoir des effets indésirables et que les tribunaux ont approuvé à des fins d'indemnisation.

    Plans, s.1.01.

    Peterson #17 at para 10.

14. In 2010, the Courts approved the "Medical Evidence Protocol" developed by the Joint Committee in consultation with medical experts entitled *Revised Medical Evidence for Section 4.01(1) and Section 4.01(2) of Article 4 the Transfused HCV Plan and the Hemophiliac HCV Plan* The Medical Evidence Protocol provides instruction to the Administrator in respect of evidence acceptable for the various disease level approvals, including for Disease Level 3.

Peterson #17 at para 11 and at Exhibit "A".

15. Presently, option B of Disease Level 3 of the Medical Evidence Protocol provides that claimants may satisfy the medical evidence requirement at section 4.01(1)(c) of the Plans (triggering the payment of $30,000), if the class member delivers a satisfactorily completed form indicating the HCV Infected Person has undergone one of the following types of Compensable HCV Drug Therapy:

(i) interferon therapy;

(ii) combination interferon and ribavirin;

(iii) interferon combined with a drug other than ribavirin; or

(iv) ribavirin combined with a drug other than interferon.

Peterson #17 at para 12.

16. Presently, option D of Disease Level 3 of the Medical Evidence Protocol provides that where options A to C have not been met, a class member can satisfy the medical evidence requirement in section 4.01(1)(c) of the Plans by:

(d) certification from a gastroenterologist, hematologist, infectious disease specialist or internist that:

a. the Approved HCV Infected Person has met or meets a protocol for Compensable HCV Drug Therapy consistent with the treatment decision factors set out in the most recent Canadian Association for the Study of the Liver (CASL) Consensus Guidelines for the Management of Hepatitis C, including some HCV disease indicator(s) in addition to a positive PCR test;

b. and which the certifying physician asserts is within generally accepted medical standards for recommending treatment.

Peterson #17 at para 13.

17. Option D was added to the Medical Evidence Protocol in 2010 to cover the circumstance where options A to C in the Medical Evidence Protocol do not apply and a treating specialist determines a class member appropriate for treatment based on a more subjective assessment of his or her condition in accordance with the factors delineated in the CASL Guidelines.

Peterson #17 at para 14.

18. At the time option D was added to the Medical Evidence Protocol, the factors delineated in the CASL Guidelines related to interferon and ribavirin therapy, and so the option D alternate Disease Level 3 trigger was directly linked to Compensable HCV Drug Therapy as currently defined.

Peterson #17 at para 15 and at Exhibit "B".

19. The Treating Physician Form completed by the physician to provide information to classify a person at the appropriate disease level, including Disease Level 3, provides a check list of options for the physician to complete that identify what drugs the patient is using for their treatment. The Medical Evidence Protocol and Treating Physician Form each reference the CASL Consensus Guidelines as one of the options to trigger the Disease Level 3 determination.

Peterson #17 at para 17, and at Exhibit "C".

The Evolution in Treatment Utilizing DAAs

20. In 2011 Health Canada approved certain DAAs for use in treatment of HCV. Those drugs were prescribed with interferon or ribavirin or both. Since then, several DAAs have been approved for treatment with HCV. Some of the more recent DAAs are prescribed without interferon or ribavirin.

Peterson #17 at para 18.

21. Affidavit evidence of Dr. Vincent Bain Professor, Division of Gastroenterology, Department of Medicine at the University of Alberta (retained by the Joint Committee) and Dr. Sam Lee, professor of medicine, University of Calgary (retained by Canada) filed by the parties in support of the December 31, 2013 financial sufficiency application and the June 2016 joint hearings of the courts on allocating excess capital outline the development of DAAs, their efficacy and their side effects.

Affidavit #1 of Dr. Vincent Bain, made March 11, 2015 (Bain #1).
Affidavit #2 of Dr. Vincent Bain, made March 31, 2016 ("Bain #2").
Affidavit #1 of Dr. Samuel S. Lee made January 26, 2016 ("Lee #1).

22. From 2000 to approximately 2011, the standard antiviral therapy offered to patients infected with HCV was pegylated interferon plus ribavirin. The pegylated interferon and ribavirin regimen was associated with cure rates of 50% for patients infected with the dominant genotype 1 subtype of HCV. The regimen typically required forty-eight weeks of subcutaneous injections of pegylated interferon in addition to oral medications. Both interferon and ribavirin can cause significant side effects. The number and adverse nature of the side effects are more pronounced with interferon. Many HCV patients had to abandon their therapy because of these side effects, or because of the complications which arose from the side effects. In addition, these drugs are contra-indicated for people with other medical conditions, co-morbidities or who are taking certain other drugs. Accordingly, there has been extensive research into DAAs which are effective without interferon and/or ribavirin.

Lee #1, at para. 19-20.
Bain #1 at para 36 and para 50.

23. The first generation of DAAs were protease inhibitors called telaprevir and boceprevir and they were approved for treatment in 2011. They were prescribed with pegylated interferon and ribavirin. These drugs were associated with severe

side effects, described more fully below, and are rarely prescribed in Canada anymore.

Bain #1, at para. 37
Bain #2 at para. 5

24. In 2013 and 2014, Health Canada granted regulatory approvals to new all-oral DAAs that make possible treatment regimens having a much shorter duration and without reliance on the use of pegylated interferon. However, Dr. Bain notes that in some cases, these DAA regimens were prescribed with interferon and/or ribavirin. The most common combinations of DAAs prescribed starting in 2014 were called Harvoni and Holkira PAK.

Lee #1, at para 22-23
Bain #1, at para. 40, 46 and 51.
Bain #2, at para. 6.

25. In 2012 and 2015 new CASL Guidelines were developed and published. The current CASL Guidelines include treatment regimens that are based on DAAs without interferon or ribavirin.

Peterson #17 at para 19 and at Exhibit "D".

26. On January 19, 2016, Health Canada granted regulatory approval for another all-oral DAA combination regimen, Zepatier, for treatment of patients with HCV genotypes 1 and 4. On July 14, 2016, Health Canada approved Epclusa, a once-daily pan-genotypic single dose tablet regimen for treatment of adults with genotype 1-6 chronic hepatitis C virus. In August 2017, Health Canada approved Vosevi, a combination of Sofosbuvir, Velpatasvir and Voxilaprevir for treatment of HCV genotypes 1 through 6. In January 2017 (and revised in August 2017), Health Canada approved Maviret, a combination of Glecaprevir and Pibrentasvir for treatment of gentopyes 1 through 6.

Lee Affidavit #1, at para. 25.
Peterson #17, at paras. 30, 31 and 32, and at Exhibit "H", Exhibit "I" and Exhibit "J".

27. Compensable HCV Drug Therapy, as currently defined in the Plans, does not capture the DAAs used for the treatment of HCV except in the circumstance where they are used in combination with interferon or ribavirin.

Peterson #17 at para 20

28. Class members who are receiving DAA therapy without interferon or ribavirin do not qualify for the $30,000 payment pursuant to section 4.01(1)(c) of the Plans (unless they meet other criteria, ie. option A or C which trigger Disease Level 3). In addition, these class members are not presently eligible for the $1000/month payment under section 4.05 of the Plans.

Peterson #17 at para 21.

Adverse Side Effects of DAAs

29. The Joint Committee consulted with Dr. Vincent Bain and Dr. Bernard Willem on the issue of adverse side effects and DAAs. The Joint Committee's understanding following these consultations is that DAAs cause far fewer adverse side effects than treatment with interferon or ribavirin in terms of the number of patients who suffer side effects and in terms of the severity of the side effects experienced by those who experience them, but some adverse side effects do occur.

Peterson #17 at para 22.

30. In some instances the success of the first generation of the DAAs was qualified. Not all HCV genotypes responded equally well to DAA therapy, and for some genotype infections optimal responses required the addition of ribavirin. There were severe side effects associated with these drugs including rashes that in some cases became life threatening, nausea, joint pain, anemia, low white blood cell counts, and anal problems such as itching, burning and hemorrhoids. Dr. Bain noted that many more patients than anticipated during the trial phase could not tolerate the full course of therapy and so treatment was discontinued in such patients prior to the prescribed length at the outset. Dr. Bain notes that in those patients with severe side effects, the treatment burden increased and the health

outcomes decreased compared to pegylated interferon and ribavirin alone. The first generation of DAAs are rarely prescribed in Canada anymore.

Bain #2 at para. 5
Lee #1, at para. 21
Bain #1, at para. 37

31. Dr. Lee does not believe there are discernible side effects associated with the DAAs approved in 2013 and 2014 or that there is a medical reason to suggest that any patient would undergo a hardship following either Holkira PAK or Harvoni treatment regimens. Dr. Lee notes that Holkira PAK may have to be supplemented with ribavirin when treating certain HCV genotypes. Dr. Lee believes that if some side effects result from the Holkira PAK regimen that might be avoided through the use of Harvoni, they nevertheless are minimal.

Lee #1, at para 22-24.

32. Dr. Bain offers the following qualifications to Dr. Lee's statement with regard to 2013 and 2014 DAAs "that there are no discernible side effects" and no patient would undergo "any hardship":

(a) DAA drugs in 2013, simeprevir and sofosbuvir, were combined with pegylated interferon and ribavirin and so those treatment regimens did not avoid the side effects associated with pegylated interferon and ribavirin although the treatment duration was shorter;

(b) one of the DAA treatment combinations approved in 2014 known commonly as Holkira PAK (it is a combination of ombitasvir, dasabuvir, partitaprevir and a boosting agent called ritonavir) must be taken with ribavirin for patients with genotypes 1a (which is very common). When combined with ribavirin, the side effects of ribavirin are not avoided and are discernible;

(c) among the patients Dr. Bain treated with Harvoni and Holkira PAK, Dr. Bain has noted some patients experiencing side effects including mild to

moderate fatigue, headache, insomnia, nausea, pruritis (itchiness), diarrhea and asthenia (lack of energy). The impact of the side effects is markedly less and the side effects do not generally impact day to day functioning compared to pegylated interferon and ribavirin, telaprevir or boceprevir regimes.

Bains #1, at para. 51.
Bain #2, at para. 6-7

33. The product monographs of the most commonly prescribed DAAs describe adverse reactions when the drugs are taken without ribavirin or interferon:

(a) Harvoni
    (i) headache; and
    (ii) fatigue.

(b) Holkira PAK
    (i) fatigue;
    (ii) nausea;
    (iii) asthenia; and
    (iv) headache.

(c) Zepatier
    (i) fatigue;
    (ii) headache; and
    (iii) nausea.

(d) Epclusa
    (i) headache; and
    (ii) fatigue.

(e) Vosevi
    (i) headache;
    (ii) fatigue;
    (iii) diarrhea;

(iv) insomnia; and

(v) asthenia.

(f) Maviret

(i) headache;

(ii) fatigue;

(iii) nausea;

(iv) diarrhea; and

(v) pruritis.

as well as long lists of adverse reactions observed in a smaller number of persons during clinical trials.

Peterson #17, at paras. 26 to 33, and at Exhibits "E", "F", "G", "H", "I" and "J".

34. The product monographs for Vosevi and Marivet contain a warning that cases of Hepatitis B virus reactivation have been reported in patients co-infected with Hepatitis C and Hepatitis B and treated with DAAs.

Peterson #17 at para 34.

35. During the class member consultation process prior to the June 2016 joint hearings of the courts on allocating excess capital, the Joint Committee received some information from class members during the townhall sessions and in written submissions sent by class members that some class members have experienced side effects as a result of undergoing treatment with DAAs. The verbal exchanges and written submissions do not allow the Joint Committee to be confident that all of these reports were made about treatment that excluded interferon and ribavirin but it was clear that class members were experiencing fatigue and possibly other symptoms such as muscle soreness and headaches while taking DAAs without interferon ribavirin.

Peterson #17 at para 23.

36. The Administrator does not hear from a great deal of claimants complaining of side effects, those who do are saying they experienced headaches, nausea, fatigue and muscle/joint pain. One class member has submitted a request for review of the Administrator's decision to deny the claim for the $1,000 per month payment based on having experienced extreme fatigue, joint pain and headaches which interfered with her ability to care for her son and required her husband to take time off work. These assertions are supported by her treating physician. Two other class members have written letters to the Administrator regarding side effects while taking Harvoni including nausea, headaches, muscle pain and fatigue.

Peterson #17 at para 24.

37. There is currently an appeal of the Administrator's refusal to approve the $1,000 per month payment in circumstances where the claimant claims to have suffered adverse side effects due to DAA therapy without interferon or ribavirin. The adverse side effects on which the appeal is based are: the requirement to use birth control during the treatment and for six months after the treatment which delayed the plans of this class member and his wife to try to have children; weight gain; difficulty sleeping; fatigue; flu-like symptoms; and increased sensitivity to exposure to sunlight.

Peterson #17 at para 25.

38. Health Canada has conducted a safety review of Galexos (simeprevir), a DAA drug, in response to a Japanese publication that connected the use of simeprevir with liver problems. As a result of this review, the manufacturer of Galexos (simeprevir) has updated prescribing information to warn about the risk of severe liver problems and related death. While the connection between simeprevir and this side effect is not certain, the Joint Committee is concerned that some of the potential side effects of the DAA may not yet be fully known to or understood by the medical community.

Peterson #17, at para 35, and at Exhibit "K".

PART 3: LEGAL BASIS

39. The Joint Committee seeks an order from the Courts approving DAAs as HCV Compensable Drug Therapy in circumstances where the treating physician certifies a class member has suffered adverse side effects as a result of taking DAAs.

40. The testimony from Drs. Lee and Bain suggests that the range and severity of side effects of the DAAs is not yet subject to consensus in the medical community. However, it is clear to the Joint Committee that class members do and could in the future suffer adverse side effects as a result of undergoing treatment with DAAs

41. The debates regarding the rate of side effects, nature of side effects and severity of the side effects of these drugs is made more complex by the fact that the development and regulatory approval of DAAs is occurring rapidly.

42. Since Compensable HCV Therapy is defined as drugs which have a propensity (in English)/ are susceptible (in French) to cause adverse side effects. DAAs cause adverse side effects in some but not all persons treated with them. As such, the Joint Committee recommends that DAAs be approved as Compensable HCV Therapy where the treating physician certifies that the person suffered adverse side effects due to the treatment.

43. If DAAs are approved as Compensable HCV Drug Therapy in the limited circumstances proposed, class members will be eligible to advance to Disease Level 3 in circumstances where the class members have experienced adverse side effects associated with DAA treatments. Such class members will also be entitled to the $1,000 per month payment that class members who take interferon and/or ribavirin receive.

44. The Joint Committee proposes that the Medical Evidence Protocol pertaining to Disease Level 3 be revised to add the following incidental changes to items iii and iv and to add item v, all of which are set out in bold below:

> **DISEASE LEVEL 3**
> To satisfy the medical evidence requirement at Section 4.01(1)(c) of the applicable Plan, the Approved HCV Infected Person must deliver to the Administrator a satisfactorily completed TRAN2/HEMO2 Treating Physician Form which indicates that the HCV Infected Person has either:
>
> ...(b) undergone one of the following types of Compensable HCV Drug Therapy:
>
> i. interferon therapy;
> ii. combination interferon and ribavirin therapy;
> iii. **treatment with** interferon combined with a drug other than ribavirin;
> iv. **treatment with** ribavirin combined with a drug other than interferon;
> v. **treatment with at least one direct-acting antiviral agent (DAA) approved by Health Canada in circumstances where the Treating Physician certifies that the HCV Infected Person suffered adverse side effects as a result of taking the DAA treatment;** or
>
> ...

Peterson #17 at para 36.

45. The Joint Committee also recommends that the section of the Medical Evidence Protocol pertaining to Disease Level 3 be revised by eliminating option D, that is the use of the CASL Guidelines as an option to satisfy the Disease Level 3 criteria of the Medical Evidence Protocol.

Peterson #17 at para 37.

46. If the Courts accept the Joint Committee's proposal that DAA treatment qualify as Compensable HCV Drug Therapy in those circumstances where the treating physician certifies the class member suffered adverse side effects as a result of taking the DAAs, the CASL Guidelines will still be too broad to serve as a protocol to assess progression to Disease Level 3 as they do not reflect the limited circumstances in which DAAs will be considered Compensable HCV Drug Therapy as proposed by the Joint Committee.

Peterson #17 at para 39.

47. The current CASL Guidelines recommend treatment for virtually all persons who are RNA positive. This would include persons who would be classified at Disease Level 1 or Disease Level 2 under the Plans and eliminate the current requirement under option D of the Medical Evidence Protocol that persons experience "some HCV disease indicator(s) in addition to a positive PCR test", ie. some disease indicators that they have progressed beyond Disease Level 2. As such, the CASL Guidelines no longer serve the purpose they were intended to serve as identifying progression from one disease stage to a higher disease stage.

Peterson #17 at para 40.

48. There are no adverse financial sufficiency implications in including DAAs as Compensable HCV Drug Therapy in the limited manner proposed as advancement to Disease Level 3 and the payment of the $1,000 per month are already considered in the restated liabilities ordered by the Courts in August 2016.

Peterson #17 at para 41.

49. The proposed amendments to the Medical Evidence CAP are in the best interests of the class members and meet the criteria of being generally medically accepted as stipulated in the Plans.

50. The jurisdiction to make these amendments is found within the 1986-1990 Hepatitis C Settlement Agreement and Plans:

(a) Articles 9 and 10 of the Agreement;

(b) the Section 1.01 definition of Compensable HCV Drug Therapy under the Plans;

(c) Section 4.01(5) of the Transfused HCV Plan and the Hemophiliac Plan and sections 4.01(5)Tran and 4.01(5)Hemo of the proposed HCV Late Claims Benefit Plan; and

(d) such further and other grounds as counsel may advise and this Honourable Court may permit.

PART 4: MATERIAL TO BE RELIED ON

51. Affidavit of Heather Rumble Peterson #17 made 13/Oct/2017;

52. Affidavit of Dr. Vincent Bain #1 made 11/Mar/2015;

53. Affidavit of Dr. Vincent Bain #2 made 31/Mar/2016;

54. Affidavit of Dr. Samuel S. Lee #1 made 26/Jan/2016; and

55. such further and other evidence as counsel may advise and this Honourable Court may permit.

The applicant estimates that the application will take **2 hours.**

☐ This matter is within the jurisdiction of a master.

☒ This matter is not within the jurisdiction of a master.

TO THE PERSONS RECEIVING THIS NOTICE OF APPLICATION: If you wish to respond to this notice of application, you must, within 5 business days after service of this notice of application or, if this application is brought under Rule 9-7, within 8 business days after service of this notice of application

(a) file an application response in Form 33,

(b) file the original of every affidavit, and of every other document, that

(i) you intend to refer to at the hearing of this application, and

(ii) has not already been filed in the proceeding, and

(c) serve on the applicant 2 copies of the following, and on every other party of record one copy of the following:

(i) a copy of the filed application response;

(ii) a copy of each of the filed affidavits and other documents that you intend to refer to at the hearing of this application and that has not already been served on that person;

(iii) if this application is brought under Rule 9-7, any notice that you are required to give under Rule 9-7(9).

Date: October 13, 2017

Signature of the British Columbia Joint Committee Member

Sharon D. Matthews, Q.C.

To be completed by the court only:

Order made

☐ in the terms requested in paragraphs ..... of Part 1 of this notice of application

☐ with the following variations and additional terms:

.....

.....

.....

Date: ....

Signature of ☐ Judge ☐ Master

APPENDIX

THIS APPLICATION INVOLVES THE FOLLOWING:

☐ discovery: comply with demand for documents

☐ discovery: production of additional documents

☐ extend oral discovery

☐ other matter concerning oral discovery

☐ amend pleadings

☐ add/change parties

☐ summary judgment

☐ summary trial

☐ service

☐ mediation

☐ adjournments

☐ proceedings at trial

☐ case plan orders: amend

☐ case plan orders: other

☐ experts

SCHEDULE A

COURT APPROVED PROTOCOL

MEDICAL EVIDENCE

REVISED ◆, 2017

This protocol sets out the acceptable medical evidence for sections 4.01(1), 4.01(2), 4.01(5), 4.02(1)(b)(i) and 4.03(1)(b)(i) of Article 4 of the Transfused HCV Plan, section 4.01(1), 4.01(2), 4.02(1)(b)(i) and 4.03(1)(b)(i) of Article 4 of the, the Hemophiliac HCV Plan and sections 4.01(1), 4.01(2), 4.01(6)(Hemo) 4.02(1)(b)(i) and 4.03(1)(b)(i) of Article 4 of the HCV Late Claims Benefit Plan.

DISEASE LEVEL 1

1. To be entitled to the fixed payment provided for at section 4.01(1)(a) of the applicable Plan, the Approved HCV Infected Person or Approved Late Claim HCV Infected Person will have delivered to the Administrator the following:

   (a) a satisfactorily completed Treating Physician Form for the applicable Plan; and

   (b) a positive HCV Antibody Test in compliance with the SOP - Criteria for Acceptable HCV Antibody Test and PCR Test.

DISEASE LEVEL 2

2. To satisfy the medical evidence requirement at section 4.01(1)(b) of the applicable Plan, the Approved HCV Infected Person or Approved Late Claim HCV Infected Person must deliver to the Administrator the following:

   (a) a satisfactorily completed Treating Physician Form for the applicable Plan; and

   (b) a positive PCR Test in compliance with the SOP - Criteria for Acceptable HCV Antibody Test and PCR Test.

DISEASE LEVEL 3

3. To satisfy the medical evidence requirement at section 4.01(1)(c) of the applicable Plan, the Approved HCV Infected Person or Approved Late Claim HCV Infected Person must deliver to the Administrator a satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has either:

   (a) developed fibrous tissue in the portal areas of the liver with fibrous bands extending out from the portal areas but without any bridging to other portal tracts or to central veins ("non-bridging fibrosis") as confirmed by a copy of a pathology report of a liver biopsy or by a positive result on Fibroscan (Elastography);

   (b) undergone one of the following types of Compensable HCV Drug Therapy:

(i) interferon therapy;

(ii) combination interferon and ribavirin therapy;

(iii) treatment with interferon combined with a drug other than ribavirin;

(iv) treatment with ribavirin combined with a drug other than interferon;

(v) treatment with at least one direct-acting antiviral agent (DAA) approved by Health Canada in circumstances where the Treating Physician certifies that the HCV Infected Person suffered adverse side effects as a result of taking the DAA treatment; or

(c) met or meets the following protocol for Compensable HCV Drug Therapy:

(i) the HCV Infected Person is HCV RNA positive as confirmed by a copy of a PCR Test in compliance with the SOP-Criteria for Acceptance of HCV Antibody Test and PCR Test;

(ii) the HCV Infected person has medically demonstrated evidence of fibrotic changes to the liver as confirmed by a copy of a pathology report of a liver biopsy or by a positive result on Fibroscan (Elastography); or

(iii) the HCV Infected Person's ALTs were elevated 1.5 x normal for 3 months or more as confirmed by liver function test reports provided; and

(iv) the infection with HCV materially contributed to the elevated ALTs as confirmed by a copy of a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist.

DISEASE LEVEL 4, LOSS OF INCOME AND LOSS OF SERVICES IN THE HOME

4. To satisfy the medical evidence requirement at sections 4.01(2), 4.02(1)(b)(i) or 4.03(1)(b)(i) of the applicable Plan, the Approved HCV Infected Person or Approved Late Claim HCV Infected Person must deliver to the Administrator a satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has developed fibrous tissue in the portal areas of the liver with fibrous bands bridging to other portal areas or to central veins but without nodular formation or nodular regeneration ("bridging fibrosis") as confirmed by a copy of a pathology report of a liver biopsy.

DISEASE LEVEL 5

5. To satisfy the medical evidence requirement at section 4.01(1)(d) of the applicable Plan, the Approved HCV Infected Person or Approved Late Claim HCV Infected Person must deliver to the Administrator either:

(a) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person:

(i) has developed fibrous bands in the liver extending or bridging from portal area to portal area with the development of nodules and regeneration ("cirrhosis") as confirmed by:

A. a pathology report of a liver biopsy;

B. a Fibroscan report (Elastography);

C. an Ultrasound report;

D. an MRI report;

E. a CT Scan report; or

(ii) in the absence of a liver biopsy, has been diagnosed with cirrhosis based on:

A. three or more months with:

(1) an increase in all gamma globulins with decreased albumin on serum electrophoresis as reported on a serum electrophoresis test provided;

(2) a significantly decreased platelet count as reported on laboratory reports provided; and

(3) an increased INR or prothrombin time as reported on laboratory reports provided;

(4) none of which are attributable to any cause other than cirrhosis; and

B. a finding of hepato-splenomegaly, supported by a copy of an ultrasound report, an MRI report or a CT scan report of an enlarged liver and spleen, and one or more of the following peripheral manifestations of liver disease, none of which are attributable to any cause other than cirrhosis:

(1) gynecomastia;

(2) testicular atrophy;

(3) spider angiomata;

(4) protein malnutrition;

(5) palm or nail changes characteristic of liver disease; or

C. one or more of the following, none of which are attributable to any cause other than cirrhosis:

(1) portal hypertension evidenced by:

a. an enlarged spleen which is inconsistent with portal vein thrombosis as confirmed by a copy of an ultrasound report; or

b. abnormal abdominal and chest wall veins as confirmed by a copy of a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist supporting the finding unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist;

(2) esophageal varices as reported on an endoscopic report provided;

(3) ascites as reported on an ultrasound report, an MRI report or a CT Scan report.

OR

(b) A satisfactorily completed Treating Physician Form for the Applicable Plan which indicates that the HCV Infected Person has been diagnosed with porphyria cutanea tarda:

(i) which failed to respond to one or more of the following treatments:

A. phlebotomy;

B. drug therapy - specifying the therapy;

C. Compensable HCV Drug Therapy; and

(ii) which is causing significant disfigurement and disability, a description of which is provided;

as confirmed by a 24 hour urine laboratory test report provided and a copy of a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist supporting the findings unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist.

OR

(c) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has thrombocytopenia unresponsive to therapy based on one or more of the following:

(i) a platelet count below 100×10^9 with:

A. purpura or other spontaneous bleeding; or

B. excessive bleeding following trauma;

as confirmed by a copy of a laboratory report and a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist supporting either finding unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist;

(ii) a platelet count below 30×10^9, as reported on a laboratory report provided.

OR

(d) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has been diagnosed with glomerulonephritis not requiring dialysis which is consistent with infection with HCV and copies of the following:

(i) a pathology report of a kidney biopsy which reports a finding of glomerulonephritis; and

(ii) a consultation or other report of a nephrologist confirming that the HCV Infected Person has glomerulonephritis not requiring dialysis which is consistent with infection with HCV unless the Treating Physician is a nephrologist.

DISEASE LEVEL 6

6. To satisfy the medical evidence requirement at section 4.01(1)(e) of the applicable Plan, the Approved HCV Infected Person or Approved Late Claim HCV Infected Person must deliver to the Administrator either:

(a) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has had a liver transplant together as confirmed by a copy of an operative report of the transplant.

OR

(b) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has decompensation of the liver based on a finding of one or more of the following:

(i) hepatic encephalopathy as confirmed by a copy of a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist supporting the finding unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist;

(ii) bleeding esophageal varices as confirmed by a copy of an endoscopic report;

(iii) ascites as confirmed by a copy of an ultrasound report, MRI report or CT Scan;

(iv) subacute bacterial peritonitis as confirmed by a copy of a laboratory report showing a neutrophil count of greater than 150 x 10^9 per ml in the ascitic fluid and/or positive ascitic culture;

(v) protein malnutrition as confirmed by a copy of a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist supporting the finding unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist;

(vi) another condition a description of which is provided as confirmed by a copy of a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist supporting the finding unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist.

OR

(c) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has been diagnosed with hepatocellular cancer based on one or more of the following:

(i) a pathology report of a liver biopsy which reports hepatocellular cancer;

(ii) an alpha feto protein blood test report and a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist supporting the finding unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist;

(iii) a report of a CT scan or MRI scan of the liver confirming hepatocellular cancer.

OR

(d) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has been diagnosed with B-Cell lymphoma as confirmed by a copy of a consultation or other report of an

oncologist or hematologist supporting the finding unless the Treating Physician is an oncologist or hematologist.

OR

(e) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has been diagnosed with symptomatic mixed cryoglobulinemia and copies of:

(i) the results of a blood test demonstrating elevated cryoglobulins; and

(ii) a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist supporting the finding unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist.

OR

(f) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has been diagnosed with glomerulonephritis requiring dialysis which is consistent with infection with HCV and copies of the following:

(i) a pathology report of a kidney biopsy which reports a finding of glomerulonephritis; and

(ii) a consultation or other report of a nephrologist confirming that the HCV Infected Person has glomerulonephritis requiring dialysis which is consistent with infection with HCV unless the Treating Physician is a nephrologist.

OR

(g) A satisfactorily completed Treating Physician Form for the applicable Plan which indicates that the HCV Infected Person has been diagnosed with renal failure and copies of:

(i) laboratory reports of serum creatinine and serum urea supporting the diagnosis; and

(ii) a consultation or other report of a nephrologist supporting the diagnosis unless the Treating Physician is a nephrologist.

Notes:

DISEASE LEVEL 3

[1]**Note**: The Administrator shall:

(a) accept the pathology report or Fibroscan report as evidence of non-bridging (or more severe) fibrosis if the pathology report or Fibroscan report is reported in terms which on their face are consistent with or exceed (in terms of severity of fibrosis) non-bridging fibrosis;

(b) accept the pathology report or Fibroscan Report as evidence of non-bridging (or more severe) fibrosis although the pathology report or Fibroscan report is not reported in such terms, if the Treating Physician is a pathologist, gastroenterologist, hepatologist, infectious disease specialist, or internist; or

(c) seek the assistance of a pathologist to interpret the pathology report. If necessary, the advising pathologist will request the pathology slides to make the determination.

DISEASE LEVEL 4

[2]**Note**: The Administrator shall:

(a) accept the pathology report as evidence of bridging (or more severe) fibrosis if the pathology report is reported in terms which on their face are consistent with or exceed (in terms of severity of fibrosis) bridging fibrosis;

(b) accept the pathology report as evidence of bridging fibrosis although the pathology report is not reported in such terms, if the Treating Physician is a pathologist, gastroenterologist, hepatologist, infectious disease specialist or internist; or

(c) seek the assistance of a pathologist to interpret the pathology report. If necessary, the advising pathologist will request the pathology slides to make the determination.

DISEASE LEVEL 5

[3]**Note**: The Administrator shall:

(a) accept the pathology report, Fibroscan report, CT Scan report, Ultrasound report or MRI report as evidence of cirrhosis if the applicable report is reported in terms which on their face are consistent with or exceed (in terms of severity of fibrosis) cirrhosis;

(b) accept the pathology report, Fibroscan report, CT Scan report, Ultrasound or MRI report as evidence of cirrhosis although the pathology report is not reported in

such terms, if the Treating Physician is a pathologist, gastroenterologist, hepatologist, infectious disease specialist or internist; or

(c) seek the assistance of a pathologist to interpret the pathology report. If necessary, the advising pathologist will request the pathology slides to make the determination.

DISEASE LEVEL 6

[4]**Note**: In the event that the Treating Physician specifies another condition at b(vi), the Administrator shall seek the advice of a gastroenterologist, hepatologist, infectious disease specialist or internist as to whether the diagnosis of decompensation of the liver would be generally accepted by the medical community in those circumstances.