

**COURT APPROVED PROTOCOL
ALTERNATIVE TO BIOPSY MEDICAL EVIDENCE**

REVISED DECEMBER, 2017

This protocol sets out the alternative medical evidence approved by the Courts under section 4.01(5) of the Transfused HCV Plan, section 4.01(5) of the Hemophiliac HCV Plan and sections 4.01(5)(Tran) and 4.01(5)(Hemo) of the HCV Late Claims Benefit Plan.

**FOR THE PRIMARILY-INFECTED HEMOPHILIAC WHO IS AN APPROVED HCV
INFECTED PERSON UNDER THE HEMOPHILIAC HCV PLAN OR THE
PRIMARILY-INFECTED HEMOPHILIAC WHO IS AN APPROVED LATE CLAIM
HCV INFECTED PERSON UNDER THE HCV LATE CLAIMS BENEFIT PLAN**

1. Section 4.01(5) of the Hemophiliac HCV Plan and section 4.01(5)(Hemo) of the HCV Late Claims Benefit Plan permits Primarily-Infected Hemophiliacs who are Approved HCV Infected Persons or Approved Late Claim HCV Infected Persons to establish:
 - (a) Disease Level 3 – Section 4.01 (1)(c)(i);
 - (b) Disease Level 4 – Section 4.01(2);
 - (c) Disease Level 5 – Section 4.01(1)(d)(i) or 4.01(1)(d)(v); and,
 - (d) Disease Level 6 – Section 4.01(1)(e)(ii) or 4.01(i)(e)(v);without the necessity of a biopsy.
2. Paragraphs 3 and 4 of this protocol shall only be available to Primarily-Infected Hemophiliacs who are Approved HCV Infected Persons and Primarily-Infected Hemophiliacs who are Approved Late Claim HCV Infected Persons where the Treating Physician certifies to the Administrator:
 - (a) that he or she is unable to assign the disease level he or she considers most appropriate for his or her patient due to the absence of a biopsy and the unavailability or inapplicability of the non-biopsy diagnostic methods set out the Medical Evidence Court Approved Protocol; and
 - (b) that his or her patient does not have any of the other medical conditions applicable at the disease level for which qualification is sought.
3. To utilize this protocol in respect of the following disease levels of the Hemophiliac HCV Plan or the HCV Late Claims Benefit Plan, the Primarily-Infected Hemophiliac who is an Approved HCV Infected Person or an Approved Late Claim HCV Infected Person must deliver the following for consideration by the Administrator:
 - (a) **FOR DISEASE LEVEL 3 - SECTION 4.01(1)(c)(i) OF THE APPLICABLE PLAN**

- (i) a satisfactorily completed Treating Physician Form; and,
 - (ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist, internist or hemophiliac treating physician based on non-invasive testing and diagnosis, complete details of which are provided, that if the Primarily-Infected Hemophiliac were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she has developed fibrous tissue in the portal areas of the liver with fibrous bands extending out from the portal area but without any bridging to other portal tracts or to central veins (i.e., non-bridging fibrous);
- (b) FOR DISEASE LEVEL 4 – SECTION 4.01(2) OF THE APPLICABLE PLAN
 - (i) a satisfactorily completed Treating Physician Form; and,
 - (ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist, internist or hemophiliac treating physician based on non-invasive testing and diagnosis, complete details of which are provided, that if the Primarily-Infected Hemophiliac were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she 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 (i.e., bridging fibrous);
- (c) FOR DISEASE LEVEL 5 – SECTION 4.01(1)(d)(i) OF THE APPLICABLE PLAN
 - (i) a satisfactorily completed Treating Physician Form; and,
 - (ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist, internist or hemophiliac treating physician based on non-invasive testing and diagnosis, complete details of which are provided, that if the Primarily-Infected Hemophiliac were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she has developed fibrous bands in the liver extending or bridging from portal area to portal area with the development of nodules and regeneration (i.e. cirrhosis);
- (d) FOR DISEASE LEVEL5 - SECTION 4.01(1)(d)(v) OF THE APPLICABLE PLAN
 - (i) a satisfactorily completed Treating Physician Form; and,
 - (ii) in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, internist, infectious disease specialist, nephrologist or hemophiliac treating physician based on non-invasive testing and

diagnosis, complete details of which are provided, that if the Primarily-Infected Hemophiliac were to undergo a kidney biopsy, such biopsy would more likely than not demonstrate that he or she has developed glomerulonephritis not requiring dialysis which is consistent with infection with HCV;

(e) FOR DISEASE LEVEL 6 – SECTION 4.01(1)(e)(ii) OF THE APPLICABLE PLAN

- (i) a satisfactorily completed Treating Physician Form; and,
- (ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist, internist or hemophiliac treating physician based on non-invasive testing and diagnosis, complete details of which are provided that if the Primarily-Infected Hemophiliac were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he/she has developed hepatocellular cancer;

(f) FOR DISEASE LEVEL 6 - SECTION 4.01(1)(e)(v) OF THE APPLICABLE PLAN

- (i) a satisfactorily completed Treating Physician Form; and,
- (ii) in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, internist, infectious disease specialist, nephrologist or hemophiliac treating physician based on non-invasive testing and diagnosis, complete details of which are provided, that if the Primarily-Infected Hemophiliac were to undergo a kidney biopsy, such biopsy would more likely than not demonstrate that he or she has developed glomerulonephritis requiring dialysis which is consistent with infection with HCV.

- 4. The Administrator may, if the Administrator deems it appropriate, obtain further medical opinions or require an independent medical examination in respect of the disease level of the Primarily-Infected Hemophiliac who is an Approved HCV Infected Person or an Approved Late Claim HCV Infected Person seeking to qualify under this protocol.
- 5. This protocol will be periodically reviewed to determine if there is any change to the medical evidence which is generally accepted by the medical profession and amendments may be sought in the future in order that it keep pace with evolving medical science.

FOR AN APPROVED HCV INFECTED PERSON (NON-HEMOPHILIAC) OR AN APPROVED LATE CLAIM HCV INFECTED PERSON (NON-HEMOPHILIAC)

- 6. Section 4.01(5) of the Transfused HCV Plan permits an Approved HCV Infected Person and sections 4.01(5)(Tran) and 4.01(6)(Hemo) of the HCV Late Claims Benefits Plan permits Approved Late Claim HCV Infected Persons to establish:

- (a) Disease Level 3 – Section 4.01 (1)(c)(i);
 - (b) Disease Level 4 – Section 4.01(2);
 - (c) Disease Level 5 – Section 4.01(1)(d)(i) or 4.01(1)(d)(v); and,
 - (d) Disease Level 6 – Section 4.01(1)(e)(ii) or 4.01(i)(e)(v);
- by medical evidence that is generally accepted by the medical community and approved by the Courts.
7. Paragraphs 11 and 12 of this protocol shall only be available to Approved HCV Infected Persons and Approved HCV Late Claim HCV Infected Persons who have:
- (a) provided evidence satisfactory to the Administrator that a biopsy is contraindicated in the circumstances of the medical condition of that Approved HCV Infected Person or Approved Late Claim HCV Infected Person; and
 - (b) provided evidence satisfactory to the Administrator that the non-biopsy diagnostic methods set out in the Medical Evidence Court Approved Protocol are not available or not applicable in the circumstances of the Approved HCV Infected Person or the Approved Late Claim HCV Infected Person.
8. Satisfactory evidence may include the opinion of a qualified gastroenterologist, hepatologist, infectious disease specialist or internist, that a biopsy is contraindicated in the circumstances of the medical condition of such Approved HCV Infected Person or Approved Late Claim HCV Infected Person and stating reasons why the non-biopsy diagnostic methods set out in the Medical Evidence Court Approved Protocol are not available or not applicable in the circumstances of the Approved HCV Infected Person or Approved Late Claim HCV Infected Person.
9. The Administrator may, if the Administrator deems it appropriate, obtain further medical opinions or require an independent medical examination as to whether a liver biopsy is contraindicated in respect of the medical condition of an Approved HCV Infected Person or Approved Late Claim HCV Infected Person.
10. Further, this protocol shall only be available to an Approved HCV Infected Person or an Approved Late Claim HCV Infected Person where the treating physician certifies to the Administrator:
- (a) that he or she is unable to assign the disease level he or she considers most appropriate for his or her patient due to the absence of a biopsy; and
 - (b) that his or her patient not have any of the other medical conditions applicable at the disease level for which qualification is sought.
11. To utilize this protocol in respect of the following disease levels of the Transfused HCV Plan and the HCV Late Claims Benefit Plan, the Approved HCV Infected Person or the Approved Late Claim HCV Infected Person must deliver the following for the consideration by the Administrator:

- (a) FOR DISEASE LEVEL 3 - SECTION 4.01(1)(c)(i) OF THE APPLICABLE PLAN
 - (i) a satisfactorily completed Treating Physician Form; and,
 - (ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist, or internist based on non-invasive testing and diagnosis, complete details of which are provided, that if the Approved HCV Infected Person or the Approved Late Claim HCV Infected Person were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she has developed fibrous tissue in the portal areas of the liver with fibrous bands extending out from the portal area but without any bridging to other portal tracts or to central veins (i.e., non- bridging fibrous);
- (b) FOR DISEASE LEVEL 4 – SECTION 4.01(2) OF THE APPLICABLE PLAN
 - (i) a satisfactorily completed Treating Physician Form; and,
 - (ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist or internist based on non-invasive testing and diagnosis, complete details of which are provided, that if the Approved HCV Infected Person or Approved Late Claim HCV Infected Person were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she 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 (i.e., bridging fibrous);
- (c) FOR DISEASE LEVEL 5 – SECTION 4.01(1)(d)(i) OF THE APPLICABLE PLAN
 - (i) a satisfactorily completed Treating Physician Form; and,
 - (ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist or internist based on non-invasive testing and diagnosis, complete details of which are provided, that if the Approved HCV Infected Person or the Approved Late Claim HCV Infected Person were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she has developed fibrous bands in the liver extending or bridging from portal area to portal area with the development of nodules and regeneration (i.e. cirrhosis);
- (d) FOR DISEASE LEVEL 5 - SECTION 4.01(1)(d)(v) OF THE APPLICABLE PLAN
 - (i) a satisfactorily completed Treating Physician Form; and,

- (ii) in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist, internist or nephrologist based on non-invasive testing and diagnosis, complete details of which are provided, that if the Approved HCV Infected Person or the Approved Late Claim HCV Infected Person were to undergo a kidney biopsy, such biopsy would more likely than not demonstrate that he or she has developed glomerulonephritis not requiring dialysis which is consistent with infection with HCV;
 - (e) FOR DISEASE LEVEL 6 - SECTION 4.01(1)(e)(ii) OF THE APPLICABLE PLAN
 - (i) a satisfactorily completed Treating Physician Form; and,
 - (ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist or internist based on non-invasive testing and diagnosis, complete details of which are provided that if the Approved HCV Infected Person or the Approved Late Claim HCV Infected Person were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he/she has developed hepatocellular cancer;
 - (f) FOR DISEASE LEVEL 6 - SECTION 4.01(1)(e)(v) OF THE APPLICABLE PLAN
 - (i) a satisfactorily completed Treating Physician Form; and,
 - (ii) in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist, internist, or nephrologist based on non-invasive testing and diagnosis, complete details of which are provided, that if the Approved HCV Infected Person or the Approved Late Claim HCV Infected Person were to undergo a kidney biopsy, such biopsy would more likely than not demonstrate that he or she has developed glomerulonephritis requiring dialysis which is consistent with infection with HCV.
12. The Administrator may, if the Administrator deems it appropriate, obtain further medical opinions or require an independent medical examination in respect of the disease level of the Approved HCV Infected Person or Approved Late Claim HCV Infected Person seeking to qualify under this protocol.
13. This protocol will be periodically reviewed to determine if there is any change to the medical evidence which is generally accepted by the medical profession and amendments may be sought in the future in order that it keep pace with evolving medical science.