

## **COURT APPROVED PROTOCOL: MEDICAL EVIDENCE APPROVED BY THE COURTS AS AN ALTERNATIVE TO BIOPSY**

### **I. FOR THE PRIMARY-INFECTED HEMOPHILIAC WHO IS AN APPROVED HCV INFECTED PERSON**

1. This Protocol sets out the alternative medical evidence approved by the Courts under Section 4.01(5) of Article Four of the HCV Plan (the “Alternative Medical Evidence Protocol”).
2. Section 4.01(5) of Article Four of the Hemophiliac HCV Plan permits a Primarily-Infected Hemophiliac who is an Approved HCV Infected Person 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.
3. This Alternative Medical Evidence Protocol shall only be available to a Primarily-Infected Hemophiliac who is an Approved 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 the Primarily-Infected Hemophiliac does not have any of the other medical conditions applicable at the disease level for which qualification is sought.
4. To utilize this Alternative Medical Evidence Protocol in respect of the following disease levels of the Hemophiliac HCV Plan, the Primarily-Infected Hemophiliac who is an Approved HCV Infected Person must deliver the following for consideration by the Administrator:
  - (a) **FOR DISEASE LEVEL 3**  
**SECTION 4.01(1)(c)(i)**
    - i) a satisfactorily completed HEMO2 Treating Physician Form; and,
    - ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, 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)**

- i) a satisfactorily completed HEMO2 Treating Physician Form; and,
- ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist 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)**

- i) a satisfactorily completed HEMO2 Treating Physician Form; and,
- ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, 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);

**SECTION 4.01(1)(d)(v)**

- i) a satisfactorily completed HEMO2 Treating Physician Form; and,
- ii) in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, internist, 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;

(d) **FOR DISEASE LEVEL 6 –  
SECTION 4.01(1)(e)(ii)**

- i) a satisfactorily completed HEMO2 Treating Physician Form; and,
- ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, 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;

**SECTION 4.01(1)(e)(v)**

- i) a satisfactorily completed HEMO2 Treating Physician Form; and,
- ii) in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, internist, 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.

- 5. 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 seeking to qualify under this Alternative Medical Evidence Protocol.
- 6. This Alternative Medical Evidence 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.

**II. FOR AN APPROVED HCV INFECTED PERSON (NON-HEMOPHILIAC)**

1. This Protocol sets out the alternative medical evidence approved by the Courts under Section 4.01(5) of Article Four of the Transfused HCV Plan (the “Alternative Medical Evidence Protocol”). This Protocol also applies to Approved HCV Infected Persons who have or had Thalassemia Major and to a Secondarily Infected Person who is an Approved HCV Infected Person.
2. Section 4.01(5) of Article Four of the Transfused HCV Plan permits an Approved HCV Infected Person 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.
3. This Alternative Medical Evidence Protocol shall only be available to an Approved HCV Infected Person who has provided evidence satisfactory to the Administrator that a liver biopsy is contraindicated in the circumstances of the medical condition of that Approved HCV Infected Person. Satisfactory evidence may include the opinion of a qualified gastroenterologist, hepatologist or internist, that a liver biopsy is contraindicated in the circumstances of the medical condition of such Approved HCV Infected Person. 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.
4. Further, this Alternative Medical Evidence Protocol shall only be available to an Approved 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 the Approved HCV Infected Person does not have any of the other medical conditions applicable at the disease level for which qualification is sought.
5. To utilize this Alternative Medical Evidence Protocol in respect of the following disease levels of the Transfused HCV Plan, the Approved HCV Infected Person must deliver the following for the consideration by the Administrator:
  - (a) **FOR DISEASE LEVEL 3**  
**SECTION 4.01(1)(c)(i)**
    - i) a satisfactorily completed TRAN2/Hemo 2 Treating Physician Form; and,

- ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, or internist based on non-invasive testing and diagnosis, complete details of which are provided, that if the approved 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)**

- i) a satisfactorily completed TRAN2/Hemo 2 Treating Physician Form; and,
- ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist or internist based on non-invasive testing and diagnosis, complete details of which are provided, that if the Approved 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)**

- i) a satisfactorily completed TRAN2/Hemo 2 Treating Physician Form; and,
- ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist or internist based on non-invasive testing and diagnosis, complete details of which are provided, that if the Approved 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);

**SECTION 4.01(1)(d)(v)**

- i) a satisfactorily completed TRAN2/Hemo 2 Treating Physician Form; and,
- ii) in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, internist or nephrologist based on non-invasive testing and diagnosis, complete details of which are provided, that if the Approved 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;

(d) **FOR DISEASE LEVEL 6 –  
SECTION 4.01(1)(e)(ii)**

- i) a satisfactorily completed TRAN2/Hemo 2 Treating Physician Form; and,
- ii) in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist or internist based on non-invasive testing and diagnosis, complete details of which are provided that if the Approved HCV Infected Person were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he/she has developed hepatocellular cancer;

**SECTION 4.01(1)(e)(v)**

- i) a satisfactorily completed TRAN2/Hemo 2 Treating Physician Form; and,
- ii) in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, internist, or nephrologist based on non-invasive testing and diagnosis, complete details of which are provided, that if the Approved 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.

- 6. 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 seeking to qualify under this Alternative Medical Evidence Protocol.
- 7. This Alternative Medical Evidence 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.