DISEASE LEVEL MEDICAL EVIDENCE PROTOCOL

1. This Protocol sets out the medical evidence that must be delivered to the Administrator for proof of Disease Level. It is subject to such further and other Protocols as may be agreed by the Parties and approved by the Courts.

2. For Disease Level 1, Section 2.04(2)(a) of the Settlement Agreement, a satisfactorily complete Treating Physician Form and a positive HCV Antibody Test in compliance with the HCV Antibody and PCR Test Protocol.

3. For Disease Level 2, Section 2.04(2)(b) of the Settlement Agreement, a satisfactorily completed Treating Physician Form and a positive PCR Test in compliance with the HCV Antibody and PCR Test Protocol.

4. For Disease Level 3, Section 2.04(2)(c) of the Settlement Agreement, a satisfactorily Treating Physician Form which indicates that the HCV Infected Class Member has:

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

b. undergone one of the following types of HCV Drug Therapy:

   i. interferon therapy;
   ii. combination interferon and ribavirin therapy;
   iii. interferon combined with a drug other than ribavirin;
   iv. ribavirin combined with a drug other than interferon; or

c. met or meets the following protocol for HCV Drug Therapy:

   i. the HCV Infected Class Member is HCV RNA positive as confirmed by a copy of a PCR Test in compliance with the HCV Antibody and PCR Test Protocol; and
   the HCV Infected Class Member's ALTs were elevated 1.5 x normal for 3 months or more as confirmed by liver function test reports provided; and
   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; or
   ii. the CASL (Canadian Association for the Study of the Liver) guidelines for HCV Drug Therapy.

5. For Disease Level 4, Section 2.04(2)(d) of the Settlement Agreement, a satisfactorily completed Treating Physician Form which indicates that the HCV Infected Class Member 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.

6. For Disease Level 5, Section 2.04(2)(e) of the Settlement Agreement, either:

a. A satisfactorily completed Treating Physician Form which indicates that the HCV Infected Class Member:

1. 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 copy of a pathology report of a liver biopsy; or

2. in the absence of a liver biopsy, has been diagnosed with cirrhosis based on:

i. three or more months with:

A. an increase in all gamma globulins with decreased albumin on serum electrophoresis as reported on a serum electrophoresis test provided;

B. a significantly decreased platelet count as reported on laboratory reports provided; and

C. an increased INR or prothrombin time as reported on laboratory reports provided;
none of which are attributable to any cause other than cirrhosis; and

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

A. gynecomastia;

B. testicular atrophy;

C. spider angiomata;

D. protein malnutrition;

E. palm or nail changes characteristic of liver disease;

F. either an enlarged or hobnail liver; or

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

A. portal hypertension evidenced by:

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

2. 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;

B. esophageal varices as reported on an endoscopic report provided;

C. ascites as reported on an ultrasound, MRI or CT scan report provided; or

iv an ultrasound, CT scan or MRI report which shows cirrhosis and a copy of a consultation or other report of a gastroenterologist, hepatologist, infectious disease specialist or internist supporting the finding of cirrhosis unless the Treating Physician is a gastroenterologist, hepatologist, infectious disease specialist or internist.

OR

b. A satisfactorily completed Treating Physician Form which indicates that the HCV Infected Class Member has been diagnosed with porphyria cutanea tarda:

1. which failed to respond to one or more of the following treatments:
   i. phlebotomy;
   ii. drug therapy - specifying the therapy;
   iii. HCV Drug Therapy; and

2. which is causing significant disfigurement and disability, a description of which is provided;

   as confirmed by a 24 hour urine porphyrine 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 which indicates that the HCV Infected Class Member has thrombocytopenia unresponsive to therapy based on one or more of the following:

1. a platelet count below 100×10^9 /L with:
   i. purpura or other spontaneous bleeding; or

ii. 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;

2. a platelet count below 30 x 10^9/L as reported on a laboratory report provided.

OR

d. A satisfactorily completed Treating Physician Form which indicates that the HCV Infected Class Member has been diagnosed with glomerulonephritis not requiring dialysis which is consistent with infection with HCV and copies of the following:

a. a pathology report of a kidney biopsy which reports a finding of glomerulonephritis; and
b. 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.

7. For Disease Level 6, Section 2.04(2)(f) of the Settlement Agreement, either:

a. A satisfactorily completed Treating Physician Form which indicates that the HCV Infected Class Member has had a liver transplant as confirmed by a copy of an operative report of the transplant.

OR

b. A satisfactorily completed Treating Physician Form which indicates that the HCV Infected Class Member has decompensation of the liver based on a finding of one or more of the following:

1. 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;
2. bleeding esophageal varices as confirmed by a copy of an endoscopic report;
3. ascites as confirmed by a copy of an ultrasound, MRI or CT scan report;
4. 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 fluid culture;

5. 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;
6. another condition a description of which is provided as confirmed by a copy of a consultation or other report of a gastroenterologist, hepatologist, pathologist, 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 which indicates that the HCV Infected Class Member has been diagnosed with hepatocellular cancer based on one or more of the following:

1. a copy of a pathology report of a liver biopsy which reports hepatocellular cancer;
2. copies of 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;

3. a copy of a report of a CT scan or MRI scan of the liver confirming hepatocellular cancer.

OR

d. A satisfactorily completed Treating Physician Form which indicates that the HCV Infected Class Member 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 which indicates that the HCV Infected Class Member has been diagnosed with symptomatic mixed cryoglobulinemia and copies of:

1. the results of a blood test demonstrating elevated cryoglobulins; and
2. 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 which indicates that the HCV Infected Class Member has been diagnosed with glomerulonephritis requiring dialysis which is consistent with infection with HCV and copies of the following:
    1. a pathology report of a kidney biopsy which reports a finding of glomerulonephritis; and
    2. 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 which indicates that the HCV Infected Class Member has been diagnosed with renal failure (hepatorenal syndrome) and copies of:
    1. laboratory reports of serum creatinine and serum urea supporting the diagnosis; and
    2. 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 as evidence of non-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) non-bridging fibrosis;
b. accept the pathology report as evidence of non-bridging (or more severe) 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 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 as evidence of cirrhosis if the pathology 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 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 7(b)(6), 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.