

## **APPENDIX A6**

### **COURT APPROVED PROTOCOL**

#### **MEDICAL EVIDENCE**

**REVISED AUGUST 2024**

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(5)(Tran), 4.01(5)(Hemo), 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:
  - (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).

OR

- (b) Undergone treatment with one of the following types of Compensable HCV Drug Therapy:
  - (i) interferon therapy;
  - (ii) combination interferon and ribavirin therapy;
  - (iii) interferon combined with a drug other than ribavirin, which other drug may include a direct-acting antiviral agent approved by Health Canada ("DAA");
  - (iv) ribavirin combined with a drug other than interferon, which other drug may include a DAA; or
  - (v) DAA treatment not combined with interferon and or ribavirin, in only those cases where the person undergoing treatment suffered adverse side effects that significantly interfered with his/her work or activities of daily living as confirmed by a DAA Certification Form completed by the Treating Physician.

#### **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 or other confirmatory test provided for in paragraph 5(a) above, 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;

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 angiomas;
- (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  $100 \times 10^9$  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; or

- (ii) a platelet count below  $30 \times 10^9$ , 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 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  $150 \times 10^9$  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 fetoprotein 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**

<sup>1</sup>**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) in the absence of (a) or (b) above, 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**

<sup>2</sup>**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) in the absence of (a) or (b) above, 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**

<sup>3</sup>**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) in the absence of (a) or (b) above, 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**

<sup>4</sup>**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.