

**ONTARIO
SUPERIOR COURT OF JUSTICE**

THE HONOURABLE MR. JUSTICE

)

Wednesday THE 19th DAY

PAUL PERELL

)

OF JUNE, 2019

B E T W E E N:

DIANNA LOUISE PARSONS, deceased
by her Estate Administrator, William John Forsyth,
MICHAEL HERBERT CRUICKSHANKS,
DAVID TULL, MARTIN HENRY GRIFFEN, ANNA KARDISH,
ELSIE KOTYK, Executrix of the Estate of Harry Kotyk, deceased
and ELSIE KOTYK, personally

Plaintiffs

and

THE CANADIAN RED CROSS SOCIETY,
HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO
and THE ATTORNEY GENERAL OF CANADA

Defendants

and

HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF ALBERTA,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF SASKATCHEWAN,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF MANITOBA,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NEW BRUNSWICK,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF PRINCE EDWARD ISLAND
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NOVA SCOTIA
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NEWFOUNDLAND,
THE GOVERNMENT OF THE NORTHWEST TERRITORIES,
THE GOVERNMENT OF NUNAVUT AND THE GOVERNMENT OF
THE YUKON TERRITORY

Intervenors

Proceeding under the *Class Proceedings Act, 1992*

Court File No. 98-CV-146405

B E T W E E N:

JAMES KREPPNER, BARRY ISAAC, NORMAN LANDRY, as Executor
of the Estate of the late SERGE LANDRY,
PETER FELSING, DONALD MILLIGAN,
ALLAN GRUHLKE, JIM LOVE and PAULINE FOURNIER
as Executrix of the Estate of the late PIERRE FOURNIER

Plaintiffs

and

THE CANADIAN RED CROSS SOCIETY,
THE ATTORNEY GENERAL OF CANADA and
HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO

Defendants

and



HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF ALBERTA,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF SASKATCHEWAN,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF MANITOBA,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NEW BRUNSWICK,
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF PRINCE EDWARD ISLAND
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NOVA SCOTIA
HER MAJESTY THE QUEEN IN THE RIGHT OF THE PROVINCE OF NEWFOUNDLAND,
THE GOVERNMENT OF THE NORTHWEST TERRITORIES,
THE GOVERNMENT OF NUNAVUT AND THE GOVERNMENT OF
THE YUKON TERRITORY

Intervenors

Proceeding under the *Class Proceedings Act, 1992*

**ORDER
(Compensable HCV Drug Therapy)**

THIS MOTION made by the Joint Committee was heard in writing this day.

ON READING the material filed including the notice of motion and the following affidavits:

- (i) Heather Rumble Peterson made May 17, 2019 and May 29, 2019;
- (ii) Dr. Vincent Bain made March 11, 2015 and March 31, 2016; and
- (iii) Dr. Samuel Lee made January 26, 2016.

AND THIS ACTION BEING STAYED AGAINST the defendant, the Canadian Red Cross Society by the order of Mr. Justice Blair made on July 20, 1998 in Ontario Superior Court of Justice Action No. 98-CL-002970 (Toronto) and subsequently extended by further orders made on August 18, 1998, October 5, 1998, January 18, 1999, May 5, 1999, July 28, 1999 and February 25, 2000,

AND ON BEING ADVISED that this motion was unopposed by the defendants and intervenors,

1. THIS COURT ORDERS that direct-acting antiviral agents which have been approved by Health Canada as treatment for HCV (“DAA”) be added to the list of drug treatments approved by the Courts for compensation as Compensable HCV Drug Therapy under section 1.01 of the Transfused HCV Plan, the Hemophiliac HCV Plan and the HCV Late Claims Benefit Plan of the 1986-1990 Hepatitis C Settlement Agreement in those cases where the treating physician certifies that the HCV Infected Person suffered side effects as a result of taking the DAA treatment which significantly interfered with his or her activities of daily living.

2. THIS COURT ORDERS that the court-approved protocol for Medical Evidence for Sections 4.01(1) and 4.01(2) of Article 4 of the Transfused HCV Plan and the Hemophiliac HCV Plan be and is hereby amended as set out in Schedule “A” hereto.

3. THIS COURT ORDERS that the plaintiffs’ outstanding motion dated November 17, 2017 concerning Compensable HCV Drug Therapy and that portion of the plaintiffs’ outstanding motion dated November 17, 2017 in respect of amendments to the Medical Evidence Protocol be and are hereby dismissed.

4. THIS COURT ORDERS that this Order shall not be effective unless and until parallel orders are approved by the Supreme Court of British Columbia and the

Superior Court of Quebec
 ENTERED AT / INSCRIPT A TORONTO
 ON / BOOK NO:
 LE / DANS LE REGISTRE NO:

JUN 24 2019


 PERELL J.

1677927 

PER/PAR

SCHEDULE A

COURT APPROVED PROTOCOL

MEDICAL EVIDENCE

REVISED JUNE, 2019

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"¹) 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.

OR

- (c) Met or meets the following protocol for Compensable HCV Drug Therapy, notwithstanding that such treatment was not recommended or, if recommended was declined:
 - (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; and
 - (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 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"²) 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"³) 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 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; or

- (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 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 150×10^9 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 condition⁴ 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

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.

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PARSONS et al.
KREPPNER et al.

vs. THE CANADIAN RED CROSS SOCIETY et al.

Plaintiffs

Defendants

Court File No. 98-CV-141369
98-CV-146405

ONTARIO
SUPERIOR COURT OF JUSTICE
PROCEEDINGS COMMENCED AT TORONTO

ORDER

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