COURT APPROVED PROTOCOL

NON-PRESCRIPTION INTRAVENOUS DRUG USE

REVISED DECEMBER, 2017

This protocol applies to sections 3.01(1)(c) and (3), 3.02(1)(a) and (c) and (2) or 3.05(5) of the Transfused HCV Plan, sections 3.01(1)(c) and (3), 3.02(1)(a) and (c) and (2) or 3.04(5) of the Hemophiliac HCV Plan and sections 3.01Tran(1)(c) and (3), 3.01Hemo(1)(c) and (3), 3.02(1)(a) and (c) and 2, 3.05(5)(Tran) and 3.05(5)(Hemo) of the HCV Late Claims Benefit Plan.

1. This protocol applies where:

   (a) there is an admission that the HCV Infected Person used non-prescription intravenous drugs;

   (b) there is no declaration that the HCV Infected Person has never used non-prescription intravenous drugs pursuant to section 3.01(1)(c), 3.02(1)(c), or 3.05(5) of the Transfused HCV Plan, section 3.01(1)(c), 3.02(1)(c), or 3.04(5) of the Hemophiliac HCV Plan or section 3.01Tran(1)(c), 3.01Hemo(1)(c), 3.02(1)(c), 3.05(5)(Tran) or 3.05(5)(Hemo) of the HCV Late Claims Benefit Plan; or

   (c) despite receipt of a declaration that the HCV Infected Person has never used non-prescription intravenous drugs, there is other evidence that the HCV Infected Person has used non-prescription intravenous drugs.

ELIGIBILITY CRITERIA WHERE THIS PROTOCOL APPLIES

2. The Administrator must be satisfied on the balance of probabilities that:

   (a) the Primarily-Infected Hemophiliac (or person with Thalassemia Major) was infected with HCV for the first time by Blood or Blood (Hemophiliac) (under the applicable Plan) received in Canada; or

   (b) the Primarily-Infected Person or Secondarily-Infected Person was infected with HCV for the first time:

      (i) by a Blood transfusion or Blood (Transfused) transfusion (under the applicable Plan) received in Canada in the Class Period;

      (ii) by a Spouse who is a Primarily-Infected Person/Primarily-Infected Hemophiliac/Opted-Out Primarily-Infected Person/Opted-Out Primarily Infected Hemophiliac; or

(iii) by a Parent who is an HCV Infected Person/Opted-Out HCV Infected Person;

as the case may be.

3. The burden to prove eligibility is on the claimant. The Administrator shall assist the claimant by advising what types of evidence will be useful in meeting the burden of proof in accordance with this protocol.

TRACEBACK

4. The Administrator shall conduct a Traceback under the Traceback Procedure Criteria Protocol or the Eligibility and Traceback Requirements for Secondarily-Infected Persons Protocol unless:

(a) in the case of a Primarily-Infected Hemophiliac (or person with Thalassemia Major), the HCV Infected Person was a regular recipient of Blood or Blood (Hemophiliac) (under the applicable Plan) prior to his or her attaining the age of 18; or

(b) in the case of a person claimed to be a Secondarily-Infected Person, the person has no history of blood transfusion.

5. If neither the Traceback Procedure Criteria Protocol nor the Eligibility and Traceback Requirements for Secondarily-Infected Persons Protocol applies, the Administrator shall perform the additional investigations required by paragraph 8 below.

6. If the result of a traceback investigation is such that the applicable Traceback protocol requires the Administrator to reject the Claim or Late Claim of the HCV Infected Person, the Administrator shall reject the Claim or Late Claim.

7. The Administrator may not accept a Claim or Late Claim where this protocol applies based on the results of a traceback investigation without performing the additional investigations required by the provisions of paragraph 8 below.

ADDITIONAL INVESTIGATIONS

8. If the Claim or Late Claim is not rejected under the applicable Traceback protocol, the Administrator shall perform the following additional investigations:

(a) obtain such additional information and records pursuant to section 3.03 of the applicable Plan as the Administrator in its complete discretion considers necessary to inform its decision; and

(b) obtain the opinion of a medical specialist experienced in treating and diagnosing HCV as to whether the HCV infection and the disease history of the HCV Infected Person is more consistent with infection at the time of the receipt of Blood or Blood (Hemophiliac) (under the applicable Plan), the Class Period

Blood transfusion(s) or Blood (Transfused) transfusions (under the applicable Plan) or the secondary infection or more consistent with infection at the time of the non-prescription intravenous drug use as indicated by the totality of the medical evidence.

9. The Administrator shall weigh the totality of evidence obtained including the evidence obtained from the additional investigations required by the provisions of this protocol and determine whether, on a balance of probabilities, the HCV Infected Person meets the eligibility criteria.

10. In weighing the evidence in accordance with the provisions of this protocol, the Administrator must be satisfied that the body of evidence is sufficiently complete in all of the circumstances of the particular case to permit it to make a decision. If the Administrator is not satisfied that the body of evidence is sufficiently complete in all of the circumstances of the particular case to permit it to make a decision, the Administrator shall reject the Claim or Late Claim.

EXAMPLES OF ADDITIONAL INVESTIGATIONS

11. Examples of the evidence the Administrator may require to inform its decision include the following:

(a) an independent medical examination with a physician of the Administrator's choice, to obtain opinion evidence on any medical issues which the Administrator believes will assist in making its decision;

(b) the medical and clinical records from any or all hospitalizations and treating physicians for the HCV Infected Person for such time frame as the Administrator considers relevant;

(c) the donation history, transmissible disease information, deferral codes or the results of any lookbacks pertaining to blood donated by the HCV Infected Person available from Canadian Blood Services and/or Hema-Quebec;

(d) an affidavit from the HCV Infected Person and a person who knew the HCV Infected Person at the time he/she used non-prescription intravenous drugs describing:

(i) whether the drug paraphernalia used was sterile;

(ii) whether the HCV Infected Person shared needles; and

(iii) the best estimate of the number of occasions and time period during which the HCV Infected Person used non-prescription intravenous drugs;

(e) a consent to conduct a criminal records search of HCV Infected Person; and

(f) an affidavit or interview of any person the Administrator believes may have knowledge about the non-prescription intravenous drug use or disease history of the HCV Infected Person.

RESULTS OF THE INVESTIGATIONS

12. Although none of these factors may prove conclusive in any individual case because the Administrator must consider the totality of the evidence, the following factors are examples of evidence that would be supportive of a finding that the person claimed to be an HCV Infected Person is eligible:

(a) identification of a Class Period Blood transfusion or Blood (Transfused) transfusion (under the applicable Plan) from an HCV antibody positive donor;

(b) the HCV Infected Person was under the age of 18 at the time of the receipt of Blood or Blood (Hemophiliac) (under the applicable Plan)or the Class Period Blood transfusions or Blood (Transfused) transfusions (under the applicable Plan);

(c) reliable evidence establishes that the non-prescription intravenous drug use took place after July 1, 1990;

(d) an HCV disease history which is more consistent with the timing of:

(i) the receipt of Blood or Blood (Hemophiliac) (under the applicable Plan) for the Primarily-Infected Hemophiliac (or person with Thalassemia Major);

(ii) the Class Period Blood transfusion(s) or Blood (Transfused) transfusions (under the applicable Plan) for which an HCV antibody positive donor has been located or for which the status of the donor remains unknown; or

(iii) the alleged secondary infection;

than with the time of non-prescription intravenous drug use;

(e) reasonably reliable evidence that the non-prescription intravenous drug use history is subsequent to the receipt of Blood or Blood (Hemophiliac) (under the applicable Plan) for the Primarily-Infected Hemophiliac (or person with Thalassemia Major), or the date of Class Period Blood transfusion(s) or Blood (Transfused) transfusions (under the applicable Plan) for the Primarily Infected Person, or the date of alleged secondary infection for the Secondarily-Infected Person;

(f) reasonably reliable evidence that the non-prescription intravenous drug use was limited to a single occasion and was done with sterile equipment which was not shared; and

(g) no medical history of unspecified Hepatitis, Hepatitis B or Non-A, Non-B Hepatitis prior to the date of the receipt of Blood or Blood (Hemophiliac) (under the applicable Plan) for the Primarily-Infected Hemophiliac (or person with Thalassemia Major), the Class Period Blood transfusion(s) or Blood (Transfused) transfusions (under the applicable Plan) for the Primarily-Infected Person or the date of alleged secondary infection for the Secondarily-Infected Person.

13. Although none of these factors may prove conclusive in any individual case because the Administrator must consider the totality of the evidence, the following are examples of evidence that would not be supportive of a finding that the person claimed to be an HCV Infected Person is eligible:

(a) failure to identify a Class Period Blood transfusion or Blood (Transfused) transfusion (under the applicable Plan) for the Primarily-Infected Person from an HCV antibody positive donor;

(b) an HCV disease history which is more consistent with infection at the time of non-prescription intravenous drug use than with the timing of:

(i) the receipt of Blood or Blood (Hemophiliac) (under the applicable Plan) for the Primarily-Infected Hemophiliac (or person with Thalassemia Major);

(ii) the Class Period Blood transfusion(s) or Blood (Transfused) transfusions (under the applicable Plan) for the Primarily-Infected Person for which an HCV antibody positive donor has been located or for which the status of the donor remains unknown; or

(iii) the alleged secondary infection;

(c) reasonably reliable evidence that the non-prescription intravenous drug use took place on more than one occasion or was done with non-sterile or shared equipment;

(d) a medical history of unspecified Hepatitis, Hepatitis B or Non-A Non-B Hepatitis prior to the date of the receipt of Blood or Blood (Hemophiliac) (under the applicable Plan) for the Primarily-Infected Hemophiliac (or person with Thalassemia Major), or the Class Period Blood transfusion(s) or Blood (Transfused) transfusions (under the applicable Plan) for the Primarily-Infected Person or the date of alleged secondary infection for the Secondarily-Infected Person;

(e) a refusal to permit the Administrator to interview any person the Administrator believes may have knowledge about the non-prescription intravenous drug use or disease history of the HCV Infected Person;

(f) a CBS or Hema-Quebec donor file which indicates that the HCV Infected Person:

(i) tested positive for the antibodies to Hepatitis B; or

(ii) had donated blood prior to the Class Period and the pre-Class Period blood donations or recipients of the pre-Class Period blood donations have subsequently tested positive for HCV antibodies; and

(g) the file is in any other way consistent with infection with HCV by non-prescription intravenous drug use prior to the receipt of Blood or Blood (Hemophiliac) (under the applicable Plan) for the Primarily-Infected Hemophiliac (or person with Thalassemia Major), or the Class Period Blood transfusion(s) or Blood (Transfused) transfusions for the Primarily-Infected Person, or the date of alleged secondary infection for the Secondarily-Infected Person.

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