

## **SOP – NON-PRESCRIPTION INTRAVENOUS DRUG USE**

### **Applicability of SOP**

1. This SOP applies where:
  - (a) a declaration has not been made in accordance with s.3.01(1)(c) or s.3.02(a) of the Transfused HCV Plan or the Hemophiliac HCV Plan that the person claimed to be an HCV Infected Person never used non-prescription intravenous drugs;
  - (b) despite a declaration having been made in accordance with s.3.01(1)(c) or s.3.02(a) of the Plans that the person claimed to be an HCV Infected Person never used non-prescription intravenous drugs, the Administrator has reasonable cause to believe that a person claimed to be an HCV Infected Person has used non-prescription intravenous drugs on at least one occasion.

### **Eligibility Criteria Where This SOP Applies**

2. Where this SOP applies, the Administrator must undertake sufficient investigation and receive sufficient information and cooperation in obtaining information from the claimant to be satisfied on the balance of probabilities that:
  - (a) in the case of a person applying under the Transfused HCV Plan, the person claimed to be an HCV Infected Person was infected for the first time with HCV by a Blood transfusion received in Canada in the Class Period or was infected for the first time by a Spouse who is a Primarily-Infected Person/Opted-Out Primarily-Infected Person or by a Parent who is an HCV Infected Person/Opted-Out HCV Infected Person, as the case may be; or
  - (b) in the case of a person applying under the Hemophiliac HCV Plan, the person claimed to be an HCV Infected Person was infected for the first time with HCV by receipt of Blood or was infected for the first time by a Spouse who is a Primarily-Infected Hemophiliac/Opted-Out Primarily-Infected Hemophiliac or 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 SOP.

## **Mandatory Investigations**

4. Where this SOP applies to a person claimed to be an HCV Infected Person applying under the Transfused HCV Plan, the Administrator must, unless the person claimed to be a Primarily-Infected Person was under the age of 18 at the time of his or her transfusion(s) and reliable evidence establishes that his or her non-prescription intravenous drug use only took place after July 1, 1990:
  - (a) request a traceback be conducted under the Traceback CAP, except in the case of a person claimed to be a Secondarily-Infected Person who has no history of Blood transfusion; and
  - (b) where the person claimed to be an HCV Infected Person has admitted or the evidence obtained suggests that the person claimed to be an HCV Infected Person engaged in non-prescription intravenous drug use prior to 1986, investigate whether the time of the infection and the disease history in the person claimed to be an HCV Infected Person is most consistent with the time of the transfusion(s)/alleged secondary infection or the time of the non-prescription intravenous drug use or both as indicated by the totality of the evidence and to do so the Administrator must obtain the opinion of a physician with experience in treating and diagnosing HCV infection.
5. Where this SOP applies to an HCV Infected Person applying under the Hemophiliac HCV Plan, the Administrator must determine whether the time of the infection and the disease history in the person claimed to be an HCV Infected Person is most consistent with the time of the receipt of Blood/alleged secondary infection or the time of the non-prescription intravenous drug use or both as indicated by the totality of the evidence and to do so the Administrator must obtain the opinion of a physician with experience in treating and diagnosing HCV infection, unless:
  - (a) the person claimed to be a Primarily-Infected Hemophiliac was under the age of 18 at the time he or she received Blood and reliable evidence establishes that his or her non-prescription intravenous drug use only took place after July 1, 1990; or
  - (b) the person claimed to be a Primarily-Infected Hemophiliac was a regular recipient of Blood prior to his or her attaining the age of 18.

## **Discretionary Investigations**

6. The Administrator may undertake any other investigations it, in its complete discretion, deems appropriate. Examples are:
  - (a) require that the person claiming to be an HCV Infected Person attend 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, including:

- (i) whether the time of the infection and the disease history in the person claimed to be an HCV Infected Person is most consistent with the time of the receipt of Blood/transfusion(s)/alleged secondary infection or the time of the non-prescription intravenous drug use; and/or
  - (ii) where a person asserts that non-prescription intravenous drug use took place on only isolated occasion(s) and/or after 1990, whether there is any medical evidence which will assist in determining whether that assertion is correct;
- (b) for the purposes of determining whether non-prescription intravenous drug use took place at any time other than those asserted by the claimant, or for the purpose of assessing whether the disease history of a person claimed to be an HCV Infected Person is consistent with the time of receipt of Blood/transfusion(s)/alleged secondary infection, obtain and review the medical and clinical records from all hospitalizations and treating physicians for the following periods of time;
  - (i) where the person claimed to be an HCV Infected Person asserts that his or her non-prescription intravenous drug use took place only after 1990, all available records from 1981 (or the 18th birthday of the person claimed to be an HCV Infected Person, if later than 1981) through 1990;
  - (ii) where the person claimed to be an HCV Infected Person has denied non-prescription intravenous drug use but the Administrator has reasonable grounds to believe there has been non-prescription intravenous drug use, all available medical records from 1976 (or the 18th birthday of the person claimed to be an HCV Infected Person, if later than 1976) to the present,
  - (iii) if the person claimed to be an HCV Infected Person has admitted non-prescription intravenous drug use prior to 1986/receipt of Blood/alleged secondary infection but asserts it was an isolated instance, all available medical records from 5 years prior (or the 18th birthday of the person claimed to be an HCV Infected Person, if less than 5 years prior) and 5 years subsequent to the acknowledged occasion of non-prescription intravenous drug use; and/or
  - (iv) for the purpose of assessing disease history, all available medical records from the time of the non-prescription intravenous drug use or the time of the receipt of Blood/transfusions(s)/alleged secondary infection, whichever is earlier;
- (c) ascertain whether the person claimed to be an HCV Infected Person has ever donated blood in Canada. If so, the Administrator shall make inquiries of the Canadian Blood Services and/or Hema-Quebec as to the donation history, transmissible disease information, deferral codes and the results of any lookbacks pertaining to blood donated by the person claimed to be an HCV Infected Person;

- (d) obtain an affidavit from the person claimed to be an HCV Infected Person (if not deceased) and a person who knew the person claimed to be an HCV Infected Person at the time he or she used non-prescription intravenous drugs describing:
  - (i) whether the drug paraphernalia used was sterile;
  - (ii) whether the person claimed to be an HCV Infected Person shared needles; and
  - (iii) the best estimate of the number occasions and time period during which the person claimed to be an HCV Infected Person used non-prescription intravenous drugs;
- (e) obtain consent to conduct a criminal records search of the person claimed to be an HCV Infected Person; and/or
- (f) interview any person the Administrator believes may have knowledge about the non-prescription intravenous drug use or disease history of the person claimed to be an HCV Infected Person.

### **Results of the Mandatory Investigations and Discretionary Investigations:**

#### **Transfused HCV Plan**

- 7. If the results of the traceback investigations are such that the Traceback CAP requires the Administrator to reject the claim of the person claimed to be an HCV Infected Person under the Transfused HCV Plan, the Administrator shall reject the claim.
- 8. If the Traceback CAP does not require the Administrator to reject the claim, the Administrator shall weigh the totality of evidence obtained from the mandatory investigations and discretionary investigations and determine whether, on a balance of probabilities, the person claimed to be an HCV Infected Person under the Transfused HCV Plan was infected for the first time by a Blood transfusion received in Canada during the Class Period or was infected for the first time by a Spouse who is a Primarily-Infected Person/Opted-Out Primarily-Infected Person or by a Parent who is an HCV Infected Person/Opted-Out HCV Infected Person, as the case may be. The Administrator must be satisfied that the body of evidence on which it is making its decision is sufficiently complete in all of the circumstances of the particular case before making a decision. In particular, if the Administrator has concerns that the body of evidence is not complete, it should request and review medical records as described in paragraph 6(b) of this SOP.
- 9. The following factors are in favour of a finding that the person claimed to be an HCV Infected Person was infected for the first time by a Blood transfusion received in Canada during the Class Period or was infected for the first time by a Spouse who is a Primarily-Infected Person/Opted-Out Primarily Infected Person or by a Parent who is an HCV Infected Person/Opted-Out HCV Infected Person, as the case may be:

- (a) an HCV antibody positive Class Period donor;
  - (b) the person claimed to be an HCV Infected Person was under the age of 18 at the time of his or her transfusion and reliable evidence establishes that his or her non-prescription intravenous drug use took place after July 1, 1990;
  - (c) a disease history which is most consistent with the time of transfusion(s) for which an HCV antibody positive Class Period donor has been located/alleged secondary infection and not consistent with the time of non-prescription intravenous drug use;
  - (d) reasonably reliable evidence which establishes that the non-prescription intravenous drug use history is subsequent to the date of transfusion(s)/alleged secondary infection;
  - (e) there is reasonably reliable evidence which establishes that the non-prescription intravenous drug use was limited to a single occasion and was done with sterile equipment which was not shared; and/or
  - (f) the medical records do not reveal a history of unspecified Hepatitis, Hepatitis B or Non-A, Non-B Hepatitis prior to the date of the Class Period transfusion(s)/alleged secondary infection.
10. The following factors are against a finding that the person claimed to be an HCV Infected Person was infected for the first time by a Blood transfusion received in Canada during the Class Period or was infected for the first time by a Spouse who is a Primarily-Infected Person/Opted-Out Primarily-Infected Person or by a Parent who is an HCV Infected Person/Opted-Out HCV Infected Person, as the case may be:
- (a) no HCV antibody positive Class Period donor;
  - (b) a disease history which is consistent with infection at the time of non-prescription intravenous drug use;
  - (c) reasonably reliable evidence indicates that the non-prescription intravenous drug use took place on more than one occasion or was done with non-sterile or shared equipment;
  - (d) the medical records indicate a history of unspecified Hepatitis, Hepatitis B or Non-A, Non-B Hepatitis prior to the date of the Class Period transfusion(s)/alleged secondary infection;
  - (e) the person making the claim refuses 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 person claimed to be an HCV Infected Person;

- (f) there is a conviction for a crime which relates to non-prescription intravenous drugs; and/or
- (g) a CBS or Hema-Quebec donor file which indicates that the person claimed to be an HCV Infected Person:
  - (i) tested positive for the antibodies to Hepatitis B;
  - (ii) had donated blood prior to his or her Blood transfusion(s) during the Class Period/alleged secondary infection and the pre-Class Period donations or recipients of the pre-Class Period donations have subsequently tested positive for the antibodies to Hepatitis C; and/or
  - (iii) the file is in any other way consistent with infection with HCV and/or non-prescription intravenous drug use prior to the Class Period Blood transfusion(s)/alleged secondary infection.

#### Hemophiliac HCV Plan

11. If the person claimed to be a Primarily-Infected Hemophiliac applying under the Hemophiliac HCV Plan was a regular recipient of Blood prior to his or her attaining the age of 18, the Administrator shall accept the claim.
12. The Administrator shall weigh the totality of evidence obtained from the mandatory investigations and discretionary investigations and determine whether, on a balance of probabilities, the person claimed to be an HCV Infected Person under the Hemophiliac HCV Plan was infected for the first time by Blood or was infected for the first time by a Spouse who is a Primarily-Infected Hemophiliac/Opted-Out Primarily-Infected Hemophiliac or a Parent who is an HCV Infected Person/Opted-Out HCV Infected Person, as the case may be. The Administrator must be satisfied that the body of evidence on which it is making its decision is sufficiently complete in all of the circumstances of the particular case before making a decision. In particular, if the Administrator has concerns that the body of evidence is not complete, it should request and review medical records as described in paragraph 6(b) of this SOP.
13. The following factors are in favour of a finding that the person claimed to be an HCV Infected Person was infected for the first time by Blood or was infected for the first time by a Spouse who is a Primarily-Infected Hemophiliac/Opted-Out Primarily-Infected Hemophiliac or a Parent who is an HCV Infected Person/Opted-Out HCV Infected Person, as the case may be:

- (h) his or her disease history is most consistent with the time of receipt of Blood/alleged secondary infection and not consistent with the time of non-prescription intravenous drug use;
  - (i) there is reasonably reliable evidence which establishes that the non-prescription intravenous drug use history is subsequent to the date of receipt of Blood/alleged secondary infection; and/or
  - (j) the non-prescription intravenous drug use was limited to a single occasion and was done with sterile equipment which was not shared.
14. The following factors are against a finding that the person claimed to be an HCV Infected Person was infected for the first time by Blood or was infected for the first time by a Spouse who is a Primarily-Infected Hemophiliac/Opted-Out Primarily-Infected Hemophiliac or a Parent who is an HCV Infected Person/Opted-Out HCV Infected Person, as the case may be:
- (k) his or her disease history is consistent with infection at the time of non-prescription intravenous drug use;
  - (l) there is reasonably reliable evidence which indicates that the non-prescription intravenous drug use took place on more than one occasion or was done with non-sterile or shared equipment;
  - (m) the person making the claim refuses to permit the Administrator to interview treating physicians, family members or associates; and/or
  - (n) there is a conviction for a crime which relates to non-prescription intravenous drugs.