

ALTERNATIVE TO BIOPSY PROTOCOL

1. This Protocol sets out the alternative medical evidence that may be provided in the absence of a biopsy. It applies to the claims of Approved HCV Infected Class Members made at Disease Levels 3, 4, 5 and 6.
2. With respect to claims regarding a Primarily-Infected Person or a Secondarily-Infected Person, this Protocol shall only be available if evidence satisfactory to the Administrator is provided that a biopsy is contraindicated in the circumstances of the medical condition of the Primarily-Infected Person or Secondarily-Infected Person. Satisfactory evidence may include the opinion of a qualified gastroenterologist, hepatologist, infectious disease specialist or internist, that a biopsy is contraindicated. The Administrator may, if the Administrator deems it appropriate, obtain further medical opinions or require an independent medical examination as to whether a biopsy is contraindicated in respect of the medical condition of the Primarily-Infected Person or Secondarily-Infected Person. If the HCV Infected Class Member is a hemophiliac, biopsy is deemed to be contraindicated without the need for further medical evidence.
3. This Protocol shall only be available where the Treating Physician certifies to the Administrator that:
 - (a) he or she is unable to assign the disease level he or she considers most appropriate for his or her patient due to the absence of a biopsy; and
 - (b) the HCV Infected Class Member does not have any of the other medical conditions applicable at the disease level for which qualification is sought.
4. To utilize this Protocol, the following must be delivered to the Administrator in addition to a satisfactorily completed Treating Physician Form:
 - (a) For Disease Level 3 fibrosis, Section 2.04(2)(c)(i) of the Settlement Agreement, in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist or internist based on non-invasive testing and diagnosis, complete details of which are provided, that if the HCV Infected Class Member were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she has developed fibrous tissue in the portal areas of the liver with fibrous bands extending out from the portal area but without any bridging to other portal tracts or to central veins (i.e., non-bridging fibrous).
 - (b) For Disease Level 4 bridging fibrosis, Section 2.04(2)(d) of the Settlement Agreement, in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist or internist based on non-invasive testing and diagnosis, complete details of which are provided, that if the HCV Infected Class Member were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she 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 (i.e., bridging fibrous).

- (c) For Disease Level 5 cirrhosis, Section 2.04(2)(e)(i) of the Settlement Agreement, in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist or internist based on non-invasive testing and diagnosis, complete details of which are provided, that if the HCV Infected Class Member were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she has developed fibrous bands in the liver extending or bridging from portal area to portal area with the development of nodules and regeneration (i.e. cirrhosis).
 - (d) For Disease Level 5 glomerulonephritis without dialysis, Section 2.04(2)(e)(v) of the Settlement Agreement, in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, internist, infectious disease specialist or nephrologist based on non-invasive testing and diagnosis, complete details of which are provided, that if the HCV Infected Class Member were to undergo a kidney biopsy, such biopsy would more likely than not demonstrate that he or she has developed glomerulonephritis not requiring dialysis which is consistent with infection with HCV.
 - (e) For Disease Level 6 hepatocellular cancer, Section 2.04(2)(f)(ii) of the Settlement Agreement, in the absence of a liver biopsy, the opinion of a gastroenterologist, hepatologist, infectious disease specialist or internist based on non-invasive testing and diagnosis, complete details of which are provided that if the HCV Infected Class Member were to undergo a liver biopsy, such biopsy would more likely than not demonstrate that he or she has developed hepatocellular cancer;
 - (f) For Disease Level 6 glomerulonephritis with dialysis, Section 2.04(2)(f)(v) of the Settlement Agreement, in the absence of a kidney biopsy, the opinion of a gastroenterologist, hepatologist, internist, infectious disease specialist or nephrologist based on non-invasive testing and diagnosis, complete details of which are provided, that if the HCV Infected Class Member were to undergo a kidney biopsy, such biopsy would more likely than not demonstrate that he or she has developed glomerulonephritis requiring dialysis which is consistent with infection with HCV.
5. For a claim regarding a Primarily-Infected Hemophiliac, the medical opinion required in sections 4 (a) to (f) above may be provided by a hemophiliac treating physician.
 6. The Administrator may, if the Administrator deems it appropriate, obtain further medical opinions or require an independent medical examination in respect of the Disease Level of the HCV Infected Class Member seeking to qualify under this Protocol.
 7. This Protocol will be periodically reviewed to determine if there is any change to the medical evidence which is generally accepted by the medical profession and amendments may be sought in the future in order that it keep pace with evolving medical science.