FORM K	APPLICATION TO JOIN THE PAYMENT SCHEME NEW CHRONIC HEPATITIS C APPLICATIONS THAT ALSO FEATURE ADVANCED HEPATITIS C

GUIDANCE NOTES FOR APPLICANTS

This form is for applicants who have never joined the Scottish Infected Blood Support Scheme, or any of the UK Schemes (e.g. Skipton Fund) with regards to Hepatitis C payments, and either:

- Were infected by Hepatitis C as a result of treatment they received themselves with NHS blood, tissue, or blood products

  Or

- Were infected by Hepatitis C as a result of the virus being transmitted from someone else, who themselves were infected by Hepatitis C as a result of treatment they received with NHS blood, tissue, or blood products

If your circumstances differ to the above, please contact the Scottish Infected Blood Support Scheme for guidance.

This form allows you to apply for Hepatitis C payments under the Scottish Infected Blood Support Scheme. This form will also help the scheme to assess whether you qualify for advanced Hepatitis C payments.

Further details are available on our website at www.nhsnss.org/SIBSS

HOW TO APPLY

You should first complete all parts in Section 1 of this form. You should then pass this form in its entirety to a medical professional, who will complete the remaining sections. The medical professional must then send the completed form directly to the Scottish Infected Blood Support Scheme.

Generally, the medical professional should be the principal clinician treating you. This will probably be the hepatologist or infectious disease specialist treating you for Hepatitis C, but in the case of applicants with bleeding disorders (such as haemophilia), it may be a haematologist.

If you have any records of how you were infected, please pass copies of them to the medical professional who will be completing the remainder of the form.

WHAT HAPPENS NEXT

When the medical professional has completed the form, they must send it along with copies of all relevant records direct to the Scottish Infected Blood Support Scheme. Provided that the information supplied confirms you are eligible to receive payment, you will receive a letter from the scheme to confirm this and will be asked to provide your bank details and any identification required at that point.

HELP WITH THIS FORM

If you require any assistance in completing this form, please contact the Scottish Infected Blood Support Scheme on 0131 275 6754.

FORM K	APPLICATION TO JOIN THE PAYMENT SCHEME NEW CHRONIC HEPATITIS C APPLICATIONS THAT ALSO FEATURE ADVANCED HEPATITIS C

SECTION 1(A)	DATA PROTECTION AND APPLICANT'S DECLARATION

✓ Please tick to confirm

☐ **I understand that** data I provide may be shared with NHS service providers and Counter Fraud Services to ensure accurate and timely payment and for the purposes or prevention, detection and investigation of crime.

DECLARATION BY APPLICANT

I agree that the information I give on this form is complete and correct.

I agree to repay any money I receive to which it is found that I am no longer entitled.

I understand if I knowingly give wrong or incomplete information I may be prosecuted.

I have not received payment from any other UK scheme as a result of my Hepatitis C infection.

I agree to NHS National Services Scotland obtaining any data held on me by the Skipton Fund or the Caxton Foundation for the purposes of providing me with financial support.

I understand that NHS National Services Scotland may require to access data held on me by other public bodies and/or make any additional enquiries with other public bodies that may be necessary in order to reach a decision regarding my application.

Signature of Applicant		Date	

HOW WE USE YOUR INFORMATION

Under the Data Protection Act 1998, we have a duty to protect personal health information. This information is securely held, closely monitored and managed according to strict guidelines. Access to personal information is only given on a strict need to know basis and there are formal authorisation processes in place to gain access to the data.

We only collect essential personal information required to process applications and make payments under the Scottish Infected Blood Support Scheme. This includes:

a) Your demographic information, marital status, National Insurance number and CHI number (this is a national database of all patients with NHSScotland, which ensures correct identification of patients).
b) Details of your healthcare providers and the care you have received.
c) Bank account details.

SECTION 1(B) APPLICANT DETAILS

Title		First Name	
Middle Name(s)		Surname	
Previous Names			
Address (this must be your main residence)			
		Post Code	
Home Telephone		Mobile Telephone	
E-Mail Address		Date of Birth	
NHS Scotland CHI Number (if known)		National Insurance Number	

What is your marital status?

Tick One Option Below	✓
Married	
Civil Partnership	
Widowed	
Divorced	
Separated	
Single	
Living with Partner	

Have you ever applied to any of the UK schemes (e.g. Skipton Fund) to receive payments with regards to your Hepatitis C infection?

Yes ☐ No ☐

If 'Yes', please advise what the outcome of your application was

SECTION 1(C) ADDITIONAL APPLICATION DETAILS

Do you believe you were infected with Hepatitis C as a result of treatment you received yourself with NHS blood, tissue, or blood products? Yes ☐ No ☐

If 'Yes', please provide as much information as you can on how and when you believe this infection occurred

Alternatively, do you believe you were infected with Hepatitis C as a result of the virus being transmitted from someone else, who themselves were infected as a result of treatment with NHS blood, tissue, or blood products? Yes ☐ No ☐

If 'No' this section is complete, if 'Yes' please provide further details below:

How do you believe the infection occurred?

Who do you believe you received this infection from?

Title | First Name

Middle Name(s) | Surname

Address

Post Code

What is/was your relationship to this person?

Have they ever registered with the Scottish or UK support schemes? Yes ☐ No ☐ Unknown ☐

If known, please advise which scheme(s)

SECTION 1(D) ADDITIONAL INFORMATION

If you have any additional information you would like to provide, please add it here:

Once you have completed all parts of Section 1, please pass the form to a medical professional to complete.

The medical professional will complete the remainder of the form and return it directly to the Scottish Infected Blood Support Scheme on your behalf.

THE FOLLOWING SECTIONS MUST BE COMPLETED BY A MEDICAL PROFESSIONAL

GUIDANCE NOTES FOR MEDICAL PROFESSIONALS

Thank you for your help with this application. In most cases this form will concern a patient who is known to you and who had been infected with Hepatitis C.

Sections 2-5 of this form should be completed in all cases. The purpose of these sections is:

- To confirm that the applicant had been chronically infected with Hepatitis C

  And

- To confirm that the infection most probably arose through treatment with NHS blood, tissue or blood products

If there are questions in this form relating to the applicant that you cannot answer, please consult other medical professionals who have treated the applicant and who would be able to provide the information.

In some cases this form will concern a patient who had been indirectly infected (e.g. by accidental needle stick) by somebody who is (or was) infected themselves through NHS treatment.

> *Please note that from May 1987, the majority of blood products used in Scotland were successfully treated against Hepatitis C. The population at risk after that date was therefore primarily those patients undergoing blood transfusion only. Hepatitis C screening of blood across the whole UK did not begin until 1st September 1991, so those receiving blood transfusions between May 1987 and 1st September 1991 were still at risk of HCV infection.*
>
> *Prior to the achievement in Scotland of successfully heat-treated concentrates (from October 1985 for Haemophilia B and from May 1987 for Haemophilia A), a patient was likely to have been infected with HCV by their treatment with concentrates, whether commercial or NHS. Haemophilia A is treated with Factor VIII concentrate and Haemophilia B is treated with Factor IX concentrate.*

Sections 6-11 should only be completed in cases where the applicant has developed either:

- Cirrhosis
- Primary liver cancer
- B-cell non-Hodgkin's lymphoma; or
- Has received a liver transplant, or is on the waiting list to receive one

If the applicant's circumstances meet the above criteria, you should complete Sections 6-11 of this form, only if you are the consultant physician currently in charge of the applicant's care.

It is intended that the existence of cirrhosis should be assessed using either existing biopsy data, or the results of non-invasive tests. A liver biopsy should not be performed purely for the purpose of making this application.

When complete, please return this form along with all relevant documents direct to the following address:

Scottish Infected Blood Support Scheme
Practitioner Services
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

ADDITIONAL NOTES ON THE LAYOUT AND COMPLETION OF SECTION 6-11

Section 6	This section asks whether the applicant has undergone liver transplantation, is currently awaiting a transplant, or has developed primary liver cancer. If any of these circumstances pertain, Sections 7-11 do not need to be completed.
Section 7	This section seeks information of liver histology, where available. Where histological proof of cirrhosis is available, Sections 6 and 8-11 do not need to be completed.
Section 8	This section asks whether the applicant has developed B-cell non-Hodgkin's lymphoma. If this is the case, Sections 6-7 and 9-11 do not need to be completed.
Section 9	This section should be completed for applicants for whom a liver biopsy has never been performed, or without recent liver histology. It asks for the calculation of two simple indices, based upon readily available laboratory tests, which have been used to predict cirrhosis. The chosen indices require recent and repeatable measurements (two samples not less than three months apart) of the two liver enzymes, aspartate aminotransferase (AST) and alanine aminotransferase (ALT), and the platelet count. Further details of these indices are shown on the next page. With regards to the payment for advanced Hepatitis C, an APRI ≥ 2.0 together with an AST/ALT ≥ 1.0 will be accepted as presumptive evidence for cirrhosis provided there are no factors other than fibrosis which are potentially affecting the AST, ALT and platelet readings. Where both these indices are at or above these cut-offs, and there are no other factors other than fibrosis which may be affecting the AST, ALT and platelet readings, then Sections 10-11 do not need to be completed.
Section 10	This section should be completed for an applicant whose application depends on establishing a diagnosis of cirrhosis and for whom a liver biopsy has not been performed (or has not been performed recently), and where the simple indices used in Section 9 do not predict cirrhosis, or there are other factors other than fibrosis influencing these readings. The purpose of this section is to record any other information already available that may assist the Scheme in determining whether cirrhosis is probable. This may include transient elastography (e.g. FibroScan®) results.
Section 11	This section must be completed in respect of an applicant who is relying upon information supplied in Section 10 to support the application. It seeks an overall clinical opinion as to whether or not cirrhosis is probable.

INDICES

i. Aspartate aminotransferase to platelet ratio index (APRI)†

This index has been developed to amplify the opposing effects of liver fibrosis on the level of aspartate aminotransferase and the platelet count.

$$APRI = \frac{(AST/ULN)\ x\ 100}{Platelets(10^9)/L}$$

where AST is in IU/L and ULN is in the upper limit of normal

For example, where a patient has a platelet count of 120 x 10^9 and an AST level of 90 (ULN = 45), the APRI is calculated as:

$$APRI = \frac{(90/45)\ x\ 100}{120} = \frac{2\ x\ 100}{120} = 1.67$$

†Wai C-T, Greenson JK, Fontana RJ, Lalbfleisch JD, Marrero JA, Conjeevaram HS, Lok AS-F. A simple noninvasive index can predict both significant fibrosis and cirrhosis with chronic hepatitis C. *Hepatology* 2003; **38**: 518-526

ii. Aspartate aminotransferase-alanine aminotransferase (AST/ALT) ration index ‡

This index is based upon the observation that, as chronic liver disease progresses, AST levels increase more than ALT levels.

$$Ratio = \frac{AST}{ALT}$$

where AST and ALT are measured in IU/L

‡Giannini E, Risso D, Botta F, Choarbonello B *et al*. Validity and clinical utility of the aspartate aminotransferase-alanine aminotransferase ratio in assessing disease severity and prognosis in patients with hepatitis C virus related to chronic liver disease. *Arch Intern Med*. 2003; **163**(2): 218-24

SECTION 2(A) MEDICAL PROFESSIONAL'S DECLARATION

✓ Please tick to confirm

☐ **I understand that** data I provide may be shared with NHS Counter Fraud Services to ensure accurate payment and for the purposes of prevention, detection and investigation of crime.

DECLARATION BY MEDICAL PROFESSIONAL

I agree that the information I give in Sections 2-11 of this form is complete and correct.

I understand that if I knowingly give or endorse wrong or incomplete information this may result in disciplinary action and I may be prosecuted.

Signature of Medical Professional		Date	

SECTION 2(B) DETAILS OF MEDICAL PROFESSIONAL COMPLETING FORM

Registered Medical Practitioner's GMC registration number (if practising in UK)

In what capacity have you completed this form? (e.g. GP, consultant, etc.)

How long have you known the person in respect of whom you have completed this form? Years Months

Your Details

Title First Name

Middle Name(s) Surname

Hospital/Surgery Address

Post Code

Telephone E-Mail Address

If you consulted any other medical professional(s) to help you complete this form, please provide their details here:

SECTION 3(A) TO CONFIRM THE APPLICANT'S ELIGIBILITY FOR PAYMENT

Are there any records to suggest the applicant has previously applied to another UK scheme (e.g. Skipton Fund) to receive payments with regards to their Hepatitis C infection? Yes ☐ No ☐

If 'Yes', please provide details below.

Has the applicant ever had a positive HCV antibody test? Yes ☐ No ☐

If 'Yes', what was the date of first diagnosis? ☐

Is the applicant currently PCR/RNA positive? Yes ☐ No ☐

If the applicant is currently PCR/RNA negative, is this as a result of past or ongoing treatment for Hepatitis C? Yes ☐ No ☐

If the applicant is PCR/RNA negative, is there radiological or pathological evidence that they were chronically infected after the acute phase (i.e. the first six months) of illness had passed? (Relevant radiological or pathological evidence would include chronic-phase raised liver-function tests, previous consideration for treatment, liver histology or radiotherapy, other symptoms of chronic hepatitis)

Yes ☐ No ☐

PLEASE PROVIDE A COPY OF MEDICAL RECORDS CONFIRMING ALL OF THE ANSWERS IN SECTION 3(A)

SECTION 3(B) TO CONFIRM WHETHER INFECTION AROSE INDIRECTLY

In your opinion, is it probable the applicant was infected as a result of transmission of the virus from another person who had themselves been infected through treatment with NHS blood, blood products, or tissue? Yes ☐ No ☐

If 'Yes', did transmission occur as a consequence of:

- Sexual intercourse? Yes ☐ No ☐
- Accidental needle stick? Yes ☐ No ☐
- Mother-to-baby transmission? Yes ☐ No ☐
- Other? (please specify) Yes ☐ No ☐

PLEASE PROVIDE DETAILS AND A COPY OF TEST RESULTS TO CONFIRM WHICH GENOTYPE THE APPLICANT IS/WAS INFECTED WITH

If any of the answers in Section 3(B) are 'Yes', please go to Section 5(B)

SECTION 4	TO BE COMPLETED ONLY IN RESPECT OF INFECTED PEOPLE, WITH HAEMOPHILIA OR OTHER INHERITED OR ACQUIRED BLEEDING DISORDERS

Does the applicant have, or is a carrier of, an inherited or acquired bleeding disorder? (e.g. Haemophilia or Von Willebrand disease) Yes ☐ No ☐

Were any of the following used to treat the applicant before September 1991?

- Whole blood or components (including platelets, red cells, neutrofils etc.) Yes ☐ No ☐
- Cryoprecipitate Yes ☐ No ☐
- Plasma/FFP Yes ☐ No ☐

Were any of the following used to treat the applicant before September 1991? (please note that the majority of these products were subjected to heat treatment to inactivate hepatitis c from May 1987)

- Factor VIII concentrate Yes ☐ No ☐
- Factor IX concentrate Yes ☐ No ☐
- FEIBA Yes ☐ No ☐
- DEFIX Yes ☐ No ☐
- Fibrinogen Yes ☐ No ☐
- Other coagulation factor concentrate Yes ☐ No ☐

If other coagulation factor concentrate, which?

Did any of the above treatments include repeated doses? Yes ☐ No ☐

Please indicate volumes used for each product.

In which NHS hospital(s) did the applicant receive the products listed before September 1991?

If none of the products listed above was used to treat the applicant before September 1991, do you think it is probable that the applicant's Hepatitis C infection was caused through treatment with NHS blood or blood products received before September 1991? Yes ☐ No ☐

If 'Yes', please provide details

PLEASE PROVIDE A COPY OF MEDICAL RECORDS CONFIRMING THE ANSWERS PROVIDED IN SECTION 4

If Section 4 has been completed and the applicant's source of infection is likely to have been a blood transfusion(s), rather than blood products, please complete Section 5(A)

Otherwise, if Section 4 has been completed, please go straight to Section 5(B)

SECTION 5(A) TO CONFIRM THAT INFECTION MOST PROBABLY AROSE THROUGH NHS TREATMENT

On which date is it believed that infection (e.g. via a blood transfusion) occurred?

In what NHS hospital or other facility is it believed infection occurred? (If the applicant had more than one blood transfusion or tissue transplant please list all the hospitals or facilities where they took place)

Please specify under what circumstances is it believed that infection occurred? (e.g. during surgical procedures, A&E treatment, etc.)

Do any records exist of the possible occasion(s) of infection and of any symptoms of infection? Yes ☐ No ☐

If 'Yes', please specify and enclose a copy of the relevant records.

Were any of the following used to treat the applicant before September 1991?

- Albumin — Yes ☐ No ☐
- Intravenous immunoglobulin — Yes ☐ No ☐
- Plasma/FFP — Yes ☐ No ☐
- Bone marrow — Yes ☐ No ☐
- Whole blood or components (including platelets, red cells, neutrofils etc.) — Yes ☐ No ☐

(Note - in Scotland albumin is not generally associated with Hepatitis C infection due to pasteurisation. Only a single batch of intravenous immunoglobulin manufactured in Scotland in 1987 was associated with a risk of Hepatitis C infection)

If so, for what purpose and did the treatment involve repeated doses? (please indicate volumes used for each product)

Does any evidence exist of any other possible source of infection? (e.g. treatment with other blood products or tissue, etc.) Yes ☐ No ☐

If 'Yes', please specify

If the date of infection cannot be proved, do you think it is probable that infection occurred before September 1991? Yes ☐ No ☐

If 'Yes', please specify

SECTION 5(B) OTHER POSSIBLE SOURCES OF INFECTION

Based on evidence or your experience, has the applicant ever been treated for, or been involved with injecting drug use? (This could include living with, or being in a sexual relationship with, a person who injects or injected drugs)

Yes ☐ No ☐

If 'Yes', please provide further details

Has the applicant ever received hospital treatment outside the UK?

Yes ☐ No ☐

If 'Yes', please confirm what treatment, where and when?

Is there any other evidence that might affect the eligibility of the applicant for payment?

Yes ☐ No ☐

If 'Yes', please specify

In your opinion, is it probable that the applicant's HCV infection was acquired as a consequence of NHS treatment received before September 1991?

Yes ☐ No ☐

If 'No', please give your reasons

SECTION 6 LIVER TRANSPLANTATION AND LIVER CANCER

Is the applicant on the waiting list for a transplant? Yes ☐ No ☐

Has the applicant undergone a liver transplantation? Yes ☐ No ☐

If 'Yes', what was the date of the transplantation?

Has the applicant developed primary liver cancer? Yes ☐ No ☐

If 'Yes', give supporting evidence in the space below:

If the applicant has undergone a liver transplantation, is on the waiting list for a transplant, or has developed primary liver cancer, there is no need to complete Sections 7-11.

SECTION 7 LIVER HISTOLOGY

Where a liver biopsy has already been undertaken as part of the applicant's clinical management, please give the following details.

Date of Biopsy:

Details of histology report and diagnosis reached:

If there is histological evidence of cirrhosis, there is no need to complete Sections 8-11.

SECTION 8 B-CELL NON-HODGKIN'S LYMPHOMA

Has the applicant developed B-cell non-Hodgkin's lymphoma? Yes ☐ No ☐

If 'Yes', please give supporting evidence in the space below:

If the applicant has developed B-cell non-Hodgkin's lymphoma, there is no need to complete Sections 9-11.

SECTION 9 SIMPLE INDICES PREDICTIVE CIRRHOSIS

This section is to be completed for an applicant for whom a liver biopsy has not been performed, or without recent liver histology. The chosen indices require recent and repeatable measurements (two samples not less than three months apart) of the two liver enzymes, aspartate aminotransferase (AST) and alanine aminotransferase (ALT), and also the platelet count.

(Note: if there are factors which could potentially affect the AST, ALT or platelet levels in this applicant, other than fibrosis, please indicate what these might be in Section 10. If the influencing factor is more recent, for instance because the applicant is/was undergoing antiviral therapy, then please either use blood results taken before or after the course of treatment and/or complete Sections 10 and 11).

	First Test Result	Second Test Result	Upper Limit of Normal (ULN)
Date Test Performed			
AST (IU/L)			
ALT (IU/L)			
Platelets x 10^9/L			

CALCULATED INDICES

	First Measurement	Second Measurement
APRI		
AST/ALT Ratio		

For further guidance on these indices, see page 7 of this form. With regards to the payment for advanced Hepatitis C, an APRI ≥ 2.0 together with an AST/ALT ≥ 1.0 will be accepted as presumptive evidence for cirrhosis.

If both of these indices are at or above the specified cut-off values, there is no need to complete Sections 10-11.

If these indices give discordant results, or both are below the specified cut-off values, please complete Sections 10 and 11.

SECTION 10 OTHER INFORMATION

(Note: Any signs of portal hypertension and/or evidence of episodes of hepatic decompensation should be mentioned in this section).

(I) CLINICAL STATUS

Clinical status and findings on physical examination:

(II) OTHER BIOCHEMICAL AND HAEMATOLOGICAL TESTS (WHERE AVAILABLE)

Date of Test:

	Result	Normal Range	
Bilirubin			µmol/litre
Albumin			g/l
Globulin			g/l
Alkaline phosphatase			IU/L
Alpha-fetoprotein			IU/ml

Prothrombin time		Secs
(Give normal range for laboratory)		Secs

Any special tests undertaken that may predict the degree of fibrosis or presence of cirrhosis

Some clinicians may have used other tests as markers of fibrosis (e.g. hyaluronic acid). Any such tests undertaken should be described below, stating the particular test(s) used, results obtained and the basis for their interpretation:

(III) ABDOMINAL ULTRASOUND (OF LIVER, SPLEEN)

Date of Test:

Report:

(IV) TRANSIENT ELASTOGRAPHY (e.g. FibroScan®)

Date of Test:

Report:

(Note: This test should be undertaken in the fasting state. Please provide details of the applicant's Body Mass Index (BMI), alcohol intake and whether they have diabetes, as these are known to affect transient elastography readings. If you have not already done so in Section 9, please also provide an ALT result from the time of the transient elastography reading as inflammation/necrosis can also influence liver stiffness independently of fibrosis. ***If this investigation is the sole evidence for cirrhosis please provide original reports of all Fibroscan tests undertaken over the last three years****).*

(V) OTHER RADIOLOGICAL EXAMINATIONS (e.g. MRI, CAT SCAN)

Date of Test:

Report:

(VI) ENDOSCOPY

Date of Test:

Report:

(VII) OTHER

Report any other tests that may be relevant:

If Section 10 has been completed, please also complete Section 11.

SECTION 11 OVERALL CLINICAL OPINION

This section must be completed in respect of an applicant who is relying on information provided in Section 10 as a basis for the application. It seeks an overall clinical view as to whether it is probable that the applicant has developed cirrhosis based on the evidence provided in Section 10.

Clinical Assessment:

Thank you for completing this form. The form and all supporting documents must be sent directly to the Scottish Infected Blood Support Scheme at:

Scottish Infected Blood Support Scheme
Practitioner Services
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB