

GUIDANCE NOTES FOR APPLICANTS

This form is for applicants who are already receiving chronic Hepatitis C payments from the Scottish Infected Blood Support Scheme with regards to their own infection, who now wish to apply for advanced Hepatitis C payments.

To be eligible to receive these payments, the applicant must have had a Chronic Hepatitis C infection and have 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 your circumstances differ to the above, please contact the Scottish Infected Blood Support Scheme for guidance.

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.

GUIDANCE NOTES

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 E

APPLICATION TO RECEIVE ADVANCED HEPATITIS C
PAYMENTS

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

What is your SIBSS reference number?

X	S	B					
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Title

First Name

Middle Name(s)

Surname

Previous Names

Address

Post Code

Home Telephone

Mobile Telephone

E-Mail Address

Date of Birth

What is your marital status?

Tick One Option Below	<input checked="" type="checkbox"/>
Married	<input type="checkbox"/>
Civil Partnership	<input type="checkbox"/>
Widowed	<input type="checkbox"/>
Divorced	<input type="checkbox"/>
Separated	<input type="checkbox"/>
Single	<input type="checkbox"/>
Living with Partner	<input type="checkbox"/>

SECTION 1(C) | 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 has been infected with Hepatitis C.

This form is for applicants who are receiving chronic Hepatitis C payments from the Scottish Infected Blood Support Scheme, who now wish to apply for advanced Hepatitis C payments.

To be eligible to receive these payments, the applicant must have had a chronic Hepatitis C infection and have 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 2-8 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 2-8

Section 3	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 4-8 do not need to be completed.
Section 4	This section seeks information of liver histology, where available. Where histological proof of cirrhosis is available, Sections 3 and 5-8 do not need to be completed.
Section 5	This section asks whether the applicant has developed B-cell non-Hodgkin's lymphoma. If this is the case, Sections 3-4 and 6-8 do not need to be completed.
Section 6	<p>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.</p> <p>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 7-8 do not need to be completed.</p>
Section 7	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 6 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 8	This section must be completed in respect of an applicant who is relying upon information supplied in Section 7 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.

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

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 120×10^9 and an AST level of 90 (ULN = 45), the APRI is calculated as:

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

†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, Rizzo 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 2-8 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 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 4-8.

SECTION 4 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 5-8.

SECTION 5 | **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 6-8.

SECTION 6 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 7. 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 7 and 8).

	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 6 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 7-8.

If these indices give discordant results, or both are below the specified cut-off values, please complete Sections 7 and 8.

SECTION 7 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 6, 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 7 has been completed, please also complete Section 8.

SECTION 8 OVERALL CLINICAL OPINION

This section must be completed in respect of an applicant who is relying on information provided in Section 7 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 7.

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