PRIVATE AND CONFIDENTIAL XSB00132

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.

RECEIVED 08 MAY 2017

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 1-4-2017

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? GRO-A

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	✓
Married	✓
Civil Partnership	
Widowed	
Divorced	
Separated	
Single	
Living with Partner	

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	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 7-8 do not need to be completed.
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.

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

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 2-8 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 26/04/17

LANARKSHIRE AREA
INFECTIOUS DISEASES UNIT
MONKLANDS HOSPITAL
AIRDRIE ML6 0JS

SECTION 2(B) DETAILS OF MEDICAL PROFESSIONAL COMPLETING FORM

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

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

How long have you known the person in respect of whom you have completed this form? Years 1 Months

Your Details

Title DR First Name

Middle Name(s) Surname [redacted]

Hospital/Surgery Address [redacted]

Post Code [redacted]

Telephone [redacted] E-Mail Address [redacted]

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

NONE

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: N/A

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	06.10.16	17.01.17	
AST (IU/L)	21	17	(45)
ALT (IU/L)	15	13	(55)
Platelets x 10^9/L	193	193	(450)

CALCULATED INDICES

	First Measurement	Second Measurement
APRI	0.24	0.196
AST/ALT Ratio	1.4	1.3

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:

Patient complaining of fatigue when last seen at clinic on 05.01.17.
Examination normal.

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

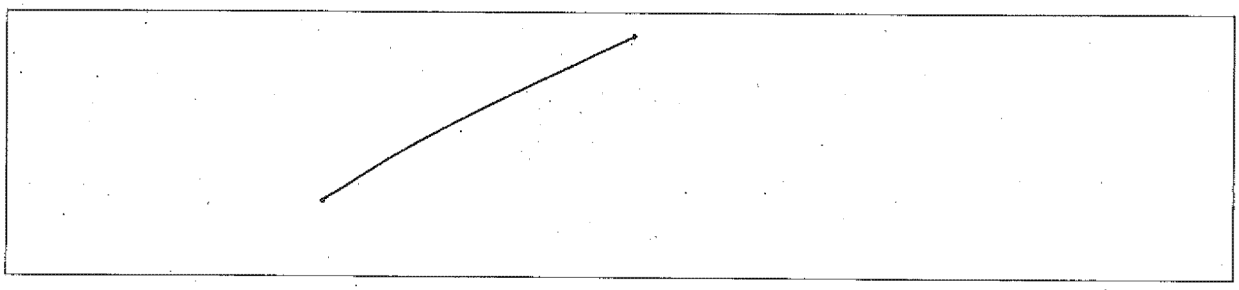
Date of Test: _____

	Result	Normal Range	
Bilirubin	5	(0-20)	µmol/litre
Albumin	44	(35-50)	g/l
Globulin			g/l
Alkaline phosphatase	58	(35-135)	IU/L
Alpha-fetoprotein	4.5 (05.01.17)		IU/ml

Prothrombin time	11.0	(9.0-13.0)	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. hydraulic 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: 10.02.17

Report:

10.02.17 — ECHO BRIGHT LIVER IN KEEPING WITH FATTY INFILTRATION. NO FOCAL ABNORMALITY. NORMAL SPLEEN

10.07.16 — ECHO BRIGHT LIVER IN KEEPING WITH DIFFUSE PARENCHYMAL LIVER DISEASE

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

Date of Test: 10.02.17

Report:

MEDIAN FIS 8.8kPa IQR 1.3 CAP 364 IQR 46

11.07.16 — FIS 14.4kPA, IQR 4.9, CAP 360 IQR 42

(Note: 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).

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

Date of Test: 16.09.16

Report:

MRI — DIFFUSE FATTY INFILTRATION OF LIVER SPLEEN AT UPPER LIMIT OF NORMAL 12.8cm.

(VI) ENDOSCOPY

Date of Test:

Report:

NORMAL — No VARICES.

(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:

I — HAD A FIBROSCAN VALUE OF 14.4kPa AT FIRST ASSESSMENT IN JULY 2016. THIS IS THE EVIDENCE THAT WE HAVE FOR CIRRHOSIS.

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

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.

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

Date of Biopsy: N/A

Details of histology report and diagnosis reached:

If there is histological evidence of cirrhosis, there is no need to complete Sections 5-8.

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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.

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SECTION 5 B-CELL NON-HODGKIN'S LYMPHOMA

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

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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:

Patient complaining of fatigue when last seen at clinic on 05.01.17.
Examination normal.

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

Date of Test: 05.01.17 & 17.05.17

	Result	Normal Range	
Bilirubin	5	(0-20)	µmol/litre
Albumin	44	(35-50)	g/l
Globulin			g/l
Alkaline phosphatase	78	(35-135)	IU/L
Alpha-fetoprotein	4.5 (05.01.17)		IU/ml

Prothrombin time	11.0	(9.0-13.0)	Secs
(Give normal range for laboratory)			Secs

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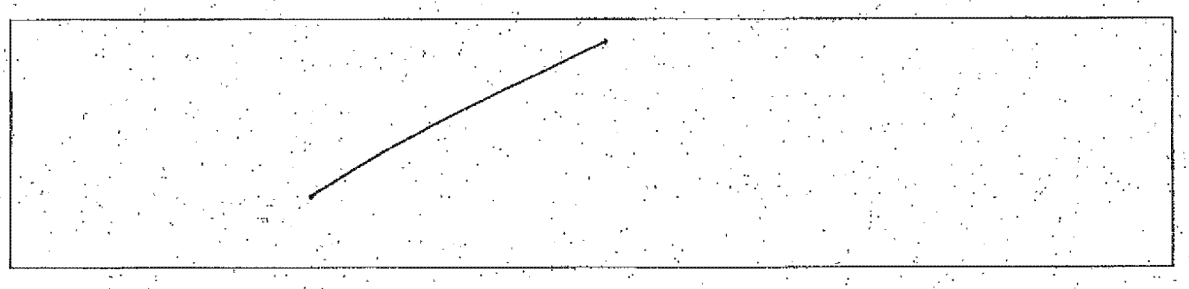

(III) ABDOMINAL ULTRASOUND (OF LIVER, SPLEEN)

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Date of Test: 10.02.17

Report:

MEDIAN FIS 8.8KPa IQR 1.3 CAP 364 IQR 46

11.07.16 — FIS 14.4KPA, IQR 4.9, CAP 360 IQR 42

(Note: 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).

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Date of Test: 16.09.16

Report:

MRI — DIFFUSE FATTY INFILTRATION OF LIVER SPLEEN AT UPPER LIMIT OF NORMAL 12.5cm.

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Clinical Assessment:

[redacted] HAD A FIBROSCAN VALUE of 14.4kPa AT FIRST ASSESSMENT IN JULY 2016. THIS IS THE EVIDENCE THAT WE HAVE FOR CIRRHOSIS.

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

(VI) ENDOSCOPY

Date of Test: 02.03.07

Report:

NORMAL - No VARICES.

(VII) OTHER

Report any other tests that may be relevant:

If Section 7 has been completed, please also complete Section 8.

XSB 00132

RICHARDS, Sally (NHS NATIONAL SERVICES SCOTLAND)

From: [redacted]
Sent: [redacted]
To: RICHARDS, Sally (NHS NATIONAL SERVICES SCOTLAND)
Subject: RE: Scottish Infected Blood Support [redacted] Clinical Advice

Dear Ms Richards

I have had an opportunity to look through the two cases and will summarise my thoughts below:

Case 1 XSB 00132

There is nothing here which strongly supports cirrhosis. There was no liver biopsy. The APRI ratio is less than 1 and although the AST to ALT ratio is over 1, ALT and AST are normal. The albumin is 44. Clinical examination was normal. An ultrasound scan shows a bright liver and normal spleen in the scan of 10.2.17 and an MRI scan showed diffuse fatty infiltration with a spleen at the upper limit of normal. A fibroscan on 10.2.17 showed a liver stiffness of 8.8 kPa which would represent only mild fibrosis. The liver stiffness on 11.7.16 showed a value of 14.4 kPa with an IQR of 4.9 making that scan result unreliable. I think overall here there is nothing to support cirrhosis. I would be interested to know whether he had treatment for his hepatitis C between the two fibroscan tests.

Case 2

I am afraid here also there is nothing to support cirrhosis. He died at the age of 17 from AIDs along with hepatitis C co-infection. There was no liver biopsy. AST to ALT ratio is over 1. His ALT is within the normal range. His APRI was normal. An ultrasound scan in April 1992 showed no significant abnormality and obviously a fibroscan was not available in 1992. I think on balance it is unlikely this man had cirrhosis.

I hope this information is of some help.

Kind regards
Yours sincerely

Royal Infirmary of Edinburgh

From: RICHARDS, Sally (NHS NATIONAL SERVICES SCOTLAND) [mailto:sallyrichards2@[redacted]GRO-C]
Sent: 02 June 2017 11:57
To: [redacted]
Subject: [redacted] Support Scheme [redacted] dvice

I have been asked to send document[redacted] self rather than his university email address which is not secure for sending confidential medical d[redacted] eed to review these cases to enable us to decide whether or not there is significant evidence to support the claim that the applicant has/had cirrhosis. Would you mind printing off these documents and passing them to Professor Hayes?

Case 1 – We are looking for confirmation that the results from the Fibroscan confirm the probability of cirrhosis?

Case 2 – The patient is deceased – does the medical evidence available support the probability of cirrhosis?
For further information on the Scottish Infected Blood Support Scheme – see our website – www.nhsnss.org/SIBSS

Thank you for your assistance in this matter.

Regards

Sally

Sally Richards
Scheme Manager
National Services Scotland
Practitioner Services Medical
Gyle Square
1 South Gyle Crescent
EDINBURGH
EH12 9EB

tel: GRO-C
email: sallyrichards2@GRO-C

Our Values Into Action

Quality | Dignity and Respect | Care and Compassion | Openness, Honesty and Responsibility | Teamwork

For more information visit: http://www.nhslothian.scot.nhs.uk/values