Cynllun Cynorthwyo Gwaed Heintiedig Cymru
Wales Infected Blood Support Scheme

**FORM E**

# APPLICATION TO RECEIVE STAGE II 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 Wales 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 Wales 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

The personal information that you provide on this form will only be used by Velindre NHS Trust for the purposes of checking your eligibility for a payment and to administer your application. By submitting this form to a medical professional, you consent to your medical details requested in Sections 2 to 8 inclusive being supplied to Velindre NHS Trust for the purpose of administering your application.

In the event of a dispute as to your eligibility for payment, your information may be disclosed to the Appeals Panel. If your application is deemed to be ineligible, Velindre NHS Trust may keep your application form on file so that we have a full historical record in the event that you lodge an appeal or if you reapply for a payment at a later stage, in any event information we hold about you will be held for the purpose we collected it and kept for at least six years.

Your information will be held in the strictest confidence and will be kept securely, in accordance with the Data Protection Act 1998, and will not be shared with any other organisation. Velindre NHS Trust are a Data Controller under the Act in respect of the personal information which we collect about you. We have notified the Information Commissioner of our data processing activities and our registration number is Z5021900.

If you have any questions regarding the use of your information, or have any concerns with how your information is being processed, or wish to obtain a copy of information held by us about you, please contact us by writing to Velindre Cancer Centre, Velindre Road, Whitchurch, Cardiff, CF14 2TL

## SECTION 1(B) APPLICANT DETAILS

What is your WIBSS reference number?

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

| | | | |
|---|---|---|---|
| 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 INFORMAION

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 Wales 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 Wales 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:

Wales Infected Blood Support Scheme
Velindre Cancer Centre
Velindre Road
Whitchurch
Cardiff
CF14 2TL

## ADDITIONAL NOTES ON THE LAYOUT AND COMPLETION OF SECTION 3-8

| | |
|---|---|
| Section 3 | This section asks whether the applicant has undergone liver transplantation, is currently awaiting a transplant, or has developed primary liver cancer. |
| Section 4 | If any of these circumstances pertain, Sections 4-8 do not need to be completed. 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.<br><br>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.

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

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 x $10^9$ 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, 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 | |
|---|---|---|---|

## 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 Wales Infected Blood Support Scheme at:

Wales Infected Blood Support Scheme
Velindre Cancer Centre
Velindre Road
Whitchurch
Cardiff
CF14 2TL