

FORM L

APPLICATIONS FOR CHRONIC AND ADVANCED HEPATITIS C PAYMENT WHERE THE INFECTED PERSON IS DECEASED

SECTION 1	(A)	DATA PR	OTECTION	I AND AF	PPLICANT'S	DECLARATION	
√ Pleas	se tick	to confirm					
and (Counte	er Fraud Serv	vices to ensu	re accurate	ed with NHS se e and timely pa stigation of crin	•	
DECLARATION	BY AF	PPLICANT					
agree that the in	nforma	ation I give or	n this form is	complete a	and correct.		
agree to repay a	any m	oney I receiv	e to which it	is found th	at I am no long	er entitled.	
understand if I	knowi	ngly give wro	ong or incom	plete inforn	nation I may be	e prosecuted.	
	confirm that I am the sole Executor of the estate of the deceased person this application relates o, or I am making this application on behalf of all the appointed Executors of the estate.						
_					•	is applications relates ding me with financial	
understand that public bodies and necessary in orde	d/or ma	ake any addi	tional enquiri	ies with oth	er public bodie	ceased person by others that may be	∍r
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 the deceased person's medical details requested in Sections 1 to 6 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 and the deceased person's 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) | APPLICATION DETAILS

Please provide your details here:	n Executor of the deceased person's estate.
Title	First Name
Middle Name(s	Surname
Address	
	Post Code
Main Telephone	Mobile Telephone
SECTION 1 (C) DECEASED PERSO	N'S DETAILS
Please provide details of the deceased person	that the application relates to:
Title	First Name
Middle Name(s)	Surname
Previous Names	
Address (their	
Main residence at the date of death)	Post Code
Date of Birth Death	Date of

SECTION 1 (D) DECEASED PERSON'S ESTATE

Did the deceased person leave a will?	Yes	No			
Has a grant of representation been requested for the deceased person's Yes No estate?					
If 'Yes', has the grant of representation been granted?	Yes	No			
Is there anyone else who might apply to the scheme for a payment in respect of the deceased person?	Yes	No			
If 'Yes', please provide their details:					
Title First Name					
Middle Name(s) Surname					
Address					
Post Code					
Date of Death Date of Birth					
Date of Birth					
What was their relationship to the deceased person?					
Why do you feel this person might apply to the scheme?					

SECTION 1 (E)

ADDITIONAL APPLICATION DETAILS

Do you believe the dec received themselves w		ed with He	epatitis C a	as a result of treatment they
or blood products?		Yes [No
If 'Yes', please provide occurred	e as much information as y	you can o	on how you	u believe the infection
transmitted from some	elieve they were infected vene else, who themselves blood products? Yes	were inf		
If 'Yes', please provide	e further details below:			
Firstly, how do you be	elieve the infection occurre	ed?		
Secondly, who do you	believe the deceased pers	1		ection from?
Title		First Na	ame	
Middle Name(s)		Surnam	ne	
Address				
		Post Co	ode	

Vhat was the deceas person's relationship person?	
SECTION 1 (F)	ADDITIONAL INFORMATION
f you have any addit	ional 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 MEICAL PROFESIONAL

GUIDANCE NOTES FOR MEDICAL PROFESSIONALS

Thank you for your help with this application. In most cases this form will concern a deceased person 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 deceased person had been chronically infected with stage I Hepatitis

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 deceased person that you cannot answer, please consult other medical professionals who have treated the deceased person and who would be able to provide the information.

In some cases this form will concern a deceased person who had been indirectly infected by somebody who is (or was) infected themselves through NHS treatment.

Sections 6-11 should only be completed in cases where the deceased person had developed either:

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

If the deceased person's circumstances meet the above criteria, you should complete Sections 6-11 of this form, only if you are the consultant physician who was in charge of the deceased person'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:

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

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

Section 6	This section asks whether the deceased person 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 deceased person 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 the deceased person 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 the deceased person 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 the deceased person 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.

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, 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

√ Plea	ase tick to confirm			
	I understand that data I provide may be shared with NHS Counter Fraud			
	vices to ensure accurate payment and for the purposes of vention, 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.			
	nat if I knowingly give or endorse wrong or incomplete information this may nary action and I may be prosecuted.			
Signature of	Date			
Medical Professional				

SECTION 2 (B)

DETAILS OF MEDICAL PROFESSIONAL COMPLETING FORM

Registered Medic (if practising in Ul	cal Practitioner's GMC registration K)	n number	
In what capacity hoonsultant, etc.)	have you completed this form? (e	e.g. GP,	
How long have yo completed this for	ou known the person in respect orm?	f whom you have	Years Months
Your Details			
Title		First Name	
Middle Name(s)		Surname	
Hospital/Surgery Address			
		Post Code	
Telephone		E-Mail Address	
If you consulted a their details here:	any other medical professional(s)	to help you comple	ete this form, please provide

SECTION 3(A)

TO CONFIRM THE DECEASED PERSON'S ELIGIBILITY FOR PAYMENT

Are there any records to suggest the deceased person or someone representing their estate had previously applied to another UK scheme (e.g. Skipton Fund) to receive payments with regards to their Hepatitis C infection?

If 'Voc' places provide details below	Yes		No
If 'Yes', please provide details below.			
Had the deceased person ever had a positive HCV antibody te	est?	Yes	No
If 'Yes', what was the date of first diagnosis?			
Was the deceased person PCR/RNA positive at the time of de-	ath?	Yes	No
If they were PCR/RNA negative at the time of death, was this a result of past or ongoing treatment for Hepatitis C? Yes	as a		No
If the deceased person was PCR/RNA negative, is there radio they were chronically infected after the acute phase (i.e. the fir passed? (Relevant radiological or pathological evidence would function tests, previous consideration for treatment, liver histological chronic hepatitis)	st six montl I include ch	hs) of illness ha ronic- phase rai	d sed liver-
Yes No No			
PLEASE PROVIDE A COPY OF MEDICAL RECORDS CONF	FIRMING A	LL OF THE AN	SWERS IN

SECTION 3(A)

SECTION 3 (B) TO CONFIRM WHETHER INFECTION AROSE INDIRECTLY

In your opinion, is it probable the deceased person was infectivirus from another person who had themselves been infecte blood products, or tissue?		
Yes No No If 'Yes', did transmission occur as a consequence of:		
Sexual intercourse?Accidental needle stick?Mother-to-baby transmission?Other? (please specify)	Yes Yes Yes	No No No

PLEASE PROVIDE DETAILS AND A COPY OF TEST RESULTS TO CONFIRM WHICH GENOTYPE THE DECEASED PERSON 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

Did the deceased person 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 deceased person before Septe	ember 1991?	
 Whole blood or components (including platelets, red cells, neutrofils etc.) Cryoprecipitate Plasma/FFP 	Yes Yes Yes	No No No
Were any of the following used to treat the deceased person before September 1	ber 1991?	
 Factor VIII concentrate Factor IX concentrate FEIBA DEFIX Fibrinogen Other coagulation factor concentrate 	Yes Yes Yes Yes Yes Yes Yes	No No No No 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 deceased person receive the products lift 1991?	sted before Sep	otember

used to treat the deceased person 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 had more than one blood transfusion or tissue transplant where they took place)	•
Please specify under what circumstances is it believed th surgical procedures, A&E treatment, etc.)	at infection occurred? (e.g. during
Do any records exist of the possible occasion(s) of infecti symptoms of infection?	on and of any Yes No
If 'Yes', please specify and enclose a copy of the relevant	records.

Were any of the following	used to treat the	deceased person	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, 	Yes	No
neutrofils etc.)		
,		
If so, for what purpose and did the treatment involve repeated doses? used for each product)	(please indicate	e volumes
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		
If the date of infection cannot be proved, do you think it is probable that infection occurred before September 1991?	Yes	No
that infection occurred before September 1991?	Yes	No
	Yes	No
that infection occurred before September 1991?	Yes	No
that infection occurred before September 1991?	Yes	No
that infection occurred before September 1991?	Yes	No
that infection occurred before September 1991?	Yes	No
that infection occurred before September 1991?	Yes	No

SECTION 5(B) OTHER POSSIBLE SOURCES OF INFECTION

Based on evidence or your experience, has the deceased person 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		
Had the deceased person ever received hospital treatment outside the UK?	Yes	No
	163	NO
If 'Yes', please confirm what treatment, where and when?		
Is there any other evidence that might affect the eligibility of the		
Deceased person for payment?	Yes	No
If 'Yes', please specify		

In your opinion, is it probable that the deceased persons 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

Was the deceased person on the waiting list for a transplant?	Yes	No
Had the deceased person undergone a liver transplantation?	Yes	No
If 'Yes', what was the date of the transplantation?		
Had the deceased person developed primary liver cancer?	Yes	No
If 'Yes', give supporting evidence in the space below:		

If the deceased person has undergone a liver transplantation, was on the waiting list for a transplant, or had 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 deceased person'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

Had the deceased person developed B-cell non-Hodgkin's lymphoma?	Yes	No
If 'Yes', please give supporting evidence in the space below:		

If the deceased person had 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 a deceased person 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 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	i		
Clinical status and finding	ngs on physical examination	on:	
(II) OTHER BIOCHEMI	ICAL AND HAEMATOLO	GICAL TESTS (WHER	E AVAILABLE)
- · · · ·			
Date of Test:			
	Result	Normal Panga	7
Bilirubin	Result	Normal Range	µmol/litre
Albumin	_		g/l
Globulin			g/l
Alkaline phosphatase			IU/L
Alpha-fetoprotein			IU/ml
1	.1		
Prothrombin time			Secs
(Give normal range for	laboratory)		Secs
Any angoighteata undar	takan that may pradict tha	dograp of fibracia or ar	acons of cirrhosis
Any special tests under	taken that may predict the	degree or librosis or pr	esence of cirriosis
Sama aliniaiana may ha	wa usad athar tasta as ma	rkora of fibracia (a.g. by	valurania asid). Any
	ive used other tests as ma should be described below		
obtained and the basis t		, otating the particular to	30t(0) 4004, 1004tto
	<u>'</u>		

(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 deceased person'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 10 has been completed, please also complete Section 11.

SECTION 11 OVERALL CLINICAL OPINION

This section must be completed in respect of a deceased person where the application 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 deceased person 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 Wales Infected Blood Support Scheme at:

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