SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	
Service	Hepatitis C virus service
Commissioner Lead	
Provider Lead	
Period	*12 months*
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

The Disease

Hepatitis C virus (HCV) is a virus transmitted in blood. It is usually asymptomatic at the time of infection and in about 75% of cases chronic infection develops. Chronic infection leads to chronic hepatitis, fibrotic liver disease, and eventually (in some) cirrhosis, end stage liver disease, and hepatocellular carcinoma. The virus was only identified in 1989 and tests for its detection developed since 1990. The virus persists as multiple different strains (genotypes) each of which has specific treatment needs. Genotypes 1 and 3 are common in the UK. Hepatitis C can be cured in more than 75% of patients treated (http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/HepatitisC/). Drug treatments include interferons, ribavirin, and direct acting antiviral drugs (as approved in a NICE TAG or by NHS England).

There are estimated to be 215 000 people chronically infected with HCV in the UK, 160 000 of them in England (http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1317135237627). However many of these, possibly as many as 50%, are unaware of their infection because it causes no symptoms until liver disease is at an advanced stage. Of those that have been diagnosed many are not receiving specialist management or treatment. In some cases there are good clinical reasons to delay or defer drug treatment for HCV, but these patients should still be kept under surveillance as accelerated disease progression is well recognised. In 2012 about 5000 people received drug treatment for HCV in the UK, and only about 3% of the prevalent pool of infected patients receive treatment each year. Treatment is currently provided by a variety of providers of varying degrees of experience and there is no national database of treatment outcomes.

As a result of the modes of transmission the prevalence of chronic hepatitis C is highest among

specific populations: these include people who received infected blood or blood products before 1991, current and previous injecting drug users, and certain ethnic minority groups. Overall, half of patients with chronic HCV infection are in the lowest socio-economic quintile, and three quarters in the lowest two quintiles.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	**Yes**
Domain 2	**Enhancing quality of life for people with long-term conditions**	**Yes**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**No**
Domain 4	**Ensuring people have a positive experience of care**	**Yes**
Domain 5	**Treating and caring for people in a safe environment and protecting them from avoidable harm**	**Yes**

Outcomes

Domain – 1 Preventing people from dying prematurely

Overarching indicators:

- 1a.i Potential Years of Life Lost (PYLL) from causes considered amenable to healthcare in adults
- 1b Life expectancy at 75 in males and females

Improvement area:

- 1.3 Under 75 mortality rate from liver disease

Hepatitis C is the cause of liver disease most clearly amenable to healthcare intervention because curative treatment exists. Successful treatment of patients with hepatitis C cures the infection and prevents them from dying prematurely: in England PHE reports that peak age of detection of hepatitis C is 40-50 years but no data on peak age of death is collected. In Scotland which, by contrast, has a well-developed national treatment service that has already been shown to reduce early deaths, the peak age of death is recorded and is known to be less than 50 years in more than half of those who die.

The overall aim of this service is to increase the number of patients who are cured of their HCV infection.

Service providers will provide outcome data on:

- Proportion of the population who are infected. These data are provided by PHE and will enable the effectiveness of service provision to be assessed
- Number of patients who initiate treatment with NICE approved antiviral therapies for HCV
- Number of patients who achieve a cure with antiviral therapy

Domain 2 Enhancing Quality of Life for people with long term health conditions.

Effective therapy for hepatitis C will reduce the burden on patients with hepatitis C induced cirrhosis by reducing disease progression and thereby reducing hospital admissions due to the complications of progressive cirrhosis – specifically effective therapy will reduce attendances for variceal haemorrhage, sepsis induced decompensation and development of liver cancer.

Domain – 4 Ensuring that people have a positive experience of care

Overarching indicator:

- 4b Patient experience of hospital care

Improvement area:

- 4.1 Patient experience of outpatient services

This service specification will ensure that outpatient hepatitis C treatment and care is delivered in a setting that is appropriate, and by staff who are appropriate, for each patient - for example by a blood-borne virus nurse in community drug services but as part of a specialist service with the optimum specialist oversight. Research indicates that in areas where treatment is exclusively available in a hospital setting this is a barrier for some patients, reducing the numbers coming forward for curative treatment.

Service providers will provide outcome data on:

- Patient experience of outpatient services through a patient questionnaire developed and validated with appropriate patient representative groups (such as The Hepatitis C Trust)
- Number of people who are referred to specialist care as a proportion of those testing positive (denominator data provided by Public Health England)
- Number of patients who initiate treatment with NICE/NHSE approved antiviral therapies for HCV as a proportion of those referred

Domain – 5 Treating and caring for people in a safe environment and protecting them from avoidable harm

Overarching indicator:

- 5a Patient safety incidents reported
- 5b Safety incidents involving severe harm or death
- 5c Hospital deaths attributable to problems in care

Improvement area:

- 5.4 Incidence of medication errors causing serious harm

This service specification will ensure specialist oversight of all hepatitis C care delivered in

England, thereby providing patients with the safest treatment possible. Current hepatitis C drugs have significant and potentially life-threatening side effects and deaths have occurred as a result of treatment being monitored by insufficiently skilled staff. Treatment carries significantly greater risk in patients with present or previously decompensated cirrhosis, and this specification allows these patients to be considered for care in a specialised setting which will minimise such risk.

PHE have estimated that approx. 4,000 people with chronic hepatitis C will have developed decompensated liver disease by 2020 and almost 12,000 will have developed cirrhosis that will eventually progress. Successful treatment prevents both decompensation and progression of liver disease and if hepatitis C treatment is commissioned effectively, we will anticipate a significant reduction in these numbers. [Hepatitis C UK 2013 report at http://www.gov.uk/phe].

Successful treatment of patients with hepatitis C cures the infection and prevents them from dying prematurely. This improves quality of life and prevents viral transmission by reducing the prevalent pool of infection. Long term, well delivered cost effective therapy offers the prospect of eliminating HCV from the indigenous population with massive health benefits and cost savings.

3. Scope

3.1 Aims and objectives of service

Aim

The aim of Specialised Hepatitis C Services for Adults is to maximise uptake and completion of HCV treatment and to cure more people of infection. This will improve quality of life, prevent premature death in line with the NHS Outcomes Framework 2014-15, and reduce the risk of onward transmission.

Objectives

- The service will deliver this aim by:
- Providing a uniform standard high quality treatment service to adults with hepatitis C infection throughout England
- Reporting objective measures to demonstrate this high quality treatment using a national standardised monitoring and outcome data collection system
- Establishing services which are responsive to local epidemiology and prevalence. This will include working effectively in partnership with appropriate local organisations from all sectors (e.g. Primary Care Services, Local Authorities, substance misuse services, Health & Justice, charities for the homeless and substance misusers).
- Contributing to tailored services to meet the needs of specific vulnerable groups (e.g. prisoners, homeless, current injecting drug users, migrant populations). Care will be delivered in ways that maximise access to treatment for all patients, and provide treatment as close to the patient as possible
- Ensuring that people with hepatitis C are given sufficient, high quality information and advice to ensure they are able to take fully informed decisions about the often complex question of when to initiate treatment
- Allowing more people to have access to clinical trials of new drugs, with consequent

improvement in outcome and reduced NHS expenditure

3.2 Service description/care pathway

Overview

The service model proposed is a formal network. It is recognised that different forms of network are being developed (for example Operational Delivery Networks), and once roles have been confirmed this service should finalise its arrangements. It is anticipated that when mature the service will be provided as a network with a host organisation (prime contractor model) who will be responsible for delivering the service via a variety of joint ventures, which will include (but not be restricted to) other hospitals, clinics, specialist addiction services, and secure environments. The NHS England commissioned service includes the cost of drugs required for treating hepatitis C infection (including specific supportive therapy), as well as the resource and facilities necessary to ensure appropriate management of all patients referred to the service (including essential investigations).

Patient Referral

The service will accept inward referrals of patients with confirmed hepatitis C infection to commence treatment from:

- Primary care, substance misuse services and all other services undertaking HCV testing and subsequent care.
- Prisons and associated institutions in association with the Health and Justice Commissioning group
- Other specialist hepatitis services
- Human Immunodeficiency Virus (HIV) services (in the case of HIV/HCV co-infection).
- Paediatric hepatitis services when the patient reaches adulthood.
- Other services recognised by local agreement

The service will accept referrals for patients who meet the following criteria

- Diagnosed as chronic hepatitis C with a documented HCV viraemia.
- Diagnosed with probable acute hepatitis C.

All eligible patients will have access to care and treatment services irrespective of their sexual orientation, gender, race, disability, psycho-social circumstances or geographical location. An important feature of all services is that appropriate pathways are developed for socially disadvantaged patients who are often difficult to engage (particularly those with addictive disorders, the homeless, and those held in Secure Environments). Patients will remain within the specialised service for management of their hepatitis C infection until discharged by the service.

Service provided

Management of patient with acute or chronic hepatitis C infection, including treatment of patients with antiviral or immunomodulatory drugs, including supportive and adjunctive therapy, in accordance with NICE and national guidelines.

Models of care

This specification does not define the exact model of care delivery. The epidemiology and demography of hepatitis C infection varies significantly in different parts of the country, and it is unlikely that a single model of service delivery will be optimal in all locations. Centres with a geographically small but densely populated catchment area may be able to deliver the bulk of their care centrally, while those with large areas to cover may need to establish outreach services or enrol smaller local providers as part of a network. Specific local models may be needed to provide a service to prisons and other secure environments. The high prevalence of HCV in some

geographically localised immigrant populations may require dedicated services to be set up. In some places greater use of technology may allow some 'virtual' management of patients. However there is an overarching principle that access to care, and supervision of treatment, must be tailored as far as possible to the needs of the patients. It is an absolute requirement that anyone providing drug treatment for hepatitis C infection must do so as part of a formal network with regular, minuted MDT meetings.

Outpatient service requirements

As a minimum, Specialist Hepatitis C Service Host Organisations must provide:

- A substantive body of consultant physician expertise covering the range of clinical aspects of HCV infection, able to provide care directly and to advise and support colleagues at other centres and in other services. There must be enough consultants with documented training in viral hepatitis and regular attendance at CPD to provide 7 day per week cover.
- An appropriate number of nurse specialists to deal with the number of patients being treated. A viral hepatitis nurse specialist would usually be expected to manage no more than 50-80 'non-complicated' patients (i.e. those without co-morbidity or cirrhosis) at any one time. Nurses managing more complex patients would be expected to manage fewer patients; the same would apply if the nurses have other roles such as running outreach clinics.
- For the purpose of cross-cover, a minimum of two nurse specialists should be available in each specialist centre
- A full time administrator with appropriate supporting staff to provide administrative support to the unit. This will be an essential element to achieve value-based returns for commissioners and to ensure best equity and access for patients locally
- A dedicated pharmacist (full or part time) to manage pharmaceutical needs of patients including adherence support, medication review and provision of specialist medications.
- Facilities (including teleconferencing facilities) for multi-disciplinary meetings which are accessible by all out-reach services
- Access to validated non-invasive methods of estimation of liver fibrosis (e.g. Fibroscan, ARFI elastography, Fibrotest)

As a minimum all centres providing therapy for patients with hepatitis C - individual providers (including out-reach centres) - must provide:

- At least one fully trained health care worker with experience and expertise in the management of patients with hepatitis C
- Access to the central multi-disciplinary meeting with telephone discussion of all patients receiving therapy
- Access to specialist support services including psychiatric support, dermatology and molecular diagnostic virology
- Assessment of all HCV patients being considered for drug treatment within 6 weeks of referral
- Care pathways to ensure that relevant investigations for decision making are available when the patient is first seen in the clinic whenever possible
- A first review for all patients by a clinician (doctor or other suitable specialist) sufficiently qualified and experienced to assess the patient for suitability for treatment
- Facilities and expertise to commence, monitor and complete treatment in a safe and effective manner
- Pathways to services that assist patients in decreasing or discontinuing excessive alcohol intake where appropriate
- Links for urgent referrals for psychological and psychiatric support
- Pathways of referral of patients for whom established therapies fail for consideration for

studies/trials of newer agents
- Expertise at difficult phlebotomy
- Access to welfare advice and support
- Administrative support to ensure accurate recording of information, and timely communication of decisions to patients and other care providers

Inpatient service requirements

Specialised hepatitis C networks must provide certain inpatient facilities to manage potential complications of hepatitis treatment, most notably hepatic decompensation and sepsis. Required facilities include:

- 7 day a week availability of consultant physician with expertise in managing hepatitis C (usually hepatology, gastroenterology, or infectious diseases) to provide advice and information to colleagues managing patients who are receiving therapy. Advice may be provided remotely
- 24 hour access to diagnostic laboratory and radiology support
- Care pathways to quaternary and other services such as liver transplantation and HPB surgery and cancer care.
- Access to dermatology advice, blood transfusion services, and high dependency and intensive care support

3.3 Population covered

Adults (aged 19 and over) with diagnosed HCV infection commencing or undergoing specific therapy for their hepatitis C. Whilst adult services are generally defined as for those aged 19 and over, it is possible that adult services may treat some patients aged 15 – 18 because of the specific needs of the individual patient (with appropriate liaison with paediatric services).

Specialised HCV treatment services will also be provided to adults in secure environments. Where these services are provided they will be under the auspices of the Specialised Service and funded to the same level as for services for the general population. Where additional costs are incurred and beyond the standard, these costs will be met through a top-up payment by Health and Justice Commissioning Teams. Services provided in prison settings must adhere to the same quality standards and provide an equivalent level of care. These may be provided on an in-house or in-reach or outpatient / inpatient basis and this will be reflected in the relevant specification for Specialised Services for Health and Justice.

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_127393)

**Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England*.

3.4 Any acceptance and exclusion criteria and thresholds

Adults (aged 19 and over) with diagnosed HCV infection commencing or undergoing management for their hepatitis C will be included in this specification. Whilst adult services are generally defined

as for those aged 19 and over, it is possible that adult services may treat some patients aged 15 – 18 because of the specific needs of the individual patient.

Patients with decompensated cirrhosis or other forms of severe liver disease are sometimes inappropriately excluded from consideration for treatment, as greater clinical expertise is needed in these patients' management. The specialised care model as established in this specification ensures that such patients can be assessed and managed in a safe clinical setting, and not excluded.

Specialised HCV treatment services will also be provided to adults in secure environments. These may be provided on an in-house, in-reach, or outpatient / inpatient basis as part of a Specialised Service, determined by critical mass of patients in the particular prison environment. (Prevention and identification of hepatitis C is outside the scope of Specialised Services).

3.5 Interdependencies with other services/providers

The Service Network must have well established links to:-

- Primary care.
- A full range of diagnostic imaging and pathology services.
- HCV virology including interpretation of resistance patterns and access to viral load quantification results within 24 hours of sample receipt.
- Access to dietetics.
- Third sector services to support adherence, peer support and self-management programmes.
- Alcohol and substance misuse services
- Dermatology and haematology services
- Liver transplantation services and hepatobiliary services for the management of HCC
- Mental health services for patients with significant mental health needs – ranging from third sector support services to clinical psychology, liaison psychiatry and liaison with community mental health services in patients' place of residence.
- Obstetric services with experience in managing HCV-infected mothers
- HIV services

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

The service will be commissioned in accordance with applicable NICE standards:

- TA 75; *Hepatitis C – Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of chronic hepatitis C* (dealing with moderate/severe disease)
- TA 106; *Pegylated interferon alfa and ribavirin for the treatment of mild chronic hepatitis C*
- TA200; *Hepatitis C – pegylated interferon and ribavirin* (update to previous TAGs)
- TA252**;** *Telaprevir for the treatment of genotype 1 chronic hepatitis C*

- TA253**;** *Boceprevir for the treatment of genotype 1 chronic hepatitis C***,**

and supports the aims and objectives of the Department of Health Hepatitis C Plan for England.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

UK consensus guidelines for the use of the protease inhibitors boceprevir and telaprevir in genotype 1 chronic hepatitis C infected patients. Ramachandran P, Fraser A, Agarwal K, Austin A, Brown A, Foster GR, Fox R, Hayes PC, Leen C, Mills PR, Mutimer DJ, Ryder SD, Dillon JF. Aliment Pharmacol Ther. 2012 Mar;35(6):647-62.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

- Patients initiating therapy should have been discussed at a multi-disciplinary meeting with documentation of the panel recommendations provided to the patient and the general practitioner
- A proportion of treated patients should be engaged in opiate substitution programs or have evidence of on-going drug addiction disorders requiring specialist support
- Patients receiving antiviral therapy should have a named care provider
- A minimum defined data set should be collected on all patients

6. Location of Provider Premises

The Provider's Premises are located at:

Not applicable

7. Individual Service User Placement

Appendix One

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Patients initiating therapy should achieve a sustained virological response (cure)	>80%	National database	Patients receive ineffective therapy
Domain 2: Enhancing the quality of life of people with long-term conditions			
Patients initiating therapy should achieve a sustained virological response (cure)	>80%	National database	Patients remain infected
Domain 3: Helping people to recover from episodes of ill-health or following injury			
I			
Domain 4: Ensuring that people have a positive experience of care			
Patients receiving antiviral therapy should have a named care provider	>90%	Local database	Patients receive inadequate care
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
Patients initiating therapy should have been discussed at a multi-disciplinary meeting with documentation of the panel recommendations provided to the patient and the general practitioner	> 85% of patients	Local database	Patients receive inadequate care