NHS England

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	F04 S f
Service	Operational Delivery Networks for Hepatitis C Care in Adults
Commissioner Lead	NHS England
Provider Lead	
Period	01.04.2015 to 31.03.2016
Date of Review	31.03.2017

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 to cirrhosis, end stage liver disease, and hepatocellular carcinoma over 20 to 30 years. The virus was first identified in 1989 and tests for its detection only developed since 1990. The virus persists as multiple different strains (genotypes) each of which has specific treatment needs. In the UK 90% of people have Genotypes 1 and 3. Drug treatments include interferons, ribavirin, and NS3 protease inhibitors, NS5A and NS5B nucleoside and non-nucleoside direct acting antiviral drugs as approved in NICE Technology Appraisals (TA) or through NHS England specialised services policies.

There are estimated to be 160,000 people chronically infected with HCV in England . 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 this equates to about 3% of the prevalent pool of infected patients receiving treatment each year. Treatment has been provided by a large number of non-specialised as well as

specialised providers and in a variety of settings, often related to other care required by patients rather than specific services for hepatitis and there is no national database of treatment outcomes.

Public Health England (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. If hepatitis C treatment is commissioned effectively, it is anticipated that there will be a significant reduction in these numbers over the next 5 to 10 years. [Hepatitis C UK 2015 report at http://www.gov.uk/phe].

As a result of the modes of transmission the prevalence of chronic hepatitis C is highest among specific populations who have been exposed to infected blood: these include current and previously injecting drug users, and certain ethnic minority groups or people who received infected blood products before 1991. 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**

Preventative strategies are important but where infection is confirmed successful treatment of patients with hepatitis C should cure the infection and prevent people from dying prematurely. This improves quality of life and prevents viral transmission to other people by reducing the prevalent pool of infection. Long term, well delivered cost effective therapy offers the prospect of minimising HCV in the indigenous population with major health benefits and cost savings across primary and secondary care.

Outcomes

Domain 1 Preventing people from dying prematurely

Overarching indicators:

- 1a 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.c Under 75 mortality rate from liver disease

Hepatitis C is the cause of liver disease most clearly amenable to healthcare intervention because well tolerated curative treatments now exist: 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 has a national service model treatment 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 majority of patients treated in the England Early Access Program for decompensated liver disease due to hepatitis C (i.e. people at high risk of death in the next 12 months) were aged 45-55 years.

The overall aim of this network model is to increase the number of patients who are cured of their HCV infection, using the most clinically effective and cost effective options

It is recognised that more accurate baseline data needs to be collected to improve current estimated data which will be used to refine the metrics as the networks develop.

Service providers will provide outcome data on:

- Proportion of the population who are estimated as infected to enable the effectiveness of the treatment service provision to be assessed
- Number of patients who initiate treatment with NICE or NHS England approved antiviral therapies for HCV
- Number of patients who achieve a "Sustained Viral Response" or 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, decompensation and development of liver cancer.

Evidence of benefit will be detected by monitoring national data on hospital admissions for decompensated cirrhosis and liver cancer over the next 5 to 10 years.

Domain 4 Ensuring that people have a positive experience of care

Overarching indicator:

- Patient experience of hospital care

Improvement area:

- Patient experience of outpatient services

This service specification will ensure that patients receive care through an Operational

Delivery Network. Outpatient hepatitis C treatment and care will be delivered in a setting that is appropriate, and by staff who are appropriate, for each patient – as an 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 outcomes data on:

- Patient experience of outpatient services through a patient questionnaire developed and validated with appropriate patient representative groups
- Number of people who are referred to specialist care as a proportion of those testing positive
- Number of patients who initiate treatment with NICE / NHS England 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:

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

Improvement area:

- Incidence of medication errors causing serious harm

This service specification for Operational Delivery Networks will ensure specialist oversight of all hepatitis C treatment delivered in England, thereby providing patients with the safest treatment possible. Hepatitis C drugs can 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 and/or with specialist support which will minimise such risk. The risk of adverse events is greatly reduced in patients receiving therapy with the new all oral anti-virals but in patients with advanced disease, mortality and adverse events remain a concern based on recent studies.

3. Scope

3.1 Aims and objectives of service

Aim

The aim of Specialised Hepatitis C Operational Delivery Networks for Adults is to maximise appropriate 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 high quality treatment using a national standardised monitoring and outcomes dataset and through supporting development of an outcome collection system.

Establishing a managed network of services which are responsive to local epidemiology and prevalence. This will include working effectively in partnership with other health care providers and local organisations from all sectors (e.g. Primary Care Services, Local Authorities, service for People Who Inject Drugs, 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 so they are fully informed about the timing of treatment and treatment choices, which can be complex issues.

Allowing more people to have access to clinical trials of new drugs, with consequent improvement in outcome and effective use of NHS resources in the long term.

3.2 Service description/care pathway

Overview

1. The proposal is for a formal Operational Delivery Network of centres that manage treatment decisions and prescribing but has a dispersed delivery model that will support partnership working and local access for patients in England. Network leadership will be provided through specialist centres with proven expertise in managing HCV, and prescribing decisions will be made through MDT meetings. The NHS England commissioned specialised services includes the cost of drugs required for treating hepatitis C infection, as well as the resource and facilities necessary to ensure appropriate management of all patients referred within a specialised service (including essential investigations).

2. Although the newer drugs for treating hepatitis C infection are less toxic than earlier regimens, selecting the most appropriate agents and course length remains highly complex. It is therefore important that expert clinicians are involved in prescribing

decisions (while maintaining local delivery of care). The networks will encompass MDT decision-making by teams experienced in the treatment of hepatitis C and in the appropriateness of initiation of treatment or continued surveillance of infected patients. MDTs including experienced clinicians will support the best quality of clinical care, and allow the most clinically appropriate and cost effective prescribing of high cost drug treatments in accordance with NHS England policy / NICE Technology Appraisals.

3. The network model will also ensure better equity of access. Many patients with chronic hepatitis C infection come from marginalised groups who may not engage well with health care, and there is a risk that without proper structures in place a significant proportion of patients in need will not get access to care. Mechanisms are needed to encourage outreach and engagement with patients outside traditional health care settings: these will be much easier to set up as part of formal clinical networks than with uncoordinated local commissioning.

4. It is recognised that ODNs are at different stages of development. Hence NHS England sought proposals from those contracted to provide specialised treatment of hepatitis C to jointly put forward proposals to operate networks comprised of a centre and partner services to serve their patient population. It is anticipated that when mature the service will be provided as a network with a host organisation who will be responsible for assuring the delivery of the service via a variety of joint ventures, which will include (but not be restricted to) other hospitals, community clinics, specialist addiction services, and secure environments.

5. A network model will support:
    - A specified network of care for Hepatitis C with a named lead Centre hosting the virtual MDT and linked treatments services
    - Specialised centres with a sufficient caseload to develop and maintain expertise in the treatment of the condition.
    - MDT decision making by experienced teams on the appropriateness of continued surveillance or initiation of treatment in infected patients and the optimal treatment regimen to use
    - Oversight of treatments with the potential for serious side effects requiring specialist liver support and expertise on the range of drug on drug interactions
    - Access to treatment services locally through partnership and outreach models
    - Optimising partnership working with local expertise in engaging hard to reach groups in treatment programmes
    - Cost effective use of high cost drug treatments in accordance with national NHS England policy / NICE TAs and guidelines
    - Development of research to support future commissioning policy
    - Development of a national database of treatment and outcomes
    - The further development of Hepatitis C networks will reduce variation in practice nationally through networks ensuring compliance with treatment guidelines and national policy.

Patient Referral

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

- Primary care, substance misuse services, genito-urinary medicine services and all other services undertaking HCV testing or 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 within the local agreement

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

- Criteria defined by NHS England policies
- 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 patients 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 describe 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. Networks with a geographically small but densely populated catchment area may be able to deliver the majority of their care centrally, while those with large areas to cover will need to establish multiple outreach services and would be expected to enrol multiple local providers as part of a network. Specific local models are likely to 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 targeted services to be set up. In some places greater use of technology may allow some 'virtual' management of patients.

Network Requirements:
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 OD network with regular, minuted Network MDT meetings.

- Description of a specified network of care for Hepatitis C with a named lead

Centre hosting the MDT and supporting co-ordination of the ODN.

- The other providers' roles and the partnership arrangements within the network should be described within its "Constitution" and agreed by its members.
- Where required provision of services through outreach and inreach should be supported by service levels agreements or a "Memorandum of Understanding" as appropriate.
- Specialised centres should demonstrate they have a caseload of complex and non-complex patients to develop and maintain expertise in the treatment of the condition for the stated population.
- There should be a single virtual network MDT with named members and their clinical role. The MDT membership should include at least two clinicians with experience in the management of hepatitis C and include a hepatologist.
- In larger networks the network can agree a local MDT which can make decisions on defined non-complex cases. The cases allowed to be discussed in this way must be defined, agreed and documented by the network in its constitution and agreed by the national. In all cases prescribing decisions need to follow NHS England national policy or NICE guidelines and nationally agreed clinical guidelines.
- MDT decision making supported by teams demonstrating the ability to decide appropriateness of continued surveillance or initiation of treatment in infected patients including those with complex presentations
- Within the Network demonstrate capability to oversee treatments with the potential for serious side effects requiring specialist liver support and drug interactions
- To promote access to treatment services locally through partnership and outreach models
- A plan to optimise partnership working with local expertise in engaging hard to reach groups in treatment programmes
- A plan to optimise working with patients such as a patient forum or other modes to increase patient involvement in the design and functioning of the network
- Agreement to adhere to clinically effective and cost effective use of high cost drug treatments in accordance with NHS England policy / NICE TAs
- Contribute to network audit and research to support future commissioning policy
- Contribute to national data collection of treatment and outcomes and support development of a national database

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. The nursing resource required needs to take into account the network role, the patient caseload, and clinical commitments such as outreach clinics. A viral hepatitis nurse specialist managing more complex patients such as those with co-morbidities would be expected to manage fewer patients.

- For the purpose of cross-cover, a minimum of two dedicated nurse specialists should be available in each specialist centre
- An administrator with appropriate supporting staff to provide administrative support to the network. 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(s) (full or part time) to manage pharmaceutical needs of patients including adherence support, medication review, provision of specialist medications and advice about drug interactions.
- 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, video-conference or face-to-face discussion of all patients proposed for, and 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 in line with national NHS referral to treatment timeline targets
- 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
- Provision of adherence support
- 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 centres with certain inpatient facilities to manage potential complications of hepatitis C 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 commissioned through NHS England Health & Justice. 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, and 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.

Paediatric patients treated within paediatric services are not covered by this specification but are included with Paediatric Medicine service specifications.

3.5 Interdependencies with other services/providers

The Operational Delivery Network must be able to demonstrate that it has well established links or an agreed plan, 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 if required.
- 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
- Obstetric services with experience in managing HCV-infected mothers
- HIV services
- Formal links to other specialist centres to facilitate transfer of care as required
- Formal arrangements to support continuation of treatment of patients moving between or leaving secure environments
- Formal pathways to support transition of paediatric patients to adult services as required
- 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.
- The OD Network should also ensure that it describes the links and interfaces of its services and care with other relevant pathways and organisations (e.g. Local Authorities) as required.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

The service will be commissioned in accordance with applicable NICE Technology Appraisal and NHS England service standards:
The service will also be commissioned to support 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)

NHS England Nationally developed Guidelines and algorithms

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 hepatitis C multi-disciplinary meeting with documentation of the recommendations provided to the patient and the general practitioner
- Networks should develop a plan to improve partnership working
- A proportion of treated patients should be engaged in opiate substitution programmes 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 when available

6. **Location of Provider Premises**

Network Population served	**Minimum Number of Networks required***	**Maximum Number of Networks required**
North West	3	4
North East	1	1
Yorkshire & Humber	2	3
West Midlands	1	2
East Midlands	2	3
East Anglia & Essex	1	2
London	3	4
South East Coast	2	2
Thames Valley	1	1
Wessex	1	1
South West	2	2
Total Number of Networks	**20**	**25**

*The number of networks required reflects that the option of cross Regional network arrangements may be considered within the overall model.

The Provider's Premises are located at:

ODN Centres and linked services have been defined through the compliance process

7. Individual Service User Placement

Not Applicable

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

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
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 recommendations provided to the patient and the general practitioner	> 85% of patients	Local database	Patients receive inadequate care