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Service Specification

**Pharmaceutical Care of Patients Receiving Treatment for Hepatitis C Infection.**

**Background**

This Service Specification is developed and managed through the Sexual Health and Blood Borne Virus Managed Care Network, within NHS Tayside.

Hepatitis C (HCV) infection is a major health concern in the UK with up to 0.7% of the population infected. It is estimated that 40% of patients prescribed methadone in Tayside carry an HCV infection. Perhaps, 25% of those infected will clear the infection spontaneously, with many of those who develop a chronic infection, going onto to develop liver cirrhosis or liver cancers. The conventional care pathway within the NHS is that patients with a high risk of having HCV infection including methadone users should be offered HCV testing. Once diagnosed, they can be referred to nurse led treatment pathways. Less than 10% of the methadone users are tested for HCV and of these fewer than 20% go onto treatment regimes that successfully clear the infection despite regular interactions with heath care staff, using the standard care pathway. Pharmacy staff have daily interactions with patients receiving methadone and are ideally placed to deliver anti HCV therapy. Pharmacists possess skills in advising on drug therapy and are developing prescribing roles to enable them to make a greater contribution to improving the health of the populations they serve.

**Detail**

a). Provision of patient information, testing and treatment advice

Patients receiving methadone should be regularly tested for HCV through Dried Blood Spot Testing (DBST) using the SH&BBV MCN standard protocol. The document “*Dry Blood Spot Testing Guidelines for Hepatitis C virus, Hepatitis B virus and HIV 2016* should be used to guide practice. It is envisaged that non-pharmacist staff will carry out testing and that the pharmacist will advise the patient about the outcome of the test and any requirement for treatment. Local evidence demonstrates that a patient is approximately four times more likely to accept a test for HCV from a pharmacy

b). Assessment of patient and generation of a prescription for treatment

Patients who receive a reactive DBST require further assessment to ascertain their HCV genotype, their degree of liver damage and whether or not they have managed to spontaneously clear the infection. Pharmacists will either refer the patient to the nurse-led service for evaluation or carry out the patient assessment in the pharmacy. All patients are accepted by the consultant physician team before a prescription is issued to authorise treatment. Local evidence demonstrates that patients are around five times more likely to complete the treatment pathway if their assessment is carried out in the pharmacy.

c). Support for an HCV treatment course by directly observed therapy or instalment dispensing

Patients who are assessed as suitable for treatment for HCV will be prescribed the DAA treatment choice advised for the genotype of their viral infection in the National Guidance. A prescription will be provided by one of the pharmacist prescribers or by a nurse prescriber. Pharmacies should ensure that the medicines required for treatment to enable commencement are available. Patients should receive directly observed administration of the medicine as carried out in usual practice, such as when supervising methadone administration.

**ANNEX A**

**Pharmaceutical Care of Patients Receiving Treatment for Hepatitis C**

**1. Service Objectives**

1.1 The specific objectives of the service to provide pharmaceutical care to patients receiving treatment for opioid addiction who are infected with hepatitis C

* to improve the clinical outcomes achieved by patients prescribed anti-HCV medicines, especially preventing treatment defaults and poor adherence to treatment courses.
* to shorten the patient journey to one that can be accomplished by the majority of patients and avoid loss to follow-up
* to ensure close clinical monitoring for patients directly affected

**2. Service Description**

2.1 This service specification allows eligible individuals, who have given informed consent to engage with this service, and to use their community pharmacy as the delivery point for pharmaceutical care, dispensing and directly observed administration of medication to treat HCV. The pharmacy service tests, advises, assesses the patient, dispenses for, supervises administration and refers the patient to agreed contacts according to their needs.

2.2 The initial consultations about test results and about treatment must be provided by the pharmacist in person.

2.3 Patients should be sign-posted to support groups or health professionals and should be able to obtain appropriate information about treatment and what it involves from the pharmacy, using standard information provided by the MCN

**3. Service Outline (Flow Chart for Hepatitis C Care Involving Community Pharmacists)**

*3.1 Service Registration and Withdrawal*

* Patients who have not been previously tested according to the list provided to the pharmacist should be offered Dried Blood Spot Testing (DBST).
* Patients with a reactive DBST should be encouraged to obtain further blood tests from one of the NHS Tayside sites that offer Phlebotomy services. If the patient fails to attend one of the phlebotomy services then the Hepatitis Team should be contacted to arrange a visit from a phlebotomist to the pharmacy. The preferred method of contact is by NHS Net e-mail.
* Individuals testing positive for active HCV infection should be either assessed by the pharmacy using the standard pathway or referred to the nurse-led service if they have a Fib-4 score of > 3.25 or other factors requiring further investigation.
* Community pharmacists assessing the patient for treatment can communicate with the specialist pharmacist who works with the multi-disciplinary hepatitis team about the patient’s suitability for treatment. A copy of the pharmacy assessment form should be used to accompany a request for a prescription. The preferred method of contact is by NHS Net e-mail.
* The community pharmacist will order sufficient medication to ensure continuous treatment of the patient for the medication regime that they are prescribed.
* A pharmacist or nurse prescriber will issue the pharmacy with a prescription for directly observed therapy for the patient, for both nurse led and pharmacist led pathways.
* The pharmacy will provide patients with directly observed administration of the HCV medication on days that the pharmacy is open and dispense a supply of medication for days that the pharmacy is not open. A Daily Log will be completed to confirm administration. Any adverse events will be recorded on the Adverse Event Log. The Daily Log will be used to record administration and common side-effects.
* At completion of the treatment for each patient, a further blood test will be undertaken by the patient to confirm that a cure (SVR) has been achieved. The pharmacy should undertake this by arranging a further DBST from the patient. If this is not feasible, the patient should be encouraged to this blood test from one of the NHS Tayside sites that offer Phlebotomy services. If the patient fails to attend one of the phlebotomy services then the Hepatitis Team should be contacted for advice. The preferred method of contact is by NHS Net e-mail.

3.2 *Patient services*

 All patients eligible for treatment must have an appropriate prescription from the clinician coordinating their care. The prescription will include the necessary instructions for instalment dispensing and directly observed therapy.

The community pharmacist should:

* Provide information and a Patient Information Sheet to each potential participant.
* Complete all records for the patient and consider the most appropriate course/s of action, the counselling and advice needs and any requirements for follow up or referral.
* Help the patient understand what their participation in testing and treatment will entail and how to obtain the best clinical outcome from the medicines they are prescribed, according to their assessed needs. Patients will require directly observed administration of their medication and on-going monitoring.
* Agreements will be made with the patient regarding how best to contact them about any issues that arise with their care. This is especially important when contact with the multi-disciplinary team is required. Details of patients’ contacts will be kept in the patient’s PCR record.

**4.0** Recording of dispensing

The pharmacy contractor will maintain a dispensing record of supplies made to all registered patients for this service. The Daily Log will be used to record that a dose has been dispensed and administered. The Daily Log will act as a running balance for all medicines dispensed for that patient.

**5. Remuneration**

5.1 A payment of £80 will be made for each patient assessed by the pharmacy on completion of the care pathway (testing for SVR).

5.2 A payment of £195 will be made for each patient who receives daily directly observed therapy for hepatitis C therapy administration at the point of new patient notification.

**6. Training and supporting staff**

6.1 Staff supervising work undertaken within this specification must have attended the specific training provided by the Board. Each pharmacy will provide a named pharmacist who has been trained to be responsible for the on-going management and delivery of the HCV treatment.

6.2 The pharmacist providing the service must be aware of and operate within the pharmacy SOPs, this specification and professional guidelines.

6.3 It is a requirement that locum staff are competent to provide directly observed administration of HCV medication so that a seamless approach to care is experienced by the patient.

6.4 The community pharmacy should maintain a list of contacts in their pharmacy to enable effective and efficient communication with the multi-disciplinary clinical team about the care of their patient.

**7.0 Staff competency**

 7.1 Dried Blood Spot Testing is a straightforward procedure undertaken by a range of providers, including staff working for health care organisations and staff working for third sector organisations.

7.2 Staff undertaking this procedure should be competent to administer the Dried Blood Spot Test and provide the patient with accurate information about the test or be able to refer the patient to someone working with them who can. Testing should not be undertaken by staff that are not competent to do so and patients should be asked to re- attend when a competent staff member is present.

7.3 Full details of available training are provided in the document “*Dry Blood Spot Testing Guidelines for Hepatitis C virus, Hepatitis B virus and HIV 2016”.*

**8.0 Infection prevention and control.**

8.1 Staff undertaking Dried Blood Spot Testing are referred to the document “*Infection and Control Advice Summary for Pharmacy Staff Undertaking Dried Blood Spot Testing With Patients Receiving Opioid Substitution Therapy”* which outlines best practice and risk control measures that should be employed as part of daily practice. The NHS Tayside Infection Control Manual is also available to provide guidance.

8.2 A safe and effective vaccine is available against hepatitis B. People who inject drugs are at increased risk of being infected with blood-borne viruses, including hepatitis B. If Standard Operating Procedures for sample collection are followed, the risk of occupational exposure is very low.

8.3 In order to further minimise risk of infection following accidental exposure, NHS Tayside recommends that all Community Pharmacy staff involved in services that involve potential exposure to blood or contaminated sharps are vaccinated against hepatitis B.

### **Relevant legislation and guidance**

The following information is taken from current publications by the Health and Safety Executive and the Department of Health. For more information, see the references.

* Employers have a legal duty to protect the health of their staff. This includes assessing the risk of infection for employees and then taking suitable precautions to protect their health, including vaccination.
* Employers should make hepatitis B vaccination available free-of-charge to employees via their Occupational Health arrangements.
* All healthcare workers who may have direct contact with patients’ blood require vaccination against hepatitis B.

HSE, Blood-borne viruses in the workplace: guidance for employers and employees. 2001: London.

HSE, Control of substances hazardous to health: approved Code of Practice and guidance. 2013, HSE Books.

Department of Health, *Immunisation against infectious disease*. 2013, The Stationery Office: London. p. 161-185.

**ANNEX B**

**Community Pharmacy Provision of Hepatitis C Medicines**

**Key Aims**

The Board’s aim in managing patient HCV treatments through community pharmacies is to:

1. Ensure patients receive the maximum benefit from their prescribed course of medication
2. Shorten treatment pathways and loss to follow-up of patients eligible for HCV treatment; minimise the opportunity for drug resistance to develop locally.
3. Minimise financial risks and administrative burdens that may impinge on the Community Pharmacy through provision of this care.

**Key Principles**

1. NHS Tayside will continue to provide remuneration for the clinical service elements of care through local SLA where this is over and above delivery of national pharmaceutical care services.
2. Whilst NHS Tayside cannot indemnify contractors against all risks and losses, a balanced supportive approach will be taken commensurate with other contractor groups e.g. GPs.

**SLA Key Elements**

Board points of contact in relation to administration of the SLA

1. NHS Tayside has a designated SLA contact to resolve / respond to payment / contractual issues / financial loss.

 Lead Clinician - Pharmacoeconomics

1. NHS Tayside to have a clinical contact to resolve clinical issues relating to individual patient care

 Consultant in Public Health Pharmacy

Risks

1. NHS Tayside should be informed of any reason for non supply related to patient behaviour, change of clinical circumstances or treatment regimen that are outwith the community pharmacy’s control.

Patient initiation / advance payment

1. Pharmacy contractors will be advised that a new patient initiation is planned well before treatment begins. This notification should typically occur 14 days prior to that initiation. Such notification should include:
	1. Patient details and CHI number
	2. The indicative start date for treatment
	3. Statement advising community pharmacy to order treatment no more than 14 days prior to the treatment initiation date
2. Advance payments covering the payment for directly observed therapy should be made to contractors in a single advance payment. Payment for completion of the care pathway will be made on receipt of a final SVR blood test, or acknowledgement that reasonable efforts have been made to obtain one.
3. Advanced payments should be made as part of normal monthly payments i.e. the use of BACS should be used only in very exceptional circumstances and at the request of the contractor.

Diagram of Typical Patient Flow

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Patient |  |  |
|  |  |  |  |  |
|  | Untested |  | Known Positive |  |
|  |  |  |  |  |
|  | DBST |  |  |  |
|  |  |  |  |  |
| Negative | Reactive |  |  |  |
|  |  |  |  |  |
| Assessment by Nurse Service | PharmacyAssessment  |  | PharmacyAssessment | Assessment by Nurse Service |
|  |  |  |  |  |
|  | Contact MDT for Prescription |  | Contact MDT for Prescription |  |
| Prescription Provided by Nurse Service |  |  |  | Prescription Provided by Nurse Service |
|  |  |  |  |  |
|  |  | Initiate Treatment |  |  |
|  |  |  |  |  |
|  |  | Directly Observed Therapy |  |  |
|  |  |  |  |  |
|  |  | Completion of Treatment Course |  |  |
|  |  |  |  |  |
|  |  | Confirmatory Blood Test (SVR) |  |  |