NHS Lothian

NHS LOTHIAN

Community Pharmacy Supply of Medicines for Hepatitis C

PHARMACEUTICAL CARE INFORMATION PACK

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INTRODUCTION TO HEPATITIS C INFECTION

Chronic hepatitis C constitutes a major global health concern as it is a leading cause of chronic liver disease, cirrhosis and hepatocellular carcinoma. The goal of therapy is to prevent these complications through viral eradication.

The hepatitis C virus (HCV) was first identified in 1989, and HCV infection has become a major health problem worldwide. Approximately 0.8% of the Scottish population is thought to be chronically infected with HCV (around 37,500 individuals). The prevalence of infection varies between population groups ranging from 50% in people who inject drugs (PWID) to less than 0.04% among new blood donors.

Up to 80% of patients infected with HCV become chronically infected and most of these patients will show evidence of chronic hepatitis.

Hepatitis C is usually slowly progressive over a period of many years. Five to fifteen per cent of patients with chronic hepatitis may progress to liver cirrhosis over 20 years. Four to nine per cent of patients with cirrhosis will develop liver failure; and two to five per cent of patients with cirrhosis will develop primary hepatocellular carcinoma.

In the UK the two major routes of transmission of HCV have been sharing of drug injecting equipment by PWID and transfusion of infected blood or blood products. Virus inactivation treatment of blood products began in 1987 and since 1991, blood donations have been screened for hepatitis C, eliminating blood products as a source of HCV infection.

GENOTYPES

HCV is characterised by genotypes and subgroups with prevalence varying depending on the geographical location. Genotype 1 can be further classified into subgroup a and b. Genotype 1 and 3 are the most prevalent in Scotland.

Genotype details are as follows:

- Genotype 1 occurs in around 50% of patients in Lothian
- Genotypes 2 occurs in less than 5% of patients; Genotypes 3 occur in around 45% of patients in Lothian; these subtypes are most prevalent in India, Pakistan, Thailand, Australia, and Scotland (PWID population)
- Genotype 4-6 occurs in less than 5% of patients; genotype 4 is most prevalent in the Middle East and Africa

Within a region, a specific genotype may also be associated with a specific mode of transmission, such as genotype 3 among persons in Scotland who abuse intravenous drugs.

TREATMENT OF HCV INFECTION

Treatment of chronic HCV infection has 2 goals. The first is to achieve sustained viral eradication of HCV (i.e. sustained virologic response [SVR]), which is defined as the persistent absence of HCV RNA in serum 3 months or more after completing antiviral treatment. This represents cure of the infection. The second goal is to prevent progression to cirrhosis, hepatocellular carcinoma (HCC), and decompensated liver disease requiring liver transplantation.

Antiviral therapy for chronic hepatitis C should be determined on a case-by-case basis. However, treatment is generally recommended who meet the following criteria;

- Age greater than 18 years
- Positive HCV antibody and serum HCV RNA test results
- Willingness to be treated and to adhere to treatment requirements
- No contraindications for treatment

The treatment of hepatitis C has evolved over the years. Historically, treatment for all genotypes consisted of combination therapy of ribavirin and pegylated interferon (PEG-IFN) for up to 48 weeks. The SVR (cure) rate with this combination was only around 60%. It had many unpleasant side-effects, and some people may still think that this is the treatment being used now. In 2011, patients with genotype 1 had option of triple therapy in which a protease inhibitor, boceprevir, or telaprevir were used in combination with ribavirin and peg-interferon which improved SVR rates. Since 2014, several new Direct Acting Antiviral (DAA) medicines have been licensed. These act directly on various parts of the viral replication life cycle, inhibiting specific proteins. **These treatments have a shorter treatment duration, minimal side effects and are expected to achieve SVR (cure) rates over 90%.** There are four classes of DAAs which are classed according to the protein they have action on, namely, NS3/4 protease inhibitors, NS5B nucleoside polymerase inhibitors, NS5B non-nucleoside polymerase inhibitors and NS5A inhibitors.

Successful treatment of hepatitis C infection has been shown to reduce the risk of developing cirrhosis and for those with established cirrhosis, reduce the risk of decompensation and HCC. Importantly data from Scotland shows a reduction not just in liver related morbidity/mortality, but also all-cause mortality, Data from Scotland and elsewhere demonstrate that successful treatment is also associated with a reduction in cardiovascular mortality, development of diabetes, and a lower risk of haematological malignancies.

The Scottish Government sets minimum treatment targets for health boards to achieve through the Scottish Blood Borne Virus Framework and has signed up to the Glasgow Declaration – a WHO sponsored commitment to eliminate Hepatitis C as a public health concern by 2030.

CURRENT HCV THERAPY

HCV is currently treated with drugs known as Direct Acting Antivirals (DAAs). These treatments are available as oral regimens with a combination of 2 to 3 DAAs in one tablet. The choice of drug regimen for each patient is made according to the most recent treatment guidelines and depends on several individual patient factors.

The following information provides a brief overview of the available treatment regimens. Further information can be found in the Summary of Product Characteristics (SPC) (www.medicines.org.uk). Drug-Drug Interaction information can also be found in the SPC as well as https://www.hep-druginteractions.org. The specialist team should be contacted if further information is required (see page 10-11 for contact details).

HCV MEDICATIONS

DAA regimen	Dose	Genotype	Caution
Glecaprevir 100mg + Pibrentasvir 40mg (**Maviret** ®)	3 tablets ONCE daily with food 8 weeks	1 - 6	Avoid in decompensated liver disease
Sofosbuvir 400mg + Velpatasvir 100mg (**Epclusa** ®)	1 tablet ONCE daily 12 weeks	1 - 6	
Ledipasvir 90mg + Sofosbuvir 400mg (**Harvoni** ®)	1 tablet ONCE daily 8 or 12 weeks	1, 4, 5, 6	
Elbasvir 50mg + Grazoprevir 100mg (**Zepatier** ®)	1 tablet ONCE daily 12 weeks	1, 4	Avoid in decompensated liver disease
Sofosbuvir 400mg + Velpatasvir 100mg + Voxilaprevir 100mg (**Vosevi**®)	1 tablet ONCE daily with food 8 or 12 weeks	1 - 6	Avoid in decompensated liver disease

MISSED DOSE ADVICE

DAA regimen	Missed dose advice	Vomiting advice
Maviret	If within 18 hours of usual time, then take the dose and continue next dose at usual time.	If vomiting occurs within 3 hours of dosing, then take another dose.
Epclusa	If within 18 hours of usual time, then take the dose and continue next dose at usual time.	If vomiting occurs within 3 hours of dosing, then take another dose.
Harvoni	If within 18 hours of usual time, then take the dose and continue next dose at usual time.	If vomiting occurs within 5 hours of dosing, then take another dose.
Zepatier	If within 16 hours of usual time, then take the dose and continue next dose at usual time.	If vomiting occurs within 4 hours of dosing, then take another dose.
Vosevi	If within 18 hours of usual time, then take the dose and continue next dose at usual time.	If vomiting occurs within 4 hours of dosing, then take another dose.

Patient should be instructed NOT to take a double dose.

Further guidance on missed/uncollected doses – please see page 8 of the document.

COMMON SIDE EFFECTS

The DAAs have generally been shown to be well tolerated in clinical trials. The most common side effects reported are headache, fatigue, and gastrointestinal (GI) upset.

If the patient complaints of intolerable adverse effects, please advise them to contact the specialist team.

PREGNANCY

All DAAs are unlicensed for use in pregnancy as there are limited data available.

Patient should be counselled that pregnancy is not recommended whilst on treatment due to unknown fetal risk, and effective contraception should be used.

If a patient becomes pregnant whilst on HCV treatment, please advise patient to stop treatment and contact the specialist team for advice immediately.

DRUG-DRUG INTERACTIONS (DDI)

Drug-drug interactions (DDIs) are checked by the specialist team prior to commencing HCV treatment. However, care should be given if a patient is started on new medications (including OTC and supplements) whilst on HCV treatment.

The safety of concomitant medications could be consulted using the individual Summary of Product Characteristics (SmPC) www.medicines.org.uk or on the Liverpool HEP-Drug interaction checker https://www.hep-druginteractions.org/, or discuss with the specialist team as appropriate.

Some example groups of drugs that may interact with the DAAs are Statins, Acid-reducing Agents, Anti-epileptics, Antipsychotics, and HIV antiretrovirals (this list is not exhaustive).

MONITORING

The DAA regimens are generally well tolerated and have a very low incidence of toxicity. Therefore, most of the patients will not require any blood test monitoring whilst on HCV treatment. Some patients may have different monitoring requirements according to individual circumstances, e.g. cirrhotic patients or patients with significant DDIs.

The specialist team will usually follow-up with the patient during treatment to check for any adverse effects and treatment compliance. Community pharmacies are also asked to monitor compliance and report to the specialist team if there are missed doses or non-collection for more than 2 days (see next section for more information).

All patients will be advised to have bloods taken 12 weeks after completing a course of HCV treatment to check HCV viral load. Undetected HCV viral load measured 12 weeks post-treatment is equivalent to a cure and is termed sustained viral response (SVR)12. Achievement of SVR12 has been found to be associated with decreased risk of developing cirrhosis, hepatocellular cancer (HCC), and reduced mortality. However, this does not prevent patients from re-infection if exposed to HCV again.

If a patient misses a significant number of doses or discontinues treatment early for any reason, the specialist team must be contacted. Bloods may need to be taken earlier than 12 weeks to assess treatment response and re-assess treatment plan.

COMMUNITY SUPPLY OF HCV MEDICATION

NHS Lothian has a commitment to deliver on the Scottish Government's policy initiative "Shifting the Balance of Care". The policy guidelines require improvements to health and social care services that improve the health and well-being of the population. Changes are required so that the work of secondary care and primary care becomes more integrated, and that care becomes located around community-based services. The development of new medicines, like those for HCV, has meant that many treatments have become available that transform previously fatal or debilitating diseases into conditions that a patient may manage successfully for many years. Realising the investment in the patient's health requires that health services commit to normalising the patient's experience of care as much as possible, through integration with standard primary-care services.

OVERVIEW

- The Board seeks to facilitate access to effective treatment by utilising the Community Pharmacy network working in partnership with the Specialist Pharmacy Team (SPT) in secondary care.
- Patients receiving treatment for HCV identify their preferred community pharmacy to provide this clinical service which encompasses support with concordance and the provision of DAAs.
- Patient treatments are co-ordinated by the SPT in secondary care.

TREATMENT INITIATION

- Patients are referred to the secondary care multidisciplinary team (MDT) in acute care, outreach, prisons, or from waiting list review.
- Pre-treatment assessments are completed by secondary care clinical nurse specialists (CNS) or the SPT, and if appropriate for treatment, a preferred community pharmacy and instalment dispensing regimen will be identified.
- These assessments are further discussed at the MDT to decide on the HCV drug regimen which is prescribed on a hospital-based prescription (HBP).
- The SPT will first contact the community pharmacy by phone to notify of patient treatment referral.
- The community pharmacy will then receive a treatment confirmation email, which includes a scanned copy of the HBPs, Patient Treatment Notification form (see attached), medication order form, and treatment start date (usually 2 weeks' from sent date) from the SPT.
- The physical HBPs covering the full treatment course will be posted to the community pharmacy by the SPT shortly after the treatment confirmation email.
- Each prescription will be for 28 days' supply. HCV treatment courses are typically between 8 – 12 weeks therefore will require 2 or 3 individual prescriptions for the full treatment.

- On receipt of the treatment confirmation email, the community pharmacy should note the treatment start date.
- Stock for the first prescription should be ordered once received HBPs; and for subsequent prescriptions a week before the due date.
- Medication must only be ordered using the specified suppliers & order forms; see Hepatitis C – NHS Lothian.
- If problems in accessing the medicine via this supply route cannot be resolved through direct dialogue with the manufacturer, contact the SPT.
- **Do not purchase from any other supply route without the approval of the Health Board.** The Health Board may request proof of ordering.
- Community pharmacies are strongly recommended to maintain records of the running balance of stock.
- Subsequent stock should be ordered in sufficient time (i.e. a week before subsequent prescription starts) to ensure continuity of supply and avoids missed doses.
- **The community pharmacy must contact the SPT or the CNS promptly by email or phone (see contact list) to raise any issues with product availability, missed doses and collections, or clinical concerns (see section on "Patient Care"), at any stage of the course that could jeopardise treatment outcome.**
- If required, the SPT will liaise with the community pharmacy to confirm arrangements for further use and remuneration for any unused stock.

PATIENT CARE

Community pharmacy plays an important clinical role in providing support to patients through the course of treatment. Cure rates of greater than 95% can be achieved if patients take the DAAs as prescribed. It is therefore vital that the treatment course is started on the stated date and that patients are supported to complete the course **without interruption.**

The community pharmacy should:

- Provide pharmaceutical care including support with concordance.
- Create a Patient Care Record (PCR) for each patient if they do not have one and document relevant issues as they arise.
- Register the patient for Medicines Care & Review (MCR) and Chronic Medication Service (CMS) if appropriate.
- Provide instalment dispensing and supervise administration where required.
- Order medication using only the approved suppliers & order forms. Ensure this is done in a timely manner to avoid any breaks in treatment. Proof of ordering may be requested.
- Ensure all members of the pharmacy team, including locum staff, are aware of the service and local process for ordering, storing and dispensing of hepatitis C medications.
- Confirm with the patient on how best to contact them regarding any issues that arise with their care. Details of patients' contacts will be kept in the care record.

- Maintain a running stock balance for each patient and demonstrate that medicine orders and dispensing records can be matched to referred patients.
- Provide a progress report and the running balance for each patient to the SPT when requested.
- The community pharmacist should be sufficiently competent and knowledgeable in this speciality to carry out the normal professional checks. A full drug interaction check will have been carried out by the SPT. However, any concerns of over-the-counter purchases or new medicines started during treatment should be checked via www.hep-druginteractions.org or with the specialist team.
- In the case of adverse reactions, the community pharmacist will contact the specialist team and discuss whether there is a need to report any adverse reactions via the MHRA Yellow Card reporting mechanism Yellow Card | Making medicines and medical devices safer.

MISSED DOSES / COLLECTIONS

- If **supervised daily** dispensing – **must report to the SPT if missed ≥ 2 days.**
- For **non-supervised** dispensing – **must report to the SPT if not collected within 2 days of due date.**
- The Specialist Team will then attempt to contact the patient to follow-up and encourage attendance.
- For repeated episodes of missed doses/collections, the SPT may request to be informed more frequently of non-attendance as the treatment plan may need to be reviewed.
- Missed doses should generally be added to the end of treatment to ensure that the patient has taken the full course of medication.
- **If missed more than 7 days of treatment, the specialist team must be contacted to review treatment plan.** This may be continuing treatment and add missed dose at the end; withholding and restarting treatment later; or discontinuing treatment early.
- If treatment courses do not start / are delayed or discontinued early, the community pharmacy must inform the SPT and they will liaise to arrange further use and remuneration for unused stock.

REMUNERATION

For each patient receiving treatment under this service agreement, a contractor will receive £445. This payment is made up of:

- £215 as a pharmaceutical care remuneration fee, and
- £230 as an exceptional fee for costs associated with delivery of the service relating to business costs and risks.

ADVANCED PAYMENT

Direct Acting Antivirals (DAAs) are high-cost medicines, and so to support mitigation of financial risk, contractors can request advanced payments to cover the procurement costs.

- Once a treatment confirmation email is received, the community pharmacy can make a request for the advanced payment. Information and request form can be found at Hepatitis C – NHS Lothian.
- Advanced payments covering the complete cost of a treatment course (i.e. 8 or 12 weeks) will be made in a single payment.
- This will be paid before the first invoice payment date if the contractor makes their application before the 10th day of the month.
- Advanced payments will be made as part of normal monthly payments.
- Prescriptions must be submitted promptly for payment in the normal way as soon as the last instalment on each form has been dispensed. Late submission of prescriptions will mean that recovery is out of synchronisation with the planned schedule.
- The Health Board will timetable recovery of advanced payments at month 6 for an advance made prior to the beginning of an 8 or 12-week course. This allows for the submission and reimbursement of all prescriptions
- See example prescription and payment schedule for a 3-month (12-week) course:

	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
CP receives notification	✓						
Treatment start		✓					
Remuneration fee		✓					
Drug purchased		1	2	3			
Single advanced payment		✓					
Prescription submitted			1	2	3		
Prescription paid					1	2	3
Supplier paid			1	2	3		
Recovery of advanced payment							✓

CONTACTS

In NHS Lothian, services for Hepatitis C are provided by specialists based at either the Regional Infectious Disease Unit (RIDU) in Western General Hospital, or the Liver Unit in Royal Infirmary of Edinburgh, often through outreach clinics at various locations across Lothian.

HEPATITIS C PHARMACY SERVICE

The specialist pharmacy team provides Lothian-wide cover.

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