**2024 - 2027 Service Level Agreement (SLA)**

**Additional Pharmaceutical Care Services**

**Pharmaceutical Package of Care for Patients on Direct Acting Antivirals (DAAs)for Hepatitis C**

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| **1.** | **Introduction** |
|  | This Service Level Agreement (SLA) acts as a contract between NHS FV and the Pharmacy Contractor and commits the Pharmacy Contractor to provide the services as defined. The SLA must be read in conjunction with the Appendices provided. Services will be provided within the legal and ethical framework of pharmacy as a whole. |
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| **2.** | **Background to Service** |
|  | Hepatitis C is a blood borne virus which can lead to chronic liver disease with relatively few symptoms. Transmission is mainly blood to blood contact. It is estimated there are still approximately 300 infected individuals within Forth Valley who still require to be diagnosed. The new direct acting antiviral treatments (DAA’s) allow patients to be treated in the community. Community pharmacies are ideally placed to support patients through treatment. |
| **3.** | **Service Aims** |
|  | To provide holistic pharmaceutical care for patients prescribed Direct Acting Antivirals and promote recovery by:   * + - Providing close liaison with Hepatology Service     - Dispensing DAAs as prescribed according to need.     - Ensuring each supervised dose is consumed in accordance with the appropriate standard operating procedure (SOP).     - Monitoring the patient’s response to prescribed treatment.     - Providing general health advice including pharmaceutical public health services and signposting to assist access to further advice or assistance     - Promoting patient safety and appropriate harm minimisation strategies. |
|  | To reduce the risk of:   * + - Overuse or underuse of medicines     - Diversion of prescribed medicines     - Poor adherence to treatment     - Patients not completing course of treatment |
| **4** | **Roles and Responsibilities:** |
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| **4.1** | **Responsibilities of Participating Contractor** |
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|  | **The Pharmacy Contractor will:** |
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|  | Take full responsibility for ensuring compliance with all aspects of the SLA. |
|  | Nominate a **Key Pharmacist** (usually the Responsible Pharmacist) and **technician/dispenser** who will have accountability for provision of the service on a day-to-day basis from that pharmacy. For pharmacies open over extended hours and particularly on a Sunday, the Participating Contractor must also ensure that the Locum/Relief manager and technician/dispenser on duty at these times has a full understanding of the SLA to be competent to maintain continuity of service. |
|  | Ensure the Standard Operating Procedures (SOPs) in place governing the service fully cover the main principles of the provision specific to the service standards operating within the pharmacy and that all involved in providing the service are fully conversant with the content of each SOP. |
|  | Ensure that all pharmacy staff offer a user-friendly, non-judgemental, person-centred and confidential service |
|  | Ensure that the services are operated from premises providing a level of confidentiality and privacy which is acceptable to the individual patient. |
|  | Ensure that the service is available to patients for the full contracted opening hours of the premises unless there are exceptional circumstances. |
|  | Ensure that all GPhC Standards are upheld during the provision of this service – in particular ensuring that children and vulnerable adults are safeguarded. |
|  | Make available to patients and carers a range of information in accessible format, including details of local support services and voluntary agencies. |
|  | Keep and maintain appropriate records, including patient medication records to enable verification of service provision and training requirements, and provide to Community Pharmacy Development Team (CPDT) for internal and external audit, evaluation, monitoring service development and payment verification purposes. |
|  | Participate in any local audit processes to the agreed levels |
|  | The community pharmacist will develop a working relationship with the prescriber and staff of the Hepatology Service. This should include a process to allow information sharing where required. This will include sharing of any medicine changes. |
|  | The community pharmacist will ensure patient contact details are current in order to assist with compliance if required |
|  | The dispensing and supervision procedure should follow the relevant procedures. |
|  | The community pharmacist will ensure that a pharmaceutical care plan is developed and maintained for each patient which will include   * monitoring the response to treatment * medicine information, advice provided * up to date contacts |
|  | Ensure training requirements are met by community pharmacy staff |
|  | The community pharmacy team will ensure compliance with the care bundle for each patient. |
|  | **The care bundle comprises of the following:** |
|  | * The community pharmacist will provide a verbal/written/electronic summary of progress to hepatology each month of treatment (hepatology will contact the community pharmacy to request this information) and if there are any issues between these times. This should include:   + Compliance issues   + Signs of side effects   + Patient issues or concerns * Assess concordance of patient e.g. check collection in timely manner * Ask patient about missed doses and respond appropriately * Assess interactions * Ask the patient about side effects e.g. nausea & vomiting, headaches, concentration, fatigue * The community pharmacist should provide information and advice (with appropriate signposting) on: * Safe storage and disposal of medicines * Alcohol awareness * Advice on polypharmacy of prescribed medicines * Smoking cessation where appropriate * Healthy eating and exercise * Sexual health advice and condom provision where appropriate * Oral Health |
|  | The community pharmacist should provide referral and/or signposting to other health services and agencies as required. |
|  | The pharmacist must ensure compliance with GPhC standard 1.8, namely that children and vulnerable adults are safeguarded. |
|  | A range of relevant information in an accessible format should be available including details of local services and agencies. |
|  | The pharmacist will record and act on any medicine incidents and report controlled drug incidents to the Accountable Officer. |
|  | Ensure the safe and effective provision of pharmacy services in line with GPhC Standard 9. |
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| **4.2** | **Responsibilities of Community Pharmacy Development Team** |
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|  | **The Community Pharmacy Development Team will:** |
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|  | Ensure an electronic copy of the SLA is forwarded to the Participating Contractor each time the service is reviewed and agreed with Community Pharmacy FV (CP FV). The Participating Contractor (or nominated representative) will formally sign a copy of the SLA as a record of acceptance of the terms and conditions of the SLA for the provision of this additional service. The signed copy requires to be returned to Pamela Calder at: Pharmacy Services, Carseview House, Castle Business Park, Stirling, FK9 4SW or [pamela.calder@nhs.scot](mailto:pamela.calder@nhs.scot) by the date specified to ensure that all relevant payments can be made. |
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|  | **All Parties:** |
|  | All parties will maintain patient confidentiality and comply with all relevant GDPR regulations. |
|  | The General Data Protection Regulation (GDPR) (EU) 2016/679 [13] and Data Protection Act 2018 [14] came into force on 25 May 2018. All organisations that process personal data are required to comply with the requirements of this legislation.  This means that personal information will be:  • Processed lawfully, fairly, and in a transparent manner.  • Collected for specified, explicit and legitimate purposes.  • Only collected so far as required for our lawful purposes.  • As accurate and up to date as possible.  • Retained for a reasonable period, in accordance with retention policies.  • Processed in a manner which ensures an appropriate level of security. |
| **5** | **Purchase and Supply** |
|  | The community pharmacist will ensure cost effective purchase of medication for Health Boards in line with local and/or national guidance |
|  | Supplies of licensed medicine indicated for use in Hepatitis C must be sourced from the distributor indicated by the Health Board using the appropriate forms and method, as advised |
|  | Current agreed distributors are:   |  |  |  |  | | --- | --- | --- | --- | | **Drug** | **Brand Name** | **Manufacturer** | **Distributor** | | Elbasvir /Grazoprevir | Zepatier | MSD | Alliance | | Sofosbuvir | Sovaldi® | Gilead Sciences | Alcura | | Sofosbuvir/Ledipasvir | Harvoni | Gilead Sciences | Alcura | | Sofosbuvir/Velpatasvir | Epclusa | Gilead Sciences | Alcura | | Sofosbuvir/Velpatasvir/Voxilaprevir | Vosevi® | Gilead Sciences | Alcura | | Daclatasvir | Daklinza | BMS | BMS | | Dasabuvir | Exviera | Abbvie Ltd | Polar Speed | | Glecaprevir/Pibrentasvir | Maviret | Abbvie Ltd | Polar Speed | | Ombitasvir/Paritaprevir/Ritonavir | Viekirax | Abbvie Ltd | Polar Speed | |
|  | If a patient is admitted to hospital during treatment, acute services will contact the community pharmacy and request an agreed number of days of medication to be dispensed by the community pharmacy for use by the patient while in hospital. |
|  | Acute services will arrange and meet the cost of a taxi service to collect the medication from the community pharmacy and deliver to the hospital. |
|  | Acute services will inform the community pharmacy when the patient has been discharged from hospital. |
| **6** | **Training** |
|  | All Key Pharmacists involved in the Service must complete the following training: |
|  | **Initially:** If required the pharmacists involved in the provision of the service can receive training on the DAA’s and treatment regimens and possible side effects from the hepatology team |
|  | **Each Year**  Pharmacists delivering the service have a professional obligation to ensure their knowledge is kept up-to-date with Hepatitis C treatment. |
|  | In line with GPhC standards for registered pharmacies 2.1 the responsible pharmacist must ensure that there are enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided |
|  | In line with GPhC standards for registered pharmacies 2.2 the responsible pharmacist must ensure that staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training |
|  | **Other useful resources include:** |
|  | GPhC Standards for Registered Pharmacies (current edition)  RPS Medicines, Ethics and Practice (current edition)  BNF section on “Infections” (current edition)  NES Adult & Child Protection TURAS Modules [Public Protection | Turas | Learn (nhs.scot)](https://learn.nes.nhs.scot/64316)  [www.hep-druginteractions.org](http://www.hep-druginteractions.org) for clear up to date information on interactions with direct acting antivirals and other prescribed, OTC, recreational medicines. There is additional information on pharmacokinetics etc that are useful on this site. |
|  | **All staff should:**   1. Know what the aims of the Service are. 2. Know where to access support materials. 3. Read and understand the content of the support material. 4. Recognise how the support materials present a Continued Professional Development (CPD) opportunity for both pharmacists and technicians. |
| **7.** | **Payments for Service Participation/Delivery** |
|  | A locally agreed fee will be paid for each package of care. The current agreed fee for the duration of this SLA is £124 per month. The fee will be paid upfront for the duration of treatment e.g 3 months when treatment is initiated. In the event of a fee change within the lifetime of the SLA, formal notification will be sent to the community pharmacy network via e-mail. |
|  | NHS Forth Valley community pharmacy contracts officer will arrange payment to community pharmacies. Information for audit and evaluation purposes may also be gathered and must be completed before any payment is made by NHS Forth Valley. Reasonable written notice would be provided prior to the completion of an audit where possible. |
|  | The Fees set out in this SLA are exclusive of any applicable Value Added Tax.  Value Added Tax will be charged at the prevailing rate and is payable by the [Commissioner] following the receipt of a VAT invoice. |
|  | **Overpayments/Recoveries** |
|  | If an over/inappropriate payment is identified, the CPDT will make arrangements to process a recovery.  The payment recovered will not exceed the amount of the over/inappropriate payment.  No additional/further financial sanction will be applied. The Pharmacy Contractor will be advised of the intention to recover monies before the recovery is made. |
|  | Any recovery will be made via the Regional Payments process and will be visible both via the PAY001 produced by Practitioner Services Division (PSD) and the local remittance produced by the CPDT. |
|  | **Advanced Payments** |
|  | If an advance payment for medicines is required for cashflow purposes then the contractor must complete the Hep C Advance Application Form (Appendix 2). This requires to be completed for each month of the course of the treatment and for each patient. |
|  | The application form must be completed in full by the deadline for the month and emailed to [Rachel.myles3@nhs.scot](mailto:Rachel.myles3@nhs.scot) No applications can be accepted after the deadline. These deadlines are set by Practitioner Services Division (PSD). |
|  | Any advanced payment made is automatically reclaimed three months after payment. |
| **8.** | **Scope of SLA** |
|  | This SLA will be effective from 1st October 2024 and will end on 31st August 2027 |
| **9.** | **Notification of Participation** |
|  | Pharmacy Contractors should indicate their willingness to participate in the service by submitting a signed copy of the Participation Form (**Appendix 1**) using the submission details contained on the form. Forms should be submitted via e-mail to [pamela.calder@nhs.scot](mailto:pamela.calder@nhs.scot) . |
| **10.** | **Withdrawal from SLA** |
|  | NHS Forth Valley reserves the right to give notice to withdraw the service from a community pharmacy based on closure history, failure to engage with other locally negotiated services, failure to participate in training stated within the SLA and/or failure to record clinical information as stated in the SLA. Similarly, the contractor also reserves the right to give notice to withdraw from this service. |
|  | Both parties will provide a minimum of three months’ notice if they wish to withdraw from this SLA. |
| **11.** | **Health and Care (Staffing) (Scotland) Act 2019** |
|  | The Health and Care (Staffing) (Scotland) Act 2019 (“the 2019 Act”) places requirements on the Health Board stating that:  *“In planning and securing the provision of healthcare from another person under a contract agreement must have regard to*   1. *The guiding principles for health and care staffing; and*   *The need for the person from whom the provision of health care is to be secured to have appropriate staffing levels in place.”* |
|  | In signing to participate in this service, the Pharmacy Contractor confirms that they have taken into consideration provisions set out in the Health and Care (Staffing) (Scotland) Act 2019 so that the level of support available to operate the service is in line with the aims of the Act and that sufficient staff are available to safely and effectively provide the service |

**Version Control**

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| **Version** | 1. **Original SLA** |
| **Name/Department of**  **Originator/author:** | Community Pharmacy Development Team |
| **Name/Title of responsible**  **Committee/individual:** | Kirstin Cassells/CPFV |
| **Date issued:** |  |
| **Review date:** |  |
| **Target audience:** | NHS Forth Valley Community Pharmacy |

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| --- | --- | --- |
| **Version** | **Date** | **Control Reason** |
| **5** | **June 2024** | **Updated and moved to new format of SLA.** |
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**Appendix 1**

**SLA Declaration of Participation:**

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| Name and Address of Contractor: |  | Contractor Code: |
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Please complete and return this form to:

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| --- | --- |
| Pamela Calder  Contracts Officer  Carseview House | E-mail to: [pamela.calder@nhs.scot](mailto:pamela.calder@nhs.scot) |
| Castle Business Park, |  |
| Stirling | **Cut-off date for submission:** |
| FK9 4SW |  |

**Agreement to Provide:**

Pharmaceutical care as defined in the SLA – Pharmaceutical Package of Care for Patients on Direct Acting Antivirals (DAAs)for Hepatitis C

(Please Tick as appropriate)

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| I wish to participate in this service and in so doing, I confirm that I have read, understood and will comply with the provisions set out in the SLA |  |

Contractor/Contractor Representative Name: ……………………………….. (*Please print)*

Signature: …………………………………………. Date: …………………..

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| **Counter Fraud Declaration**: I accept that the information provided on this form may be used to verify any claim associated with this service and may be shared with other bodies/agencies for the purposes of prevention and detection of crime.  In signing this form, I consent to this use and acknowledge that if I provide false information then I may be liable to criminal prosecution, referral to my professional body and/or recovery proceedings. |

Please sign this document and retain for your own records. Please submit a copy as above.

**Signed on behalf of NHS Forth Valley:**

**Contracts Manager Date:**

**Appendix 1**

**HEP C ADVANCED APPLICATION FORM**

Contractor Name:

Contractor Code:

Address:

**Finance Section**

Advance Required:

Date Required:

Date to be recovered:

(3 months from date required)

**Drug Detail**

No of patients:

Drug Supplied:

No of packs:

Treatment Duration:

Please submit by the deadline as per the timetable for the month required to [Rachel.myles3@nhs.scot](mailto:Rachel.myles3@nhs.scot)