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| **NHS Grampian****Service Level Agreement****Provision of Hepatitis C Medication via Community Pharmacy** |

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| **SLA Reference** | SLA Provision of Hepatitis C Medication |
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| **Version Number** | **Effective Date** | **Reason for Change** |
| 2 | April 2019 | Annual update of SLA |
| 3 | April 2020 | Annual update of SLA |
| 4 | April 2021 | Annual update – update to format and wording, removal of need to enter details on PCR, addition of appendices |
| 5 | April 2023 | Annual update |
| 6 | April 2024 | Annual Update, additional emphasis on approved procurement routes added; minimum period to starting reduced to 7 days,  |

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# **1. Introduction**

This Service Level Agreement (SLA) acts as a contract between NHS Grampian and the pharmacy contractor and commits the contractor to provide the services as defined by, and using documents provided in, this SLA. Services will be provided within the legal and ethical framework of pharmacy as a whole.

A three month notice period must be provided if either party wish to terminate this contract. Where a breach in terms of the SLA has occurred the 3 month notice period may not apply.

# **2. Background to service**

Since 2014 several new oral direct-acting antiviral (DAA) medications have been licensed for the treatment of Hepatitis C. The use of a DAA medications in Hepatitis C treatment has been proven to achieve sustained virological response (SVR) rates of greater than 95% in most patient groups, with improved tolerability and reduced durations of treatment. These treatment courses usually last 8 or 12 weeks, depending on the patient’s genotype, viral load and liver function.

Treatment of chronic hepatitis C viral (HCV) infection has two patient-orientated goals:

1. Clear the infection and achieve sustained eradication of HCV. This is known as achieving a sustained virological response (SVR) and is defined as the persistent absence of HCV RNA in serum at least twelve weeks after completing antiviral treatment.
2. Prevent progression of liver damage to cirrhosis, **hepatocellular carcinoma** (HCC) and decompensated liver disease requiring liver transplantation.

Pharmacy contractors are ideally placed to deliver Hepatitis C treatments, with enhanced compliance support, support with the successful delivery of patient centred care for Hepatitis C patients within NHS Grampian. Community pharmacy involvement contributes to strong local patient compliance with regimens and related success in terms of positive treatment outcomes.

# **3. Service aims**

3.1 The pharmacy contractor will supply Hepatitis C medications to patients identified by the Hepatology Specialist Team as suitable for community pharmacy supply. Supply should be made as per directions on Hospital Based Prescription (HBP) and information sent to the pharmacy contractor from the Hepatology Specialist Team.

3.2 To provide data, both ad-hoc and via the timely submission of the Patient Compliance Reporting Form (Appendix 1), to the Hepatology Specialist Team to inform individual patient treatment plans and to help assess compliance impact on treatment outcomes.

3.3 To ensure a timely and uninterrupted supply of DAA medication(s) to the patient.

3.4 To ensure that the NHS Grampian approved procurement route (as detailed in documentation sent from Hepatology Specialist Team) of UK supplied medication is adhered to so that NHS Grampian can receive the primary care rebate associated with these products. Primary care rebates ensure that when a drug is supplied in the community setting the health board receives a rebate that makes the net acquisition cost the same as if it had procured the drug via hospital contract. Contractors must purchase from the supply route directed by the Board to ensure the NHS receives rebates as agreed with pharmaceutical companies. This SLA specifically excludes all non-approved sourcing of medication in response to prescriptions dispensed under this SLA. The SLA requirements specifically exclude the use of grey or parallel imported products, or products procured via secondary wholesale routes such as UK hospitals or outpatient dispensaries that receive medications on hospital contract price – rebates are not available to NHS Grampian for any procurement outside of the approved route. Deviation from the approved procurement route will be a material breach of the contract laid out in the SLA.

3.5. To undertake clinical checks to ensure suitability of prescribed DAA medication(s) alongside all other prescribed and over the counter medication.

# **4. Service outline and standard**

4.1 The provision of this service requires engagement and regular interaction between the pharmacy contractor and the Hepatology Specialist Team. Key steps in Community Pharmacy Supply of Hepatitis C medication are detailed below:

4.1.1 Decision made by Hepatology Specialist Team to start a patient on DAA medication for Hepatitis C. The Hepatology Specialist Team will counsel the patient on the service and make them aware of their intended medication regimen. The patient will nominate a community pharmacy from which it would be convenient to receive their DAA medication supplies.

4.1.2 The Hepatology Specialist Team will ensure that the patient’s nominated pharmacy is participating in SLA and make contact with the pharmacy contractor to inform them of a potential patient. Other than in exceptional circumstances, contact via telephone will be made a minimum of 7 days prior to intended treatment commencing.

4.1.3 The Hepatology Specialist Team will provide all relevant information to the community pharmacy via email to their NHS email account. This will include:

* Patient Transfer Form
* Information regarding DAA medication procurement
* Pharmaceutical Care Information Pack
* A scanned copy of the intended HBP prescription form(s).

4.1.4 Upon receipt of a new Patient Transfer Form the pharmacy contractor should create a PMR for the patient (if there isn’t already one) and record any relevant information within the notes.

4.1.5 Upon receipt of the emailed copy of the HBP(s) the pharmacy contractor will order the required medication (as detailed in documentation sent from Hepatology Specialist Team) and enter all details from HBP(s) onto patients PMR including instalment dates (when appropriate).

* Medication should be ordered from NHS Grampian agreed suppliers and using the order forms provided by the Hepatology Specialist Team.
* Stock should only be ordered on a **month to month basis** (i.e. maximum one month treatment at a time). Subsequent month’s medication should be ordered no earlier than 7-14 days before it is required.

4.1.6 The Hepatology Specialist Team will send the physical HBP(s) to the pharmacy contractor 7 days prior to the patient’s intended start date (each HBP form will allow a 28 day supply to be made).

4.1.7 At the appropriate start date (as agreed with the Hepatology Specialist Team) the pharmacy contractor will dispense and supply the patient’s Hepatitis C medication(s) as per directions on the HBP. A running balance of stock (per patient) should be maintained using Appendix 2.

4.1.8 The pharmacist will ensure the patient understands when and how to collect their medication and has an opportunity to ask any questions. The patient should be asked to confirm if they take any other prescribed or over the counter medication to ensure a full and robust clinical check can by undertaken.

4.1.9 If a patient fails to present to collect medications on or within a day of the next due date, the pharmacy contractor should contact the patient directly to arrange a collection.

* If the patient fails to respond, the Hepatology Specialist Team should be notified via telephone (01224 554757 or 01224 559348).
* If the patient responds but still misses a dose, the Hepatology Specialist Team should be notified via email (gram.hepatologypharmacyteam@nhs.scot).

ALL missed doses should be recorded on the monthly compliance forms regardless of if they have been reported in real time to allow the Hepatology Specialist Team to accurately collate and assess the impact of all missed doses.

4.1.10 At the end of the prescription duration the community pharmacy will endorse the HBP prescription to reflect what was supplied and sent to PSD for payment.

4.1.11 The pharmacy contractor will complete, in full, the ‘Patient Compliance Reporting Form’ (Appendix 1) at the end of every HBP prescription (i.e. every four weeks) and submit to gram.hepatologypharmacyteam@nhs.scot. This must be completed for all patients – even those who drop out of the service.

4.2 The table below lists medications which can be supplied as part of the SLA:

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug**  | **Brand Name**  | **Manufacturer**  | **Distributor**  |
| Elbasvir/Grazoprebir  | Zepatier®  | MSD  | AAH  |
| Sofosbuvir  | Sovaldi®  | Gilead Sciences  | Alcura  |
| Sofosbuvir/Ledipasvir  | Harvoni®  | Gilead Sciences  | Alcura  |
| Sofosbuvir/Velpatasvir  | Epclusa®  | Gilead Sciences  | Alcura  |
| Sofosbuvir/Velpatasvir/Voxilaprevir  | Vosevi® | Gilead Sciences  | Alcura  |
| Glecaprevir/Pibrentasvir  | Maviret®  | Abbvie Ltd  | Polar Speed  |

# 4.3 Communication between pharmacy contractor and Hepatology Specialist Team

4.3.1. The Hepatology Specialist Team will provide all information to the pharmacy contractor in advance of any patient start date (sent via secure NHS email to the pharmacy contractor generic NHS email address).

4.3.2 The Hepatology Specialist Team will be available (via contact details in Appendix 3) for any urgent and non-urgent queries the pharmacy contractor may have.

4.3.3. For any urgent enquiries, including but not limited to; missed doses where the patient cannot be contacted, procurement of medication(s), HBP issues, the Hepatology Specialist Team can be contacted on 01224 554757 (Liver Specialist Nurses) or on 01224 559348 (Hepatology Pharmacy Team). For any other issues, please email gram.hepatologypharmacyteam@nhs.scot and someone will respond in due course. All contact details can be found in Appendix 3.

4.3.3 The pharmacy contractor will provide timely submission of all ‘Patient Compliance Reporting Form’ (Appendix 1) to the Hepatology Specialist Team to ensure seamless patient care. The sending of all documentation with patient identifiable information should be sent to and from a secure NHS email account.

4.3.4 The Hepatology Specialist Team will contact the pharmacy contractor if there are any changes to be made to the patient’s treatment plan, or if the patient has been admitted to hospital.

# **5. Training requirement**

5.1 All staff members involved in the delivery of pharmaceutical services on behalf of NHS Grampian should have undertaken all core training modules as detailed on the NHS Grampian Core SLA Training document.

5.2 The pharmacy contractor is responsible for ensuring that all pharmacy staff are suitably trained in their roles and responsibilities with regard to the provision of this service and are competent to deliver them.

5.3 The pharmacy contractor should ensure that all staff involved in the provision of this service have access to and have completed the necessary training.

5.4 Pharmacists involved in this SLA should read and understand the Pharmaceutical Care Information Pack which is sent by the Hepatology Specialist Team alongside all new patient notifications. .

# **6. Monitoring & evaluation**

6.1 The submission of ‘Patient Compliance Reporting Forms’ (Appendix 1) and content within can be used for the purposes of auditing SLA compliance.

6.2 Information pertaining to all patients, orders and claims should be retained in the pharmacy and be made available to NHS Grampian, if requested, for audit purposes.

# **7. Claims and payment**

## 7.1 Service fees

7.1.1 Payment of fees will be automatically made to contractors. This is triggered by the Hepatology Specialist Team informing the Pharmacy and Medicine Directorate of a new patient.

7.1.2 For each patient receiving treatment under this SLA the pharmacy contractor will receive £400 (this will be paid ONCE per patient regardless of treatment duration). . This payment will includes:

* Procurement of the medication via the approved route only
* Delivery of a care as detailed in the Pharmaceutical Care Information Pack (sent to pharmacy contractor with notification of new patient). This can be paid ONCE per patient regardless of treatment duration.
* Patient compliance support and reporting including provision of consume on premises – when instructed on HBP prescription. This includes when a nutritional supplement needs to be consumed at the same time where the medication needs to be taken with food.
* Reimbursement of costs associated with delivery of the service relating to business costs and risks.

7.1.3. To receive remuneration the pharmacy contractor must deliver the service to the standards detailed within this SLA and submit a fully completed ‘Patient Compliance Reporting Form’ (Appendix 1) for each patient at the end of each 4-weekly HBP prescription. Failure to undertake either of these requirements will result in payment being withheld or clawed back.

7.1.4. This service will be subject to payment verification processes and they include the sourcing of the medication being compliant with NHS Grampian approved procurement for Hep C treatments under this SLA. Any deviation from the approved procurement (including actions the pharmacy might wish to take to deal with a shortage situation) must be pre-approved by the Pharmacy and Medicines Directorate. If problems in accessing the medicine via this supply route cannot be resolved through direct dialogue with the manufacturer, contact the Pharmacy and Medicines Directorate. Do not purchase from any other supply route without the approval of the Health Board.

Verification checks are undertaken to compare reimbursement data with manufacturers sales data. Where a pharmacy has supplied a medicine from a source not specified or approved in the individual service pack for each medicine the Health Board retains the right to take further action as deemed appropriate, including but not restricted to, reclaiming the appropriate service fee and making a claim against the contractor for the loss of primary care rebate. In cases involving potential fraud, a referral may be made to the General Pharmaceutical Council, NHS Counter Fraud Services or Police Scotland.

Contractors must maintain procurement records for supplies made under this agreement for 2 years following supply for the purpose of payment verification.

7.1.4 In the event that NHS Grampian cancels a patient’s treatment, or a patient fails to complete their treatment programme, and withdraws from the service **after** their treatment has commenced, the contractor will be entitled to retain the full service fee.

7.1.5 Where a patient does not commence their intended treatment, gram.pharmaceuticalcareservices@nhs.scot should be informed and no service fees will be paid.

## **7.2 Medication reimbursement**

### 7.2.1 Advanced payment

7.2.1.1 Due to the high cost of Hepatitis C medications pharmacy contractors can receive an ‘advance payment’ for all medications listed in section 4.2. Advanced payments will be processed by PCCT and then made by Practitioner Services Division (PSD). This will appear on the eSchedule under ‘HepCAdvance’

7.2.1.2 Pharmacy contractors will automatically be provided with an advance payment on receipt of notification of treatment arrangements from the Hepatology Specialist Team unless a contractor has opted out of the advance arrangement. Contractors wishing to opt out of the advance payment system should confirm via the 2024/2025 Single Sign-Up Sheet.

7.2.1.3 For pharmacy contractors who opt to receive the advance payment a single payment will be authorised to cover the complete treatment course as part of normal monthly payments.

7.2.1.4 Advanced payment recovery is not linked to submission and payment of prescriptions. Advance payment recovery starts 3 months after the month of advance payment. Contractors are responsible for ensuring timely submission of prescriptions to NSS in line with the schedule associated with this agreement.

### 7.2.2 Financial risk

7.2.2.1 Where a pharmacy contractor is at financial risk due to ordering stock for a patient who subsequently fails to start treatment or only completes part of a course of medication NHS Grampian will underwrite the financial risk to ensure the pharmacy contractor has no financial burden in relation to of medicine costs.

7.2.2.2 For Hepatitis C medications which are **not** covered by the [‘Whole Pack Payment’](http://apps.cps.scot/WebApp/WholePacks) rule NHS Grampian will ensure no financial burden to the pharmacy contractor. Any instances where a financial burden relating to these medications is identified by the pharmacy contractor they should contact gram.pharmaceuticalcareservices@nhs.scot to escalate the situation.

7.2.2.3 For Hepatitis C medications which ARE covered by the ‘Whole Pack Payment’ rule the current [NHS National Services Scotland pricing rules](https://nhsnss.org/services/practitioner/pharmacy/endorsing-guide/appendix-4-different-pack-types-pricing-rules/) will ensure no financial burden to the pharmacy contractor and no further action is required.

7.2.2.4 NHS Grampian will be monitoring the list of Whole Pack Payment drugs and where we identify a contractor has been paid WPP more than once for the same medication we will reclaim costs.

**Appendix 1**

**Patient Compliance Reporting Form for Hepatitis C Treatment**

*This form must be submitted at the end of every prescription cycle to* *gram.hepatologypharmacyteam@nhs.scot**.* *Forms should be completed even for patients who exit the service.*

*Copies of forms should be retained for audit purposes and made available to NHS Grampian upon request.*

|  |
| --- |
| **Pharmacy contractor details** |
| Pharmacy name |  |
| Pharmacy address |  |
| Name of person completing form |  |
| Role of person completing form |  |
| Date |  |

|  |
| --- |
| **Patient details** |
| Patient name |  |
| Patient CHI/DOB |  |
| Date treatment commenced  |  |
| Method of supply (delete as appropriate) | Daily COP / Daily / Weekly / Fortnightly / Monthly |
| Treatment month number(delete as appropriate) | Month 1 / Month 2 / Month 3 |

|  |
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| Has the patient collected all medication as per expected schedule? **Yes / No**If ‘No’ please provide full details of missed doses including dates: |

|  |
| --- |
| Any other comments |

# **Appendix 2**

**Hepatitis C – Medication Running Balance**

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| **Patient details** |
| Patient name |  |
| Patient CHI/DOB |  |
| Date patient commenced treatment |  |
| Method of supply (delete as appropriate) | Daily COP / Daily / Weekly / Fortnightly / Monthly |
| Treatment month number(delete as appropriate) | Month 1 / Month 2 / Month 3 |

|  |  |
| --- | --- |
| Medication details |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Quantity issued | Running Balance | Checked by |  | Date | Quantity issued | Running Balance | Checked by |
| Opening balance |  |  |  |  |  |  |  |
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**Appendix 3**

**Contact details**

**Hepatology Specialist Team**

All clinical pharmacy, patient transfer and initiation enquiries and procurement issues should be made to the Hepatology Pharmacy Team.

* Telephone – 01224 559348
* Bleep – 3712 (via hospital switchboard 0345 456 600)
* Email – gram.hepatologypharmacyteam@nhs.scot

Other clinical issues can be discussed with the Hepatology Nurse Specialist Team. Where possible ask to speak with the Hepatology Nurses indicated on the patients transfer form.

* Telephone – 01224 554757
* Email – gram.livernurses@nhs.scot

**Payment Queries**

All payment related enquires, e.g. advance payment, prescription reimbursement and recovery, should be made to the service payment administration contact.

* Steven Brodie (Primary Care Contracts)
* Email – gram.pcctpharmacy@nhs.scot

**Appendix 4**

**Opt out of Hepatitis C Advance Payment**

The pharmacy contractor detailed below wishes to **OPT OUT of the advanced payment for the Hepatitis C SLA.** Complete and sign this document and submit a copy to: nhsg.pcctpharmacy@nhs.scot (retain a copy for your records)

|  |
| --- |
| **Pharmacy contractor details** |
| Pharmacy name |  |
| Pharmacy address |  |
| Name of person completing form |  |
| Role of person completing form |  |

|  |
| --- |
| **Declaration**I declare that the information I have given on this form is correct and I understand that if it is not, action may be taken against me. I declare that the procurement of medication under this SLA has been via the NHS Grampian approved route and acknowledge that I may be required to provide copies of any invoices associated with supplies under this SLA as part of payment verification. By signing this declaration I confirm I am aware that procurement via non apporved routes is a breach of this contract.I acknowledge that this information will be authenticated from appropriate records, and that any payment made to my pharmacy based on this information, will be subject to Payment Verification. Where NHS Grampian is unable to obtain authentication, I acknowledge that the onus is on my pharmacy to retain and provide, when requested, documentary evidence to support the information provided  |
| **Signed** |  |
| **Date** |  |