NHS Grampian
Service Level Agreement

Provision of Hepatitis C Medication via Community Pharmacy

SLA Reference	SLA Provision of Hepatitis C Medication
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Revision Chronology		
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,
7	April 2025	Strengthened approach to approved procurement and protection of primary care rebate

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NHS Grampian

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, or connection with, 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 support Hepatitis C treatment, with the successful delivery of patient centred care for Hepatitis C patients, including enhanced compliance support, 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 provide Hepatitis C medications to patients identified by the Hepatology Specialist Team as suitable for community pharmacy supply. Supply should be made as per directions provided within 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 undertake clinical checks to ensure suitability of prescribed and over the counter medication supplied by them alongside DAA medication(s).

3.5 To procure Hepatitis C medications through the approved route of supply protecting the primary care rebate that NHS Grampian receives from the manufacturer, which brings the net price in to line with hospital pricing.

4. Service outline and standard

4.1 The provision of this service requires engagement and regular interaction between the pharmacy contractor, the Hepatology Specialist Team and the patient. 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 contact the patient's nominated community pharmacy to check if **they are participating in SLA** and make contact with the nominate community pharmacy to inform them of a potential patient. Other than in exceptional circumstances, contact via telephone will be made a minimum of **14 days** prior to intended treatment commencing. **Prescriptions will only be sent to community pharmacies who have a signed SLA in place.**

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 treatment. Patient specific information regarding the type of support required by the patient e.g. monthly collection, weekly collection, consume on premises etc
- Pharmaceutical Care Information Pack, including details of the required route of **procurement**.

  Important: If problems in accessing the medicine via this supply route cannot be resolved through direct dialogue with the manufacturer, contact the Health Board**. Do not purchase from any other supply route without the approval of the Health Board.** The Pharmaceutical Care Services Team can be contacted by email at gram.pharmaceuticalcareservices@nhs.scot

  - NHS Scotland has a pricing agreement in place with individual manufacturers that ensures the drug cost to NHS Scotland for this medicine is the same via community pharmacies as via hospital pharmacies. Health Boards receive retrospective rebates from the

manufacturer. This pricing agreement is enabling patient access to this medicine via community pharmacies – without it, it would not be cost-effective to use community pharmacies to supply this medicine. Contractors **must** purchase from the supply route directed by the Board to ensure the NHS receives rebates as agreed with pharmaceutical companies.

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 Pharmacy Contractor must nominate a **Key Pharmacist** (usually the Responsible Pharmacist) **and Technician/Dispenser** who will have accountability for provision of each individual element of the service on a day to day basis from that pharmacy. For pharmacies open over extended hours and particularly on a Sunday, the Pharmacy Contractor must also ensure that the Locum/Relief Manager and Technician/Dispenser on duty at these times, has a full understanding of the SLA and Service Outline & Standards to be competent to maintain continuity of service.

4.1.6 The pharmacy contractor will order the DAA medication based on the information included in the Patient Transfer Form, following the guidance within this SLA for ordering the medication.

4.1.7 Upon receipt of the DAA medication in the community pharmacy, a copy of the invoice will be sent to the Hepatology Specialist Team, by NHS e-mail, for review, and the team will check the medication has been sourced from the correct supplier. Only once this has been verified, will the Hepatology Specialist Team send a copy of the prescription to the pharmacy contractor via email, and post the original out on the same day to the pharmacy contractor. This serves to validate the correct procurement route prior to the issuing of the prescription. When this verification of the invoice has been completed and approved, there will be no reclaim pursued by the board should there be future queries into the ordering – this process is the only payment verification step required to satisfy the board that the item has been ordered correctly.

No reclaim will be pursued as part of board verification processes if the above processes have been followed. Invoice received will satisfy the board that the item has been ordered via correct route.

4.1.8 At the appropriate start date (as agreed with the Hepatology Specialist Team) the pharmacy contractor will begin supply of the dispensed medication by the patient as per the information provided by the Hepatitis C service and prescription received.

4.1.9 Pharmacy contractors must maintain an accurate running balance of Hepatitis C medicines supplied under this service, updating stock records as medicines are received, supplied, returned, or otherwise adjusted to ensure stock levels can be reconciled at all times.

4.1.10 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.

4.1.11 The pharmacist must ensure that if a prescription says a patient requires to consume their medication on the premises that this is done as per prescription directions on each day the pharmacy is open.

4.1.12 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.

4.1.13 At four weekly intervals the community pharmacy will submit the 'Patient Compliance Reporting Form' (Appendix 1) to gram.hepatologypharmacyteam@nhs.scot. This must be completed for all patients – even those who drop out of the service.

4.1.14 Ensure Standard Operating Procedures (SOPs) in place governing the service, fully covers 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.

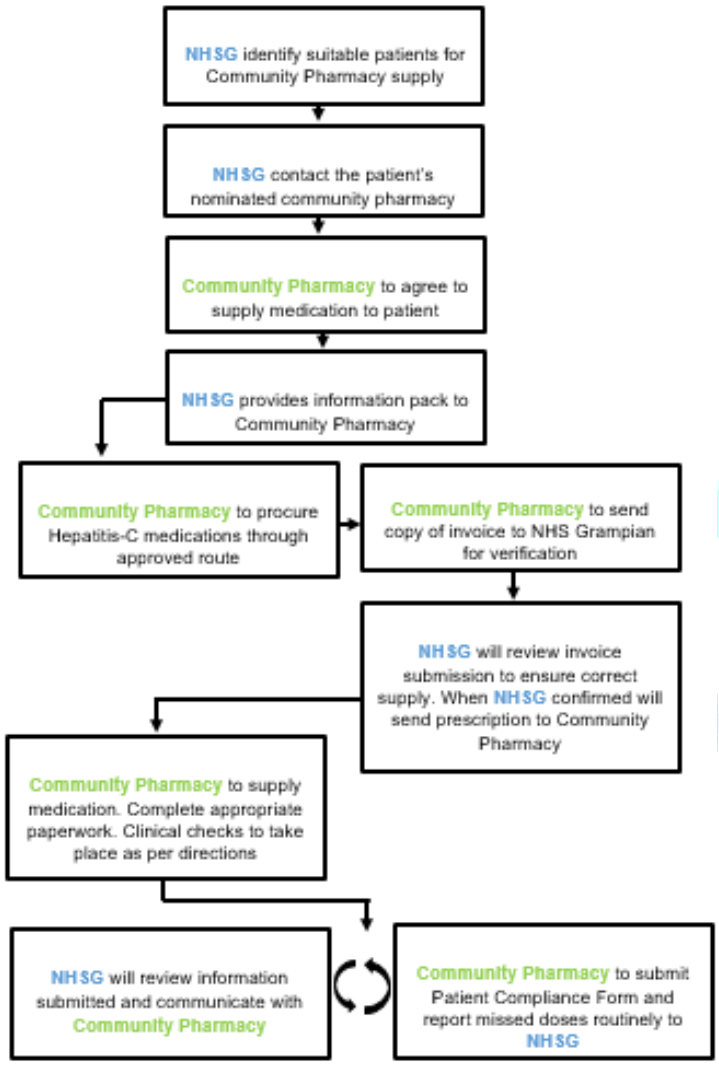
4.1.15 At the end of the prescription duration the community pharmacy will endorse the HBP prescription to reflect what was supplied and sent to PSD for payment.

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

Drug	**Brand Name**	**Manufacturer**
Sofosbuvir	Previously/also known as Sovaldi®	Gilead Sciences
Sofosbuvir/Ledipasvir	Previously/also known as Harvoni®	Gilead Sciences
Sofosbuvir/Velpatasvir	Previously/also known as Epclusa®	Gilead Sciences

Sofosbuvir/Velpatasvir/Voxilaprevir	Previously/also known as Vosevi®	Gilead Sciences
Glecaprevir/Pibrentasvir	Previously/also known as Maviret®	Abbvie Ltd

4.3 SLA Process Flowchart



5 Communication between pharmacy contractor and Hepatology Specialist Team

5.1 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).

5.2 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.

5.3 For any urgent enquiries, including but not limited to, missed doses where the patient cannot be contacted and supply 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. If you are unable to source the medication from the required supplier then please advise the Hepatology Team immediately.

5.4 The pharmacy contractor will provide timely submission of the invoice copy along with patient ID as a reference to make it easily identifiable by the Hepatology Team for verification.

5.5 The pharmacy contractor will also provide timely submission of every '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.

5.6 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.

6. Training requirement

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

6.2 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. This includes the required procurement routes and rules.

6.3 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.

7. Monitoring & evaluation

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

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

7.3 This service will be subject to payment verification processes. Contractors must maintain records relating to delivery of this SLA for 2 years following collection / supply for the purpose of payment verification. This includes all procurement information that demonstrates compliance with the required routes of procurement.

7.4 Verification checks will be undertaken to compare reimbursement claims with manufacturer sales data. Where a pharmacy has supplied a medicine from a source that is not specified or approved within the individual medicine service pack, the Health Board reserves the right to take appropriate action. This may include recovery of the relevant service fee and reimbursement of any loss of primary care rebate incurred by the Health Board.

Where evidence demonstrates that a medicine has been supplied from an unapproved source, or that an invoice has been fraudulently provided to the Hepatology Service for verification purposes, the Health Board may seek recovery of up to the total value of Substance Use Service (SUS) and Hepatitis C service fees paid in respect of that patient during the relevant calendar year.

Where there is evidence of potential fraud, the matter may be referred to the General Pharmaceutical Council (GPhC), NHS Counter Fraud Services and/or Police Scotland for investigation

8. Claims and payment

8.1 Service fees

8.1.1 Payment of fees will be made to contractors based on the final submission of each patient's compliance form. This is triggered by the Hepatology Specialist Team informing the Pharmacy and Medicine Directorate of a new patient having completed their course, all compliance feedback submitted and procurement rules complied with.

8.1.2 For each patient receiving treatment under this SLA the pharmacy contractor will receive **£625** (this will be paid ONCE per patient regardless of treatment duration). This payment will includes:

- Procurement of the Hepatitis C medication via the required procurement route with supporting evidence of compliance i.e. invoices
- Receipt, storage and all administration associated with the Hepatitis C medicines supplied by ARI
- Provision of a collection service for the patient in line with the time intervals indicated in the patient treatment plan provided as part of the patient initiation documentation.
- 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.
    - For example, some patients may require a nutritional supplement to be consumed at the same time as their Hepatitis C medications. When instructed by the Hepatology service pharmacy staff will remove a daily dose for the patient, provide that dose to the patient with a suitable drink and observe consumption of the dose for compliance reporting purposes..

8.1.3. To receive remuneration the pharmacy contractor must deliver the service to the standards detailed within this SLA including evidencing the route of procurement as described earlier and submit a fully completed 'Patient Compliance Reporting Form' (Appendix 1) for each patient at the end of each 4-weekly period of treatment, including the final period to end of treatment. Failure to undertake either of these requirements will result in payment being withheld or clawed back.

8.1.4 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.

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

8.1.6 Failure to comply with the procurement requirements may lead to withholding of the patient prescription, non-payment of service fees and the potential for the Board to seek damages from the contractor for any and all rebates lost due to the procurement outside of required channels.

8.2.1 Advanced payments

Due to the high cost of Hepatitis C medications pharmacy contractors can receive an 'advance payment'. 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 SLA 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.

Appendix 1

Patient 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 and confirmation of procurement compliance	
Pharmacy name	
Pharmacy address	
Name of person completing form	
Role of person completing form	
Signature confirming the DAA medication was procured in line with SLA requirements via the required procurement route	
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

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

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							

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. The team cover other clinical areas of the hospital, so if unable to get via telephone, please bleep or email.

- 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: Fraud Declarations

- **I am senior representative of the Community Pharmacy NHS Contractor detailed below.**
- **I understand** that:
  - This service must be provided in accordance with the SLA including only sourcing medicines from the specific supply route set out within this agreement.
  - Verification checks are undertaken against manufacturers' sales data and where products have been sourced from an unauthorised supply route, appropriate action will be taken, including but not restricted to, a claim against the contractor for the loss to the Health Board of the primary care rebate or in cases involving potential fraud, referral to the General Pharmaceutical Council, NHS Counter Fraud Services and/or Police Scotland.
- **I confirm** that controls are in place to source medicines only from the specific supply route set out in the relevant service pack within this agreement.
- **I declare** that the information I have given on this form is **both accurate and complete.**

Trading name of pharmacy	**Date**
Contractor Code	**Pharmacy Stamp/ Pharmacy Address**
Contractor Representative Name	**Contractor Representative Job Title**
Contractor Representative Signature	

Template Declaration Wording (Claim Form): Steven – for PCCT****

How/where can we include this?

- **I am a senior representative of the Community Pharmacy NHS Contractor detailed below.**
- **I confirm** that:
  - I am claiming reimbursement for the provision of services as outlined in this form.
  - For the purposes of payment verification, I confirm that the service has been provided in line with the service specification including that medicines dispensed as part of providing this service have been sourced from the specific supply route set out in the service specification.
- **I understand** that:
  - Verification checks are undertaken against manufacturers' sales data and where products have been sourced from an unauthorised supply route, appropriate action will be taken, including but not restricted to, a claim against the contractor for the loss to the Health Board of the primary care rebate or in cases involving potential fraud, referral to the General Pharmaceutical Council, NHS Counter Fraud Services and/or Police Scotland.
  - I must promptly tell the Health Board of anything that may affect my entitlement to make this claim.
- I declare that the information I have given on this form is both accurate and complete.

Trading name of pharmacy	**Date**
Contractor Code	**Pharmacy Stamp/ Pharmacy Address**

Contractor Representative Name	**Contractor Representative Job Title**
Contractor Representative Signature	

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