

### **1 SCHEDULE 2 – THE SERVICES**

#### A. Service Specifications

Service Specification No:	SSX-Pharm003		
Service	Community Pharmacy: Supply of Oral Antiviral Medication for the Treatment of COVID-19 and Management of Influenza		
Commissioner Lead	Liz Davis, Director of Primary Care Operations Chirag Patel, Associate Director of Medicines Optimisation, Brighton and Hove		
Provider Lead			
Period	22.01.2024 - 31.12.2027		
Date of Review	01.06.2024		

#### 1. Population Needs

#### 1.1 National/local context and evidence base

This locally commissioned service (LCS) specification for **Supply of Oral Antiviral Medication for the Treatment of COVID-19 and Management of Influenza** outlines the specialised service to be provided by contracted community pharmacies in Sussex following an 'expression of interest' process. The purpose of this service is to ensure timely patient access to require therapies in-hours and out-of-hours (including evenings and weekends, dependent on opening hours): community pharmacies are required to stock and supply antivirals for the treatment of COVID-19 in non-hospitalised patients and management of community influenza cases.

Since there is a requirement to start antiviral treatment promptly in both COVID-19 and influenza, the supply of antivirals for both indications are covered in this LCS. This is to ensure patients receive their antiviral promptly to reduce disease severity/duration and to avoid hospital admission. There are existing vaccination arrangements within Sussex, as part of national programmes; these services, however, cater for disease prevention rather than treatment, therefore, not ensuring availability of stock for the purpose of treating active disease.

#### For treatment of COVID-19 in non-hospitalised 'highest risk' patients

Following publication of NICE <u>TA878</u>, NHS England have set out requirements that local systems work with system partners to transition to routine access to COVID-19 treatments, in line with NICE recommendations.

For management (treatment or prophylaxis) of influenza

 'In season' flu – when national surveillance indicates influenza virus is circulating generally in the community. Usual supply route is via FP10 presented to the patient's nominated pharmacy. When the patient's nominated pharmacy is unable to supply in a timely manner, the patient may need to be directed to a pharmacy holding stock.



- 'Out of season' flu outside the periods when national surveillance indicates that influenza virus is circulating generally in the community, there are no fixed dates. Supply route via Patient Specific Direction (PSD) (see Appendix 1).
- This specification includes avian influenza (unlicensed use).

No part of this specification by commission, omission or implication defines or redefines essential or additional services. This service must be provided in a way that ensures it is equitable in respect of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.

#### 2. Outcomes

#### 2.1 NHS Outcomes Framework Domains and Indicators

Domain 1	Preventing people from dying prematurely		
Domain 2	Enhancing quality of life for people with long-term conditions		
Domain 3	Helping people to recover from episodes of ill-health or following injury		
Domain 4	Ensuring people have a positive experience of care		
Domain 5	Domain 5 Treating and caring for people in safe environment and protecting them from avoidable harm		

#### 2.2 Local defined outcomes

- To improve patient access to antivirals when they are required by ensuring timely supply.
- To remove unwarranted variation to access and therefore outcomes across Sussex.
- To gather intelligence, as part of the audit submission, about any issues related to access because of local routine supply processes.

#### 3. Scope

#### 3.1 Aims and objectives of service

- To optimise oral antivirals use by providing safe and timely access to treatment when routine routes of supply may cause clinically unacceptable delay.
- To ensure patients are appropriately counselled on their antiviral treatment.
- To support people, carers, and clinicians through provision of up-to-date information and advice, and refer where appropriate.
- To reduce the risk of complications from, and spread of, COVID-19 and influenza
- To reduce complications and non-elective hospital admission.



#### 3.2 Quality Standards – Influenza only

Provision of antivirals is determined by Department of Health and Social Care according to the state of circulating flu levels in conjunction with UK Health Security Agency. Antiviral medicines are Prescription Only Medicines (POM) and so these regulations remain in force at all stages and commissioning of services that involve the supply of antiviral medicines to patients will need to reflect these.

The following describes flu arrangements at national level and the responsible commissioner at these levels:

Level 1 (Out of Season) NHS Sussex will commission primary care professionals to respond to localised outbreaks, assess patients and if indicated recommend the use of antiviral medicines for exposed persons in at risk groups. However, outside of times when the chief medical officer and chief pharmaceutical officer has advised that seasonal influenza is circulating, independent prescribers in community are unable to prescribe antivirals under the General Medical Services regulations for prophylaxis and alternative local commissioning arrangements need to be made. NHS Sussex at this stage is responsible for healthcare assessment of individuals and contacts, drug costs and any professional service arrangements with pharmacies.

**Level 2 Chief Medical Officer (CMO) Alert** issued to allow GPs and prescribers working in primary care to prescribe antiviral medicines for the prophylaxis and treatment of influenza at NHS expense. Community pharmacies therefore will cease to operate at Level 1 and respond to presentation of NHS FP10 prescriptions. NHS FP10 prescriptions are submitted to the NHS Business Services Authority (NHSBSA) in the usual way.

#### Reference:

1. NHS England. Services for the provision of antiviral drugs for the treatment and post-exposure prophylaxis of influenza-like illness (ILI) in at-risk patients including care home residents. 4 November 2022. Available at: https://www.england.nhs.uk/long-read/services-for-the-provision-of-antiviral-drugs-for-the-treatment-and-postexposure-prophylaxis-of-influenza-like-illness-ili-in-at-risk-patients-including-care-home-residents/

2. National Institute for Health and Care Excellence. Amantadine, oseltamivir and zanamivir for the treatment of influenza, technology appraisal guidance [TA168]. 25 February 2009. Available at: <a href="https://www.nice.org.uk/guidance/ta168/chapter/2-Clinical-need-and-practice">https://www.nice.org.uk/guidance/ta168/chapter/2-Clinical-need-and-practice</a>

#### 3.2 **Population covered and exclusions**

This service specification is designed to meet the needs of the Sussex population; it also includes non-Sussex residents, for example, those visiting Sussex during holidays.

People who have received flu or COVID-19 vaccinations, are within the scope of this service.

The service is available to all nursing and care homes residents across Sussex to access.

Antivirals for the management of influenza are available to patients of all ages as part of this specification. COVID-19 treatment is only available to the people over 18 years of age.



Patients/Patient representatives are required to:

- Present with a valid FP10 prescription (or via EPS Electronic Prescription Service) for the oral antiviral medication issued by:
  - COVID-19 treatment:
    - GP Federation Alliance for Better Care (ABC)
  - Influenza 'in season' management:
    - Any suitably qualified clinician
- Present with a valid PSD for the oral antiviral medication issued by any suitably qualified clinician for the **management of influenza** 'out of season'.

Please see appropriate Summary of Product Characteristics, NICE guidelines and BNF for further inclusion and exclusion prescribing criteria.

#### 3.2.1 Community Pharmacy Contractors:

#### Essential criteria

The participating community pharmacies must be:

- Located within the Sussex geography.
- Meet the core contractual obligations required by NHS England.
- Operate a medicines delivery service for patients unable to collect medication\*.
- Contracted hours will be for a minimum of opening Monday to Saturday. Opening on a Sunday and/or extended hours is desirable.
- Able to access NHS e-mail during operating hours.

\*Patients must only be considered eligible for delivery if there are circumstances where collection of medication cannot be arranged

#### Exclusion criteria

- Community pharmacies outside Sussex.
- Distance Selling Pharmacies (DSPs).

#### 3.3 Addressing inequalities

NHS Sussex is committed to reducing health inequalities, particularly in Sussex's most deprived communities and amongst population groups which have the poorest health outcomes.

This service must be provided in a way that ensures it is equitable for patients in respect of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.

#### Additional resources:

To access interpreting and translation services please complete the highlighted sections of the form in <u>Translation and interpreting - NHS Sussex (ics.nhs.uk)</u>



Community pharmacy teams have an enhanced role in supporting the local population, based around the principles of medicines optimisation, personalised care, and support planning. There is guidance for community pharmacies to follow as part of good practice, in relation to Trauma Informed Practice, as set out in the Royal Pharmaceutical Society <u>Tackling health inequalities</u> position paper (Jan 2023).

#### 3.4 Service description/care pathway

To provide the service, the pharmacy must be able to meet the following requirements:

#### Stock requirements

- The pharmacy holds the specified medicines (as per table 2), required to deliver this service, in stock and will dispense (and re-order) these in response to a suitable prescription presented.
- The pharmacy must keep a minimum stock level of the drugs described below in section 3.4.1. Full packs must be kept in stock.
- When drugs held in stock expire stock must be replenished as soon as possible. A claim can be made by the pharmacy to NHS Sussex via claim form to cover the cost and replacement of these drugs.
- At the time of writing this specification, for an unspecified limit of time, the supply of COVID-19 antivirals has been made available Free of Charge (FOC). This is due to a large amount of centrally held stock so no claim for expired stock of antivirals for COVID-19 treatment must be submitted. Once FOC stock has been exhausted, claims for expired stock that was purchased by the pharmacy can be submitted (this will be closely monitored and communicated to all participating contractors).

#### Supply of antivirals

- Dispense prescriptions (including PSD) presented for the oral antiviral medication for COVID-19 treatment and/or Influenza management.
- For clinical queries, pharmacist to contact the prescriber as detailed on the prescription.
- Each supply must be recorded on the template data collection form (Appendix 2).
- If the pharmacy is not able to dispense the prescription when presented, the patient must be signposted to an alternative community pharmacy that is able to fill the prescription. This must be done by telephoning another community pharmacy to ensure they have the medication in stock, it should not be assumed that because a community pharmacy is on the service list they can supply on every occasion.
- In the event of supply issues or long-term availability problems, the pharmacy will inform the Medicines Optimisation Team at NHS Sussex by email: <a href="mailto:sxicb.mot-admin@nhs.net">sxicb.mot-admin@nhs.net</a>.

#### Patient counselling

- The pharmacy must ensure the patient receives appropriate counselling on the following:
  - Preventing the spread of infection.
  - Seeking medical help if symptoms worsen rapidly or significantly at any time.
  - Encouraging to send a representative to collect the medication from the pharmacy.
    - Ensure the patient's representative understands the instructions and is counselled in line with the summary of product characteristics and patient information leaflet for the medication.
      - Ensure the patient's representative can advise the patient how to take the medication. The route of administration is oral.

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 For patients with moderate renal impairment, a dosage may be required which is not in line with the original pack (example image Appendix 3). This may require the removal of nirmatrelvir tablets from the pack strips to ensure dispensing is in line with the quantity prescribed and information contained within the <u>Paxlovid - Summary of</u> <u>Product Characteristics</u>.

#### Collection and delivery of antivirals

- Patients are requested not to attend in person if they have recently tested positive for COVID-19. If a patient is unable to send a representative, they can attend in person, however they must not enter the pharmacy. It is recommended a member of the pharmacy team take the medication outside to give to the patient, for example in their car.
- Where a patient is unable to send a representative to collect the medication/attend in person, arrange a same day delivery. Any requests received within 3 hours of the pharmacy closing for that day can be delivered the following morning, and as early as possible.
- If a prescription is received requiring delivery outside of the contractor's usual catchment area, a courier or taxi must be utilised, prescriptions should not be declined.
- If a prescription is not collected within 24 hours must notify the prescriber as detailed on the prescription as soon as possible.
- Pharmacy contractors may wish to consider adding signage to the pharmacy door reminding those with COVID-19 or influenza not to enter the pharmacy.

#### **Operation requirements**

The pharmacy:

- will have and maintain a standard operating procedure to meet the service requirements and reflect changes in practice or guidelines. This should have a regular review scheduled (every 24 months as a minimum).
- must demonstrate it has sufficient indemnity cover to support the provision of this service.
- Must ensure that all members of staff are offered and can access the influenza vaccination.
- Must notify the NHS Sussex' Medicines Optimisation Team urgently of any forced closures by email: <u>sxicb.mot-admin@nhs.net</u>.
- Must be available for communication via the telephone.

To facilitate the service, NHS Sussex will:

- Promote awareness of the service with prescribers and other healthcare professionals including the acute trusts and pharmacy contractors. This will enable signposting where required.
- Review the service and drug choices at regular intervals to ensure the availability of new medicines and changes in practice or guidelines are reflected.

#### 3.4.1 Drugs covered

Each provider will be required to stock (as a minimum) the following items:

#### Table 1. Minimum pharmacy stock of antivirals used in the treatment of COVID-19

Medication	Minimum Pharmacy Stock holding	
Molnupiravir (Lagevrio®) 200mg capsules (40)	7	
Nirmatrelvir/Ritonavir (Paxlovid®) 150mg/100mg tablets (30)	21	



#### Table 2. Minimum pharmacy stock of antivirals used in the management of Influenza

Medication	Minimum Pharmacy Stock holding	
Oseltamivir (Tamiflu®) 30mg capsules (10)	30	
Oseltamivir (Tamiflu®) 45mg capsules (10)	30	
Oseltamivir (Tamiflu®) 75mg capsules (10)	90	
Oseltamivir (Tamiflu®) 6mg/ml oral suspension sugar free 65ml*	5	

\*Reserved for children <1 year of age, as per <u>Sussex Partner Formulary</u>

**N.B.** Zanamivir may be required to be stocked by LCS participants, should a dominant circulating strain of influenza have a higher risk of oseltamivir resistance. In these circumstances, the NHS Sussex will inform participating pharmacies and all principles within the specifications apply.

#### 3.5 Audit and Quality Assurance

The provider is required to complete and return a quarterly data collection form to confirm stock holding levels, monitor service use and identify issues with routine supply routes in Sussex (see Appendix 2). These require submission in advance of the following dates:

2023/24				Q4 – 15/03/2024
2024/25	Q1 – 14/06/2024	Q2 – 13/09/2024	Q3 – 11/12/2024	Q4 – 31/03/2025

Please note submission deadlines for Q3 and Q4 have been adjusted to account for the Christmas and Easter bank holidays.

NHS Sussex will send reminder emails to the community pharmacy two weeks prior to the submission deadline.

#### 3.6 Interdependence with other services/providers

Details of the contracted pharmacies will be circulated to all GP practices, on-call out of hours service providers for GP practices, Accident and Emergency departments of local NHS hospitals, NHS 111, locality walk-in centres and other community pharmacies.

#### 4. Applicable Service Standards

The Provider is responsible for ensuring that,

- **Premises** used for the service provision are in a suitable setting
- Training meets all relevant criteria set out in national and local guidance
- Serious Incidents within this service are reported to NHS Sussex alongside the pharmacy contractors routine reporting mechanism.
- Infection Control Guidance is adhered to
- Privacy and Dignity Guidance are adhered to

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- Health and Safety standards are met
- Information Governance Standards are met
- Safeguarding Adults, Children and Looked After Children Guidance is adhered to including statutory training

#### 4.1 Applicable national standards (e.g., NICE)

- Community pharmacy contractual framework <u>Community Pharmacy Contractual Framework:</u> <u>2019 to 2024 GOV.UK (www.gov.uk)</u>
- <u>TA878 Casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for</u> treating COVID-19
- NHSE <u>Interim Clinical Commissioning Policy: remdesivir and molnupiravir for nonhospitalised</u> patients with COVID-19 UKHSA Influenza: treatment and prophylaxis using anti-viral agents
- UKHSA Investigation and initial clinical management of possible human cases of avian influenza with potential to cause severe human disease
- National Institute for Health and Care Excellence <u>Influenza seasonal | Health topics A to Z |</u> <u>CKS | NICE</u>

#### 4.1.1 Infection control

Pharmacy contractors must ensure that latest national infection control and prevention guidance is adhered to. Please follow current national guidance which includes, but not exclusive of the following:

- Infection Prevention Society Guidance National Guidance for England
- <u>Healthcare associated infections- Prevention and Control in Primary and Community Care</u> National Institute for Health and Care Excellence (NICE) [CG139]
- Infection Prevention and Control Quality Standards NICE [QS61]
- <u>Health and Social Care Act 2008: code of practice on the prevention and control of infections</u> Department of health and Social Care
- <u>Coronavirus Primary Care</u> National Health Service England and NHS Improvement
- National Standards of Healthcare Cleanliness

Other resources and information can be found locally at NHS Sussex intranet page: Infection prevention and control - NHS Sussex (ics.nhs.uk)

#### 4.1.2 Chaperoning, privacy, and dignity

Pharmacy contractors must ensure they have a chaperoning policy in place:

• <u>GPhC sexual boundaries guidance</u>

#### 4.1.3 Quality

Contractors must comply with all the National Quality Requirements as set out in the <u>NHS Standard</u> <u>Contract</u>



- 4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g., Royal Colleges)
  - NHS Sussex Flu outbreak in-hours | LCS specification

#### 4.3 Applicable local standards

• Sussex Partner Formulary

#### 4.3.1 Quality Requirements

- Community pharmacy contractor providers of this service will comply with the General Pharmaceutical Council (GPhC) standards of conduct, ethics, and performance at all times.
- Responsible pharmacists providing the service must comply with the GPhC standards for Pharmacy Professionals.
- The pharmacy contractor must have a standard operating procedure (SOP) describing how the pharmacy contractor will deliver and meet all the requirements of this service.
- Serious incidents related to this service must be reported to the NHS Sussex Medicines Optimisation Team at <u>sxicb.mot-admin@nhs.net</u> within 72 hours. The Pharmacy Contractor may submit a copy of their own incident report form or utilise the NHS Sussex 'incident monitoring form' (see appendix 4). This will inform further discussion, learning points and shared problem solving. Common queries can be acted upon and learnt lessons anonymously shared. The contents of the incident monitoring forms are strictly private and confidential and the individuals completing the form may remain anonymous.
- If changes are made to the pharmacy contract, i.e., opening hours are amended, NHS Sussex must be notified via <u>sxicb.mot-admin@nhs.net</u>. In this circumstance, the suitability of the pharmacy to continue offering the service may be reviewed.
- Clinical Governance arrangements for this service are as set out in Schedule 5 of the NHS Standard Contract. In addition, the provider is required to evidence an effective system of clinical governance and put in place appropriate and effective arrangements for quality assurance, continuous quality improvement and risk management.
- Where appropriate, patient satisfaction feedback about the service should be offered to all
  patients accessing this service and quality improvements should be made as an outcome of this
  feedback.

#### 4.3.2 Safeguarding

Pharmacy contractors must have appropriate Safeguarding Policies, Procedures and Governance arrangements in place which comply and reflect the principles of the Pan Sussex Safeguarding Procedures (<u>Children</u> and <u>Adults</u>) and adhere to all Safeguarding and Looked After Children related legislation.

Community pharmacies are required by their regulator (the General Pharmaceutical Council) to adhere to professional standard 1.8 (safeguarding of children and vulnerable adults) for registered pharmacies, as stipulated within the <u>Standards for Registered Pharmacies</u>.

#### 4.4 Training requirements

It is the provider's responsibility to ensure that all personnel involved in delivery of this LCS are familiar with the requirements and any relevant guidance.



The pharmacy contractor must ensure that pharmacists and staff, including locums, involved in the provision of this service have the relevant knowledge and are trained as deemed appropriate by the contractor. This includes having an awareness of, and operating within, local and national guidelines and protocols.

Training and accreditation may be achieved through:

- Self-directed learning, e.g., NHS Learning Hub COVID-19 Antiviral Treatments
- In house learning events
- NHS Sussex educational events (where available)

Training must be recorded and made available as evidence if required.

Training costs are provided to the contractor as part of this specification (except where otherwise specified) as per section 6. It is the contractor's responsibility to access and pay for appropriate training.

#### 5. Coding, Records, Data Quality and Audit

#### 5.1 Records

Adequate records must be maintained for pre and post payment verification to be undertaken by NHS Sussex, should this be required.

#### 6. Payment/Claiming



#### 6.1 Contractors will be paid as follows:

Initial set up fee (one-off)	£490.56	
Reimbursement of initial drug stock*	As per drug tariff price plus VAT	
Monthly retainer fee	£79.64	
PSD professional service fee	C12 per DSD	
(out of flu season only)	£12 per PSD	
Reimbursement of influenza stock supplied on		
PSD	As per drug tariff price plus VAT	
(out of season only)		
Delivery fee within usual delivery	£11 per delivery	
period/catchment area		
Delivery fee outside of usual delivery	As per receipt supplied	
period/catchment area		
Replacement of date expired stock*	As per drug tariff price plus VAT	
(alongside supporting evidence)		

- \*Note stock of antivirals used in COVID-19 treatment is currently free of charge therefore claims must not be submitted. Once FOC stock has been exhausted, claims for expired stock that was purchased by the pharmacy can be submitted.
- Influenza antivirals supplied on an FP10 must be replenished by the pharmacy contractor, no reimbursement will be provided from NHS Sussex following the initial stock set up fee.
- For influenza items supplied on a PSD the Drug Tariff price plus VAT will be reimbursed, alongside a professional service fee.
- There is a standard payment rate for deliveries supplied within the pharmacy's usual delivery period and catchment area. Payments for deliveries outside of the pharmacies usual delivery period and area will be based on receipts for delivery charges incurred. There is a maximum limit of £1,000 per annum for these claims. If a pharmacy is nearing the claim threshold contact should be made with NHS Sussex to determine next steps.
- NHS Sussex will reimburse date expired drugs stocked as a requirement of this specification at Drug Tariff price plus VAT. NHS Sussex requires the community pharmacy to supply a copy of the invoice for the replacement stock & forward evidence of the expired medicines packaging (including the expiry date).
- Quarterly data collection forms should be submitted promptly by the submission dates detailed in section 3.5. NHS Sussex reserve the right to withhold payment until these are received.

#### 6.2 Claims

Pharmacy contractors should submit claims utilising the multi-claim form, available on the NHS Sussex <u>website</u>. These should be sent to <u>sxicb.sussex-lcs-claims@nhs.net</u>.

Pharmacy contractors will be required to hold an account as suppliers/providers via the Commissioning Support Unit (CSU) – please contact <u>scwcsu.QNXfs@nhs.net</u> to check whether the pharmacy is registered as a supplier / provider on SBS.

All suitable claims should be submitted on a monthly basis

NHS Sussex will seek expressions of interest from all community pharmacies for inclusion in this locally commissioned service upon review where gaps in service provision are identified, or additional coverage required.



NHS Sussex will review the provision of the locally commissioned service across Sussex as and when existing community pharmacies notify of changes in their pharmacy contract i.e., opening hours are reduced.

Pharmacy contractors whose claims are at variance with expectations may be asked to submit additional evidence to support past or future claims.

Where a contractor is in receipt of advance payment(s) (for example for equipment or training) but do not subsequently provide reasonable service activity under the LCS, NHS Sussex (acting reasonably and after discussion with the contractor), reserves the right to reclaim the advance payment(s). NHS Sussex reserves the right to check pharmacy contractors' held information at any time to support post-payment verification.

#### 6.2.1 Late or inaccurate claims

Where a pharmacy contractor is aware of any delay or inaccuracy in claims it must notify NHS Sussex contracting team without undue delay.

- Past overpayments will be recovered over a reasonable timeframe in agreement with the Pharmacy Contractor
- Past underpayments (which must be supported by appropriate evidence) where claims are delayed by less than 6 months or fall within the same financial year (April-March), will be honoured. Delayed claims falling outside this timeframe will be managed on a discretionary basis.

#### 7. Termination

#### 7.1 Termination

The provider may terminate this agreement by giving NHS Sussex three months' notice in writing of its intention to do so. Such notice, once given, may only be withdrawn with the agreement of NHS Sussex who shall not be required to agree.

NHS Sussex may terminate this agreement:

- By giving three months' notice of termination in writing. Such notice, once given, may only be withdrawn with the agreement of the provider who shall not be required to agree.
- If it is brought to NHS Sussex's attention that a provider has breached the requirements as set out in this service specification, then the provider may be asked to withdraw from providing the service.
- NHS Sussex may require the contractor to suspend the provision of the service immediately if it
  has reasonable grounds for believing that patient health or safety is at risk as a result of
  continuing provision of this service. This includes the availability for communication via the
  telephone. Should clinicians, patients or NHS Sussex fail to reach the pharmacy via telephone
  on three or more occasions this will be considered a breach of contract and termination of the
  service will be considered.



Upon service termination, pharmacies will be requested to return either the drugs held in stock or the equivalent funding for the remaining drugs held in stock.

#### Appendix 1: Patient specific directions (PSD)

Reference: Specialist Pharmacy Service. Patient specific directions (PSD). 9 January 2023. Available at: <u>https://www.sps.nhs.uk/articles/questions-about-patient-specific-directions-psd/</u>

#### Patient specific direction (PSD)

Whilst not defined in legislation a Patient Specific Direction (PSD) is the traditional written instruction, signed by a prescriber for medicines to be supplied and/or administered to a named individual after the prescriber has assessed that individual on a one-to-one basis.

In practice a PSD is commonly referred to as a prescription by those who write them or use them as the legal basis to administer a medication because this indicates that it is written by a prescriber.

#### **Clarifications about PSDs**

#### A PSD must be written

A PSD must be written and signed by the prescriber as required for all prescriptions (the electronic copy fulfils legal requirements for a PSD and a signed original copy is not required).

Legislation states that all POM medications must have a written direction for administration, and this has been confirmed by the MHRA.

The PSD will be sent via NHS mail.

A PSD is prescribing

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When a prescriber makes a decision based on the knowledge of an individual following a clinical assessment and writes an instruction for the supply and/or administration of the medicine to the individually tailored to the needs of that individual this is prescribing.

#### What a PSD must include

The information required in a PSD for administration of a medicine at a minimum must:

- Name of the individual and/or other individual identifiers including age if a child
- Name, form and strength of medicine (generic or brand name where appropriate)
- Route of administration
- Dose
- Frequency
- Date of treatment/number of doses/frequency/date treatment ends as applicable.
- Signature of prescriber and date PSD written.

A PSD is individually tailored to the needs of an individual so more information may be required to enable safe supply and/or administration of some medicines and to manage identified risks.

A PSD for the supply of medicines is classified as a prescription form. This form is a legal document and must comply with the requirements for prescriptions as specified in the Human Medicines Regulations 2012.





# Appendix 2: Data collection form for oral antiviral medication for the treatment of COVID-19 and management of influenza (available as standalone document here)

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**NO patient identifiable** data to be included. This includes any patient names, NHS numbers and addresses. All sections of the form must be **typed** and **not handwritten** (other than the signature).

#### <u>Please note that payment will not be made unless this form has been completed FULLY in the line</u> with the requirements above

Pharmacy stamp (including name and address):

address):	Quarter/time period covered:
	Total number of patients prescribed influenza antivirals:
	Total number of patients prescribed COVID-19 antivirals:
	Stock check undertaken & minimum stock levels reflect those detailed within specification: Yes/No

This form is required **<u>quarterly</u>** from each pharmacy contractor and page 2 must be completed for each supply\* to fulfil the service requirements for:

- 1) Advising patients or carers about:
  - preventing the spread of infection
  - o seeking medical help if symptoms worsen rapidly or significantly at any time
- 2) Supply of antiviral medication against FP10 or PSD
- \* one entry detailing total number of patients is sufficient

Lead contact name (BLOCK CAPITALS)	
Lead contact position	
Lead contact signature	
Lead contact email address	
Lead contact telephone number	
Date	



Please detail any service user feedback provided relevant to the commissioning of this service, if available (not a requirement of service)

Please return this completed form to: <a href="mailto:sxicb.sussex-lcs-claims@nhs.net">sxicb.sussex-lcs-claims@nhs.net</a>





# Appendix 2: Data collection form for oral antiviral medication for the treatment of COVID-19 and management of influenza (form .... of....)

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one entry detailing total number of patients is sufficient

	Supply number				
Question <b>↓</b>	1	2	3	4	5
1. Drug and quantity prescribed					
<ul> <li>Was full quantity supplied on presentation of the FP10/PSD (no requirement for an owing)? [Y/N]</li> </ul>					
If no: 2a. Reason for non-supply or partial supply					
2b. Action taken					
<ol> <li>Were other pharmacies tried before presenting to you [Y/N]</li> </ol>					
If yes: 3a. Reason (if known) for referral to you from another community pharmacy					
3b. Name / address of previous sites tried					
4. Infection prevention counselling provided [Y/N]					

Please return this completed form to: <a href="mailto:sxicb.sussex-lcs-claims@nhs.net">sxicb.sussex-lcs-claims@nhs.net</a>

### Appendix 3: Paxlovid example image







## Appendix 4: Incident monitoring form (available as standalone document <u>here</u>)

Please note, this is a generic form designed for a variety of incidents and it may not always exactly fit the incident you wish to describe. If this is the case, please complete the sections where you can and include a separate sheet detailing the incident.

No patient identifiable data to be included. This includes any patient names, NHS numbers and addresses.

Form completed by: .....

Name of Pharmacy: .....

Date: .....

Nature of the incident:

Who was involved e.g. client and pharmacist (can be anonymous)

Details of the incident:

Please return this completed form to: sxicb.mot-admin@nhs.net