Service Specification No.	TBC		
Service	Supply of medication for the urgent treatment of COVID-19 by community		
	pharmacy providers within NHS Frimley ICB		
Commissioner Lead	NHS Frimley Health & Care ICB		
Provider Lead	Named community pharmacy premises		
Period	<mark>Start 1st Feb 2024</mark>		
Date of Review	1 st April 2025		

1. **Population Needs**

1.1 National/local context and evidence base

1.1.1 Introduction

This locally commissioned service (LCS) specification outlines the specialised service to be provided by a limited number of community pharmacies with Frimley Health & Care ICS. The specification of this service is designed to cover the supply of medication following prescription of the treatment to a Frimley Health & Care patient by a clinician within the COVID medicines delivery unit. There is a requirement to start treatment quickly in line with the recommendations included in <u>NICE TA878</u>.

1.1.2 Background

Integrated Care Systems have been delivering drug treatments for COVID-19 for high risk non-hospitalised patients since 16th December 2021 through a Covid Medicines Delivery Unit (CMDU). The service has been provided in line with the national pandemic <u>Clinical Commissioning Policy</u>: treatments for non-hospitalised patients with COVID-19. Following the release of <u>NICE TA878</u> NHS England have requested that systems work with system partners to transition the service to a more business-as usual model in line with the recommendations made by NICE. The aim of this service is to supply medications for the treatment of COVID-19, safely and effectively, under a local enhanced service (LES) from a small number of community pharmacies across the geography of Frimley Health &

2. Outcomes

Care ICS.

2.1 NHS	Outcomes Framework Domains & 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	n 4 Ensuring people have a positive experience of care 🗸	
Domain 5Treating and caring for people in safe environment and protecting them from avoidable harm		

2.2 Local defined outcomes

- To improve the access to these medicines when they are required by ensuring timely supply.
- To support patients and carers by providing up-to-date advice and guidance on self-care.
- To gather intelligence about any issues related to access because of local routine supply processes.

3. Scope

3.1 Aims and objectives of service

3.1.1 Aim:

To reduce the risk of complications from and spread of COVID-19, and to optimise treatment use by providing safe access to treatment in a timely manner to avoid clinically unacceptable delays.

3.1.2 Objectives:

- To ensure that people with COVID-19 and who have been prescribed medication are :
 - Able to access the oral anti-virals within primary care, promptly, from a choice of locations within Frimley Health & Care ICS geography (at least one per place will be commissioned).
 - Able to access IV treatment within primary care promptly (only 1 pharmacy will be commissioned)
 - Appropriately counselled on their treatment.
 - \circ $\;$ Provided with advice on self-care of COVID-19 infection.
- To learn from use of the service if there are any issues with local routine routes of supply.

Drugs covered

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

Drug	Preparation	Volume
Paxlovid	150mg/100mg tablets	3 original packs
		(30 tablets)
Molnupiravir	200mg capsules	2 original packs
		Note continued inclusion of molnupiravir will be
		reviewed after NICE have completed their appeal process

In addition to the above one of the providers will also be commissioned for IV treatment and will be required to also stock the following items:

Drug	Preparation	Volume
Sotrovimab	500 mg/8 mL (62.5 mg/mL)	10 (1 single dose vial)
	single-dose vial	

Note: sotrovimab is a fridge line: the provider commissioned for IV treatment must be able to maintain the cold chain throughout service provision

3.3 Population covered (inclusion and exclusion) criteria

XX community pharmacies will provide the oral anti-viral service based on location and opening hours. One of these community pharmacies will also be commissioned to provide an IV and on-call service. An expression of interest form is available at appendix 1 to apply for service provision. Appointed sites are listed in appendix 2. NOTE AIMING FOR 5 ACROSS Frimley ICB

Inclusion:

- Adults as per NICE guidance, BNF and SpC.
- Patients can only be accepted into the service on presentation of a valid FP10 prescription (or via EPS Electronic Prescription service) for the oral anti-viral medication issued by the COVID medicines delivery unit.
- In line with the SPC treatment should be commenced within 5 days of symptom onset. Treatment commencement may be extended up to a maximum of 7 days from symptom onset if clinically indicated (treatment commencement beyond 5 days from symptom onset is off-label).

3.4 Service description/care pathway

The service requires the pharmacy to:

- Fill prescriptions presented for the oral anti-viral medication for urgent treatment of COVID-19 following prescription by the COVID medicines delivery unit.
- Fill any prescription presented for the oral anti-viral medication presented for urgent treatment of COVID-19 when referred by a pharmacy that cannot supply without significant delay following prescription by the COVID medicines delivery unit.

- <u>For the IV service (1 community pharmacy)</u>: dispense against a Patient Specific Direction (PSD) IV medication for urgent treatment of COVID-19 following prescription by the COVID medicines delivery unit (Appendix 7).
- Have undergone training in relation to the use of Paxlovid / Molnupiravir (and sotrivimab if providing the IV service) for the treatment of COVID-19.
- Advise patients or carers about:
 - preventing the spread of infection.
 - o seeking medical help if symptoms worsen rapidly or significantly at any time.
- Patients are encouraged to send a representative to collect the medication from the pharmacy.
- Patients are requested not to attend in person as 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. A member of the pharmacy team should take the medication outside to give the medication to the patient, for example in their car.
- Where a patient is unable to send a representative to collect the medication/ attend in person as per point 6, 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.
- Ensure the patient/ patient's representative understands the instructions and is counselled in line with the Summary of Product Characteristics for the medication. Where by a delivery service is arranged (above bullet point) the patient / patient's representative will need to be appropriately counselled via the telephone.
- Ensure the patient's representative can advise the patient how to take the medication. The route of administration is oral.
- <u>For the IV service (1 community pharmacy)</u>: advise the patient / patient's representative that you will be notifying the community service provider (providing details including name/ address / telephone number) so that they can arrange an appointment time to come and administer the IV treatment at the patient's home (Appendix 6)
- UK residents who are eligible to receive COVID-19 medicines in England will have to pay a prescription charge for COVID-19 medicines prescribed in primary care if they are not exempt.
- For clinical queries, pharmacist to contact the prescriber as detailed on the prescription.
- If a prescription is not collected within 24 hours to notify the prescriber as detailed on the prescription.
- Complete and return a quarterly data collection form to monitor service use and identify issues with routine supply routes in Frimley ICB(appendix 3).

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

- The pharmacy holds the specified oral anti-viral medicines required to deliver this service in stock and will dispense (and re-order) these in response to an NHS prescription presented.
- For the IV service (1-2 community pharmacies): the pharmacy holds the specified IV medicines, required to deliver this service, in stock and will dispense against a PSD and re-orders further supply using a signed order from Frimley Park Hospital (add details) note: this is DHSC stock available FOC that cannot be obtained via wholesalers.
- The pharmacy must keep a minimum stock level of the drugs described in section 3.2. Full packs as described in section 3.2 must be kept in stock.
- If the pharmacy is not able to dispense the prescription for oral medication when presented, then they need to find another community pharmacy that is able to fill the prescription. This should 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.

- <u>For the IV service (1-2 community pharmacies)</u>: if the pharmacy is not able to dispense the IV medication against a PSD then they should notify the prescriber at the COVID Medicines Delivery Unit and notify the Medicines Optimisation Team at FrimleyICB
- In the event of supply issues or long-term availability problems, the pharmacy will inform the Medicines Optimisation Team at Frimley Health & Care ICB by email enabling the issue to be cascaded to relevant parties:

NHS Frimley Health & Care ICB Medicines Optimisation Team: frimleyicb.prescribing@nhs.net

- The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the delivery of the service.
- The pharmacy will have and maintain a Standard Operating Procedure to meet all these service requirements and reflect changes in practice or guidelines.
- The pharmacy must demonstrate it has sufficient indemnity cover to support the provision of this service.
- The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols. This includes all locum pharmacists.
- The ICB will promote awareness of the service with prescribers and other healthcare professionals including the Acute Trusts.
- The ICB will regularly review the service and drug choice to ensure that it reflects the availability of new medicines and changes in practice or guidelines.
- When drugs held in stock expire stock should be replenished as soon as possible. Currently the supply has been made available Free of Charge (FOC) due to a large amount of centrally held stock so no claim for expired stock is required. When the FOC stock has been utilised a claim can be made by the pharmacy to the ICB via Claim form (appendix 4) to cover the cost and replacement of these drugs.
- The ICB will disseminate information on the service to other health care professionals in order that they can signpost patients to the service.
- The ICB and Local Pharmaceutical Committee will disseminate information on the service to other pharmacy contractors in order that they can signpost patients to the service.

On-call

- One community pharmacy will be reimbursed to provide on-call cover for Bank Holidays. This will require an on-call contact number to be provided to the East Berkshire Primary Care team who undertake the triage, clinical assessment and if appropriate dispensing for the COVID medicines delivery unit (CMDU) service to enable them to communicate with regards to prescriptions issued.
- The on-call pharmacy will provide cover from 10am-4pm on the Bank Holidays.
- The community pharmacy providing on-call cover will also be the community pharmacy providing the IV service.

3.5 Interdependence with other services/providers

• Details of the pharmacies will be circulated to East Berkshire Primary Care CMDU team, all GP surgeries, Acute Trusts, Out of Hours GP providers and to other Community Pharmacies.

3.6 Monitoring and Audit

• The provider should audit the standards of the service on an annual basis to ensure compliance with the LCS requirements and identify areas for improvement, which the provider would need to address. Complete and return a quarterly data collection form to monitor service use and identify issues with routine supply routes in Frimley Health & Care ICS (appendix 3).

- The provider is required to submit an annual (1st April 31st March) audit return form (appendix 5) to the ICB's Medicines Optimisation Team (MOT) on an annual basis (by the 30th April of each year).
- The level of service provided will be monitored by such means as required by Frimley Health & Care ICB.
- The provider should obtain feedback on the service from the patients who use it. This feedback should be reviewed by the provider and where appropriate, changes should be made in order to improve the quality of the service. If feedback obtained is related to changes in this LCS, this should be given to the ICB.

4. Training and Competence

The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service. The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols. This includes all locum pharmacists.

5. Applicable Service Standards

5.1 Applicable standards

Applicable standards include but are not limited to:

- Community pharmacy contractual framework <u>Community Pharmacy Contractual Framework: 2019 to 2024 -</u> <u>GOV.UK (www.gov.uk)</u>
- <u>NICE TA878</u>

5.2 Further information

- British National Formulary (BNF) BNF (British National Formulary) | NICE
- Surrey PAD <u>Prescribing Advisory Database (res-systems.net)</u>
- Summaries of Product Characteristics (SPC) Home electronic medicines compendium (emc)

6. Pricing and Costs

6.1 Pricing

Frimely Health & Care ICB agree to pay the following:

- Annual retainer of £435 for pharmacies participating in the scheme.
- Payment for stock levels required to initiate the service at Drug Tariff price plus VAT (where applicable initially available FOC).
- Reimburse the cost of medicines on the list which have expired (when applicable initially available FOC). The reimbursement will be claimed by invoicing the ICB at the cost in the Drug Tariff (plus VAT) at the time of the claim. Payments will be made within 30 days of the invoice. A template is available at appendix 4.

Note stock is currently free of charge.

- Should, following a review, items be removed from the list then the usual 'out of date' claims process should be followed. The removed items should not be re-ordered and any remaining undispensed stock (after 3 months) should be claimed as 'out of date/no longer in use'. Such changes will be communicated to the providers and timescales outlined.
- Payments for delivery are £11 per delivery for any delivery associated with supply within the pharmacies
 usual delivery catchment area and delivery times. In mitigating circumstances when it is not possible for
 the contracted pharmacy to use their usual delivery service within the delivery catchment area the
 pharmacy can utilise a courier or deliver themselves. Payments for deliveries outside of the pharmacies
 usual delivery area (or in mitigating circumstances within usual delivery catchment area) will be based on
 receipts for the delivery charges or at a rate of £0.56 per mile. These should be claimed monthly.
- IV service (one site only agreed with ICB ; same site as providing on-call service):
 - Dispensing fee / notification to community provider: £15 per item supplied by PSD
- On-call service (one site only agreed with ICB):
 - \circ On-call cover for bank holidays: one off payment per year £4,000
 - \circ $\,$ Call out fee: per call out £50 $\,$

6.2 Claims

• Each community pharmacy contracted to provide this service will receive payment from the ICB following receipt of the invoice claim form (appendix 4), via NHS Shared Business Services.

The Provider must submit an invoice to SBS via an e-Invoicing platform in accordance with SC 36.49 with the invoice claim form as an attachment to the electronic invoice. E-Invoicing guidance can be found here: https://www.sbs.nhs.uk/supplier-einvoicing

The invoice claim form

- Must be completed FULLY,
- Must be scanned legibly,
- Must have all sections of the form completed by **typing** and **NOT handwritten** (other than the signature).

Providers transitioning to e-Invoicing may continue to submit invoice claim forms on paper but only with the written permission of the Commissioner.

Invoice claim forms that are submitted on paper:

- Must be completed FULLY,
- Must be legible as they will be scanned by SBS,
- Must not be printed on dark paper or in purple ink as this will spoil the scanning process,
- Must have all sections of the form completed by **typing** and **NOT handwritten** (other than the signature),
- Must NOT have staples as this may create problems when the form is scanned by SBS and Must be sent to:

NHS FRIMLEY ICB, FAO Danielle Cotterrell, QNQ PAYABLES N085, PO BOX 312, LEEDS, LS11 1HP

Personal identifiable data must not be included with any invoice or any on documentation relating to claims for payment sent to the Commissioner.

7. Termination

The provider may terminate this agreement by giving NHS FrimleyICB 3 months' notice in writing of its intention to do so. Such notice, once given, may only be withdrawn with the agreement of NHS Frimley ICB who shall not be required to agree.

NHS Frimley ICB may terminate this agreement:

- By giving 3 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.
- By giving any period of notice it considers appropriate, including none, if it considers this to be necessary in the interests of patient safety.
- If it is brought to the ICB'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.

8. Location of Provider Premises

The list of providers who are commissioned to provide this service is available here <mark>[insert URL to document on Meds Op webpages]</mark>

9. References

- 1. Summary of Product Characteristics:
- Paxlovid https://www.medicines.org.uk/emc/product/13145

2. <u>NICE TA878</u>

Appendix 1:

Expression of interest to provide a COVID-19 medicines stock supply service within NHS Frimley Health & Care ICS

ALL SECTIONS ON THIS APPLICATION FORM MUST BE COMPLETED

Pharmacy stamp (including name and address): Opening hours:

Mon:
Tue:
Wed:
Thu:
Fri:
Sat:
Sun:

Pharmacy premises questions		
The pharmacy premises has a consultation room available?		
This consultation room can provide sufficient level of privacy and safety and meets any national contractual requirements?		

I wish to provide this service and on appointment, I will ensure that the requirements as set out in the service specification are adhered to when providing this locally commissioned service.

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

Please return this completed form to:

- Frimley Health & Care ICB: frimleyicb.prescribing@nhs.net
 - On receipt of the completed application form, the Medicines Optimisation Team will review all expressions of interest received and appoint up to five pharmacies with at least one in each of North East Hampshire & Farnham, Surrey Heath, Bracknell, Royal Borough of Windsor & Maidenhead and Slough. Longer opening hours will be given preference if there are multiple applications from any one Place.
- You will be contacted to confirm the decision made in relation to you expression of interest.

Appendix 2:

Current Community Pharmacy Providers of the COVID-19 medicines stock supply service within NHS Frimley Health & Care ICS

Date:xx/xx/xxx

Place	Pharmacy name & address	Telephone number	Opening hours	

*denotes the pharmacy that is signed up to provide on-call cover and IV service

Appendix 3:

Data collection form for COVID-19 medicines stock supply service within NHS Frimley Health & Care ICS

ALL SECTIONS ON THIS APPLICATION FORM MUST BE COMPLETED

Pharmacy stamp (including name and address):

Time period covered:
Total number of patients:

This form is required quarterly from each provider and should be completed for each patient seen to fulfil the service requirements of:

- 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) Completing and returning a quarterly data collection form to monitor service use and identify issues with routine supply routes in Frimley Health & Care ICS.

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

Please return this completed form to:

• Frimley Health & Care ICB: <u>frimleyicb.prescribing@nhs.net</u>

Individual Patient Data collection form for COVID-19 oral anti-viral stock supply service within NHS Frimley Health & Care ICS (form

Of)					
Patient→ Question↓	1	2	3	4	5
1. Drug and quantity prescribed					
2. Was all quantity supplied on presentation of the prescription/ PSD and no requirement for an owing [Y/N]					
If No: 2a. Reason for non-supply or partial supply					
2b. Action taken e.g. signpost to alternative supplier					
 Day & Date prescription issued 					
4. Date and time medication supplied					
 Were other pharmacies tried before presenting to you [Y/N] 					
If Yes: 6a Reason (if known) for referral to you from another community pharmacy					
6b Name / address of previous sites tried					
 Infection prevention control advice given [Y/N] 					

Of....)

Appendix 4:

COVID-19 medicine stock supply invoice claim form

Requirements of this form

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

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

Pharmacy stamp (including name and address): Contact details:

Name:
Position:
Email:
Tel:

Billing address	Invoice date:
	*Invoice number:

NHS FRIMLEY ICB

FAO Danielle Cotterrell QNQ PAYABLES N085 PO BOX 312 LEEDS LS11 1HP

QUANTITY	DESCRIPTION (delete rows as necessary)	UNIT PRICE (£)	AMOUNT (£)
1	Annual retainer	435	
	Insert year covered		
	Delivery		
	Within usual delivery area	11	
	Outside of usual delivery area <i>As per receipt</i> /		
	£0.56 / mile		
	Expired stock Use current drug tariff price +VAT		

	TOTAL DUE
Dispensing Fee per item PSD / no community provider	otification to 15
<u>Call out fee</u>	50
<u>On-call annual cover</u> Insert year covered	4000
Insert drug name, presentation an For IV / oncall service only	id quantity

*Invoices received without an invoice number will be returned. NHS Shared Business Services is able to process invoice numbers of up to 39 alphanumeric characters.

Appendix 5:

Annual audit return form 1st April – 31st March

Please return this FULLY completed form by the 30th April of each year to:

• Frimley Health & Care ICB: <u>frimleyicb.prescribing@nhs.net</u>

Pharmacy stamp (including name and address):

Please confirm that your standard operating procedures for this service have been updated within the last 24 months:
 Please confirm that that you have obtained feedback on the service from the patients who use in order to improve the quality of the service provided?

• If any of the patient feedback obtained was related to changes in this LCS, please include this below:

.....

• Please confirm that pharmacists (including locum pharmacists) and staff involved in the provision of the service are aware of and operate within local protocols relevant to this service:

.....

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

Appendix 6:

Contact Details for the Community Service Providers Administering the IV treatment

DETAILS TO BE ADDED

Appendix 7:

Patient Specific Direction to be used for sotrovimab

PATIENT DETAILS									
Title:									
First name:					Date of Birth:				
Surname:					NHS Number:				
PCR/LFT Date:					Symptom Onset Date:				
Address and					Prescription Status:	New Patient			
Postcode:					Known Allergies / Sensitivities:				
Preferred Phone:				Parent/Carer name:					
Email address:									
GP Name & Address and Postcode:					GP Email:				
HOSPITAL DETAILS									
Clinic Name, Address and Postcode:	East Berkshire Primary Care, Inspired, Easthampstead Road, Bracknell, RG12 1YQ Frimley Health NHS Foundation Trust, Frimley Park Hospital, Portsmouth Road, Frimley, Surrey GU16 7UJ								
PRESCRIBING INFO	RMATIO	N							
Disclaimer									
 By signing this prescription, I confirm the following; The patient has been clinically assessed and is suitable for treatment I have discussed and provided sufficient information about the service to the above-named patient and the patient has agreed to the referral into the service including the sharing of their personal information with a 3rd party. 									
Drug N	ame		Dose		Frequency	Route			
Sotrovimab 500 m	ng/8 mL	-	500mg	Once only		To be administered in 100ml NaCl 0.9% IV over 30 minutes			
Where treatmen	nt is beir	ng initiate	ed on day 6-7 f	rom sympton	n onset, by signing this				
		-			and they have consented		-		
Number of Fills:		1 fill							
Prescriber's Signature	ature:		Prescriber's Qualification	GMC INP PIP		PIP			
Print Name:					Registration No.:				
Date:					NHS Trust Pharmacy Screen:	N/A	Date:	N/A	
Blueteq Number: (if applicable)					Purchase Order No: (If applicable)				
Please return completed form to: XXXXXXXX Tel: XXXXXXXX Fax: XXXXXX Email: XXXXXX									