Service	**Service Specification** **COVID-19 Therapeutics for Non-Hospitalised Patients** **Community Pharmacy**
Author	NHS Greater Manchester
Provider	Community Pharmacy on the NHS Greater Manchester Pharmaceutical List
Period	15th July 2024 – 14th July 2025

1. Purpose

1.1 The purpose of the service is to provide a Covid-19 therapeutics service for non-hospitalised adult patients as per GM CMDU pathway based on NICE guidance.

1.2 Only oral antiviral medication is in scope for this service.

1.3 COVID Medicine Delivery Units (CMDUs) began operating in December 2021 on an interim basis as part of the NHS COVID-19 pandemic response.

1.4 In September 2022, NHS England wrote to Chief Medical Officers from all Integrated Care Boards to ask them to plan for sustainable community access to COVID-19 treatments for individuals at highest risk of hospitalisation, to ensure ongoing local service provision and to support transition to more sustainable services over the longer term.

1.5 The complete commissioning framework is accessible via the link: Commissioning Framework: COVID-19 therapeutics for non-hospitalised patients

1.6 Treatment for COVID-19.

1.6.1 The NICE FDG for Therapeutics for people with COVID-19 has been published, accessible via this link: Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19

1.6.2 The therapies now recommended by NICE are:

People eligible for the service are / have:

- Aged 18 or over
- Have tested positive for Covid-19
- Are at increased risk for progression to severe COVID 19, as defined in section 5 of NICE's technology appraisal guidance on nirmatrelvir plus ritonavir, sotrovimab and tocilizumab

1.6.3 National recommendations for treatment of Covid 19 are included in NICE technology appraisals (TA878, TA900 and TA971) and NICE clinical guideline NG191.

1.6.4 Commissioning arrangements for molnupiravir are included in NHSE's interim commissioning policy https://www.england.nhs.uk/publication/interim-clinical-commissioning-policy-remdesivir-and-molnupiravir-for-non-hospitalised-patients-with-covid-19/

1.6.5 Treatments recommended exclusively for use in hospital (e.g. remdesivir) and in patients requiring hospitalisation (e.g. tocilizumab) as well as other non-oral therapies (e.g. sotrovimab) are out of scope of service specification.

1.6.6 Treatments in scope of this service specification are only the oral therapies recommended for patients not requiring hospitalisation:

- nirmatrelvir plus ritonavir (Paxlovid)
- molnupiravir (Lagevrio)

1.6.7 Eligibility criteria are drug- specific and listed in NICE TA878 and the NHSE interim commissioning policy and are assured by CMDU prescriber.

NB Use of molnupiravir is subject to NICE TA outcome (expected in January 2025). Changes to drugs included in this service specifications may be necessary during the contract period due to updates of national guidance.

See NICE Guideline NG191: 4 Therapeutics for COVID-19 | COVID-19 rapid guideline: managing COVID-19 | Guidance | NICE

A full list of eligible patients is available via the link below: 4 Implementation | Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 | Guidance | NICE

Please see appendix 3 for GM CMDU Pathway.

2 Requirements for service provision

2.1 Prior to provision of the service, the community pharmacy contractor must:

2.1.1 Fully comply with the Terms of Service as outlines in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. The commissioner reserves the right to remove any contractor from provision of this service if the contractor, for whatever reason, cannot meet the Terms of Service during the period of this specification.

2.1.1.1 Failure to comply with the full terms and conditions as outlined in the specification may result in suspension from the service. Before any suspension, the pharmacy contractor and the commissioner will discuss the reason for the suspension to identify a possible solution.

2.1.2 Fully compliant with the essential services and clinical governance requirements of the Community Pharmacy Contractual Framework (CPCF).

2.1.3 In good standing with the commissioner.

2.1.4 Must be invited to participate by the commissioner.

2.1.5 Can comply with all elements described in this service specification.

2.1.6 Ability to mobilise within the agreed timescale set by the commissioner.

2.1.7 The pharmacy must be able to offer consultations inside a confidential consultation room that complies with relevant GPhC standards. The consultation area must be clearly signed as a private consultation area and must be an area where service users and the pharmacy team member are able to sit and speak normally, without being overheard.

2.1.8 Be on the GM Pharmaceutical list.

2.1.9 Have a minimum of 6 day opening. Seven day opening and/or extended hours are preferred.

2.1.10 Have not experiences three or more unplanned pharmacy closures in a calendar month within the most recent twelve-month period.

2.1.11 Ensure that pharmacists and staff involved in the provision of the service have received the appropriate training. Where necessary relevant training in the operation of new or unfamiliar equipment, software or procedures will be provided or arranged. Staff will be expected to attend any necessary courses that provide relevant training.

2.1.12 Be satisfied that all staff, including pharmacists, involved in provision of the service are competent to do so, including any locum or relief staff.

2.1.13 Be able to provide the service for all contracted opening hours (core and non-core).

2.2 Prior to service provision, the provider should review and make any necessary amendments to their Business Continuity Plan. This should be reviewed annually or following any significant incident or change to the service.

2.3 The provider will have and will update a standard operating procedure (SOP) which includes call out and ensures delivery of the service to this service specification and which is updated to reflect changes in practice or guidelines where appropriate.

2.4 The provider shall notify the commissioner of the name and contact details of the lead pharmacist for this service and shall notify the commissioners of any changes.

3 Service Aims and Intended Outcomes

3.1 The provider will maintain an agreed stock of medicines used in the treatment of covid-19, intended for supply by the community pharmacy against FP10 prescriptions.

3.2 Maintaining stock of medicines used in the treatment of covid-19 will ensure the public has access to these medicines during both normal working hours, and evenings and weekends, where the pharmacy is open. The stock list may be subject to changes in line with national or local guidance.

3.3 The Provider will, in their best endeavours, dispense prescriptions presented for covid-19 medicines within one hour of receipt.

3.4 The Provider will support patients, carers, and clinicians by providing them with up-to-date information and advice, with referral to specialist services where appropriate.

3.5 To participate in the development and provision of a local pathway ensuring routine access to COVID-19 oral medication treatment for individuals at highest risk of hospitalisation.

3.6 To act as a point of contact for patients during their course of treatment in line with core contractual requirements around provision of advice and support for prescribed medicines and liaise with local services as deemed appropriate.

3.7 Approach to health inequalities – local pathway to ensure equitable access to services.

3.8 Data and reporting requirements – ensure effective monitoring and data sharing to support service improvement and commissioning of service after pilot.

3.9 Where requested, the pharmacist will provide advice to the healthcare professional regarding the prescribing or dosage that should be administered to the patient.

3.10 The Provider will accept patient's medicine returns for destruction from patients, carers, or other healthcare professionals as per the NHS Community Pharmacy Contract: Essential Services Disposal of Unwanted Medicines.

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	Treating and caring for people in a safe environment	✓

4 Service Description

4.1 The service will be provided by a pharmacist registered with the General Pharmaceutical Council.

4.2 This service is available to all patients who have been triaged and clinically assessed as being at high risk of severe disease from COVID-19.

4.3 Provider(s) commissioned under this service specification are required to maintain stock levels of nirmatrelvir plus ritonavir (Paxlovid) as follows:

4.4 Paxlovid 150mg/100mg film coated tablets 30 tablets x 6

4.5 Molnupiravir 200mg capsules 40 x 2

4.6 Should there be an outbreak, the commissioner may require an increased level of stockholding. Any requirements to increase stockholding will be communicated to providers by NHS mail.

4.7 When prescriptions are dispensed for this product, stock should be re-ordered to maintain a regular stock level of 6 packs of 30 tablets for Paxlovid and 2 packs of 40 capsules for molnupiravir.

4.8 If there is a supply issue which results in an inability to maintain the stock levels outlined above, the Provider will contact the commissioner by emailing gmhscp.gmtop@nhs.net

4.9 Provider(s) are required to ensure that there is availability on site of at least one pharmacist trained to provide this service throughout the pharmacy's core and non-core opening hours.

4.10 Eligible patients presenting with a positive covid test will be referred to an appropriate prescriber within Greater Manchester. The prescriber will undertake clinical assessment, triage and prescribing via local arrangements, following NICE guidance and prescribe an antiviral as appropriate. The medication must be taken within five (5) days of symptom onset. It is the prescriber's responsibility to ensure that a prescription is made available as soon as practicably possible within this timeframe.

4.11 A prescription for nirmatrelvir plus ritonavir (Paxlovid) or molnupiravir (Lagevrio) will be issued by a prescriber with a signature and sent to the participating provider of the patient's choice. EPS prescriptions will be issued as standard. If EPS is unavailable, the prescriber will scan the prescription and send via secure NHS email to the provider. The prescriber will then ensure the hard copy of the FP10 is received by the provider within 72 hours. In this situation the prescriber will telephone the provider to confirm the alternative arrangements.

4.12 The patient will be asked by the clinical triage team / prescriber their preferred pharmacy from the pharmacies signed up to this Local Enhanced Service.

4.13 The request will be sent to the participating pharmacy chosen by the patient or their representative.

4.14 Patients will be informed of the need to send a representative to collect the medication from the pharmacy by the referring prescriber.

4.15 Patients are requested by the prescriber 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 should avoid entering 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.

4.16 The provider will ask the patient to contact the pharmacy in advance if they are unable to send a representative, this will ensure the pharmacy team will know if the patient is waiting outside for the medication.

4.17 A referral will also be created and sent via NHS mail / Adastra / PharmOutcomes by the prescriber, to the same participating pharmacy which the EPS prescription has been sent, outlining the clinical circumstances of the prescribed treatment. The pharmacist may consider checking the patients clinical record via GP Connect or GM Care Record.

4.18 The Provider is responsible for holding stock of the medication in order that treatment is not unduly delayed.

4.19 In circumstances where the Provider is unable to supply the item(s) on demand, they will direct/signpost the patient, carer, or healthcare professional to the nearest pharmacy provider of Covid Therapeutic medication checking first that they have the required item(s) in stock. A list of participating pharmacies will be available on PharmOutcomes.

4.20 In circumstances where the Provider is unable to supply the item(s) on demand, they will inform the prescriber by telephone of the issue(s) with providing the medication to the patient.

4.21 The Provider must maintain appropriate records for the pharmacy and the commissioner which are included in the PharmOutcomes module prepared for this service by the commissioner. All payment claims will also be made through PharmOutcomes submission.

4.22 The Provider will receive the referral in PharmOutcomes and the prescription and will undertake a clinical check to:

4.23 Ensure there are no contraindications to the prescribed medication.

4.24 Complete drug interaction check (e.g., referring to the Liverpool COVID 19 drug

interaction checker Liverpool COVID-19 Interactions (covid19-druginteractions.org)

4.25 The provider will ensure any identified interactions are managed appropriately, in consultation with the prescriber as appropriate.

4.26 The provider will determine that the medication has been prescribed appropriately.

4.27 The provider shall dispense the items from the Covid Therapeutic stock in response to NHS prescriptions presented to the pharmacy in line with the dispensing service of the NHS Community Pharmacy Contractual Framework.

4.28 Prescriptions will be dispensed promptly upon receipt, with the aim of dispensing within 1 hour where practicably possible.

4.29 The Provider is to contact the patient or their nominated representative on the contact number provided in the PharmOutcomes referral to confirm the anti-viral supply is ready to collect the provider must also confirm whether the patient or patients representative will collect the anti-viral supply or whether a delivery is required (deliveries must be made in line with this service specification).

4.30 Where appropriate the Provider will make best endeavours to counsel the patient or the patient's representative on appropriate use of the prescribed medication via telephone or video consultation.

4.31 The Provider will also ensure the patient or patient's representative understands the instructions and is counselled in line with the Summary of Product Characteristics for the medication.

4.32 The Provider will ensure the patient or patient's representative can advise the patient how to take the medication. The route of administration is oral.

4.33 Patients are at liberty to refuse this service.

4.34 Any clinical queries or concerns raised by the Provider at any point during the service should be escalated to the prescriber for discussion and resolution.

4.35 Where a patient is unable to send a representative to collect the medication, the pharmacist must arrange a same day delivery. Any requests received within 2 hours of the pharmacy closing for that day can be delivered the following morning, and as early as possible.

4.36 Where a delivery must be made, the contractor will be reimbursed £15 + VAT for deliveries within 5 miles and an additional £1 + VAT per mile above this.

4.37 Taxi services can be utilised in exceptional circumstances and will be reimbursed £15 + VAT for deliveries within 5 miles and an additional £1 +VAT per mile above this.

4.38 Where the medication has not been collected or delivered within 24 hours of receipt of the request, notify the prescriber, as soon as possible.

5. Training Requirements

5.1. The Provider shall ensure that pharmacists and staff involved in the provision of the service are appropriately trained, are aware of and operate within national and regional guidelines outlined below.

5.2. Providers are required to:

5.3. Watch a recording of a locally delivered clinical webinar which will be confirmed to all participating community pharmacies by emails. This is a maximum of 1.5 hours in duration.

5.4. Familiarise themselves with NICE TA 878 https://www.nice.org.uk/guidance/ta878 and NICE Guideline NG191: 4 Therapeutics for COVID-19 | COVID-19 rapid guideline: managing COVID-19 | Guidance | NICE

5.5. Familiarise themselves with the SPC for nirmatrelvir plus ritonavir (Paxlovid) and molnupiravir (Lagevrio) https://www.medicines.org.uk/emc/product/13145 https://www.medicines.org.uk/emc/product/13044

5.6. Familiarise themselves with the Liverpool COVID 19 drug interaction checker Liverpool COVID-19 Interactions (covid19-druginteractions.org))

6. Quality and Clinical Governance Standards

6.1. The Provider must comply with all the requirements of the Essential services of the NHS Community Pharmacy Contractual Framework and in line with NICE guidance https://www.nice.org.uk/guidance/ta878

6.2. The Provider must ensure that the premises shared NHS mailbox (list in the GM Pharmaceutical list, maintain by the GM Primary Care Contracts Team) is regularly checked (in line with core contractual requirements) as this will be the route the commissioner will utilise to communicate with the provider regarding this locally commissioned service.

6.3. The Provider shall ensure that any documentation relating to the service, local procedures and guidelines issued by the commissioner are accessible within the pharmacy.

6.4. All relevant records must be managed in line with the records Management Code of Practice for Health and Social Care.

6.5. Provider(s) are required to report any issues and patient safety concerns in line with existing processes to gmhscp.gmtop@nhs.net

6.6. Providers must comply with General Pharmaceutical Council standards of conduct, ethics and performance at all times.

6.7. Providers must review their SOPs and referral pathways for the service on a regular basis, at least every two years.

6.8. Provider(s) must be able to demonstrate, on request, that pharmacists involved in provision of this service have undertaken Continuing Professional Development (CPD) relevant to the service.

7. Health inequalities

7.1. Equitable access to treatment: Arrangements should be in place to ensure patients can access the appropriate first line treatment in accordance with clinical policy regardless of the healthcare setting. Services should ensure eligible people in other non-hospital healthcare settings (e.g., patients in prisons and care homes) can be assessed and offered treatment on an equitable basis. If prescribed oral antivirals, arrangements should be in place to ensure they can be prescribed, dispensed, and delivered to their care provider. Post codes of people referred, triaged, and treated should be collected by the Provider and shared with the commissioner as part of the pilot service to ensure equity.

7.2. The Provider must ensure the service is accessible, appropriate, and sensitive to the needs of all service users. No eligible person shall be excluded or experience difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity or age and in doing so comply with the requirements of the Equality Act 2010. It is the responsibility of the pharmacy contractor to make reasonable adjustments to meet the individual needs of its patients.

8. Communication and Engagement

8.1. NHS Greater Manchester, (NHS GM) will work with service leads to ensure GM populations are aware of the service and how to access it.

8.2. Any resource required to promote the services will be supplied by the commissioner.

9. Monitoring and Evaluation

9.1. Providers will be expected to keep records of each patient consultation and dispensing in PharmOutcomes.

9.2. Providers must participate in any commissioner-led audit of service provision or assessment of service user experience. CPGM will be consulted during the development of any such audits to ensure they are reasonable for providers to participate in.

10. Remuneration

10.1. A set-up fee of £420 will be paid to cover initial stocking of the required medication and the training required in section 7. This will be paid following receipt of the signed service specification.

10.2. Each patient dispensing and consultation will be reimbursed at the rate of £18 which will be paid in response to the correct records being made and submitted in PharmOutcomes.

10.3. Should the service be commissioned after the initial pilot year, an annual retainer fee of £240 will be paid to help support the pharmacy with any administration costs and training associated with the service.

10.4. Medication requiring delivery will be reimbursed at a rate of £15 per delivery within 5 miles of the pharmacy and an additional £1 per mile where over 5 miles from the pharmacy.

Payments will be made by BACS within 28 days of claim being submitted via PharmOutcomes on the 5th of the month.

14. Declaration

Service level agreements with the commissioners must be signed for each Provider wishing to supply medicines through this scheme. It is the Provider's responsibility to ensure that every pharmacist that supplies medicines understands the terms of this agreement.

Annex 1

To be populated for participating providers once bank holiday arrangements are finalised.

Appendix 1
ROLES AND RESPONSIBILITIES UNDER THE PATHWAY

Prescribing Clinician

- Clinical triage of all referrals (via telephone) to assess suitability for treatment, liaising with specialist consultant for any clinical queries
- Prescribing of medication
- Send prescription to pharmacy for dispensing
- Respond to queries from dispensing pharmacy
- Respond to queries from patients
- Record-keeping in line with requirements and fulfil reasonable requests for reporting to ICB as part of the pilot

Screening and Dispensing Pharmacist

- Maintain appropriate stocks of medication
- Undertake clinical check to:
    - Ensure no contraindications to prescribed oral antiviral
    - Complete drug interaction check (e.g. Liverpool COVID-19 Drug Interaction Checker)
    - Ensure any identified interactions are managed appropriately
    - Determine that oral antiviral has been prescribed appropriately
    - Dispense and dispatch oral antiviral to patient
    - Counsel patient on prescribed medication, reinforce key points
- Escalate clinical queries to prescribing clinicians
- Work with ICB to develop process for failed deliveries
- Work with ICB to implement PharmOutcomes
- Report incidents and errors to ICB
- Provide reasonable information to ICB to support pilot
- Ensure availability on site of at least one pharmacist trained to provide this service

APPENDIX 2

SERVICE DATA

The indicative activity below is based on the most recent data provided by the incumbent provider.

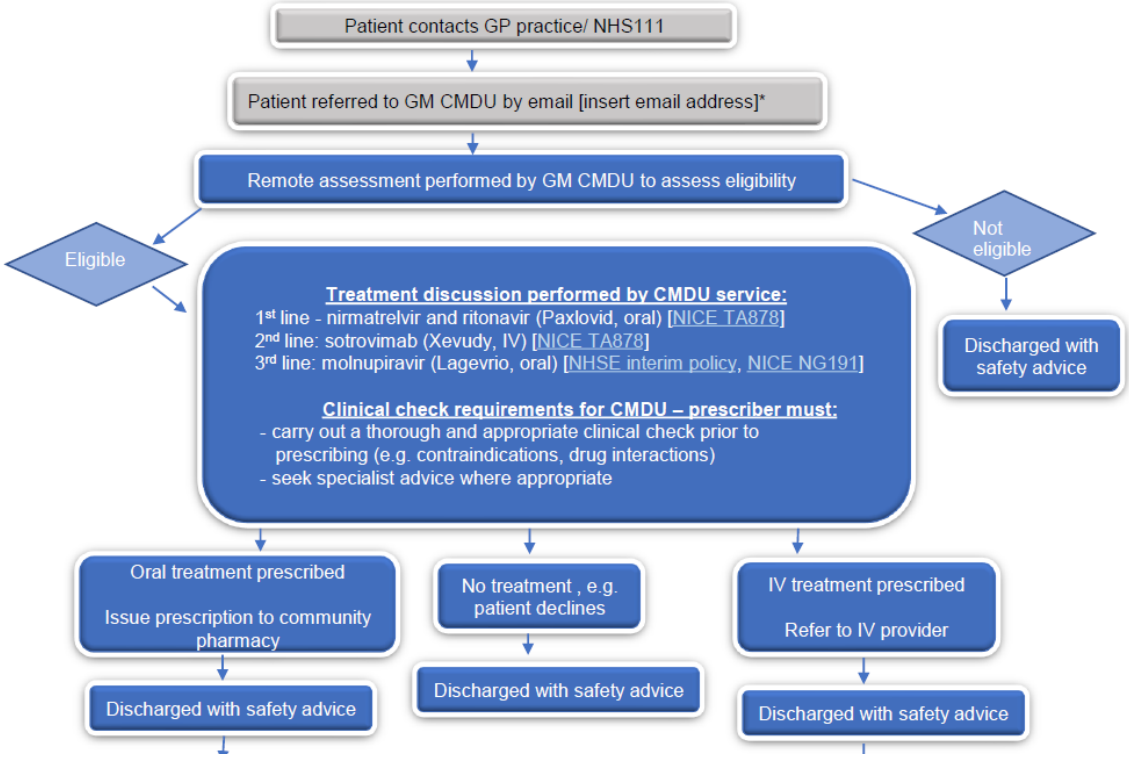
The average number of monthly referrals removing surge periods is 300 per month; on average 8% went on to receive treatment. Please not this could increase in respect of numbers treated due to the change in provider. It takes the current provider approximately 30 minutes to triage a patient. The average amount of time to screen and dispense the oral medication is 10-15 minutes.

Please also note that the eligibility criteria for Covid-19 therapeutics has been expanded and the impact of these cohorts on activity level is unknown.

NHS
Greater Manchester

APPENDIX 3

GM Community Covid19 Medicines Delivery Pathway for non-hospitalised adult patients FINAL



Who can have COVID-19 treatment?

Eligibility for COVID-19 treatment without being admitted to hospital if all the following apply [adults only]:

- at high risk of hospitalisation as per NICE MTA878 sections 1.1 and 5**
- symptomatic
- tested positive for COVID-19 (within 5-days)

Who is eligible for GM CMDU?

- Covid19-positive (LFT within 5 days) and symptomatic
- patients registered with GM GP
- adults only*
- not requiring hospitalisation for Covid19**
- at high risk of hospitalisation as per NICE MTA878 sections 1.1 and 5**

Exclusion criteria:

- under 18
- not registered with a GM GP
- requiring hospitalisation for Covid19
- requiring supplemental oxygen

NOTES

1. This pathway allows for routine use of treatments endorsed by NICE MTA878 (Paxlovid, sotrovimab) and as per NHSE interim policy (molnupiravir)

2. Combination treatment (monoclonal antibody and antiviral) is