|  |  |
| --- | --- |
| Service | **Service Specification**  **COVID-19 Therapeutics for Non-Hospitalised Patients**  **Community Pharmacy** |
| Author | NEL ICB |
| Provider | TBD |
| Period | 1st July 2023– 30th June 2024 12-Month Pilot |

1. Purpose

* 1. The purpose of the service will be to pilot a COVID-19 therapeutics service for non-hospitalised patients who will benefit from them the most. Providers will be asked to provide timely access to medication and to provide reasonable information to support the ICB to commission the future service.
  2. Only oral antiviral medication is in scope for this service.
  3. COVID Medicine Delivery Units (CMDUs) began operating in December 2021 on an interim basis as part of the NHS COVID-19 pandemic response.
  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. There is a need to plan or transition away from pandemic-specific arrangements to more routine access, which will be system-led and will need to clarify the clinical pathways for care across primary care, community services and acute care. This planning will help with the implementation of NICE's multiple technology appraisal (MTA) COVID-19 treatment recommendations
  5. The complete commissioning framework is accessible via the link below:

<https://www.england.nhs.uk/coronavirus/publication/commissioning-framework-covid-19-therapeutics-for-non-hospitalised-patients/>

The NICE FDG for Therapeutics for people with COVID-19 has been published

<https://www.nice.org.uk/guidance/ta878>

* 1. The therapies now recommended are:
* Paxlovid Oral – outpatient / inpatient (adults)
* Sotrovimab Intravenous – outpatient / inpatient (12 years and older)

1.7 People eligible for the service are:

* Aged 12 or over
* At highest risk of getting seriously ill from Covid-19
* Have symptoms of Covid-19
* Have tested positive for Covid-19

A full list is available via the links below:

<https://digital.nhs.uk/coronavirus/treatments#who-can-access-the-treatment>

and

<https://www.gov.uk/government/publications/higher-risk-patients-eligible-for-covid-19-treatments-independent-advisory-group-report-march-2023/defining-the-highest-risk-clinical-subgroups-upon-community-infection-with-sars-cov-2-when-considering-the-use-of-neutralising-monoclonal-antibodies>

**2. Service Outline**

The pilot pathway has been split into three (3) segments:

A picture containing text, screenshot, font, line

Description automatically generated

This service specification covers Part 2 of the pathway, namely the stockholding, prescription screening, dispensing and rapid dispatch of the oral antiviral medication. This will be a local enhanced service for holding stock and dispatching the medication.

* 1. 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.
  2. The patients will self-refer into the service following a positive PCR or lateral flow test and undergo clinical assessment, triage and prescribing via local arrangements in place
  3. The medication must be taken within five (5) days of symptom onset
  4. A prescription will be issued by an independent prescribing clinician with a signature and sent to the nominated pharmacy.
  5. A discharge summary will be sent to the patient’s GP via electronic means.
  6. The dispensing pharmacy is responsible for holding stock of the medication in order that treatment is not unduly delayed.
  7. The screening / dispensing pharmacist is responsible for conducting a clinical check of the prescription, this may include accessing SCR, the Liverpool COVID-19 Drug Interaction Checker (<https://www.covid19-druginteractions.org/checker> ) and holding a consultation with the patient via telephone.
  8. The consultation includes ascertaining the appropriateness of the medicine for the patient and counselling the patient about the prescribed medicine for COVID treatment. Patients are at liberty to refuse this service.
  9. The medication can either be collected by a patient representative (NOT the patient) or couriered from the dispensing pharmacy
  10. Any clinical queries or concerns raised by the dispensing pharmacy at any point during the service should be escalated to the prescriber for discussion and resolution.

1. Service Aim and Intended Outcome
   1. To ensure the timely access and efficiency of supply of COVID-19 oral antiviral therapeutics for the treatment of COVID-19 to eligible patients
   2. 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. To offer support and advice to patients and their carers on the oral antiviral COVID-19 therapeutics supplied to treat COVID-19.
   4. To act as a point of contact for patients during their course of treatment and liaise with local services as deemed appropriate.
   5. Approach to health inequalities – local pathway to ensure equitable access to services Data and reporting requirements – ensure effective monitoring and data sharing to support service improvement and commissioning of service after pilot
   6. This service will require the pharmacy to maintain the required stock of Covid Therapeutic Medication in line with the agreed list in [Appendix 1](#_bookmark13). The stock list may be subject to changes in line with national or local guidance
   7. Where requested, the pharmacist will provide advice to the healthcare professional regarding the prescribing or dosage that should be administered to the patient.
   8. The pharmacy and the pharmacist will provide an extended and out-of-hours (OOH) service to the patients who have been prescribed medication by the NEL prescribing provider as outlined in [Appendix 2](#_bookmark14) for Covid Therapuetic medication ONLY. OOH is defined as the hours where the pharmacy is not in operation.
   9. The pharmacy 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.
2. **Service Specification and Service Standards**
   1. The service will be provided by a practicing pharmacist registered with the General Pharmaceutical Council.
   2. The pharmacy contractor shall maintain the required stock (range and quantity) of Covid Therapeutics as defined in paragraph 1.6.
   3. There must be named individual(s) who ensures that the stock is managed appropriately.
   4. The pharmacy contractor 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.
   5. The pharmacy must maintain minimum stock levels as directed by the NEL Pharmacy and Medicines Optimisation team. The contractor will identify where supply problems prevent compliance with this requirement and notify the Pharmacy and Medicines Optimisation Team, within **one working day**
   6. The pharmacy contractor must operate this service in line with the hours of operation of the prescribing service. This is defined as follows:

* between 9am and 5pm Monday to Friday,
* between 9am and 1pm on Saturday
* between 10am and 2pm on Sunday

* 1. The pharmacy contractor shall provide an on call service for patients who require urgent dispensing of the drugs, where this is defined as being:
  2. A patient who was been symptomatic for more than 4 days but less than five
  3. In these circumstances the contractor shall ensure that the drugs are dispensed and delivered before the end of the five-day period
  4. The pharmacy contractor must maintain appropriate records for the pharmacy and NEL ICB to cover ordering, receipt, batch number, expiry date checks and audits to meet legal and NEL ICB requirements and ensure effective, ongoing service delivery.
  5. The pharmacy contractor will have and will update specific standard operating procedures (SOP) to meet all of these service requirements and reflect changes in practice or guidelines where appropriate.
  6. The pharmacy contractor will ensure that pharmacists and staff involved in the provision of the service have received the appropriate training and can deliver the service for the full contracted and voluntarily extended opening hours as well as have a SOP for when the pharmacist is called OOH.
  7. In circumstances where the pharmacy 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.
  8. In circumstances where the pharmacy is unable to supply the item(s) on demand, they will inform the prescriber of the issue with providing the medication to the patient.
  9. The pharmacy contractor shall notify NEL ICB Pharmacy and Medicines Optimisation team of any changes to the contact details of the pharmacy manager and/or lead pharmacist for this service.
  10. The pharmacy core and supplementary (combined) opening times are equivalent to 55 hours per week.
  11. The pharmacy will be open for Monday to Saturday and must be able to provide on call services on a Sunday or Bank Holiday.

1. **Access and service description for on call or Bank Holiday access for medication**

5.1 To ensure that there is 7 days a week availability of covid therapeutic medicines in North East London (NEL) and that these medicines can be dispensed and delivered to patients within the five-day deadline for effective use. The expectation is that providers of this service shall ensure that:

* Dispense and deliver medication to the patient on the same day of prescribing or as soon as possible on the next day and that,
* Where patients are approaching the end of 5-day period of symptom onset that the drugs shall be dispensed and delivered within that period as part of an on call service or extended hours service

5.2 The Hours of operation of the GP prescribing provider are

* between 9am and 5pm Monday to Friday,
* between 9am and 1pm on Saturday
* between 10am and 2pm on Sunday and on Bank Holidays.
  1. Where a patient requires and urgent prescription as defined in paragraph 4.7, the pharmacist would be contacted by the GP prescribing provider
  2. If the pharmacist receives such a call and is unable to attend the pharmacy then The GP Prescribing Provider would contact the next pharmacist on the list until a pharmacist is available.
  3. The pharmacist must be able to provide the medication within 2 to 3 hours in response to an out of hours call.
  4. Please note, the pharmacist will be contacted out of hours via their personal mobile number. This is not shared widely. If there is a change in the mobile number, the commissioner must be informed. It is the responsibility of the pharmacist to ensure their mobile phone is available at all times, to respond to a possible call. Where due to unforeseen circumstances, the pharmacist will be unable to deliver on service out of hours, the commissioner must be informed.

1. **Training Requirements** 
   1. The pharmacy contractor shall ensure that pharmacists and staff involved in the provision of the service are appropriately trained, are aware of and operate within local procedures and guidelines.
   2. NEL ICB and the current service provider will work with NHS England to provide relevant training.
   3. Pharmacists dispensing this medication must attend NEL ICB training as directed
   4. The contractor has a duty to ensure that pharmacists and dispensary staff involved in the provision of the service are aware the medication being dispensed as per the Summary of Product Characteristics:
2. Paxlovid - <https://www.medicines.org.uk/emc/product/13145>
3. Molnupiravir - <https://www.medicines.org.uk/emc/product/13044>
4. **Quality and Clinical Governance Standards**

* The pharmacy contractor 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>
  1. The pharmacy contractor must provide NEL ICB with a premises specific e-mail address which is accessed by the pharmacy at least once a day during opening hours.
  2. The pharmacy contractor shall ensure that any paperwork relating to the service, local procedures and guidelines issued by NEL ICB are easily accessible within the pharmacy.

1. **Oral anti-viral medication ordering and supply**
   1. Antiviral stock will be available to order from the Foundry stock management system under the same ODS code as the Covid -19 vaccines where the pharmacy has also offered this service, or via an ODS provided.
   2. The stock will be delivered weekly on a fixed delivery day.
   3. The antiviral medication will be supplied free of charge to the pharmacy and remains the property of the NHS until the point of supply to a patient.
   4. The pharmacy is only authorised to supply the antiviral medication in the original pack (quantity may be dependent on renal function dosing) on the provision of a Patient Specific Direction from the Waltham Forest FedNet triage service email: tbc
2. **Service delivery specification**
   1. The supply will be through a Patient Specific Direction (PSD) supplied by the WF FedNet clinical triage team.
   2. The patient will be asked by the clinical triage team their preferred pharmacy from the pharmacies signed up to this Local Enhanced Service.
   3. Patients are encouraged to send a representative to collect the medication from the pharmacy.
   4. The request will be sent to the pharmacy chosen by the patient or their representative.
   5. 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 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.
   6. If requested, members of the pharmacy team must join a C-19 therapeutics community pharmacies WhatsApp group and monitor activity regularly and acknowledge receipt of any messages sent to the group naming their pharmacy.
   7. The pharmacist must access their NHS mail, pharmacy.ODScode@nhs.net and print the Patient Specific Direction.
   8. The pharmacist must dispense the oral antiviral drug as per the Patient Specific Direction, ensuring the record of the supply is saved on the pharmacy electronic Patient Medication Record system for audit purposes. The drug must be dispensed within three hours of receipt of the Patient Specific Direction, within the pharmacy’s contracted opening hours.
   9. Pharmacist to contact the patient or their nominated representative on the contact number provided on the PSD to confirm the anti-viral supply is ready to collect. Patient’s representative to collect the medication.
   10. Where a patient is unable to send a representative to collect the medication, 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.
   11. Ensure the patient’s representative understands the instructions and is counselled in line with the Summary of Product Characteristics for the medication.
   12. Ensure the patient’s representative can advise the patient how to take the medication. The route of administration is oral.
   13. Once the supply has occurred respond to the original e-mail requesting supply confirming either ‘collected’ or ‘delivered’.
   14. Where the medication has not been collected or delivered within 24 hours of receipt of the request, notify the triage team by e-mail, as soon as possible.
   15. For clinical queries, pharmacist to contact the prescriber as detailed on the PSD.
   16. Residents must be able to contact the service by telephone during the following hours

* between 9am and 5pm Monday to Friday,
* between 9am and 1pm on Saturday
* between 10am and 2pm on Sunday

1. **Health inequalities**
   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 ICB as part of the pilot service to ensure equity.
   2. A detailed comms and engagement plan to reach out to homeless and un-registered people across NEL will be led by NEL ICB, following the successful approach developed during the Covid-19 vaccination drives.
2. **Communication and Engagement**
   1. The NEL Communications Team will work with service leads to ensure NEL populations are aware of the service and how to access it.
3. **Monitoring and Evaluation**
   1. In addition to standard activity reporting, due to the requirements of the pilot evaluation, reasonable information to support future commissioning of the services, including activity, staffing models and courier activity, shall be shared.
      * + 1. Remuneration
      1. Pharmacy Contractors participating in the scheme may access stock at no cost in the initial phases of this scheme.
      2. £18 service fee for each time the stock is given out (whilst stock is free, no charge for the actual stock, after the free stock is not available, the ICB will also pay for each pharmacy on this LES to hold one box at DT price and will reimburse expiry thereafter of stock expires)
   2. The pharmacy contractor will receive, on an annual basis, a fee of £250 to help support the pharmacy with any administration costs and training associated with the service. The fee will be paid on the submission of the memorandum of understanding and submission of an invoice.
      1. £200 call out fee (should only be used in emergency if there is no pharmacy open and the patient is 24 hrs away from needing to start medication) as defined in paragraph 4.7

13.5 The Pharmacist Contractor will be paid £15 for each delivery to a patients home where the medication cannot be collected

* 1. NEL ICB will fund back fill at a cost of £300 for qualified staff to attend relevant training. Please use the invoice template in Appendix 5 for claims and reimbursements
  2. The Pharmacy will submit claims on a template to be provided by NEL ICB

# **Declaration**

Service level agreements with NEL ICB must be signed for each individual pharmacy wishing to supply medicines through this scheme. It is the contractor’s responsibility to ensure that every pharmacist that supplies medicines understands the terms of this agreement.

**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 Pharmaoutcomes
* 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

5. Activity

APPENDIX 2

SERVICE DATA

The indicative activity below is based on the past almost 14 months’ of data received from the current provider, April 2022 – 15 May 2023.

The average weekly referral number removing surge periods is 75 per week. 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 note that the main access route to the service, responsible for 68% of referrals, will change on 1 July 2023, moving from an automated algorithm to self-referral. The impact of this on the activity level is unknown.

Please also note that additional high-risk cohorts eligible for these medications have recently been announced, and the impact of these cohorts on activity level is unknown.

**Triage Annual Summary 22/23 (with surge periods)**



**Oral Medication Prescribed by Month**



|  |  |  |
| --- | --- | --- |
| **ORAL Antivirals** | | |
| **NEL Place** | **22/23 Total** | **Average Monthly Oral Activity** |
| Barking & Dagenham | 94 | 8 |
| City and Hackney | 202 | 17 |
| Havering | 255 | 21 |
| Newham | 160 | 13 |
| Redbridge | 234 | 20 |
| Tower Hamlets | 189 | 16 |
| Waltham Forest | 204 | 17 |
| **Grand Total** | **1,338** | **112** |
|  |  |  |
|  |  |  |
| **IV Antivirals** | | |
| **NEL Place** | **22/23 Total** | **Average Monthly IV Activity** |
| Barking & Dagenham | 33 | 3 |
| City and Hackney | 65 | 5 |
| Havering | 101 | 8 |
| Newham | 82 | 7 |
| Redbridge | 119 | 10 |
| Tower Hamlets | 68 | 6 |
| Waltham Forest | 80 | 7 |
| **Grand Total** | **548** | **46** |
|  |  |  |
|  |  |  |
|  |  |  |
| **IV and Oral Antivirals** | | |
| **NEL Place** | **22/23 Total** | **Average Month** |
| Barking & Dagenham | **127** | **11** |
| City and Hackney | **267** | **22** |
| Havering | **356** | **30** |
| Newham | **242** | **20** |
| Redbridge | **353** | **29** |
| Tower Hamlets | **257** | **21** |
| Waltham Forest | **284** | **24** |
| **Grand Total** | **1,886** | **157** |
|  |  |  |
|  |  |  |
| **Triage** | |  |
| **NEL Place** | **22/23 Total** | **Average Month** |
| Total NEL | 5,983 | 452 |
| % Conversion | 32% |  |