NHS Lothian

Title:

Treatment of non-hospitalised patients with COVID Policy

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Policy Owner:	Medical Director (Acute)		
Executive Lead:	Director of Pharmacy		
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Version Control

Date	Author	Version/Page	Reason for change
Nov 2022 - March 2023	Advanced Clinical Pharmacist, COVID Antiviral Service Associate Director of Pharmacy, Primary Care	v0.1-5	New policy development
Mar 2023	Advanced Clinical Pharmacist, COVID Antiviral Service Associate Director of Pharmacy, Primary Care	v1.0	Approved by Policy Approval Group
June 2023	Advanced Clinical Pharmacist, COVID Antiviral Service	v1.1	Updates following publication of NICE TA878, revised UK commissioning policy and changes to high-risk definition
September 2023	Advanced Clinical Pharmacist, COVID Antiviral Service	v1.2-3	Recommended to the Policy Approval Group by Area Drugs and Therapeutics Committee
Oct 2023	Advanced Clinical Pharmacist, COVID Antiviral Service	v2.0	Approved by the Policy Approval Group

Executive Summary

This policy outlines the available therapies for symptomatic non-hospitalised patients with COVID-19 within NHS Lothian. This policy is based on the current UK treatment guidelines and will be updated if this is superseded or if the evidence base for these therapies changes significantly.

Clinical guidance is available within the associated guideline of the same name, and the associated procedure describes in detail the roles and responsibilities of teams involved in this pathway. A separate document is available detailing the available treatments for hospitalised patients.

In Lothian, as per national guidance, Paxlovid (nirmatrelvir with ritonavir) will be offered to eligible patients as first-line therapy. Molnupiravir will be offered to eligible patients who cannot receive Paxlovid. Remdesivir and sotrovimab are not currently routinely available in Lothian.

This local pathway has been developed by clinical experts in infectious diseases. Primary Care Clinicians supporting patients through this non-hospitalised pathway have direct access to senior clinical decision makers if it is necessary to consider the prescribing of either remdesivir or sotrovimab in exceptional cases.

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Contents

		Page number
1.0	Purpose	4
2.0	Policy statement	4
3.0	Scope	4
4.0	Definitions	4
5.0	Implementation roles and responsibilities	7
6.0	Associated materials	8
7.0	Evidence base	8
8.0	Stakeholder consultation	9
9.0	Monitoring and review	9

1.0 Purpose

This purpose of this policy is to outline the provision of therapies for symptomatic non-hospitalised patients with COVID-19 within NHS Lothian.

It describes the local implementation of the national guidance and commissioning policies from NICE, the Department of Health & Social Care and the Scottish Government.

2.0 Policy statement

The policy describes which patients are eligible for available COVID-19 therapies and the key responsibilities of the staff groups involved in the provision of this service.

In Lothian, as per national guidance, Paxlovid (nirmatrelvir with ritonavir) will be offered to eligible patients as first-line therapy. Molnupiravir will be offered to eligible patients who cannot receive Paxlovid (where clinical benefits are expected to outweigh risks) while applying the principles of realistic medicine and shared decision-making.

Sotrovimab and remdesivir are not routinely available in NHS Lothian, as agreed with the Area Drugs and Therapeutics Committee. This decision is based on the lack of evidence supporting their use against current variants of COVID. However, Primary Care clinicians supporting patients through this non-hospitalised pathway have direct access to senior clinical decision makers if it is necessary to consider the prescribing of either remdesivir or sotrovimab in exceptional cases.

3.0 Scope

This policy applies to adult patients (aged ≥18 years or aged 16-17 and not under the care of any specialist paediatric team). Currently, the available oral antiviral therapies are only licensed for adults aged >18 years.

A separate document, titled Drug Treatments of COVID-19 in Hospitalised Adult Patients (available on the NHS Lothian intranet) should be referred to for patients who are hospitalised.

This policy primarily describes the provision of therapies for patients who are registered with a GP in NHS Lothian. However, it is recognised that patients who are temporarily residing in Edinburgh and the Lothians may be unable to access treatment from their usual healthcare provider. In this case, these patients should have equal access to treatment, where is it is clinically safe and appropriate to provide this.

4.0 Definitions

Non-hospitalised adult patients are eligible for oral antiviral treatment if:

- SARS-CoV-2 infection is confirmed by either lateral flow test (LFT) or polymerase chain reaction (PCR) testing, and;

- They are symptomatic with COVID-19 and are showing no signs of clinical recovery, and;
- The patient is a member of a 'highest' risk group (as defined in Patients Considered to be at Highest Risk of Adverse Outcomes from COVID-19, and;
- Their symptom onset is within 5 days at the time of referral, and;
- They have not been treated with oral antivirals in the preceding 30 days

Further details about clinical assessment of the patient can be found in the accompanying Therapies for Symptomatic Non-Hospitalised Patients with COVID-19 Guideline. [*in development* – hyperlink to be added].

4.1 Oral antiviral therapies

As of November 2022, there are two oral antivirals available for the treatment of COVID-19 infection: Paxlovid (nirmatrelvir with ritonavir) and Lagevrio (molnupiravir).

Nirmatrelvir/ritonavir (Paxlovid) has conditional marketing authorisation in Great Britain (England, Scotland and Wales) for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19.

Molnupiravir has conditional marketing authorisation in Great Britain (England, Scotland and Wales) for use in the treatment of mild to moderate COVID-19 in adults (aged 18 years and over) with a positive SARS-CoV-2 diagnostic test and who have at least one risk factor for developing severe illness.

Paxlovid is considered the first-line choice of antiviral, however the assessing clinician will determine the most appropriate treatment option taking into account the person's medical and drug history. The clinical guideline on Therapies for Symptomatic Non-Hospitalised Patients with COVID-19 [*in development* – hyperlink to be added] should be referred to for more detail on the choice of oral antiviral.

The prescribing clinician should be aware of the evolving evidence base for efficacy of antiviral therapies. Oral antiviral treatment options may be added or withdrawn in line with national clinical guidance or if a medicine's marketing authorisation is suspended or revoked by the MHRA.

4.2 Intravenous antiviral therapy

Remdesivir has conditional marketing authorisation for use as a treatment for COVID-19 in Great Britain (under the Medicines and Healthcare Products Regulatory Authority (MHRA)) and a full marketing authorisation in Northern Ireland (under the European Medicines Agency (EMA)) for the following indications:

- treatment of COVID-19 in adults and paediatric patients (at least 4 weeks of age and weighing at least 3 kg) with pneumonia requiring supplemental oxygen (low or high-flow oxygen or other non-invasive ventilation at start of treatment), for a treatment duration of 5-10 days.

- treatment of COVID-19 in adults and paediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19 within 7 days of symptom onset, for a treatment duration of 3 days.

Remdesivir is not currently routinely available in Lothian. Primary Care clinicians supporting patients through this non-hospitalised pathway have direct access to senior clinical decision makers if it is necessary to consider the prescribing of remdesivir in exceptional cases.

4.3 Neutralising monoclonal antibodies

Sotrovimab delivered intravenously has conditional marketing authorisation in Great Britain (England, Scotland and Wales) for the treatment of symptomatic adults, and adolescents (aged 12 years and over and weighing at least 40kg) with acute COVID-19 infection who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID-19 infection.

Sotrovimab is not currently routinely available in Lothian. Primary Care Clinicians supporting patients through this non-hospitalised pathway have direct access to senior clinical decision makers if it is necessary to consider the prescribing of sotrovimab in exceptional cases. Prescription of Sotrovimab can only occur after an MDT discussion and would not normally be prescribed in NHS Lothian.

Evusheld (tixagevimab with cilgavimab) and Ronapreve (casirivimab with imdevimab) are not recommended within the UK and therefore are not available within NHS Lothian.

4.4 Other therapies for hospitalised patients

Other therapies commissioned for use in hospitalised patients (e.g. corticosteroids, interleukin-6 inhibitors, baricitinib) are beyond the scope of this policy and therefore will not be considered. See Drug Treatments of COVID-19 in Hospitalised Adult Patients .

4.5 Children and Young People

Paxlovid (nirmatrelvir with ritonavir) and molnupiravir only have a marketing authorisation for use in adults (aged 18 years or older). Therefore, there are no routinely available therapies for children and young people (aged up to 17 years old) within NHS Lothian.

Further guidance on individuals aged 12 to 18 years old who are considered at high risk from COVID-19 can be found in Box 2 of the Independent Advisory Group report (see section 7 of this policy).

4.6 Non-eligible patients

Where patients are ineligible for treatment under this policy, recruitment to relevant clinical trials e.g. PANORAMIC should be supported. Further information about recruitment to the PANORAMIC trial within NHS Lothian can be found in the associated procedure [*in development*].

5.0 Implementation roles and responsibilities

The roles and responsibilities of teams involved in carrying out this policy are outlined below. However, full details on each step of the process are described in the Therapies for Symptomatic Non-Hospitalised Patients with COVID-19 Procedure [*in development* – hyperlink to be added].

5.1 Flow Navigation Centre

The Flow Navigation Centre (FNC) will operate a single point of contact telephone number (0300 790 6769) to receive phone calls from patients who wish to access treatments. FNC staff will send a referral to the primary care clinicians for a full clinical assessment. FNC staff will provide worsening advice to patients and advise when patients should expect to be contacted.

5.2 Primary Care Clinician

The COVID Antiviral Service will be staffed by Primary Care clinicians (usually pharmacist independent prescribers) from Monday to Friday, excluding public holidays. Referrals from the Flow Navigation Centre will be prioritised based on the day that symptoms began. The Primary Care pharmacist will assess the patient's eligibility and suitability for antiviral treatment, provide medicines information advice and arrange a supply via community pharmacy. The assessment will be sent to the patient's GP for information, and to the community pharmacy for supply. An HBP(5) prescription will be sent to the community pharmacy within 72 hours.

5.3 Community Pharmacy

The community pharmacy will receive an email containing an "intention to prescribe" antiviral treatment, which they will dispense and raise a payment claim via their dispensing system. They will arrange delivery via courier or taxi, or contact the patient to collect via a representative where the patient has indicated that they would prefer this. Completed prescriptions will be sent to Practitioner Services Division (PSD).

5.4 General Practice Staff

General practice staff will ensure that patients who are considered at high-risk of adverse outcomes of COVID-19 are provided with the single point of contact number to allow them to access therapies. GPs remain responsible for the clinical care of non-hospitalised patients with COVID.

5.5 Regional Infectious Diseases Unit

The Regional Infectious Diseases Unit (RIDU) clinicians will provide clinical advice to the primary care clinician where appropriate, i.e., for patients who are not suitable to receive

routinely available therapies, where an alternative therapy may be considered in exceptional circumstances.

5.6 Clinical Specialists

The primary care clinician may contact clinical specialists for advice about managing interacting medicines, e.g. to confirm a management plan or to check if it is appropriate to temporarily stop specialist therapies.

Clinical specialists should provide the contact number for the Flow Navigation Centre to patients they believe to be at the highest risk of adverse outcomes from COVID-19. The patient will then be assessed by the primary care clinician.

6.0 Associated materials

Patients considered to be at highest risk of Adverse Outcomes from COVID-19, approved by the NHS Lothian Area Drugs and Therapeutic Committee (ADTC), September 2023

COVID Antiviral Service Referral Form, approved by the NHS Lothian Area Drugs and Therapeutic Committee (ADTC), June 2023

COVID Antiviral Service Assessment Form, approved by the NHS Lothian Area Drugs and Therapeutic Committee (ADTC), August 2023

Treatment of Non-Hospitalised Patients with COVID-19 Guideline [*under development*]. This guideline contains clinical guidance on assessing patients for antiviral therapy.

Treatment of Non-Hospitalised Patients with COVID-19 Procedure [*under development*]. This procedure contains greater detail of the process for obtaining antiviral therapies.

Drug Treatments of COVID-19 in Hospitalised Adult Patients, approved by UHD D&T Committee, June 2022 (available on the NHS Lothian intranet)

7.0 Evidence base

Department of Health & Social Care. COVID-19 Therapeutic Alert. Treatments for Highest Risk Non-Hospitalised Patients (Adults and Children) with COVID-19. Published 28/11/22. Accessed via https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=104092

Department of Health & Social Care. UK Interim Clinical Commissioning Policy. Therapies for symptomatic non-hospitalised adult and paediatric patients with COVID-19. Version 4, Published 28/11/22. Accessed via https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=104093

Department of Health & Social Care. Rapid Policy Statement. Interim Clinical Commissioning Policy: Treatments for non-hospitalised patients with COVID-19. Published 28/11/22.

Accessed via https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=104094

Department of Health & Social Care. Independent report: Defining the highest risk clinical subgroups upon community infection with SARS-CoV-2 when considering the use of neutralising monoclonal antibodies (nMABs) and antiviral drugs (updated March 2023). Last updated 5 April 2023. Accessed via 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

Department of Health & Social Care. COVID-19 Therapeutic Alert: Publication of NICE Multiple Technology Appraisal (MTA) - Treatment Recommendations for COVID-19. CEM/CMO/2023/001. Published 29 March 2023. Accessed via https://www.sehd.scot.nhs.uk/cmo/CEM_CMO(2023)001.pdf

National Institute for Health and Care Excellence (NICE). Casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19. Technology appraisal guidance [TA878]. Published 29 March 2023, last updated 05 April 2023. Accessed via https://www.nice.org.uk/guidance/ta878

National Institute for Health and Care Excellence (NICE). COVID-19 rapid guideline: managing COVID-19. NICE guideline [NG191]. Published 23 March 2021, last updated 29 March 2023. Accessed via https://www.nice.org.uk/guidance/NG191

NHS England. Rapid Policy Statement: Interim Clinical Commissioning Policy: remdesivir and molnupiravir for non-hospitalised patients with COVID-19. Published 11 May 2023. Accessed via https://www.england.nhs.uk/wp-content/uploads/2023/05/PRN00453-RPS-ICCP-Remdesivir-and-molnupiravir-for-non-hosp-patients-with-COVID-19-May-2023.pdf

8.0 Stakeholder consultation

Feedback from staff involved in the implementation of this policy has been incorporated.

9.0 Monitoring and review

This policy is based on the current UK and will be reviewed every 3 years as a minimum, or updated before if this is superseded or if the evidence base for these therapies changes significantly.