Treatment of non-hospitalised patients with COVID guideline

NHS Lothian

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Version Control

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July 2024	Primary Care and Community Pharmacy Co-ordinator	v1.0	Policy changed to this guideline and reviewed. Approved by UHD DTC.

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Contents

1.0 Purpose

This purpose of this guideline 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 National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC), the Department of Health & Social Care and the Scottish Government.

2.0 Guideline statement

The guideline 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, Paxlovid (nirmatrelvir with ritonavir) will be offered to eligible highest-risk patients as first-line therapy. Molnupiravir remains a second-line option for eligible highest-risk patients who cannot receive Paxlovid (where clinical benefits are expected to outweigh risks) and who still wish to receive antiviral treatment, while applying the principles of realistic medicine and shared decision-making.

Sotrovimab is 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 its 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 sotrovimab in exceptional cases.

3.0 Scope

This guideline 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 guideline 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 COVID antivirals in the preceding 30 days.

NHS Lothian will not expand the availability in non-hospitalised patients of Paxlovid to additional groups as defined in NICE TA878 (updated 13 March 2024). Therefore, treatment will not be available to non-hospitalised patients who are aged 70 years and over, or who have a body mass index (BMI) of 35 kg/m2 or more, diabetes or heart failure. However, these groups will not be excluded from treatment where patients have other risk factors for progression to severe COVID-19, as defined in Section 5 of NICE TA878.

Additionally, there will be no expanded access to any other groups for any interim period, based on age or other co-morbidities beyond those defined in Section 5 of NICE TA878. This decision has been made locally following review of the clinical evidence and cost-effectiveness predictions by Infectious Diseases Consultants, Medical Director (Acute), Director of Pharmacy, and has been supported by the Executive Leadership Team and Drugs and Therapeutics Committee.

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 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 is only recommended for use in NHS Scotland as an option for treating highest risk patients with COVID-19 in hospitals, therefore it is not available for non-hospitalised patients.

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 guideline 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.

Risk factors for progression to severe COVID-19 in young people aged 12 to 17 years can be found in Box 2 of NICE TA878, Section 5 (see section 7 of this guideline).

4.6 Non-eligible patients

Patients referred to the COVID Antiviral Service who are not eligible for treatment under this guideline will be provided with self-care and worsening advice. Patients who wish to escalate their concerns about not receiving COVID treatments (where they are not eligible according to this treatment guideline) will be signposted to the NHS Lothian Patient Experience Team.

5.0 Implementation roles and responsibilities

The roles and responsibilities of teams involved in carrying out this guideline 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.

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). The provision of clinical cover will be adapted according to a locally agreed escalation and retraction plan. Staffing resource will be prioritised to minimise treatment delays, with a focus on reducing service gaps to ensure that eligible patients can access treatment in a timely manner. 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. The pharmacy will contact the patient when the prescription is ready to collect to allow a patient representative to collect the medicine. If collection is not possible, as indicated on the assessment form, they will arrange delivery via their own driver or an NHS courier or taxi. 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

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

Therapies for Symptomatic 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, July 2024 (available on the NHS Lothian intranet).

7.0 Evidence base

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 13 March 2024. 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 08 May 2024. Accessed via https://www.nice.org.uk/guidance/NG191

National Institute for Health and Care Excellence (NICE). Remdesivir and tixagevimab plus cilgavimab for treating COVID-19. Technology appraisal guidance [TA878]. Published 08 May 2024. Accessed via https://www.nice.org.uk/guidance/ta971

NHS England. Rapid Guideline Statement: Interim Clinical Commissioning Guideline: 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

Scottish Medicines Consortium (SMC). Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19. Collaborative Advice Document SMC2557. Published 29 March 2023, last updated 13 March 2024. Accessed via https://www.scottishmedicines.org.uk/medicines-advice/nirmatrelvir-and-ritonavir-paxlovid-full-smc2557/Scottish Medicines Consortium (SMC). Remdesivir powder for concentrate for solution for infusion (Veklury®). Collaborative Advice Document SMC2550. Published 08 May 2024, last updated 10 May 2024. Accessed via https://www.scottishmedicines.org.uk/medicines-advice/remdesivir-veklury-c19-smc2550-1/

8.0 Stakeholder consultation

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

9.0 Monitoring and review

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