Classification: Official
Publication approval reference: C1574

To: General practices

cc. Community pharmacies,
Regional chief pharmacists

NHS England and NHS Improvement
Skipton House
80 London Road
London
SE1 6LH

**31 January 2022**

Dear colleagues,

## Update to policy for COVID-19 treatments for highest risk non-hospitalised patients for 12 years and over

The UK four nations policy for providing neutralising monoclonal antibodies (nMABs) or antiviral treatments for the highest risk non-hospitalised patients for 12 years and over with COVID-19 has been updated to include:

- Additional treatment options: PF-07321332 (nirmatrelvir) plus ritonavir - marketing name is Paxlovid; and, remdesivir, which can be commenced within 7 days of symptom onset.

- Allowing a positive PCR **OR** registered lateral flow test to confirm COVID infection.

All of these changes will take effect from **10 February 2022.**

**Key information you must know:**

- You will not need to prescribe or dispense nMABs or antivirals.

- The majority of highest risk patients who test positive should be automatically contacted by their COVID-19 Medicines Delivery Unit.

- A small proportion of highest risk patients testing positive through a PCR or registered lateral flow result may contact their GP practice (in hours) or 111 (out of hours) for an urgent referral to a COVID-19 Medicine Delivery Unit (CMDU) if they test positive for coronavirus via a PCR or lateral flow test. Guidance on this is provided below.

- You can refer patients to the local CMDU using the electronic Referral Service (e-RS). Of note, Paxlovid has multiple potential drug interactions so inclusion of the patient's medications in the referral is vital.

- Highest risk patients should have received a letter or email telling them in advance they may be eligible for these treatments. Specialists are helping provide equivalent information to patients who may not have received the letter but are likely to be eligible e.g. those newly diagnosed.

- You are encouraged to help recruit to the PANORAMIC study which is testing antivirals in a wider group of patients including over-50s (further details below).

More detailed guidance (Annex A) and a pathway flowchart (Annex B) is included below. Further guidance on the treatment and assessment of patients with COVID-19 is here. Please ensure this letter is shared among staff at your practice including all those triaging patients.

Yours sincerely,

**Dr Kiren Collison**
GP and Deputy Medical Director for Primary Care
NHS England and NHS Improvement

**Ursula Montgomery**
Director for Primary Care
NHS England and NHS Improvement

## ANNEX A: Guidance for general practice teams and community pharmacies.

This letter explains what **general practice teams** need to be aware of, and information useful to **community pharmacies** who may be asked patient questions. A pathway flowchart is also included (Annex A), and further guidance on the treatment and assessment of patients with COVID-19 is here.

### What is the policy for highest risk patients?

In summary, antivirals or neutralising monoclonal antibodies (nMABs) are recommended to be available as a treatment option for non-hospitalised patients 12 years and over at highest risk from COVID-19 infection treated in accordance with the guidance set out in the policy.

The highest risk cohorts have been agreed by the Government, based on advice from an independent DHSC-commissioned group of clinical experts. The cohorts are detailed in annex 1 of the policy. The policy will be kept under review as new data and licensing decisions emerge.

### How will patients receive treatment?

Most of the highest risk patients have received a letter or email telling them in advance they may be eligible for these treatments in the event they test positive for COVID-19. They should also have received a priority PCR test to keep at home. Any 'new entrants' to cohorts (e.g. new diagnoses of multiple sclerosis) will be made aware of the policy via their hospital specialists and will be able to request a PCR test.

From 10 February patients can also demonstrate coronavirus infection via a positive lateral flow test result that has been registered via gov.uk or 119 but they will be encouraged to also take a confirmatory PCR test in line with national guidance and to support coronavirus surveillance.

Each integrated care system (ICS) has established one or more local CMDUs to roll out nMABs or antivirals as a treatment for COVID-19. Your local Clinical Commissioning Group (CCG) will be able to advise you of the site of the local CMDU(s).There are two routes by which eligible patients may access treatment:

1. **NHS outreach**: In the event of a positive registered lateral flow (from 10 February) or PCR, a local CMDU will contact the majority of patients directly to discuss the treatment and confirm eligibility. The CMDU will arrange treatment if appropriate.

2. **Patient in-reach (via PCR or lateral flow test)**: A small proportion of PCR and registered lateral flow results cannot be matched to a patient's health record. We are encouraging patients not contacted directly by the NHS within 24 hours of a positive PCR or registered lateral flow test result to phone their GP practice (in hours) or 111 (out of hours) for an urgent referral to a CMDU. GPs and 111 can refer these patients to CMDUs via eRS. GP practices **will not** need to prescribe treatment; only refer.

These treatments must be delivered quickly following symptom onset. Practices and 111 should use the clinical policy document to help identify if a patient is potentially eligible. They will not need to confirm eligibility or discuss treatment options as this will be undertaken by the CMDU.

**General practices: how should patients be referred for treatment?**

If an eligible patient does not receive instructions from the CMDU on how to access treatment, you will need to refer the patient to a local CMDU using the electronic Referral Service (e-RS).

We have asked ICSs to list CMDUs on the e-RS under the 'Infectious Diseases' specialty and clinic type 'Not otherwise specified'. CMDU service names will include the wording 'COVID Medicine Delivery Unit (CMDU)'. Using e-RS will ensure that there is a record of the referral and that receiving CMDUs have accurate details for the patient , but you may need to use alternative referral routes if these have been agreed locally.

Referral information will only need to include the patient details, the date of the PCR or registered lateral flow test, and the condition(s) that you think might make them eligible for treatment. Please include any medications, allergies and preferred contact details as normal. The medications are especially important as Paxlovid has multiple potential drug interactions.

GPs do not need to prescribe COVID treatments under this policy. Practices should refer potential eligible patients to CMDUs.

**For pharmacists** – if a patient in these highest risk cohorts with a positive PCR or lateral flow test contacts the pharmacy then advise them to stay at home and contact their GP for a referral to a CMDU, or to call NHS 111 if out of hours, if they have not been contacted within 24 hours of a positive test result.

**Where will patients receive nMABs or antivirals treatment?**

nMABs and some antiviral treatments are administered intravenously so a patient will need to safely travel to a CMDU site. If the CMDU decides that an oral antiviral is the

most appropriate treatment option, these will be dropped off to a patient's home, either via a friend or family member of the patient, or via a delivery service.

**Antivirals study**

In addition to this policy,  oral antivirals are available to a wider cohort of at-risk patients through a national study known as PANORAMIC. This will gather data on the effectiveness of antivirals in a vaccinated population, as studies to date have focused on unvaccinated populations. In addition, the study will help to deliver vital clinical data on the effectiveness of these treatments against the Omicron variant.

Patients can join the PANORAMIC study if they are:

- aged 50 and over, or aged between 18 to 49 years with underlying health conditions that make them clinically more vulnerable (see PANORAMIC); and
- have been unwell with COVID-19 for less than five days.
- have a recorded positive PCR or registered lateral flow test within the past seven days.

Much of the study is delivered remotely by the trial team and medicines are distributed by an online pharmacy. Local GP hubs have also been established by the NIHR to support patient enrolment.

You are encouraged to help recruitment by reviewing the list you receive each day of patients from your practice who test positive and either signpost those eligible to consider enrolling in the study using the PANORAMIC website or refer to a GP hub you may be linked with. This should be done urgently on the same day to enable eligible patients to enroll in the study as soon as possible. To find out more information, please visit the PANORAMIC website: www.panoramictrial.org

Patients in the highest risk cohorts who are eligible to receive an nMAB or antiviral treatment are not excluded from the study. However, these patients must first be referred to a CMDU for routine access to treatments. The CMDU can then offer patients the chance to enrol in the PANORAMIC study, if they meet the eligibility criteria and have not already received an antiviral treatment. The PANORAMIC team will complete the consent process and take responsibility for issuing any antiviral drug they are randomised to receive. The PANORAMIC study is not the right avenue for obtaining antivirals for those patients at highest risk from COVID infection.

### Further information for patients

For any general patient queries about COVID-19 treatments, please refer patients to https://www.nhs.uk/conditions/coronavirus-covid-19/treatments-for-coronavirus/. For more detailed information about access and eligibility, please refer to the policy.

## ANNEX B – Patient Pathway

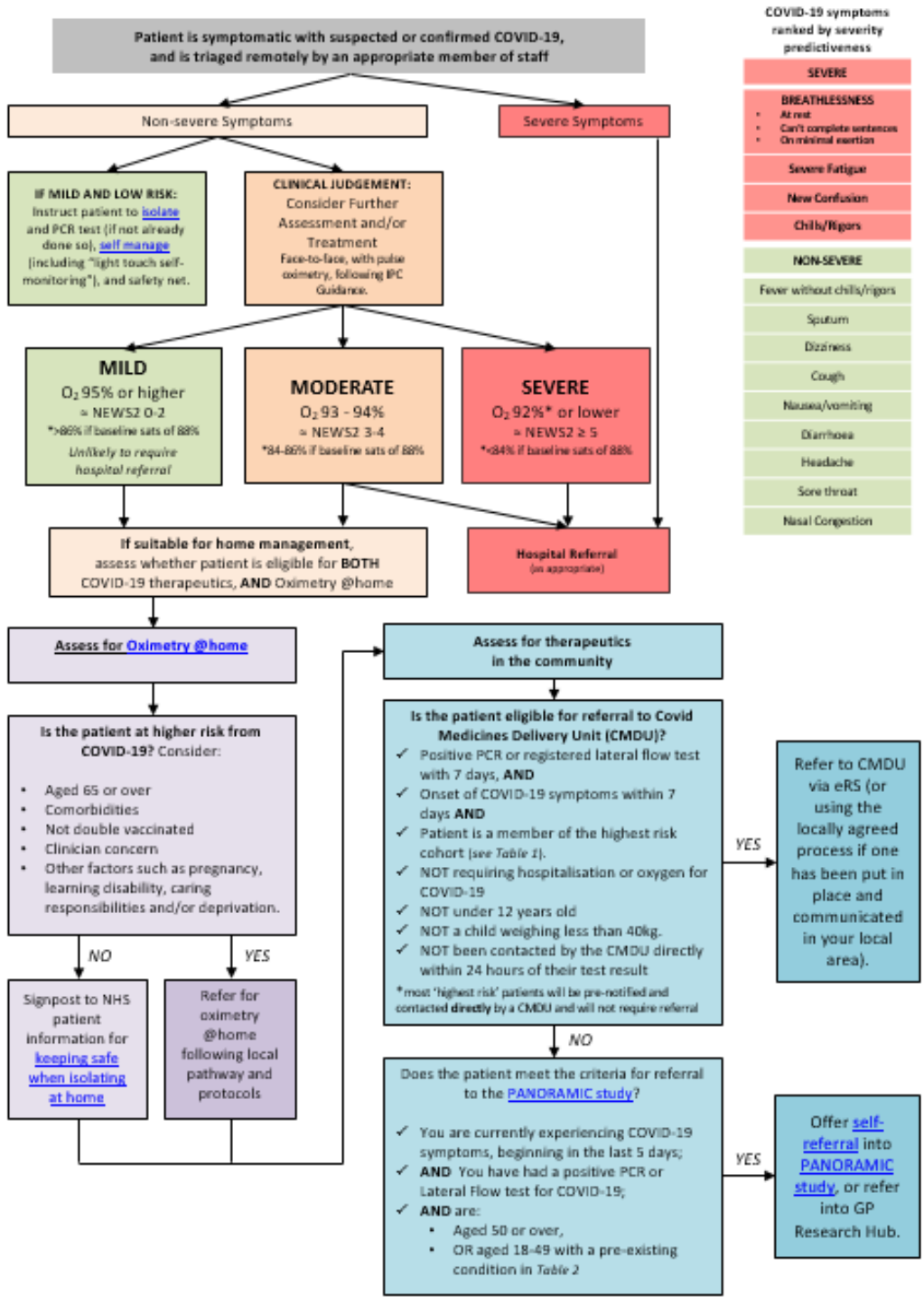

**Table 1:** ***Eligibility for Covid Medicines Delivery Unit referral***

| Cohort | Description |
|---|---|
| Down's syndrome | All patients with Down's syndrome |
| Sickle cell disease | All patients with a diagnosis of sickle cell disease |
| Patients with a solid cancer | • Active metastatic cancer and active solid cancers (at any stage)<br>• All patients receiving chemotherapy within the last 3 months<br>• Patients receiving group B or C chemotherapy 3-12 months prior<br>• Patients receiving radiotherapy within the last 6 months |
| Patients with a haematologic malignancy | • Allogeneic haematopoietic stem cell transplant (HSCT) recipients in the last 12 months or active graft vs host disease (GVHD) regardless of time from transplant (including HSCT for non-malignant diseases)<br>• Autologous HSCT recipients in the last 12 months (including HSCT for non-malignant diseases)<br>• Individuals with haematological malignancies who have o received chimaeric antigen receptor (CAR)-T cell therapy in the last 24 months, or o radiotherapy in the last 6 months<br>• Individuals with haematological malignancies receiving systemic anti-cancer treatment (SACT) within the last 12 months except patients with chronic phase chronic myeloid leukaemia (CML) in molecular response or first or second line tyrosine kinase inhibitors (TKI).<br>• All patients with myeloma (excluding MGUS) or chronic B-cell lymphoproliferative disorders (e.g. chronic lymphocytic leukaemia, follicular lymphoma) or myelodysplastic syndrome (MDS) who do not fit the criteria above.<br>• All patients with sickle cell disease.<br>• Individuals with non-malignant haematological disorder (e.g. aplastic anaemia or paroxysmal nocturnal haemoglobinuria) receiving B-cell depleting systemic treatment (e.g. anti-CD20, anti-thymocyte globulin [ATG] and alemtzumab) within the last 12 months. |
| Patients with renal disease | • Renal transplant recipients (including those with failed transplants within the past 12 months), particularly those who:<br>  ○ Received B cell depleting therapy within the past 12 months (including alemtuzumab, rituximab [anti-CD20], anti-thymocyte globulin)<br>  ○ Have an additional substantial risk factor which would in isolation make them eligible for nMABs or oral antivirals<br>  ○ Not been vaccinated prior to transplantation<br>• Non-transplant patients who have received a comparable level of immunosuppression<br>• Patients with chronic kidney stage (CKD) 4 or 5 (an eGFR less than 30 ml/min/1.73m2) without immunosuppression |
| Patients with liver disease | • Patients with cirrhosis Child's-Pugh class B and C (decompensated liver disease).<br>• Patients with a liver transplant<br>• Liver patients on immune suppressive therapy (including patients with and without liver cirrhosis)<br>• Patients with cirrhosis Child's-Pugh class A who are not on immune suppressive therapy (compensated liver disease) |
| Patients with immune-mediated inflammatory disorders (IMID) | • IMID treated with rituximab or other B cell depleting therapy in the last 12 months<br>• IMID with active/unstable disease on corticosteroids, cyclophosphamide, tacrolimus, cyclosporin or mycophenolate.<br>• IMID with stable disease on either corticosteroids, cyclophosphamide, tacrolimus, cyclosporin or mycophenolate.<br>• IMID patients with active/unstable disease including those on biological monotherapy and on combination biologicals with thiopurine or methotrexate |
| Primary immune deficiencies | • Common variable immunodeficiency (CVID)<br>• Undefined primary antibody deficiency on immunoglobulin (or eligible for Ig)<br>• Hyper-IgM syndromes<br>• Good's syndrome (thymoma plus B-cell deficiency)<br>• Severe Combined Immunodeficiency (SCID)<br>• Autoimmune polyglandular syndromes/autoimmune polyendocrinopathy, candidiasis, ectodermal dystrophy (APECED syndrome)<br>• Primary immunodeficiency associated with impaired type I interferon signalling<br>• X-linked agammaglobulinaemia (and other primary agammaglobulinaemias)<br>• Any patient with a secondary immunodeficiency receiving, or eligible for, immunoglobulin replacement therapy |
| HIV/AIDS | • Patients with high levels of immune suppression, have uncontrolled/untreated HIV (high viral load) or present acutely with an AIDS defining diagnosis<br>• On treatment for HIV with CD4 <350 cells/mm3 and stable on HIV treatment or CD4>350 cells/mm3 and additional risk factors (e.g. age, diabetes, obesity, cardiovascular, liver or renal disease, homeless, those with alcohol-dependence) |
| Solid organ transplant recipients | • All recipients of solid organ transplants not otherwise specified above |
| Rare neurological conditions | • Multiple sclerosis<br>• Motor neurone disease<br>• Myasthenia gravis<br>• Huntington's disease |

**Table 2:** ***Eligibility for PANORAMIC study***

- **All patients aged 50 or over, <u>OR</u>**
- **Patients aged 18-49 with one of the following:**
  - Chronic respiratory disease (including chronic obstructive pulmonary disease (COPD), cystic fibrosis and asthma requiring at least daily use of preventative and/or reliever medication)
  - Chronic heart or vascular disease
  - Chronic kidney disease
  - Chronic liver disease
  - Chronic neurological disease (including dementia, stroke, epilepsy)
  - Severe and profound learning disability
  - Down's syndrome
  - Diabetes mellitus (Type I or Type II)
  - Immunosuppression: primary (e.g. Inherited immune disorders resulting from genetic mutations, usually present at birth and diagnosed in childhood) or Secondary due to disease or treatment (e.g. sickle cell, HIV, cancer, chemotherapy)
  - Solid organ, bone marrow and stem cell transplant recipients
  - Morbid obesity (BMI >35)
  - Severe mental illness
  - Care home resident
  - Considered by recruiting clinician to be clinically vulnerable