COVID-19 nMAB and antiviral treatments in the community FAQs

Questions:

Does the Practice need to do anything to ensure patients who are eligible can access nMABs or antivirals for treating COVID-19?

In most cases no – this service is managed by the NHS through COVID Medicines Delivery Units (CMDUs) based within hospitals.

The CDMUs have the list of eligible patients in their area and is notified of positive PCR tests for this group.

When a positive PCR is received they contact the patient, assess if treatment is appropriate and arrange supply of an nMAB or antiviral (where a nMAB in contra-indicated or it is not possible to administer a nMAB)

Any reporting or monitoring will be managed by CMDUs although if a patient experienced an adverse drug reaction the GP practice should complete a yellow card and if a person taking molnupiravir became pregnant during or shortly after completing the course the GP practice should report the pregnancy to UK COVID-19 Antivirals in Pregnancy Registry on 0344 892 0909 (see relevant FAQs).

Please see the following FAQs for advice when a GP Practice does need to support a patient access this medication:

My patient believes they are eligible for COVID-19 treatments but they have not received a national letter – what should I do?

A patient has contacted me because they have received a letter advising they are eligible for COVID-19 treatment in the community AND have currently got COVID-19 confirmed by a positive PCR result but they have not been contacted to arrange treatment– what should I do?

Can GPs prescribe nMABs or antivirals for treating COVID-19?

No – these treatments are only available from COVID Medicines Delivery Units (CMDUs). Practices must not issue prescriptions for these treatments.

How do patients access nMABs and antivirals for treating COVID-19 in the community?

People in the high risk group should be sent a letter advising them that they are eligible for COVID-19 treatments should if they become infected. It is not clear currently if GP practices will be notified which of their patients have received this letter.

They will also be sent a PCR test that they can do at home if they develop symptoms of COVID-19.

If the person develops any of the main symptoms of COVID-19 (a high temperature, a new continuous cough or a loss or change in sense of smell or taste) they should take the PCR test as soon as possible, even if symptoms are mild and post the test as soon as possible. They also need to register the test ensuring they enter their NHS number and postcode correctly..

If the PCR test is positive they will be contacted by the NHS within 24 hours of the positive test result to arrangement treatment. This will usually be by text, email or phone.

Treatments for coronavirus (COVID-19) - NHS (www.nhs.uk)
https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/12/C1480-patient-notification-letter-important-information-about-new-treatments-for-coronavirus.pdf

Which nMAB and antiviral treatments for COVID-19 are available in the community?

Sotrovimab (Xevudy) - a neutralising monoclonal antibody (nMAB) that both blocks viral entry into healthy cells and clears cells infected with SARS-CoV-2. Treatment is a single 500mg IV infusion.

Molnupiravir (Lagevrio) - an antiviral that inhibits viral replication. Treatment is molnupiravir 800 mg (four x 200 mg capsules) taken orally every 12 hours for 5 days. It can be taken with or without food. The capsules should be swallowed whole with a sufficient amount of fluid (e.g., a glass of water). The capsules should not be opened, crushed or chewed. This drug is used where an nMAB is contraindicated or the administration of an nMAB is not possible and only in those 18 and over.
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103861
Lagevrio 200 mg hard capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Which people are eligible for COVID-19 nMAB and antiviral treatments in the community?

All of the following criteria must be met for a patient to be eligible for COVID-19 treatment in the community:

- Patient is aged 12 and over and weighs at least 40 kg
  AND
- SARS-CoV-2 infection is confirmed by polymerase chain reaction (PCR) testing within the last 5 days
  AND
- Onset of symptoms of COVID-19 is within the last 5 days
  AND
- The patient is a member of the 'highest' risk group as set out in the NHSE policy

Patients are **not** eligible for nMAB treatment in the community if they meet any of the following:

- Require hospitalisation for COVID-19
  AND/OR
- New supplemental oxygen requirement specifically for the management of COVID-19 symptoms
  AND/OR
- Children weighing less than 40kg
  AND/OR
- Children aged under 12 years

https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103862

Which patients are considered to be 'highest' risk with regards COVID-19 treatments in the community?

Patient cohorts considered at highest risk from COVID-19 and to be prioritised for treatment with nMABs

The following patient cohorts were determined by an independent advisory group commissioned by the Department of Health and Social Care (DHSC)

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) • All patients receiving chemotherapy within the last 3 months • Patients receiving group B or C chemotherapy 3-12 months prior • 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 • Autologous HSCT recipients in the last 12 months • Individuals with haematological malignancies who have received chimaeric antigen receptor (CAR)-T cell therapy in the last 24 months, or anti-CD20 monoclonal antibody therapy in the last 12 months • Individuals with chronic B-cell lymphoproliferative disorders receiving systemic treatment or radiotherapy within the last 3 months • Individuals with chronic B-cell lymphoproliferative disorders with hypogammaglobulinaemia or reduced peripheral B cell counts • Individuals with acute leukaemias and clinically aggressive lymphomas who are receiving chemotherapy or within 3 months of completion at the time of vaccination • Individuals with haematological malignancies who have received anti-CD38 monoclonal antibody or B-cell maturation agent (BCMA) targeted therapy in the last 6 months • Individuals with chronic B-cell lymphoproliferative disorders not otherwise described above

Patients with renal disease	• Renal transplant recipients (including those with failed transplants within the past 12 months), particularly those who: o Received B cell depleting therapy within the past 12 months (including alemtuzumab, rituximab [anti-CD20], anti-thymocyte globulin) o Have an additional substantial risk factor which would in isolation make them eligible for nMABs or oral antivirals o Not been vaccinated prior to transplantation • Non-transplant patients who have received a comparable level of immunosuppression • 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). • Patients with a liver transplant • Liver patients on immune suppressive therapy (including patients with and without liver cirrhosis) • 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 • IMID with active/unstable disease on corticosteroids, cyclophosphamide, tacrolimus, cyclosporin or mycophenolate. • IMID with stable disease on either corticosteroids, cyclophosphamide, tacrolimus, cyclosporin or mycophenolate. • 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) • Undefined primary antibody deficiency on immunoglobulin (or eligible for Ig) • Hyper-IgM syndromes • Good's syndrome (thymoma plus B-cell deficiency) • Severe Combined Immunodeficiency (SCID) • Autoimmune polyglandular syndromes/autoimmune polyendocrinopathy, candidiasis, ectodermal dystrophy (APECED syndrome) • Primary immunodeficiency associated with impaired type I interferon signalling • X-linked agammaglobulinaemia (and other primary agammaglobulinaemias)
HIV/AIDS	• Patients with high levels of immune suppression, have uncontrolled/untreated HIV (high viral load) or present acutely with an AIDS defining diagnosis • 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 • Motor neurone disease • Myasthenia gravis • Huntington's disease

https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103862

Which symptoms of COVID-19 are used when assessing eligibility for treatment in the community?

A wider range of COVID-19 symptoms are used when assessing if treatment is appropriate which are: Feverish, chills, sore throat, cough, shortness of breath or difficulty breathing, nausea, vomiting, diarrhoea, headache, red or watery eyes, body aches, loss of taste or smell, fatigue, loss of appetite, confusion, dizziness, pressure or tight chest, chest pain, stomachache, rash, sneezing, sputum or phlegm, runny nose.
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103862

Who decides which people are eligible and which treatment a person is given?

The NHS decides who is eligible and which treatment, if any, is suitable.
Treatments for coronavirus (COVID-19) - NHS (www.nhs.uk)

Can nMABs and antivirals be used to prevent COVID-19 infection?

No, currently these therapies are only available to treat COVID-19 infection in eligible patients.

My patient believes they are eligible for COVID-19 treatments but they have not received a national letter – what should I do?

Does the patient meet the criteria for being at the highest risk of COVID-19?

If yes send an email to mft.gm.cmdu@nhs.net advising that the practice believes the patient (provide patient details) is eligible for COVID-19 treatment in the community but has not received notification. Provide details of which eligibility criteria the patient meets. NB this email address is for clinicians only and must not be given to patients. This email address is to be used until the CMDU is available on eRS.

The patient will be triaged by the service who will determine eligibility.
Coronavirus » COVID Medicine Delivery Unit Directory (england.nhs.uk)

A patient has contacted me because the have had a positive lateral flow test and are eligible for COVID-19 treatment – what should I do?

If the patient has received a national letter stating they are eligible advise the patient to complete their PCR test and self-isolate whilst awaiting the results.

If the patient has not received a national letter see - My patient believes they are eligible for COVID-19 treatments but they have not received a national letter – what should I do?

A patient has contacted me because they have received a letter advising they are eligible for COVID-19 treatment in the community AND have currently got COVID-19 confirmed by a positive PCR result but they have not been contacted to arrange treatment– what should I do?

Patients who are eligible for COVID-19 treatments have been advised that if they are not contacted within 24 hours of a positive PCR test, call:

- your GP surgery (during their usual opening hours)
- 111 (during evenings and at weekends) – they will be able to make an urgent referral

The **GP practice** needs to send an email to mft.gm.cmdu@nhs.net advising that the patient (provide patient details) is eligible for COVID-19 treatment in the community and has had a positive PCR test but has not been contacted to arrange treatment. At this time it is not clear what the response time will be. However, given that treatment must be started within 5 days from the onset of symptoms we would expect a response within 24 hours.

NB this email address is for clinicians only and must not be given to patients.
How and when to have sotrovimab - NHS (www.nhs.uk)
https://www.england.nhs.uk/coronavirus/publication/covid-medicine-delivery-unit-directory/

My patient who is eligible for COVID-19 treatment will not be able to travel to a hospital what should I do?

Nothing – the CMDUs are responsible for arranging supply.

CMDUs must ensure that patients eligible for an nMAB who cannot travel to a treatment site are able to access the treatment via alternative routes.

In respect of oral antiviral treatment, CMDUs must make arrangements to ensure the patient can access the treatment without having to attend the service in person (e.g. courier delivery or medicine collected on behalf of the patient, depending on options available within the treatment window).
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103861

My patient is going abroad for several months and is eligible for nMABs or antivirals to treat COVID-19 infection, can they access a supply to take with them?

No

My patient has asked in they can access nMABS or antivirals privately to treat and/or prevent COVID-19 infection, is this possible?

No

I think my patient may have experienced an adverse event following treatment of COVID-19 with a nMAB or antiviral – what should I do?

Healthcare professionals are asked to report any suspected adverse reactions (including congenital malformations and or neurodevelopmental delays following treatment during pregnancy) via the United Kingdom Yellow Card Scheme www.mhra.gov.uk/yellowcard

https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103862

My patient is taking molnupiravir and has missed a dose – what should they do?

If the patient misses a dose of molnupiravir within 10 hours of the time it is usually taken, the patient should take as soon as possible and resume the normal dosing schedule. If a patient misses a dose by more than 10 hours, the patient should not take the missed dose and instead take the next dose at the regularly scheduled time. The patient should not double the dose to make up for a missed dose.
Lagevrio 200 mg hard capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

My patient is taking molnupiravir and is struggling to swallow the capsules, can they be opened/crushed/chewed or the dose spread out throughout the day?

No. The 4 capsules must be swallowed whole and taken at the same time to form a single dose.

The capsules should not be opened, crushed or chewed.

The CDMU should have assessed the patients ability to take molnupiravir as part of their processes. If a patients is having problems they should be advised to contact the helpline/medicines information department that the CMDU provided or the hospital pharmacy who provided the medication (their phone number should be on the label).
Lagevrio 200 mg hard capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

My patient is currently taking molnupiravir and is experiencing side effects what should I do?

The patient should be advised to contact the helpline/medicines information department that the CMDU provided or the hospital pharmacy who provided the medication (their phone number should be on the label)

My patient is taking molnupiravir and no longer has symptoms – should they complete the course?

Yes, to reduce the possibility of emerging resistance, patients should be advised to complete the whole course of treatment even if their symptoms improve and/or they feel better.
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103862

My patient has completed their 5 day course of molnupiravir and still has symptoms, do they need a longer course?

No, treatment must not be extended beyond 5 days
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103862

My female patient has taken molnupiravir and has had unprotected sexual intercourse whilst taking or within 4 days of completing the course – what should I do?

There is no data from the use of molnupiravir in pregnant women, however, studies of molnupiravir in animals have shown reproductive toxicity. Molnupiravir is not recommended during pregnancy. Individuals of childbearing potential prescribed molnupiravir should be advised to use effective contraception for the duration of treatment and for 4 days after the last dose of molnupiravir.

You will need to discuss this with the patient along with their options.
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103862

My patient has become pregnant whilst taking, or shortly after taking molnupiravir – what should I do?

There is no data from the use of molnupiravir in pregnant women, however, studies of molnupiravir in animals have shown reproductive toxicity. All pregnancies in people taking molnupiravir must be reported to the UK COVID-19 Antivirals in Pregnancy Registry on 0344 892 0909
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103862

What is the evidence base for nMABs and antivirals when treating COVID-19?

Recent evidence suggests that nMABs and oral antivirals significantly improve clinical outcomes in non-hospitalised patients with COVID-19 who are at highest risk of progression to severe disease and/or death.

Sotrovimab administered intravenously to non-hospitalised patients with mild-to-moderate disease and at least one risk factor for disease progression decreased the risk of hospitalisation or death by 85% (Gupta et al, 2021).

Final results from the Phase 3 MOVe-OUT trial show that the oral antiviral molnupiravir resulted in a relative risk reduction of 30% in the composite primary outcome of hospitalisation or death at day 29 (6.8% in the molnupiravir group vs 9.7% in the placebo group, p=0.0218).
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103861

Is there any patient information about COVID-19 treatments in the community?

Yes – use this link Treatments for coronavirus (COVID-19) - NHS (www.nhs.uk)