Department of Health & Social Care

Deployment of community based treatments for COVID-19

COVID treatments to date

- Primarily for hospitalised patients e.g. Dexamethasone, Tocilizumab, Remdesivir
- A UK NHS success story: for example, Dexamethasone was trialled and tested via RECOVERY in Wave 1 and deployed for use in hospitals within hours of the trial readout publication
- However, there is now one novel **antiviral** and two **neutralising monoclonal antibody treatments (nMAB)** that are licensed for non-hospitalised patients to reduce the risk of hospitalisation & death.
- Both antivirals & monoclonal antibodies need to be administered quickly after symptom onset.
- NHS is leading the way globally in making these treatments available to non-hospitalised patients.
- We expect more treatments to become available over the coming months

What is the Antivirals National Study?

- In October 2021, the UK government announced the procurement of two ground-breaking oral antivirals for the treatment of COVID-19 in the community.
- These antiviral treatments will be made available to UK patients through a national study called the '***P**latform **A**daptive trial of **NO**vel antivi**R**als for e**A**rly treat**M**ent of COVID-19 **I**n the **C**ommunity*' (**PANORAMIC**), which will be run by the University of Oxford.
- The first antiviral treatment that will be made available through PANORAMIC will be molnupiravir (also known as Lagevrio), which is made by Merck , Sharp and Dohme (MSD).
- Molnupiravir is a licensed product for the treatment of COVID-19 in the UK, having received Conditional Marketing Authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) on 4th November 2021.

Why do we need to run a National Study?

- Although the company-run clinical trials of Molnupiravir have identified that the treatment has a benefit in reducing the risk of hospitalisation from COVID-19 in high-risk patients, **these trials have only used unvaccinated participants, whereas the UK has a mostly vaccinated adult population.**
- The MHRA's approval of Molnupiravir means we can make this treatment available to UK patients with the greatest need this winter. In doing so, **we also want to gather more data to see if the same level of benefit is found when the treatment is given to the mostly vaccinated UK population.**
- This data will help the NHS to develop plans on how to best make Molnupiravir available in the future to patients who would benefit most from this treatment.

What does it mean to take part of the study?

- Those who receive a positive PCR test for COVID-19 and are eligible will be contacted by either the trial team or a local health professional to consider enrolling in the study. Alternatively, patients can sign up themselves via the study website: **www.panoramictrial.org**
- All participants will be randomly allocated to one of two groups:
    - **Group A:** Standard of care + a course of antiviral treatment for COVID-19.
    - **Group B:** Standard of care only.
- All participants will be required to complete a daily diary for 28 days through the PANORAMIC website or receive a phone call on days 7, 14, and 28 to speak about their symptoms.

Who is eligible to take part in the study?

- The national study will prioritise those at greater risk of being severely ill if they test positive for COVID-19. Eligibility for the study is therefore limited to those who meet the following criteria, except for those who are designated as at highest risk of hospitalisation and death from COVID-19:

    1. Have received a PCR positive test for COVID-19.
    2. Feel unwell with symptoms of COVID-19 that started in the last 5 days.
    3. Are aged 50+, or 18-49 years old with an underlying medical condition that can increase chance of having severe COVID-19.

- The study will be open to individuals living anywhere across all four UK nations. Wide geographical participation is strongly encouraged to ensure the data collected in the study is diverse and representative of the UK population. We are estimating that around 10,600 people will need to be recruited per antiviral to generate the data required.

- The quicker those eligible sign up to the study, the quicker the recruitment target is met for the study and the trial produces results, enabling well-informed wider deployment of antivirals and alleviate some of the burden on the NHS.

How is the healthcare system supporting PANORAMIC?

- The trial will be predominantly run remotely by the study team and antivirals distributed by an online pharmacy. However the healthcare system will play a crucial role in the success of the study by helping to promote PANORAMIC and signpost eligible patients to enrol.
- The primary role will be signposting eligible patients to the study website to consider enrolling if they are eligible to participate.
- In England there will be ~60 GP hubs who will be able to refer potential participants onwards for enrolment in the study through their hub site.
- In the devolved nations the trial will be run using different models most appropriate for each nation.
- In Wales, all potential participants will be contacted following positive test (PCR or LFT) to enrol. An all-Wales remote medical team will confirm eligibility.
- In Scotland, in addition to signposting, a number of Health Boards are establishing secondary care based clinical trial teams to support enrolment of participants into the study.
- In Northern Ireland, further to patient self-referrals, we are initially setting up 1-2 GP hubs resourced to enable participant enrolment across our referral practices.

Targeted deployment to highest risk patients

- Patients deemed at the very highest risk of deterioration, hospitalisation or death will be able to access a COVID-19 treatment (either Neutralising Monoclonal Antibodies or Antivirals) within the community through the NHS, alongside the national study taking place.
- An independent expert working group commissioned by DHSC has assessed the eligible cohorts based on detailed clinical evidence.
- Patients in the eligible cohorts will be sent PCR tests to keep at home by NHS Test & Trace.
- If they test positive for COVID, a COVID Medicines Delivery Unit (CMDU) clinician will assess them over the phone and explain how to access any treatment.
- A PCR positive patient can also be referred by 111 or a GP to a CMDU if they are not contacted within 24 hours.
- **Neutralising monoclonal antibody treatments (nMABS)** will be the initial focus and is administered intravenously. A patient will need to travel to a CMDU – which in most cases are based in hospital settings. They will be given clear advice on how to travel safely or alternative COVID-safe arrangements.
- **Any antiviral treatment** is likely to be delivered to the patient's home – either via a friend/family member or delivery service.
- The majority of patients will be informed via a 'pre-notification' letter or email if they have a condition that may make them eligible for neutralising monoclonal antibodies or antivirals should they test positive.

Targeted deployment: the NHS' role in England

- **CMDU clinicians** will assess & prescribe treatments & administer nMABs
- NHS Digital is providing CMDUs with a digital dashboard to identify and contact patients
- Eligible patients will be encouraged to contact their **GP** (in hours) or **111** (out of hours) only if they have not been contacted by the CMDU within 24 hours of their PCR result
- **Specialist clinicians** will also need to help raise awareness about COVID community treatments with 'new entrants' to the cohorts
- At this stage, **community pharmacists** are not expected to support deployment.
- Information for patients on COVID treatments will be available on nhs.uk
- The deployment model may evolve if, for example, antivirals become more widely available.

Target deployment - simple pathway