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Standing Operating Procedure:
COVID Medicine Delivery Units (CMDUs)

Future updates made to this document will be highlighted in yellow

This guidance is correct at the time of publishing. However, as it is subject to updates, please use the hyperlinks to confirm the information you are disseminating is accurate.

Contents

1. Scope and Purpose

This standard operating procedure (SOP) describes how to operationalise COVID Medicine Delivery Units (CMDUs), and has been written to support local system leads. CMDU services will provide access to COVID treatments for non-hospitalised patients believed to be at greatest risk of disease progression, hospitalisation or death. The SOP applies to England only.

The treatments are a key element in the offer to higher risk patients, reducing hospital admissions and death.

1.1 Related Guidance and Advice

This SOP must be read in conjunction with:

The published UK clinical commissioning policy covering access to neutralising monoclonal antibodies or antivirals for non-hospitalised patients with COVID-19.

1.2 Equalities and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

2. Summary Service Requirements

The summary service requirements of CMDUs under the published clinical policy providing access to neutralising monoclonal antibodies (nMABs) or antivirals for non-hospitalised patients with COVID-19 are:

- A 7 day a week service (or 5-6 day service with additional administrative and on-call clinical arrangements to enable patient contact, triage and treatment / dispensing over the weekend to ensure patients do not miss the option of treatment within the confined treatment window). This must include cover over bank / public holidays.

- Full population / geographical coverage in line with local CCG's(s') commissioning responsibilities.
- Provision planned for adults and for children (aged 12 years and above).
- Core staffing provision that enables the review (at least twice daily, 7 days a week) and pro-active contact of potentially eligible patients, presented in the webview tool established nationally. This requires ICSs to identify webtool users and that those users have smart cards and smart card readers with the appropriate permissions (including CCG Organisational Data Service (ODS) codes) assigned. A copy of the webview user guide, along with further information regarding smart card roles, is available on the NHS Future Collaboration Platform.
- CMDU services are established and visible on the Directory of Services (DoS) and the electronic Referral Service (e-RS) to enable the parallel receipt and management of referrals from other routes including primary care and NHS 111. Further information is provided in sections 3 to 5 and a digital checklist is available on the Future NHS Collaboration Platform.
- Medical clinical assessment / triage (for local determination but potentially led from an emergency medicine, respiratory medicine, immunology or infectious diseases discipline) to assess eligibility against the published clinical policy, support treatment decisions and arrange associated prescriptions.
- Registration (by site) to participate in COVID-19 (and medicine) specific supply arrangements, via Blueteq™. Blueteq should also then be used to confirm pre-authorisation for individual patients. Sites not already registered should contact england.blueteq@nhs.net
- Aseptic preparation facility on-site or capability for bed / chairside aseptic preparation and administration. NB storage and preparation requirements will be medicine specific, and in general options to transport the prepared nMAB product beyond the site on which it is prepared should be assumed to be limited.
- An intravenous (IV) infusion service designed for polymerase chain reaction (PCR) positive patients in line with relevant Infection Prevention and Control (IPC) guidance and with appropriate patient consent arrangements in line with local protocols. The service should be planned around treatment administration over approximately 30 minutes with an expected further monitoring period in line with local medical practice, with the ability to manage potential side effects including (very rarely) anaphylaxis. Please note that sub-cutaneous administration may be a possible alternative to IV administration for Ronapreve, but this must not materially affect preparation or administration time.

- Where the patient is prescribed an oral anti-viral treatment, the ability to arrange for antivirals to be dispensed and collected from a hospital pharmacy by a non-household member acting on behalf of the eligible patient, or for the antiviral to be delivered to the location of the patient, for example, through a courier service or a voluntary service with which the CMDU/hospital may already have appropriate established arrangements, such as Nationwide Association of Blood Bikes. Pick-up and delivery arrangements must be in place 7 days a week including bank holidays.
- Arrangements in place for patient transport for those patients unable to make their own COVID-safe travel arrangements.
- Arrangements in place to ensure that eligible inpatients in other healthcare settings (e.g. inpatient mental health units) can be assessed and offered treatment on an equitable basis. If prescribed oral antivirals, arrangements should be in place to ensure they can be prescribed, dispensed and delivered to their inpatient care provider.
- Similarly agreed pathways should be in place, in advance, for patients in secure / detained settings.
- Surge capacity plans enabling service capacity to be escalated, including mutual aid arrangements between ICSs / regions, if required (for example to manage local outbreaks).

3. Central Identification and Referral of Potentially Eligible Patients

Patients who are potentially eligible for treatment will:

- fall into one of the highest risk clinical cohorts set out in the clinical policy (cohorts established through an independent advisory group commissioned by DHSC)
- be SARS-CoV-2 positive, confirmed by a PCR test, symptomatic and be within the therapeutic window set out in the policy

NHSE&I has worked closely with a range of specialist clinicians and experts alongside NHS Digital who were commissioned to develop the business rules and digital infrastructure to support central identification of potentially eligible patients. These business rules draw on a range of clinical and demographic data sources including but not limited to GP practice, hospital, radiotherapy, chemotherapy and COVID-19 test results data.

NHS Digital access COVID-19 testing data from pillars 1, 2 and 4 and check each positive result against the inclusion criteria business rules. Where a positive COVID-19 result is matched to a patient's health data and then to the policy inclusion criteria, two actions will follow simultaneously:

1. An SMS and email will be sent to the patient (in addition to the usual positive result message sent by NHS Test and Trace) informing the patient that having tested positive for COVID-19, they may be eligible for a treatment to help manage their symptoms. The SMS and email will inform the patient that a local NHS service (the CMDU) will contact them directly within 24 hours to make a fuller assessment to ensure the treatment is right for them, and what action to take if they are not contacted for any reason.
2. The patient's details will be made available directly to the local CMDU via a 'webview' within the Population Health Platform (please refer to the section in this SOP on 'Access to the Webview System'). CMDUs will be presented with the patient's name, NHS number, date of birth, postcode prefix and the contact details the patient provided in the test registration journey, alongside the contact details held within the patient demographic service.

Note: CMDUs should be aligned to CCG populations. Potentially eligible patients will be aligned to CMDUs using the following approach: Patient aligned with Registered GP Practice aligned with CCG. CMDUs must ensure they have local processes in place to refer patients and transfer patient information to an alternative CMDU, for example, where a patient may not be near to their usual place of residence and therefore the CMDU to which they have been aligned through central cohorting.

Whilst the majority of positive COVID-19 can be matched to a patient's health data, we know that 10-15% may not be. This can be for a number of reasons, for example data entry discrepancies during the patient's test registration journey. In this scenario, the patient would still be notified of their positive COVID-19 result by phone and/or email but would not receive a second message about potential eligibility for these new treatments subsequent to their result.

To help mitigate for this, NHSE&I will be contacting patients (via letter or email) to advise them that should they become positive for COVID-19, confirmed by a PCR test, they may be eligible for these new treatments.

These communications will inform patients that should they test positive for COVID-19 and are not contacted by the local NHS provider (CMDU) within 24 hours of their positive result, they should contact their GP practice (in-hours) or NHS111 (out of hours and at weekends). GP Practice teams and NHS111 Clinical Assessment Services (CASs) will need to be able to refer patients that they consider likely to meet the eligibility criteria to a CMDU.

GP Practice teams and CAS clinicians are not expected to make the final decision of whether the treatment is right for a patient or prescribe any treatment, rather to refer patients that meet the policy criteria in broad terms. The CMDU clinical team will make the assessment and discuss with the patient if the treatment is right for them.

In order for GP practice teams and NHS111 CAS clinician to be able to refer patients, the CMDU services must be made visible and searchable on:

- NHS Directory of Service (DoS)
- NHS Electronic referral service (e-RS)

In general, NHS111 will make referrals via DoS and GP Practice teams will make referrals via e-RS. Within e-RS CMDU services should be listed under the 'Infectious Diseases' speciality and 'non-specific' clinic type. The CMDU service name should include the wording 'COVID Medicine Delivery Unit (CMDU)'. Further information on how to complete each field on the DoS eRS template is available here: Directory of Services (creating and maintaining services) on the NHS e-Referral Service - NHS Digital.

The National DoS teams have created a z-code which CMDU services should be attached to in the DoS. This enables CAS clinicians to easily identify and refer patients to the appropriate CMDU service. If Commissioners or CMDUs require assistance establishing CMDU services on DoS, they should contact the local DoS lead (see annex 1).

4. Contacting Patients Presented in the Webview or Referred via Dos or e-RS

CMDUs should access the webview on the Population Health Management Tool at least twice daily and review the list of potentially eligible patients identified through central and national cohorting. This will ensure that patients can be contacted and assessed promptly and invited for treatment quickly given the short window of efficacy for treatment which is set out in the clinical policy.

It is important for CMDUs to note that DoS and e-RS referrals will be received in addition to those patients identified and presented on the Webview and must have robust processes in place to ensure that all referrals received through these routes (including potential duplicate referrals) are received and handled in a timely manner.

Potentially eligible patients will be informed that CMDUs will contact them no later than the next day after they receive the positive PCR result. CMDU should therefore attempt to contact patients within this timeframe.

There may be instances where patients are referred to CMDUs through specialists / consultants, for example oncology teams. NHSE&I will be writing to specialist services with regard to these treatments and CMDU services and would expect them to follow existing processes for referring patients using either DoS or e-RS.

CMDUs must have a local process in place for agreeing and transferring patients to another CMDU (both within and beyond the home ICS footprint), for example to manage out of area registered patients or students that may be temporarily resident at home but registered with a GP in a different part of England.

5. Access to the Webview System

NHS Digital have developed a webview to support frontline NHS services to quickly identify and contact potentially eligible patients that may be suitable for these treatments at the point they test positive. The webview has been developed within the Population Health Platform. A controlled version of the user guide for this service will be made available within the platform, but key information from the user guide is replicated below to support commissioners and providers in preparing to access the webview. A current draft of the user guide is also available on the FutureNHS collaboration area.

The purpose of the webview is to enable CMDUs to identify and contact patients to arrange a triage assessment with a clinician. The service is not a decision support tool and there is no direction that clinicians must deliver treatment. Any decision to progress with treatment will be after clinical assessment and must be based upon a clinician's decision about their patient.

CMDUs can use the tool to view a list of highest risk patients (aligned with the clinical policy) and their contact details, to facilitate clinical triage to see if these patients would benefit from these new treatments.

This webview will list patients who:

- have tested positive for COVID-19 with a PCR test from pillars 1, 2 and 4
- have been identified as being in the target cohort as stated in the UK Clinical Commissioning Policy, according to the data coded in their medical records
- are registered with General Practices or equivalent that are aligned to the constituent Clinical Commissioning Groups (CCGs) of an Integrated Care System (ICS) footprint

This tool will not list patients who:

- have positive lateral flow, Loop-Mediated Isothermal Amplification (LAMP) or LamPORE test results
- have not provided enough personal information during their test registration journey to be matched on the Personal Demographic Service (PDS) to their National Health Service (NHS) record

Technical Requirements

Supported browsers

Operating System	Browser
Windows	Internet Explorer 11
	Edge 88 (Windows 10 only)
	Chrome 88

IMPORTANT: To support smartcard functionality, your Information Technology (IT) equipment is required to be set up and configured to support the NHS Care Identity Service 2 (CIS2) smartcard authentication. Guidance for local IT departments can be found here. Also see the 'Accessing the Webview' section below.

To check if your IT equipment is set up to work with the Care Identity Authentication, you can run a diagnostic here.

Users connecting to the Population Health Platform will be determined by their organisation's IT policy.

Accessing the Webview

The webview on the Population Health Platform can be accessed via this weblink:

https://viewer.populationhealth.nhs.uk/

(Note: this live weblink will not be available to access prior to the frontline service going live to end users on 16 December 2021)

To access the webview you will be required to sign in with your CIS2 smartcard. The specific **CMDU Admin** Role Base Access Control (RBAC) code **R9817** must be assigned to your smartcard to gain access. You will need to contact your associated Registration Authority (RA) to get this RBAC code added to your smartcard. To note: Virtual Smartcard access is not supported.

You will only be able to view patients related to the ODS codes associated with your smartcard. For the purposes of this tool, users should **ensure their smartcards are assigned with the CCG ODS code(s) for the geographies which they require access to**. For multiple CCG geographic locations you may need to contact different RAs to ensure the CMDU Admin role and the ODS codes are assigned. Note, individual General Practice level ODS codes do not need to be assigned to users.

CCGs should work with closely with their associated Registration Authorities so that Ras are aware of and have a robust and rapid process in place for assigning CCG permissions to non primary care staff (e.g. Trust staff operating CMDUs for ICSs)

When you log in to the webview, if your CCG area(s) are not listed, contact your IT support service or the associated Registration Authority to confirm your assigned ODS codes and check you have the CMDU Admin assigned role. This will involve different IT support services and RAs if you support multiple CCG geographic locations.

Users experiencing any issues with accessing the webview should contact their IT support service in the first instance to ensure their I.T. equipment is configured correctly.

6. Medicine Supply, Storage and Preparation

The Chief Pharmacists of NHS Trusts or NHS Foundation Trusts who hold the lead responsibility for COVID Medicine Delivery Units (CMDUs) are responsible for ensuring the safe handling and use of all medicines, including oral antiviral medicines and neutralising monoclonal antibodies, delivered through those CMDUs or the associated hospital pharmacies. Corporate and professional governance for use of these medicines should be based on normal pharmacy governance arrangements. Appropriate risk assessments, controls and continuing assurance must be in place.

CMDUs will be supported by one or more nominated (usually hospital) pharmacies. Depending on whether the CMDU is co-located with the pharmacy, the pharmacy will aseptically prepare or advise on chair / bedside aseptic preparation of neutralising monoclonal antibodies.

6.1 Casirivimab and Imdevimab Neutralising Monoclonal Antibody

The casirivimab and imdevimab combination is licensed in Great Britain for the treatment of COVID-19 in individuals aged 12 years and above and weighing at least 40 kg.

Trusts who have not yet done so should register (by site) to participate in COVID-19 specific casirivimab and imdevimab supply arrangements, via Blueteq™. Blueteq should then be used to confirm pre-authorisation for individual patients. Sites not already registered should contact england.blueteq@nhs.net.

Organisations should note that following initial nationally determined allocations to participating hospitals, ongoing supplies to each hospital will be replenished on the basis of relative use / need. Ongoing ordering will be through existing (business as usual) routes, supported by volume-based caps (reflecting estimated eligible admissions) where required.

Organisations should note that initial supply will be available within 'global pandemic' packaging, which differs from the Great Britain (GB) licenced packaging / labelling i.e. the pandemic packs display a use by date 24 months from manufacture, but current GB regulatory requirements require the product is used within 12 months of the date of manufacture. A 'Dear Healthcare Professional' letter is available and will explain any differences in packaging/labelling. Regular stock updates should be provided to trust / hospital and regional pharmacy procurement lead / chief pharmacists.

To order stock Trusts should ideally order via the companies EDI system. Descriptors to use are:

6ml (0.6g packs)

CASIRIVIMAB/IMDEVIMAB 300MG/2.5ML 2IV IE

Pack Size - 2 vials

EAN Code - 7613326044608

IMS / DCC Code - H8XR

20ml (2.4g packs)

CASIRIVIMAB/IMDEVIMAB 1332MG / 11.1ML / 2 IE

Pack Size - 2 vials

EAN Code - 7613326044585

IMS / DCC Code - H93H

Hospital pharmacies and CMDU sites should enter the medicine onto the pharmacy stock control and/or prescribing system as described below:

Casirivimab 300 mg per 2.5 mL (120 mg/mL) with Imdevimab 300 mg per 2.5 mL (120 mg/mL) with the dose description as: 2 vial pack

AND

Casirivimab 1332 mg per 11.1 mL (120 mg/mL) with Imdevimab 1,332 mg per 11.1 mL (120 mg/mL) with the dose description as: 2 vial pack

The Hospital Chief Pharmacist associated with the CMDU should assure themselves that the Specialist Pharmacy Service (SPS) guidance has been followed with respect to storage and preparation of casirivimab/imdevimab, and that the cold chain requirements are managed and are complied with, particularly where stock is being transferred to another site for **administration**.

6.2 Molnupiravir

Oral antiviral medicines will be made available to designated hospital pharmacies aligned to CMDUs. The Regional Chief Pharmacist and Regional Pharmacy Procurement Specialist should be made aware of any hospital pharmacies who will be holding oral antiviral medicines on behalf of the CMDUs, aligned to Integrated Care Systems. The pharmacy stock control systems should be set up as follows:

Pharmacy stock control system set up

- Create product line on pharmacy systems using the template below based on dm+d nomenclature: : Virtual Medicinal Product (VMP) - Molnupiravir 200mg capsules - dm+d browser (nhsbsa.nhs.uk)
- Consider removing all system triggers that would initiate a new system purchase order being created, for example
    - *Do not include minimum order levels*
    - *Do not include within normal scheduled reordering routines*
- Set the supplier to Alloga UK or McKesson (AAH). Your Regional Pharmacy Procurement Specialist will be able to help you identify which supplier this will be.

- Consider isolating purchase orders for molnupiravir from routine Alloga UK / McKesson (AAH). You may wish to consider creating a separate supplier file for managing molnupiravir.

RPPS checklist for managed supplies	
Product description	Molnupiravir 200mg capsules
Brand Name	Lagevrio
Pack Size	40 Capsule Pack
Multiple order quantity	None Known
dm+d reference	Virtual Medicinal Product (VMP) - Molnupiravir 200mg capsules - dm+d browser (nhsbsa.nhs.uk)
Price	FOC
Pip (or product) code(s)	Unknown
GTIN	0191778023473 and / or 0191778023510
Manufacturer/brand	Merck Sharp & Dohme (UK) Ltd
Storage Requirements	No special storage requirements
Batch/expiry (if relevant)	Unknown
Supplier/wholesaler(s)	Alloga or McKesson depending on geography (English Hospitals)
Licensed/unlicensed	Licensed
Routine purchase order or open order (for multiple shipments)	Open Orders
Back orders to be cancelled?	N/A
Delivery charge?	None known
Allocation frequency: one off or recurring e.g. weekly	Initial priming stocks released to each site. Follow up orders will be outlined over the coming weeks.
Allocation type: fixed units (e.g. no of packs) or fixed total (e.g. total mg)	Initial priming stock will be determined under an allocation model.
Supporting documents / processes / additional instructions e.g. BlueTeq or supplier registration	BlueTeq forms will need to be completed in line with the policy

How to access and replenish supply

Stock will be allocated to each nominated Trust based on a national apportionment model. This stock will be transferred under a push model and sent direct from the distributor, but trusts need to create a record of ordering, receipting and issuing using the pharmacy computer system. Trusts will need to consider:

- Create an open purchase order for molnupiravir for 999 packs
- **IMPORTANT: You are NOT required to send this order to the supplier / distributor**
- Receive the delivered goods onto their Pharmacy systems
    - Take care to only receive the delivered quantity
    - Include a record of the delivery note number, batch number(s) and expiry date(s) in line with local practice
- If you identify a discrepancy between your expected allocation and delivery, please contact your Regional Pharmacy Procurement Specialist.
- You will NOT be invoiced for the goods that have been delivered. Consider processing a dummy invoice against the delivery note, but note not to process any values as goods are Free of Charge.

IMPORTANT: Stock replenishment will work on an apportionment model based on issues and inventory. Trusts must not contact Alloga, McKesson (AAH) or Merck Sharp & Dohme (UK) Ltd for further allocations. Further guidance will be communicated to outline the process of obtaining further supplies over the coming weeks

Monitoring of trust stockholding via Rx-Info Exend

Stock of molnupiravir will be monitored nationally using Exend which provides daily updates on the inventory held at each storage location in each Hospital. Exend will not display inventory records until there has been some issue activity. To prime the system to function, each Trust will need to issue and return one pack of tablets immediately after receipt of their first supply.

Exend will pick up the transaction in its daily data pick up, match it to inventory and start displaying the inventory on the live system. Trusts are encouraged to ensure that this been completed, and that Exend continues to display accurate stock data

7. Clinical Triage of Potentially Eligible Patients

Patients flagged to CMDUs via the national webview or the DoS and e-RS systems will require an initial virtual (remote) triage by an appropriately qualified clinician to assess eligibility and suitability for treatment with nMABs or antivirals. Triaging clinicians may include doctors (for example from emergency medicine, respiratory, immunology or infectious diseases disciplines) or allied healthcare professionals

such as advanced nurse practitioners or pharmacists (if suitably supported by their organisations to do so).

The central identification system has been designed such that it is sensitive rather than specific, which means a proportion of patients flagged to CMDUs may not be eligible for treatment with nMABs or antivirals. Clinicians are therefore required to ensure that flagged/referred patients meet the eligibility criteria listed in the published UK Clinical Commissioning Policy.

Other key questions for triage should include:

- Timing of symptom onset
- Assessment of severity of symptoms to confirm the patient does not require hospitalisation
- Vaccination status (to assess for risk of disease progression)
- Past medical history – patients will need to be within at least one of the priority cohorts as outlined in the published policy
- Drug and allergy history, including any previous history of anaphylaxis

Clinicians will also need to assess the patient's suitability to travel to the CMDU to access intravenous treatment. Where this is not possible, alternative arrangements should be made for the delivery of treatment to the patient (such as via an outreach model, where available). Where the treatment of a patient with an nMAB is contraindicated or not feasible, antiviral treatment may be considered as an alternative. Further guidance is available in the UK Clinical Commissioning Policy. If appropriate, prescriptions may be issued in advance to support patient flow through the system.

As molnupiravir is **not recommended** during pregnancy, all individuals of childbearing potential who are prescribed molnupiravir should be advised to use effective contraception for the duration of treatment and for 4 days after the last dose of molnupiravir. All healthcare professionals are asked to ensure that any patients who receive a COVID antiviral while pregnant are reported to the UK COVID-19 antivirals in pregnancy registry on 0344 892 0909 so that they can be followed up. For more information, go to http://www.uktis.org/.

Patients under the care of specialist teams (such as cancer services and those on immunosuppressive treatment) may require further discussion with their parent teams to determine suitability for treatment. For paediatric patients (aged 12-17 years inclusive), paediatric multidisciplinary team (MDT) assessment may be deemed necessary to determine clinical capacity to benefit from the treatment. A 24-hour paediatric MDT service is available for discussion of treatment decisions in this cohort and clinicians are advised to contact their local paediatric MDT service for further guidance.

8. Arranging Treatment

8.1. Access to Patient Transport

Support with access to patient transport services for eligible patients should be managed in line with national guidance and current local arrangements.

8.2. Access for Children

Noting that patients eligible under the policy may include those aged 12 to 17 years, local systems should aim to provide services in age-appropriate facilities. Some systems are for example referring eligible children to a virtual CMDU service provided on a paediatric hospital site.

8.3. Consent

Patient consent should be obtained in line with local trust guidance and practice.

8.4. Infection Prevention and Control (IPC) Guidance

Services should be provided in line with the latest Infection prevention and control guidance. Eligible individuals accessing the service in person will have recently tested positive for COVID-19.

8.5. Treatment Access for Patients in Secure or Detained Settings

Referral and treatment pathways should be agreed in advance for potentially eligible individuals within secure or detailed settings falling within the CMDU's catchment area. This should include an agreement about whether individuals can be supported to attend the CMDU for treatment or whether outreach treatment can be offered within the secure / detailed unit.

8.6. Treatment Access for Patients in Other (non-acute) Healthcare Settings

Arrangements should be in place to ensure that eligible inpatients in other healthcare settings (e.g. inpatient mental health units) can be assessed and offered treatment on an equitable basis. This may include provision of intravenous therapy, if clinically appropriate, within the individual's existing healthcare setting. If prescribed oral antivirals, these should be delivered to the individual's healthcare provider.

8.7 Determining Responsibility for Service Delivery for Patients Living Close to the England / Wales Border

The following rules have been tested and jointly agreed with CCGs adjacent to the border with Wales and with Wales commissioning colleagues:

- Patients registered with an English GP practice and those not registered with a GP but resident in England – on potentially eligible patient list for ICS services
- Patients registered with a Welsh GP practice and those not registered with a GP but resident in Wales – responsibility of Welsh community MABs services
- Named service leads contact details are to be shared to ensure prompt liaison between Welsh and English services on any individual patient service responsibility uncertainty to ensure treatments are not delayed

8.8 Arranging Treatment for Eligible Patients Currently Out of Area

CMDUs should ensure that eligible patients wishing to receive treatment but currently residing outside of their home area are urgently referred to another CMDU (or their equivalent in Northern Ireland, Scotland or Wales) for treatment. CMDUs

must provide a contact telephone number and email to facilitate transfers. Once agreed, transfers must be confirmed by email and acknowledged by the receiving CMDU or their devolved nation equivalent as well as confirmed to the patient.

8.9 Priority PCR Tests

Patients covered by this standard operating procedure will be provided with a priority PCR test to keep at home and be able use quickly if they develop coronavirus symptoms. When a patient uses a one of these PCR tests, it will be re-supplied automatically by NHS Test and Trace. If a CMDU treats a patient with either nMABs or AVs, they should inform the patient for long they should not re-test for coronavirus.

9. Delivering Treatments

9.1 Administration of Monoclonal Antibodies

Before intravenous or subcutaneous administration, casirivimab and imdevimab vials should be removed from refrigerated storage and allowed to equilibrate to room temperature for approximately 20 minutes before preparation.

Casirivimab and imdevimab administered intravenously must be administered together after dilution as a single infusion. Information on preparation and rate of infusion is available in the published clinical policy and the Summary of Product Characteristics. Preparation and administration of casirivimab and imdevimab should be initiated and monitored by a qualified healthcare provider using aseptic technique. Administration should be under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible. Individuals should be monitored post-intravenous infusion according to local medical practice.

Casirivimab and imdevimab should be injected consecutively during subcutaneous administration. Each of four injections (2x casirivimab 300mg and 2x imdevimab 300mg) should be at a different site, e.g. the upper thigh, the upper outer thigh or abdomen (except for 5cm around the navel and avoiding the waistline). When administering the subcutaneous injections, it is recommended that healthcare professionals use different quadrants of the abdomen or upper thighs or upper outer arms to space apart each 2.5ml subcutaneous injection of casirivimab and imdevimab.

9.2. Arranging Access to Oral Antivirals

CMDU designated (usually hospital) dispensaries will dispense prescriptions issued by the CMDU. A legal mechanism for prescribing (via paper prescription or utilising an existing electronic prescribing system) must be agreed with the Chief Pharmacist who is providing pharmaceutical oversight to the CMDU. Molnupiravir should be prescribed as 4x200mg capsules (800mg) to be taken 12 hourly for five days. One pack of 40x200mg capsules will be issued.

Prescriptions should only be dispensed once confirmation has been received from the prescriber that the patient meets the access criteria (see section 10 below). It is the prescriber's responsibility to confirm that the patient meets the criteria.

Due to the short time window for initiation of treatment (i.e. within 5 days of symptom onset and following a positive PCR test) the prescription should be ideally be collected by a patient relative/designated supporter. If this is not possible alternative arrangements need to be in place to deliver the prescription to the patient's residence (including residential facilities) within the timeframe stated above. Patients should be advised to complete the whole course of treatment even if their symptoms improve and/or they feel better. This is to reduce the possibility of emerging resistance.

10. Patient Charges, Treatment of Private Patients and Those Not Usually Eligible for NHS Funded Care.

The guidance set out in sections 10.1 and 10.2 (below) is taken from COVID-19: migrant health guide - GOV.UK (www.gov.uk) and reflects regulations that came into force on 29 January 2021 to add coronavirus (COVID-19) to Schedule 1 of the NHS (Charges to Overseas Visitors) Regulations.

10.1 No Charges for Coronavirus (COVID-19) Testing, Treatment and Vaccination

Overseas visitors to England, including anyone living in the UK without permission, will not be charged for:

- testing for COVID-19 (even if the test shows they do not have COVID-19)
- treatment for COVID-19, including for a related problem called multisystem inflammatory syndrome that affects some children
- vaccination against COVID-19

No immigration checks are needed for overseas visitors if they are only tested, treated or vaccinated for COVID-19.

10.2 Charges for Hospital Treatment of Secondary and Subsequent Illness

While COVID-19 testing and treatment is exempt from charges, this exemption is not intended to cover hospital treatment of any secondary or subsequent illness. Secondary or subsequent illness refers to:

- conditions or complications which arise from the initial COVID-19 infection, including long COVID
- any co-existing conditions a patient may have

These conditions remain chargeable. Under the Charging Regulations, the duty is on NHS Trusts to assess, based on the views of clinicians, what treatment for COVID-19 is exempt or chargeable.

10.3 Prescription Charge Exemption

TBC

11. Reporting Requirements

11.1 Completion of Blueteq Form

Casirivimab/imdevimab

Trusts who have not yet done so should register (by site) to participate in COVID-19 specific casirivimab and imdevimab supply arrangements, via Blueteq™.

Blueteq should also then be used to confirm pre-authorisation for individual patients. Sites not already registered should contact england.blueteq@nhs.net.

Molnupiravir

Sites do not need to separately register to receive molnupiravir packs but they must confirm pre-authorisation of the patient receiving molnupiravir using the patient specific molnupiravir Blueteq form.

Due to the possibility that use of molnupiravir may lead to antiviral resistance emerging it is vital that only those patients eligible to receive molnupiravir do so. Full completion of the Blueteq form is mandatory. Depending on local arrangements, prescribers should either complete a hard copy of the Blueteq form or provide other evidence to the dispensing pharmacy that the patient meets the access criteria as set out in the interim clinical commissioning policy. Failure to provide this information will result in the prescription not being dispensed.

Monitoring of longer-term progress of individuals receiving COVID therapies is strongly recommended via recruitment to the ISARIC-CCP study.

11.2 Patient Handovers and Discharge

All handovers of clinical care (including between hospitals if patients are transferred, between levels of care and clinical teams within hospitals, and between hospitals and primary care) should explicitly record the treatment that has been given together with the dose and date of administration. CMDUs must ensure that discharge letters to primary care explicitly record the treatment that has been given, together with the dose and date of administration.

The following SNOMED codes should be used to support evaluation and to inform subsequent treatment decisions:

Administration of Ronapreve

Procedure code: 47943005 |Administration of anti-infective agent (procedure)|

Presentations:

- Casirivimab 300 mg per 2.5 mL (120 mg/mL) with Imdevimab 300 mg per 2.5 mL (120 mg/mL) 2 vial pack - 40025711000001108
- Casirivimab 1332 mg per 11.1 mL (120 mg/mL) with Imdevimab 1,332 mg per 11.1 mL (120 mg/mL) 2 vial pack – 39654011000001101

Provision of Molnupirivir

Procedure code: 427314002 |Antiviral therapy (procedure)|

Presentation:

- Molnupiravir 200mg capsules, 40 capsule – 40251211000001109

11.3. Suspected Adverse Reactions

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 or search for MHRA Yellow Card in the Google Play or Apple App Store8.

11.4. Surveillance

Commissioned providers of CMDU services are encouraged to support additional testing or data requirements where requested under country specific or UK wide surveillance programmes, in line with current guidance. Please note that a data sharing agreement is in place to enable the UK Health Security Agency (UKHSA) to access Blueteq data to support service evaluation and surveillance activities.

11.5. Activity Reporting

CMDUs will be required to submit activity data to NHS England and NHS Improvement on a weekly basis, in arrears.

Each CMDU will be asked to submit data, by CCG, for the preceding 7 days:

a. Numbers of new potentially eligible patients visible to the CMDU via the webview tool
b. Number of additional patients referred via e-RS or DoS (please do not count patients who were already visible through the webview tool)
c. Number of patients referred in from another CMDU / UK nation
d. Number of patients triaged
e. Number of patients assessed as ineligible for treatment (e.g. outside of treatment window)
f. Number of patients assessed as eligible for treatment

Of which:

I. Number of patients treated (Blueteq forms must be submitted for each patient)
II. Number of patients who declined treatment
III. Number of patients referred to another CMDU for treatment (e.g. children treated through an agreed paediatric CMDU arrangement or patient choice)
IV. DNAs

12.Communications

CMDUs should have available:

- Guidance/script when phoning patients to book appointments which should include:
    - An overview of the treatment(s) and what the patient should expect, including how and where the treatments are administered and how long the appointment will take
    - The location of any treatment site
    - Advice on how patients can travel safely to any appointment outside their home whilst minimising the risk of passing infection to others. CMDUs will need to check any local guidance that may be in place in their areas, but they can draw from national guidance on travelling to a PCR test site. This may look like the following:
        - Avoid contact with other people as much as possible when going to your appointment
        - Wear a face covering when going to or from your appointment
        - Do not go to the treatment centre without an appointment
        - Do not use public transport or taxis
        - Do not drive to your appointment if you do not feel well enough – ask someone you live with to drive you if you can
        - Do not make any unnecessary stops when going to or from your appointment
        - After your appointment, go straight home and self-isolate (transport for patients eligible for transfers to and from the CMDU will be organised based on local arrangements)
        - What patients need to do when they arrive at the treatment centre, including any infection prevention control advice on how to enter the building safely without passing on infection to others
        - Advice on attending with carers/others
        - Advice on travelling home safely after treatment
    - Signage outside and around any treatment centres and one-way systems

In addition to the above operational communications guidance to CMDUs, the following communications will be prepared nationally:

- Information for patients via nhs.uk/CoronavirusTreatments
- Letter and/or email to most eligible patients informing them of the availability of COVID-19 treatments. For some cohorts who cannot be contacted centrally, a template letter will be shared via specialist clinicians responsible for a patient's care. This letter will raise awareness about the availability of COVID treatments and explain what they need to do in the event they have COVID symptoms.
- Briefings with patient group charities & professional bodies so they can provide accurate information to their members and supporters.
- A Frequently Asked Questions (FAQ) document.
- National patient-facing communications materials will aim to be made available in 'easy read', other languages, and braille wherever possible.

Annex 1 – National and Local Director of Services (DoS) Contacts

National

- National – england.dos@nhs.net

London

- London – nelcsu.londondos@nhs.net

South East

- Hampshire, Thames Valley and Somerset – scwcsu.hub@nhs.net
- Kent, Surrey and Sussex – syheartlandsccg.surreydosteam@nhs.net

South West

- Cornwall – cornwall.dos@nhs.net
- Devon – devon.dos@nhs.net
- Dorset – doccg.dorset.dos@nhs.net
- South West (North) – dosteam.southwest@nhs.net

North East and Yorkshire

- North East – necsu.northeastdos@nhs.net
- Yorkshire and Humber – yorkshireandhumber.dos@nhs.net

North West

- North West – england.northwestdos@nhs.net

Midlands

- East Midlands – england.eastmidlandsdos@nhs.net
- West Midlands – dosleads@wmas.nhs.uk

East of England

- East of England – england.eastofenglanddos@nhs.net