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Commissioning Framework: COVID-19 Therapeutics for Non-Hospitalised Patients

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1. Purpose

The purpose of this commissioning framework is to support Integrated Care Boards (ICBs) as commissioners of COVID-19 therapeutics for non-hospitalised patients who will benefit from them the most. This framework is intended to assist ICBs in establishing and maintaining timely access to COVID-19 therapeutics during the remainder of 2022/23 in preparation for **transition to** routine provision.

2. Background

In April 2021, the UK Government established an Antivirals Taskforce (ATF) with the aim of identifying new COVID-19 antiviral therapeutics. The first of the new oral antiviral medicines received a conditional marketing authorisation (CMA) from the Medicines and Healthcare products Regulatory Agency (MHRA) and was approved for use in the NHS in December 2021.

COVID Medicine Delivery Units (CMDUs) began operating in December 2021 on an interim basis as part of the NHS COVID-19 pandemic response. CMDUs provide access to COVID-19 therapeutics for non-hospitalised patients at highest risk, which currently includes approximately 1.8 million potentially eligible patients.

As the NHS moves from a pandemic to an endemic response to COVID-19 infections, ICBs will be at the forefront of providing timely access to COVID-19 therapeutics to their local populations. As part of that transition, we expect ICBs to support access to existing COVID-19 therapeutics, as well as new therapeutics as they become available.

The long-term ambition for the NHS is for access to COVID-19 therapeutics to become part of routine services, with the long-term preferred route of access through primary care and integrated urgent care. NICE have commenced a Multi Technology Appraisal (MTA) to review the clinical and cost effectiveness of currently available COVID-19 treatments in the longer term, which is expected to read out early in 2023. Therefore, whilst systems should urgently progress work to determine their local interim delivery model from autumn 2022, we expect systems to work towards routine provision **to coincide with the end of the NICE MTA implementation period**.

3. Scope

This commissioning framework sets out the expectations for the establishment of services to enable access to COVID-19 therapeutics for the following patient populations:

- Non-hospitalised 'highest' risk patients with COVID-19, eligible for oral antiviral treatments and intravenous neutralising monoclonal antibodies (nMABs) and antivirals as defined in the Department of Health and Social Care commissioned [Independent Advisory Group Report](#).
- Other patients eligible for treatment following the outcomes of the [PANORAMIC](#) study and any other relevant information.
- Patients potentially eligible for any new therapeutics that may be approved for use in England.
- Wider patient cohorts identified in the event of a surge in COVID-19 infections, vaccine escape or emergence of a variant of concern (VoC), in line with the [Viral evolution scenarios](#) published by the Scientific Advisory Group for Emergencies (SAGE).
- All of these patients should be given oximeters (if they do not already have one) and given safety netting information about how to monitor their illness, when they should seek help and the expected recovery time.

This framework sets requirements and standards that ICBs are expected to meet when determining and commissioning local delivery models for access to COVID-19 therapeutics. It sets out:

- Service requirements – the elements of the service that ICBs should provide to ensure timely access to treatments
- Approach to health inequalities – expectations of how ICBs should support equitable access to services
- Data and reporting requirements – to ensure effective monitoring and support service improvement
- Roles and responsibilities – summary of the roles and responsibilities of the key partners
- Support and resources available to systems – links to future guidance to support implementation

The preferred service delivery model should be determined by ICBs to meet the needs of their local population. These models may be based in primary, community or secondary care, or may be based on a hybrid model. ICBs may wish to consider how services align or integrate with other initiatives such as those being considered under [winter resilience plans](#), for example [Acute Respiratory Infection \(ARI\) hubs](#).

4. Service Requirements

4.1 Access

Timely access to assessment and triage for COVID-19 positive patients will be vital in ensuring that COVID-19 treatments can be administered within the required timeframe. For most therapeutics currently approved for use in England, they should be started within 5 days of symptom onset. To ensure timely access, the COVID-19 therapeutics services should:

- Ensure full coverage of the eligible population in each system, including eligible children.
- Meet the five-day treatment window for patients. This should include providing services with on call clinical arrangements to enable patient contact, triage, assessment, and treatment and dispensing over the weekend, out of hours and during bank holidays.
- Have a clear entry route into the patient pathway communicated to the local population and healthcare professionals working within the system.
- Include a non-digital pathway access route.
- Enable access across different settings, for example care homes, secure mental health settings and prisons.

Until the end of the NICE MTA implementation period, ICBs should ensure services continue to proactively contact all potentially eligible highest risk patients who are identified to them as COVID-19 positive by the WebView digital platform or referred to them by other services, for example, GP teams, NHS111 or hospital specialists.

4.2 Triage

The triage and assessment model used is for local determination. To support effective triage and treatment decisions, the service should:

- Include triage and clinical assessment to determine eligibility against the published [clinical policy](#), support treatment decisions and arrange associated prescriptions or referral to infusion services.
- Enable advice and support on current available treatments and be available for any new treatments as may be deployed. Recognising these are novel treatments there is a need to ensure healthcare professionals have access to appropriate advice and guidance to support their assessments and treatment decisions.
- Be supported by digital access to patients' medical records including drug history.
- Include signposting to monitoring and self care resources including how to access oximeters.

4.3 Treatment

The service will need to ensure timely access to different treatments options as they become available. The service will therefore need to:

- Provide an intravenous (IV) infusion service for treatment of patients with nMABs and antivirals.
- Enable oral antiviral medicines to be dispensed by local community pharmacy and/or hospital pharmacy.
- Provide any service necessary to meet any newly approved treatment types, for example, intramuscular injections.

4.4 Surge planning

As part of plans to manage any surges in demand on COVID-19 therapeutic treatment services, ICBs should have robust plans in place that enable increases in service capacity as and when required. Surge activity and associated additional capacity should have limited impact on routine NHS activities.

To aid surge planning, systems should test local arrangements for different surge scenarios. Contingency plans to scale up access to COVID-19 treatments may include:

- Mutual aid arrangements, for workforce and medicines supply, between systems and regions, if required for example to manage local outbreaks.
- Identified surge locations where activity is moved into centralised

assessment and treatment services which may also include nominated medicine supply hubs. ICBs may wish to consider whether surge locations could be aligned with other initiatives, such as [ARI hubs](#).

- Having 'sleeper' arrangements so that access to local services is able to be sustained for all patients.

5. Health Inequalities

Health inequalities in England have been exacerbated by the pandemic and has had a disproportionate impact on ethnic minority groups. The 2021 [Health Profile for England](#) found COVID-19 deaths among Black and Asian people were 1.50 times higher than expected and death rates were more than double the rate of the White population. As we move forward, we need to ensure that the health inequalities gap is not further widened but instead reduced. [Coverage and uptake of antivirals and neutralising monoclonal antibodies for the treatment of non-hospitalised patients with COVID-19](#) shows variation in treatment uptake within different health inequalities groups. All systems should consider how the service will maximise the accessibility of therapeutics to eligible patients most at risk of health inequalities, with the aim of preventing any further widening of the inequalities gap.

Systems should seek to understand the needs of its local population as defined in [NHS England's CORE20PLUS](#) population health management approach for narrowing health inequalities.

- **Core 20:** The most deprived 20% of the national population as identified by the national Index of Multiple Deprivation (IMD).
- **PLUS:** Population groups we would expect to see identified are ethnic minority communities; inclusion health groups; people with a learning disability and autistic people; coastal communities with pockets of deprivation hidden amongst relative affluence; people with multi-morbidities; and protected characteristic groups; amongst others.

Inclusion health groups include people experiencing homelessness, drug and alcohol dependence, vulnerable migrants, Gypsy, Roma and Traveller communities, sex workers, people in contact with the justice system, victims of modern slavery and other socially excluded groups.

5.2 Actions to address health inequalities

Equitable access to treatment

Arrangements should be put in place:

To ensure patients can access the appropriate first line treatment in accordance with clinical policy regardless of the healthcare setting, or residential setting, geographical location, or protected characteristics (e.g., disability or age) within the effective treatment window.

Ensure eligible inpatients in other healthcare settings (e.g., inpatient mental health units, patients in prisons and care homes) 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.

For patient transport to intravenous treatment services for those highest risk patients unable to make their own COVID-19 safe travel arrangements.

Non-digital routes of access to the pathway in the form of telephone and/or walk-in access to prevent digital exclusion.

Targeted outreach

During the remainder of 2022/23 and until routine access arrangements are in place, systems should continue to provide proactive outreach to highest risk patients identified in the WebView platform as having registered a positive COVID-19 test or referred to them from general practice and/or NHS111.

Systems should also plan to provide additional targeted outreach case finding to support access for those potentially eligible patients in their area most at risk of health inequalities as part of the development of a routine access model.

Targeted outreach may involve:

- Contacting patients identified as being within a CORE20PLUS group as soon as possible but within 24-48 hours of the patient's positive COVID-19 result being made visible to the service provider.
- Ensuring a nominated member of the service provider team is available during core hours to proactively reach out to patients flagged as being at risk of health inequalities, have tested positive for COVID-19 and have

been identified from their health records as being potentially eligible an assessment of eligibility for treatment.

- Arranging for a clinical appointment where a patient indicates they wish to be assessed for treatment eligibility following their positive COVID-19 test result.

Targeted communication and engagement

As described in the NHS statutory guidance [Working in partnership with people and communities](#), systems should work with local partners, community, voluntary, faith and health inclusion groups to tailor and supplement communications and engagement activity to the needs of their local population. They should collaborate, coproduce and codesign with local partners, community action groups and champions to increase awareness of and seek feedback to make improvements to the access pathway for groups at risk of health inequalities.

Where necessary the diverse communication needs of the populations should be met through support such as BSL and language translation/interpretation.

Learning and improvement

Systems should apply learning from and build on the approaches taken by other successful NHS programmes, such as the COVID-19 vaccination programme to reduce barriers and increase awareness and uptake within their local populations.

Systems should continue to monitor the demographic data of those identified as potentially eligible for treatment, the treatment uptake rates, and triage outcomes to ensure access pathways are as inclusive as possible within their areas. Where variation in triage and uptake is identified, action should be taken to focus local efforts to improving awareness and understanding of the pathway and improve uptake rates as appropriate.

6. Data and Reporting

6.1 Data and reporting requirements

Accurate recording of data is a statutory requirement of all commissioners and providers of NHS Services. Recording and/or submission of data relating to COVID-19 therapeutics (including assessment triage and treatment) enables effective insights. These insights support teams at national, regional, and local

levels to improve service delivery and reduce unwarranted variation in access and outcomes, supporting their respective public sector equality duties.

During the transition to a system led delivery model, the expectation is that the current reporting arrangements will remain in place (including WebView and Blueteq) to maintain oversight of access and outcomes during this period. However, NHS England is committed to work with ICBs during this period to reduce the burden of data collection. As ICBs transition to their longer-term sustainable delivery models, NHS England will review any ongoing reporting requirements and agree sustainable long-term data and reporting arrangements.

Data reported and collated during the second half of 22/23 will be used to support service providers and commissioners in resource planning, service resilience and to shape ICBs future service delivery models.

Assurance

ICBs will be asked to submit a high level bi-monthly (every two months) report to NHS England, to:

- provide assurance that potentially eligible patients in each system continue to have timely access to assessment and treatment
- update NHS England on the ICBs progress towards transition out of pandemic-specific arrangements, to more routine and local access for patients in the longer-term.

6.2 Key metrics

The key metrics to support implementation and improvement at national, regional and system level will be:

- Assessment uptake rate (by age bracket/gender/ethnicity/condition group)
- Triage outcomes (by age bracket/gender/ethnicity/condition group)
- Treatment uptake rate (by age bracket/gender/ethnicity/condition group)
- Time from symptom onset to treatment (adherence to clinical policy five day window)
- Hospitalisation rates: eligible population treated/not treated (by age bracket/gender/ethnicity/condition group)
- 28 day mortality rates: eligible population treated/not treated (by age

bracket/gender/ethnicity/condition group)

- Vaccination status of patients eligible/treated.

6.3 Responsibilities for recording and reporting data

During the transition period:

Treatment location	Data relating to digitally identified potentially eligible patients	Data relating to triage outcomes	Data relating to treatments planned / provided	Data relating to dispensing events from community pharmacy
Secondary or community care	No ICB / Provider requirements – automated data flow from NHS Digital.	ICB or provider record triage outcomes within Webview. Automated data flow from NHS Digital to NHS England.	Secondary or community care providers submit a Blueteq form for each treatment provided and ensure discharge summaries to primary care explicitly record the treatment that has been given, using the SNOMED codes described in the latest COVID-19 therapeutic alert , together with the dose and date of administration. Primary Care record treatments given in secondary and community care using the SNOMED codes described in the latest COVID-19 therapeutic alert .	N/A
Primary care (PC) or detained estate (DE) healthcare services	No ICB / PC / DE requirements – automated data flow from NHS Digital.	ICB / PC / DE record triage outcomes in Webview. Automated data flow from NHS Digital to NHS England.	PC / DE / ICB submit a Blueteq form for each treatment provided.	Community pharmacies report dispensed medicines to BSA in the usual way.

Post transition:

Treatment location	Data relating to digitally identified potentially eligible patients	Data relating to triage outcomes	Data relating to treatments provided	Data relating to dispensing events from community pharmacy
Secondary or community care	ICB led reporting requirements	ICB led reporting requirements	ICB led reporting requirements	N/A
Primary care or detained estate healthcare services	No ICB / PC / DE requirements – automated data flow from NHS Digital (GPES Extract).	PC / DE providers record assessment in patient record. Automated data flow from NHS Digital (GPES extract) to NHS England.	Primary Care / Detained Estate providers PC / DE providers record prescription of oral antiviral in the patient record. Appropriate SNOMED codes will be created to enable recording and monitoring.	Community pharmacies report dispensed medicines to BSA in the usual way.

Data monitoring

- Pseudonymised data relating to identification, triage and treatment of patients will be shared with NHS England for reporting purposes.
- Through the federated national data platform, NHS England will share a COVID-19 Antiviral and nMAB reporting dashboard at national, regional and ICB level with appropriate governance and restrictions in place at each level.
- Together with the national programme team within NHS England, ICB systems should monitor reporting for their area, reviewing general trends in activity levels, treatment uptake against clinical policy, impact of service improvement initiatives, and pathway demographic metrics.
- Systems should monitor the demographic data of those identified as potentially eligible for treatment, the treatment uptake rates, and triage outcomes to ensure access pathways are as inclusive as possible within their areas. Where variation in triage and uptake is identified, action should be taken to focus local efforts to improving awareness and understanding of the pathway and improve uptake rates as appropriate.

7. Roles and responsibilities

7.1 Integrated Care Boards

Integrate Care Boards are responsible for working with partners to determine and agree the most appropriate COVID-19 therapeutics service delivery model for their local population area. ICBs should:

- Work to ensure local service pathways meet the service requirements described in section 4.
- Commission targeted outreach services to support access for potentially eligible patients at most risk of health inequalities, see section 5
- Ensure any data reporting requirements are met, see section 6.
- Ensure local services are coproduced and codesigned with local partners.
- Assure and monitor the services are of high quality and ICBs use internal governance arrangements, such as Quality Committees and/or System Quality Groups, to monitor and assure the quality of services.

- Ensure sustainable and scalable services are in place ahead of transition, for ongoing access through routine pathways.

7.2 Healthcare professionals

There may be local variation in service delivery and therefore in the healthcare professional who provides each element of the COVID-19 therapeutics patient access pathway. All healthcare professionals involved in the provision of COVID-19 therapeutics should:

- Ensure they are familiar with the available COVID-19 therapeutic treatments and patient eligibility criteria, as described in the clinical policy.
- Understand their role in the triage, assessment, monitoring and treatment of patients, including which COVID-19 therapeutics they are authorised to prescribe.
- Understand how to access support for clinical decision making (e.g. specialist pharmacy service, local networks) including when and where to refer eligible patients into other services for assessment or treatment with COVID-19 therapeutics in line with their local patient access pathway.
- Undertake relevant training that is made available (including any COVID-19 therapeutics modules) and ensure clinical competencies for assessment and prescribing are regularly maintained and updated as new treatments are made available.
- 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.

7.3 Healthcare Providers

Healthcare providers should work with ICBs to provide services in line with the preferred delivery model for their local populations. This may include:

- Putting in place clear referral pathways and sources of specialist support and advice within and between neighboring organisations.
- Community pharmacy and/or hospital pharmacies should dispense and deliver oral antiviral medicines as soon as possible after receipt of prescription to meet the window of treatment efficacy.

- Community pharmacies and/or hospital pharmacies should ensure they can dispense oral antivirals as required to eligible patients or for collection by a patient representative
- Verbal advice and patient information leaflets for oral antiviral treatments should be provided at the point of dispensing.
- Clinicians and specialist teams in secondary and tertiary care setting should directly prescribe COVID-19 therapeutics to eligible patients within their care in line with the clinical policy when they present directly to them to avoid further referral onto a separate service.

7.4 National support

- Eligibility for treatment and the clinical access policy will be determined nationally by the UK Chief Medical Officers, based on clinical advice from an independent advisory group commissioned by the Department of Health and Social Care.
- Digitally identified highest risk patients will continue to be made aware of their potential eligibility by NHS England via letter or email.
- UKHSA will ensure these patients will receive lateral flow test kits in advance of them becoming symptomatic.
- NHS England and UKHSA will provide guidance on how other eligible patients can access COVID-19 lateral flow test kits when changes in eligibility criteria are made.
- NHS England will continue to support the identification of potentially eligible patients at the point of a positive COVID-19 test result with patients receiving a SMS text message and email advising them that they may be eligible for these treatments and will be contacted by their system led service.
- NHS England will continue to support services to proactively contact highest risk patients by listing potentially eligible patients in the WebView platform if the patient registers a positive COVID-19 test.
- NHS England, with DHSC and UK Government will be responsible for any associated national communications and public messaging to support patient awareness of eligibility.

8. Supporting Resources

[Higher-risk patients eligible for COVID-19 treatments: independent advisory group report - GOV.UK \(www.gov.uk\)](#) Department of Health and Social Care, May 2022.

[Academics: Viral evolution scenarios, 10 February 2022 - GOV.UK \(www.gov.uk\)](#) Scientific Advisory Group for Emergencies, February 2022

[Health Profile for England 2021 \(phe.org.uk\)](#). Public Health England, September 2021.

[Coverage and uptake of antivirals and neutralising monoclonal antibodies for the treatment of non-hospitalised patients with COVID-19](#). OpenSAFELY.

[NHS England » Core20PLUS5 – An approach to reducing health inequalities](#) NHS England

[NHS England » Working in partnership with people and communities: statutory guidance](#) NHS England, July 2022

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