NHS
North East London

Interim arrangements for the treatment of COVID-19 from 1st July 2023 – 1st October 2023 in North East London ICS

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Background

From the 1st April 2023, the commissioning responsibility for all COVID-19 treatments was transferred from NHS England to Integrated Care Boards (ICBs). NICE Multiple Technology Appraisal (MTA) Guidance TA878 – Casirivimab plus imdevimab (Ronapreve), nirmatrelvir plus ritonavir (Paxlovid), sotrovimab and tocilizumab for treating COVID-19 was published on 29th March 2023, providing positive recommendations for Paxlovid, sotrovimab and tocilizumab and a negative recommendation for Ronapreve. On 22nd June 2023,the NICE TA was further updated with a section with supporting information on risk factors for progression to severe COVID-19. This supporting information was provided by the independent advisory group commissioned by the Department of Health and Social Care.

The recommendations of the NICE MTA878 for Paxlovid, sotrovimab and tocilizumab were ratified by the North East London Integrated Medicines Optimisation Committee (NEL IMOC) for implementation across North East London.

Baracitinib does not have a licence for the use of treatment in COVID -19 and is therefore an off-label use. For this reason, it also meant it fell outside of the scope for the NICE MTA878 and could not be included in the recommendations. However, NHS England wrote to all ICB Medical Directors in April 2023 directing them to a template baracitinib policy in the treatment of patients hospitalised due to COVID-19.

Remdesivir and Molnupiravir were excluded from the NICE TA subject to an appeal from the manufacturing companies, however recommendations were also made in the NICE rapid guidelines. From the appeal hearing in May 2023, many elements of the appeal were upheld and the NICE appraisal committee have been asked to make further considerations before their final draft, hence the final publication will be further delayed.

Prepared by Lisa Boateng & Natalie Hollins in collaboration with NEL ICB, Barts Health NHS Trust, Homerton University Hospital, Barking Havering and Redbridge University Trust. August 2023

Interim Treatment pathway

An interim treatment pathway for patients across North East London who have COVID-19 is required. The interim pathway will include the treatment options available for (1) inpatients admitted to a Trust in North East London due to COVID-19, (2) hospital on-set of COVID-19 (no oxygen requirement) and (3) non-hospitalised patients across North East London. The interim pathway will include the use of baricitinib, as an off-label agent for COVID-19, and remdesivir and molnupiravir whilst awaiting the final NICE recommendations being published following the appeals process.

The treatment pathway will adhere to the recommendations set out in the interim Clinical Commissioning Policy: remdesevir and molnupiravir for non-hospitalised patients with COVID-19. This interim policy from NHS England provides guidance on the use of remdesevir and molnupiravir, alongside NICE guideline NG191 - COVID-19 rapid guideline: managing COVID-19, until the outcomes of the appeals are determined.

Inpatients

The following treatment pathways are being recommended for use in North East London.
Appendix one contains detailed information about the drug treatments.

(1) Inpatients' with severe COVID-19 who have been hospitalised in a North East London Hospital Trust:

- **All** +ve patients on O2 should receive corticosteroids

Further treatment options are based on the patients' individual clinical picture.

- Consider tocilizumab and / or baracitinib as per patient eligibility criteria
- Consider remdesevir for patients who are on low flow O2 as per patient eligibility criteria

Please note that patients may receive multiple therapies as indicated (see appendix 1).

(2) Patients with mild COVID-19 (nosocomial or community onset) in a North East London Trust for other conditions and not requiring supplemental oxygen:
First line: Paxlovid
Second line: Sotrovimab
Third line: Remdesivir
Fourth line: Molnupiravir

The following patients should be discussed with local COVID panel/specialist MDT.

1. **If treating clinicians wish to use drug outside of patient eligibility criteria**
2. **Patients with severe immunosuppression**
3. **Patients with persistent SARS-CoV-2 RNA detection +/- symptoms**

For all actions/decisions outside of the guidance these should be managed through Trust chairs actions.
(Sarilumab to be used only in the event of tocilizumab shortage.)

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Non-hospitalised patients

This interim treatment pathway for non-hospitalised patients will adhere to the recommendations set out in the interim Clinical Commissioning Policy: remdesevir and molnupiravir for non-hospitalised patients with COVID-19.

Appendix two contains detailed information about the drug treatments.

(1) Non-hospitalised patients across North East London

First line: Paxlovid
Second line: Sotrovimab
Third line: Remdesivir (where supply is available)
Fourth line: Molnupiravir

Acquisition of drugs

Pre-purchased Department of Health and Social Care (DHSC) stock will continue to be used until supplies are exhausted for all treatments. This stock continues to be available for Paxlovid, sotrovimab and molnupiravir. Tocilizumab, sarilumab and baricitinib are provided from NHS stock and will be cross charged to the ICB.
The usage for financial year 2022/23 is shown below with current prices to indicate possible maximum expenditure if the COVID drugs to the ICB.

Remdesivir pre-purchased DHSC stock has however been depleted.
Until the recommendations following the appeal to NICE have been released for the use remdesivir, the drug costs will be funded by the Trusts for inpatient treatments. Remdesivir is available at £358.88 + VAT per 100mg vial directly from Gilead.

Post Interim Projected Costs

The projected costs have been calculated from 2022/23 usage based on 2022/23 guidelines. However, the guidelines will be reviewed with the final NICE TA publication hence this may not reflect future costs. Usage is also likely to be lower for 2023/24 with increased overall immunity to COVID-19 through infection or vaccination though difficult to quantify.

Projected Cost Table
This table takes into account the pre-purchased DHSC stock, that is expected to cover for at least 6 months from 1st July 2023 – 1st October 2023.

	Barts Health no. of patients (2022/23)	BHRUT no. of patients (2022/23)	◊Homerton no. of patients (From December 2021)	Number of CMDU patients in 2022/23	Maximum Total number of Patients 1st April – 1st October	Unit cost with VAT	Projected cost for 1st April – 1st October 2023
Paxlovid 150 mg/100mg Tablets	499	21	17	94	631	£994.80	prepaid stock
Sotrovimab 500 mg in 8mL Infusion	551	1	0	52	604	£2,650.2	prepaid stock
*Tocilizumab 400mg in 20mL Infusion	53	32	16	0	50	£723.45	£36,172
**Baricitinib 2mg or 4mg tablets	Limited data				5	£184.10	£920
Molnupiravir 200 mg Capsules						no current price	prepaid stock
Remdesivir 100 mg Infusion powder					24	£430.59	£10,334
Total							**£47,426**

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*Tocilizumab 8mg per kg (calculation of cost is 400mg vial [£482.30] + 200mg vial [241.15])
Sarilumab will be used in the place of tocilizumab only. (Acquisition cost £728.58 per 175mg pair). Usage is predicted to be minimal

**Baricitinib 4mg x 28tablets = £460.27 (inclusive of VAT)
Calculation made for adult course only: 4mg once a day for 10 days = £184.10

◊Homerton data was provided from December 2021 to March 2023, therefore the projected costs for 2023/24 will be lower than stated above for Homerton hospital.

Data collection

The Trusts will continue to submit Blueteq forms for reporting purposes as an interim measure until a longer-term solution can be agreed for reporting with NEL ICB.

References

NICE NG191 Overview | COVID-19 rapid guideline: managing COVID-19 | Guidance | NICE
NICE MTA 878 for Paxlovid, sotrovimab, tocilizumab (positive recommendation) and Ronapreve (negative recommendation) Overview | Casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 | Guidance | NICE
NICE MTA Project information | Molnupiravir, remdesivir and tixagevimab plus cilgavimab for treating COVID-19 [ID6261] | Guidance | NICE
Rapid Policy Statement Interim Clinical Commissioning Policy: remdesivir and molnupiravir for nonhospitalised patients with COVID-19
Microsoft Word - PRN00453_Rapid Policy Statement - Interim Clinical Commissioning Policy - remdesivir and molnupiravir for non-hospitalised patients with COVID-19_May 2023 (england.nhs.uk)

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Appendix 1

Further information for Treatment COVID-19 hospitalised patients

Treatment of patients who have been hospitalised due to ACUTE COVID-19 illness management and require supplemental oxygen

Treatment	Corticosteroids All Patients requiring oxygen	Tocilizumab (IL6 inhibitors_ Anti-inflammatory) Adults only For patients with inflammatory symptoms CRP (>75) or respiratory support no concomitant infection No restriction on duration onset of symptoms	Remdesivir (Antiviral) Paediatrics and Adults Beneficial in early diagnosis (<7 days) Low flow oxygen only	Baricitinib Janus kinase (JAK) inhibitor_ Anti-inflammatory Unlicensed Use Paediatrics and Adults For patients with inflammatory respiratory support no concomitant infection No restriction on duration onset of symptoms
Eligibility criteria for treatment	Patient requires supplemental oxygen to meet their prescribed oxygen saturation levels **OR** Have a level of hypoxia that needs supplemental oxygen but who are unable to have or tolerate it **AND** There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients	• SARS-CoV-2 positive by diagnostic PCR on this hospital admission or MDT has high level of confidence that COVID-19 is most likely diagnosis **AND** • The patient has pneumonitis with saturations <92% on room air requiring: a) supplemental oxygen AND CRP ≥ 75 mg/L; **OR** b) requiring advanced respiratory support (HFNO, CPAP or other non-invasive ventilation or invasive mechanical ventilation) within the last 48 hours, regardless of CRP **AND**	• SARS-CoV-2 positive by diagnostic PCR on this hospital admission or MDT has high level of confidence that COVID-19 is most likely diagnosis **AND** • Have Covid19 pneumonia **AND** • Hospitalised and need low flow supplemental oxygen **AND** • Adults and paediatric patients (at least 4 weeks of age and weighing at least 3 kg) **AND**	• SARS-CoV-2 positive by diagnostic PCR on this hospital admission or MDT has high level of confidence that COVID-19 is most likely diagnosis **AND** • Viral pneumonia syndrome[2] is present **AND** • > 2 years of age[3] **AND** • Receiving supplemental oxygen or respiratory support (HFNO, CPAP or other non-invasive ventilation or invasive mechanical ventilation) for the treatment of COVID-19 **AND**

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		• > 18 years of age **AND** • Already receiving or has completed a course of dexamethasone or equivalent corticosteroid (*unless contra-indicated*) **AND** • Have not received an IL-6 inhibitor (tocilizumab, sarilumab) during this admission episode **AND** • The MDT is confident of a low probability of any active infection other than COVID-19 (consider checking procalcitonin). This includes bacterial superinfection such as HAP, UTI, cellulitis. **AND** • No known pre-existing condition or treatment resulting in ongoing immunosuppression **AND** • ALT/AST< 10 times upper limit of normal (caution with pre-existing liver disease) **AND**	• Within 7 days of symptom onset *(unless exempt)* **AND** • eGFR >30ml/min (use with caution if GFR <50ml/min) *OR* the patient is established on renal replacement therapy (haemo- or peritoneal dialysis) **AND** • ALT < 5 x ULN and NO history of chronic liver disease (Childs Pugh C) **AND** • ISARIC 4C score ≥ 4 **AND** • There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients	• Already receiving dexamethasone or an equivalent corticosteroid *(unless contraindicated)* **AND** • eGFR >15mL/min/1.73m^2 [if patient is <9 years, eGFR should be >30mL/min/1.73m^2] **AND** • Not receiving dialysis or haemofiltration **AND** • No history of severe hepatic disease **AND** • Absolute neutrophil count (ANC) >0.5 x 10^9 cells/L and haemoglobin >8g/dL **AND** • Patient does not have active tuberculosis **AND** • Patient is not pregnant or breastfeeding (*women of childbearing potential should use effective contraception during and for at least 1 week after treatment* **AND** • There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients

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Platelet count ≥ 50 x 10^9/L

AND

Neutrophil count ≥ 1 x 10^9/L (caution)

AND

There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients
Baricitinib may be considered in people who meet the above criteria, and who cannot have tocilizumab. When there is clinical deterioration despite treatment with tocilizumab, it may be appropriate to add baricitinib.

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<td></td>
<td>Baricitinib may be considered in people who meet the above criteria, and who cannot have tocilizumab. When there is clinical deterioration despite treatment with tocilizumab, it may be appropriate to add baricitinib.</td>
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<tr>
<td>Dose and treatment duration</td>
<td>Dexamethasone
PO 6mg OD or 6.6mg IV OD (if unable to tolerate PO)
OR
Prednisolone PO 40mg OD
OR
Hydrocortisone succinate IV 50mg TDS

Total treatment duration up to 10 days

Continue corticosteroids for up to 10 days unless there is a clear indication to stop early, which includes discharge from hospital or a hospital-</td>
<td>Tocilizumab:
Dosing based on weight and stock availability as per table

Total treatment duration: STAT dose ONLY</td>
<td>Remdesivir (adults and children >40kg)
200mg IV STAT dose on day 1, then 100mg IV OD for days 2 to 5

Total treatment duration: 5 days

For significantly immunocompromised patients a course of remdesivir can be extended to a maximum of 10 days
Refers to patients with a significant impairment of humoral immune response (antibody production) and/or cellular immune competence).</td>
<td>Baricitinib*
<table>
<tr><th></th><th>eGFR >60mL/min</th><th>eGFR ≥30 to <60 mL/min</th><th>eGFR 15 to <30mL/min</th></tr>
<tr><td>≥ 9 years old and adults</td><td>4mg OD</td><td>2mg OD</td><td>2mg on alternate days</td></tr>
<tr><td>Children 2 to <9 years old</td><td>2mg OD</td><td>2mg on alternate days</td><td>avoid</td></tr>
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	supervised virtual COVID ward.			*Co-administration of an Organic Anion Transporter 3 (OAT3) inhibitor with a strong inhibition potential e.g., probenecid – Dose reduced to Baricitinib PO 2mg OD Total treatment duration: **10 days** (or until discharge if sooner)
Approval form	No	Yes	Yes	Yes

Treatment of patients with symptomatic hospital onset COVID-19, who have been hospitalised for other conditions and contracted COVID-19 during their admission without requiring supplemental oxygen)

Treatment	**Paxlovid (nirmatrelvir plus ritonavir)** First Line	**Sotrovimab** Second line	**Remdesivir** Third line	**Molnupiravir** Fourth line
Eligibility criteria for treatment	• The patient does not need supplemental oxygen for COVID-19 **AND** • Confirmed by PCR OR lateral flow test. **AND** • Symptomatic with COVID-19 and showing no signs of clinical recovery. **AND** a) The patient is a member of a 'highest' risk group **OR** b) The COVID-19 infection presents a material risk of destabilising a pre-existing	• The patient does not need supplemental oxygen for COVID-19 **AND** • Confirmed by PCR OR lateral flow test. **AND** • Symptomatic with COVID-19 and showing no signs of clinical recovery **AND** a) The patient is a member of a 'highest' risk group **OR**	• The patient does not need supplemental oxygen for COVID-19 **AND** • Confirmed by PCR OR lateral flow test **AND** • Symptomatic with COVID-19 and showing no signs of clinical recovery **AND** a) The patient is a member of a 'highest' risk group **OR**	• The patient does not need supplemental oxygen for COVID-19 **AND** • Confirmed by PCR OR lateral flow test **AND** a) The patient is a member of a 'highest' risk group **OR** b) The COVID-19 infection presents a material risk of destabilising a pre-existing condition or illness or compromising recovery from surgery or other hospital

	condition or illness or compromising recovery from surgery or other hospital procedure (as determined by MDT assessment) **AND** • > 18 years of age **AND** • Treatment is commenced within 5 days of symptom onset[1] **AND** • No history of severe renal or liver disease. These patients require their treatment to be discussed with the responsible specialist clinical team. **AND** • Pregnancy has been excluded in women of childbearing age. Breast-feeding should be discontinued during treatment and for 7 days after last dose **AND** • Deemed safe after assessing potential drug interactions. Please note there are numerous significant drug interactions associated with Paxlovid. **AND**	b) The COVID-19 infection presents a material risk of destabilising a pre-existing condition or illness or compromising recovery from surgery or other hospital procedure (as determined by MDT assessment) **AND** • > 12 years of age and at least 40kg **AND** • Treatment with Paxlovid is contraindicated or not clinically suitable. **AND** • Treatment is delivered within 5 days of symptom onset[1] **AND** • Patient does not have a new supplemental oxygen requirement specifically for the management of COVID-19 **AND** • There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients	b) The COVID-19 infection presents a material risk of destabilising a pre-existing condition or illness or compromising recovery from surgery or other hospital procedure (as determined by MDT assessment) **AND** • Treatment is commenced within 7 days of symptom onset **AND** • Adults and children (BUT weighing at least 40kg) **AND** • Treatment with Paxlovid, and Sotrovimab, are both contraindicated or not clinically suitable **AND** • Patient does not require hospital-level care (i.e., Group 1) for the management of acute COVID-19* **AND** • Patient does not have a new supplemental oxygen requirement specifically for the management of COVID-19. **AND**	procedure (as determined by MDT assessment) **AND** • Treatment is commenced within 5 days of symptom onset **AND** • >18 years of age and not pregnant **AND** • Treatment with Paxlovid, Sotrovimab and Remdesivir are all contraindicated or not clinically suitable **AND** • There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients

	• Patient does not require hospital-level care for the management of acute COVID-19* **AND** • There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients, or drug interactions **If there are significant drug interactions present between Paxlovid and the patient's current medication regimen, please consider 2nd & 3rd line treatment options.** **If Paxlovid is the most appropriate treatment of choice, please contact the respective specialist team for further advice on the management of the drug interactions.**		• There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients **AND** • eGFR is >30ml/min, **OR** • Patient has end-stage renal failure and is on haemodialysis **AND** • ALT <5 times the upper limit of normal	
Dose and Treatment Duration	**Paxlovid (nirmatrelvir plus ritonavir)** **Patients with eGFR >60ml/min:** 300mg (2x150mg nirmatrelvir tabs) PO with 100mg (1x100mg ritonavir tab) PO BD for 5 days. **For patients with eGFR ≥30ml/min – 60ml/min**: 150mg (1x150mg nirmatrelvir tabs) PO with 100mg (1x100mg ritonavir) PO BD for 5 days Total treatment duration: **5 days**	**Sotrovimab: 500mg IV** Total treatment duration: **STAT dose ONLY**	**Remdesivir** 200mg IV STAT dose on day 1, then 100mg IV OD for days 2-3. Total treatment duration: **3 days**	**Molnupiravir** PO 800mg BD Total treatment duration: 5 **days**
Approval form	Yes	Yes	Yes	Yes

Appendix 2

Further information for Treatment COVID-19 non-hospitalised patients

Treatment of patients with non-hospitalised adults and children aged over 12 years and older with COVID-19, who are symptomatic

Treatment	Paxlovid (nirmatrelvir plus ritonavir) First Line	Sotrovimab Second line	Remdesivir Third line (where supply is available)	Molnupiravir Fourth line
Eligibility criteria for treatment	• The patient does not need supplemental oxygen for COVID-19 **AND** • Confirmed by PCR OR lateral flow test. **AND** • Symptomatic with COVID-19 and showing no signs of clinical recovery. **AND** a) The patient is a member of a 'highest' risk group **OR** b) The COVID-19 infection presents a material risk of destabilising a pre-existing condition or illness or compromising recovery from surgery or other hospital procedure (as determined by MDT assessment) **AND**	• The patient does not need supplemental oxygen for COVID-19 **AND** • Confirmed by PCR OR lateral flow test. **AND** • Symptomatic with COVID-19 and showing no signs of clinical recovery **AND** a) The patient is a member of a 'highest' risk group **OR** b) The COVID-19 infection presents a material risk of destabilising a pre-existing condition or illness or compromising recovery from surgery or other hospital procedure (as determined by MDT assessment) **AND**	• The patient does not need supplemental oxygen for COVID-19 **AND** • Confirmed by PCR OR lateral flow test **AND** • Symptomatic with COVID-19 and showing no signs of clinical recovery **AND** a) The patient is a member of a 'highest' risk group **OR** b) The COVID-19 infection presents a material risk of destabilising a pre-existing condition or illness or compromising recovery from surgery or other hospital procedure (as determined by MDT assessment) **AND**	• The patient does not need supplemental oxygen for COVID-19 **AND** • Confirmed by PCR OR lateral flow test **AND** a) The patient is a member of a 'highest' risk group **OR** b) The COVID-19 infection presents a material risk of destabilising a pre-existing condition or illness or compromising recovery from surgery or other hospital procedure (as determined by MDT assessment) **AND** • Treatment is commenced within 5 days of symptom onset

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	• > 18 years of age **AND** • Treatment is commenced within 5 days of symptom onset[1] **AND** • No history of severe renal or liver disease. These patients require their treatment to be discussed with the responsible specialist clinical team. **AND** • Pregnancy has been excluded in women of childbearing age. Breast-feeding should be discontinued during treatment and for 7 days after last dose **AND** • Deemed safe after assessing potential drug interactions. Please note there are numerous significant drug interactions associated with Paxlovid. **AND** • Patient does not require hospital-level care for the management of acute COVID-19* **AND**	• > 12 years of age and at least 40kg **AND** • Treatment with Paxlovid is contraindicated or not clinically suitable. **AND** • Treatment is delivered within 5 days of symptom onset[1] **AND** • Patient does not have a new supplemental oxygen requirement specifically for the management of COVID-19 **AND** • There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients	• Treatment is commenced within 7 days of symptom onset **AND** • Adults and children (BUT weighing at least 40kg) **AND** • Treatment with Paxlovid, and Sotrovimab, are both contraindicated or not clinically suitable **AND** • Patient does not require hospital-level care (i.e., Group 1) for the management of acute COVID-19* **AND** • Patient does not have a new supplemental oxygen requirement specifically for the management of COVID-19. **AND** • There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients **AND**	**AND** • >18 years of age and not pregnant **AND** • Treatment with Paxlovid, Sotrovimab and Remdesivir are all contraindicated or not clinically suitable **AND** • There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients

	• There are no drug contra-indications e.g., hypersensitivity to any active substances or excipients, or drug interactions **If there are significant drug interactions present between Paxlovid and the patient's current medication regimen, please consider 2nd & 3rd line treatment options.**		• eGFR is >30ml/min, **OR** • Patient has end-stage renal failure and is on haemodialysis **AND** • ALT <5 times the upper limit of normal	
Dose and Treatment Duration	**Paxlovid (nirmatrelvir plus ritonavir)** **Patients with eGFR >60ml/min:** 300mg (2x150mg nirmatrelvir tabs) PO with 100mg (1x100mg ritonavir tab) PO BD for 5 days. **For patients with eGFR ≥30ml/min – 60ml/min**: 150mg (1x150mg nirmatrelvir tabs) PO with 100mg (1x100mg ritonavir) PO BD for 5 days Total treatment duration: **5 days**	**Sotrovimab: 500mg IV** Total treatment duration: **STAT dose ONLY**	**Remdesivir** 200mg IV STAT dose on day 1, then 100mg IV OD for days 2-3. Total treatment duration: **3 days**	**Molnupiravir** PO 800mg BD Total treatment duration: 5 **days**