NHS
Greater Manchester
Integrated Care

23 June 2023

To: GP Practices
Community Pharmacy
Deputy Place Based Leads
Associate Medical Directors
Medical Directors – Acute Trusts
Medicines Optimisation Leads
Primary Care Leads

Dear colleagues

Re: Access to Covid Treatments – Confirmation of existing pathway/referral arrangements

I am writing to update you on the recent update to NICE guidance in respect of access to covid treatments and to confirm arrangements for NHS GM.

NICE have published guidance on use of antivirals/monoclonal antibodies on 29 March 2023 https://www.nice.org.uk/guidance/TA878/chapter/1-Recommendations (updated on June 2023). This guidance recommends use of nirmatrelvir plus ritonavir (Paxlovid, antiviral) and sotrovimab (Xevudy, monoclonal antibody, mNAb) for outpatient use by Covid Medicines Delivery Units, (CMDU). The new guidance also recommends an expansion the eligibility criteria for patients considered high risk.

All national digital infrastructure will be stood down on 26 June. Consequently, patients will no longer be digitally identified and matched following a reported positive test result. Patients will instead need to contact local NHS services to access assessment and treatment. NHSE has committed that those patients deemed at highest risk who can currently be digitally identified will receive a letter (by post or email) ahead of the 26 June asking them to contact local services should they test positive for COVID in the future.

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However, as we move out of the pandemic and levels of community infection are reducing, Integrated Care Boards will need to embed COVID treatments into long-term, sustainable pathways to ensure access for highest risk patients. For NHS GM, we have maintained our current provision and pathway, currently delivered by Manchester Foundation Trust. The pathway/service has been reviewed and updated to ensure compliance with the NICE guidelines. A GM working group has also been established to review arrangements and consider options for future delivery.

In the meantime, GPs and Specialists can refer patients by email to the Covid Medicine Delivery Unit mft.gm.cmdu@nhs.net. Additional information can be found in the attached appendices. A referral form which can be integrated with GP clinical systems will follow shortly however referrals can be made using appendix one.

Should you have any queries, please do not hesitate to contact either sara.roscoe@nhs.net, Commissioning Lead for the CMDU or the service direct at the e-mail address above.

Yours sincerely

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Chief Medical Officer

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Referral pathway for Covid-19 infection in Greater Manchester

Introduction:
Treatment for Covid-19 infection for non-hospitalised patients is recommended for patients who are deemed to be the very highest risk of an adverse COVID outcome, namely hospitalisation and death. When such patients contract Covid-19 infection, they need to be referred to the Covid Medicine Delivery Unit (CMDU) established in December 2021 which will triage, assess and treat these patients according to NICE recommendations.

Eligibility:
This would be as per the updated eligibility criteria defined by the Independent Advisory Group:

Higher-risk patients eligible for COVID-19 treatments: independent advisory group report (March 2023) - GOV.UK (www.gov.uk)

Please see Appendix for eligible conditions.

Referral pathway
GPs and Specialists can refer patients by email to the Covid Medicine Delivery Unit mft.gm.cmdu@nhs.net. This is a 7-day service operating from 9 am to 5 pm. It is important to refer patients as soon as possible as the treatment window is very narrow (first 5 days after symptom onset – extendable to 7 days in exceptional circumstances). It is also important that patients who are seriously unwell with Covid-19 infection are not referred to the CMDU and are instead directed to the emergency services for in-patient assessment and treatment. This pathway is appropriate for mild to moderate severity of infection. It would be helpful if the referring clinician can complete the attached proforma for referral which would help the CMDU in their assessment.

Patients can also approach NHS111 for onward referral to the CMDU.

CMDU Assessment
Adult patients are triaged on telephone by trained nurses to assess their eligibility, Symptom review and date of onset, Medical and medication history, Pregnancy risk and details of covid vaccination. Following this assessment, eligible and symptomatic patients are referred to the junior doctor who assesses the patient on the phone and reviews interactions with covid medicines. Patients whose symptoms continue to deteriorate or have significant symptoms are treated with NICE recommended medications. Oral Medication, if indicated, is delivered from either Wythenshawe Hospital pharmacy or Trafford drive-through pharmacy. Courier delivery option is available if the patient or their representative are not able to pick up the medications. We are currently looking at expanding the pharmacy options. Intravenous infusion, if indicated, is delivered in a dedicated side room in Manchester Royal Infirmary. Pulse oximeters are dispensed along with the treatment to patients who don't have them. Patients who are treated are discharged to local virtual covid wards for follow up.
Paediatric patients are referred to Paediatric Infectious Diseases Team at the Royal Manchester Children's Hospital who follow a similar triage, assessment and treatment pathway to adults.

Accessibility
Telephone interpreter services are used where necessary. CMDU staff are able to speak to carers if the patients are unable to communicate. Patients in care homes need to be referred by their GP.

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Appendix 1

Referral format

Name
Date of birth
NHS number
Contact Telephone number:
Eligibility condition(s) (see Appendix 2 for list of eligible conditions) –

Current medications:

Drug Allergies:

Date of Covid symptom onset:
Date of Covid test (LFT/PCR):
Covid Vaccination history:

Any other clinical information which would be helpful for the treating physician:

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Appendix 2

Groups of patients with highest risk of hospitalisation

Please follow this link for detailed explanation and helpful explanations:

Higher-risk patients eligible for COVID-19 treatments: independent advisory group report (March 2023) - GOV.UK (www.gov.uk)

Down's syndrome and other genetic disorders

All individuals with Down's Syndrome or other chromosomal disorders known to affect immune competence.

Solid cancer

- metastatic or locally advanced inoperable cancer
- lung cancer (at any stage)
- people receiving any chemotherapy (including antibody-drug conjugates), PI3K inhibitors or radiotherapy within 12 months
- people who have had cancer resected within 3 months and who received no adjuvant chemotherapy or radiotherapy
- people who have had cancer resected within 3 to 12 months and receiving no adjuvant chemotherapy or radiotherapy are expected to be at less risk (and thus less priority) but still at increased risk compared with the non-cancer populations

Haematological diseases and recipients of haematological stem cell transplant (HSCT)

- allogeneic HSCT recipients in the last 12 months or active graft versus host disease (GVHD) regardless of time from transplant (including HSCT for non-malignant diseases)
- autologous HSCT recipients in the last 12 months (including HSCT for non-malignant diseases)
- individuals with haematological malignancies who have received CAR-T cell therapy in the last 24 months, or until the lymphocyte count is within the normal range
- individuals with haematological malignancies receiving systemic anti-cancer treatment (SACT) within the last 12 months, or radiotherapy in the last 12 months
- all people who do not fit the criteria above, and are diagnosed with:
    - myeloma (excluding monoclonal gammopathy of undetermined significance (MGUS))
    - AL amyloidosis
    - chronic B-cell lymphoproliferative disorders (chronic lymphocytic leukaemia, follicular lymphoma)
    - myelodysplastic syndrome (MDS)
    - chronic myelomonocytic leukaemia (CMML)

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- myelofibrosis
- any mature T-cell malignancy

- all people with sickle cell disease
- people with thalassaemia or rare inherited anaemia with any of the following:
    - severe cardiac iron overload (T2 * less than 10ms)
    - severe to moderate iron overload (T2 * greater than or equal to 10ms) plus an additional co-morbidity of concern (for example, diabetes, chronic liver disease or severe hepatic iron load on MRI)
- individuals with non-malignant haematological disorders (for example, aplastic anaemia or paroxysmal nocturnal haemoglobinuria) receiving B-cell depleting systemic treatment (for example, anti-CD20, anti-thymocyte globulin (ATG) and alemtuzumab) within the last 12 months

Renal disease

- renal transplant recipients (including those with failed transplants within the past 12 months), particularly those who have:
    - received B cell depleting therapy within the past 12 months (including alemtuzumab, rituximab [anti-CD20], anti-thymocyte globulin)
    - an additional substantial risk factor which would in isolation make them eligible for monoclonals or oral antivirals
- non-transplant renal patients who have received a comparable level of immunosuppression[footnote 3]
- patients with chronic kidney stage (CKD) 4 or 5 (an estimated glomerular filtration rate (eGFR) less than 30ml per min per 1.73m^2) without immunosuppression

Liver diseases

- people with cirrhosis Child-Pugh (CP) class A,B and C, whether receiving immune suppressive therapy or not. Those with decompensated liver disease (CP B and C) are at greatest risk
- people with a liver transplant
- people with liver disease on immune suppressive therapy (including people with and without cirrhosis)

Solid organ transplant recipients

Solid organ transplant recipients not in any of the above categories.

Immune mediated inflammatory disorders

- people who have received a B-cell depleting therapy (anti-CD20 drug for example, rituximab, ocrelizumab, ofatumab, obinutuzumab) in the last 12 months.
- people who have been treated with cyclophosphamide (IV or oral) in the 6 months prior to positive PCR or relevant COVID test

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- people who are on corticosteroids (equivalent to greater than 10mg per day of prednisolone) for at least the 28 days prior to positive PCR
- people who are on current treatment with mycophenolate mofetil, oral tacrolimus, azathioprine, mercaptopurine (for major organ involvement such as kidney, gastro-intestinal tract, liver and/or interstitial lung disease), methotrexate (for interstitial lung disease or asthma[footnote 5] only) and/or ciclosporin. No minimum dose threshold is suggested[footnote 6]
- people who exhibit at least one of: (a) uncontrolled or clinically active disease (that is, required recent increase in dose or initiation of new immunosuppressive drug or IM steroid injection or course of oral steroids within the 3 months prior to positive PCR); and/or (b) other high risk comorbidities (for example, body mass index (BMI) greater than 30, diabetes mellitus, hypertension, major organ involvement such as significant kidney, liver or lung inflammation or significantly impaired renal, liver and/or lung function)

Respiratory

- asthma in people on oral corticosteroids (defined above). Any asthma patient taking immunosuppressants for their asthma including but not exclusively methotrexate, ciclosporin
- COPD on long term home non-invasive ventilation (NIV). Patients on long term oxygen therapy. People with moderate or severe disease (FEV1 greater than or equal to 50% predicted) who have required 4 or more courses of prednisolone 30mg for 5 days or greater in last 12 months
- interstitial lung disease (ILD) - all patients with idiopathic pulmonary fibrosis
- sub-types of ILD - for example, connective tissue disease related, sarcoidosis, hypersensitivity pneumonitis, NSIP (non specific interstitial pneumonia) who have received a B-cell depleting therapy in last 12 months, or IV or oral cyclophosphamide in the 6 months prior to testing positive for COVID-19. Any ILD patient on current treatment with corticosteroids, mycophenolate mofetil, azathioprine, tacrolimus, cyclosporin or methotrexate. No minimum dose criteria
- any people with any type of ILD who may not be on treatment due to intolerance but has severe disease with an FVC predicted less than 60%
- NIV - all patients requiring this type of support regardless of the underlying disorder (which might include COPD, obesity hypoventilation syndrome, scoliosis, bronchiectasis, genetic muscular diseases refer to neurology section)
- lung cancer patients, refer to ‘Solid cancer’ section above
- lung transplant patients (refer to solid organ transplant section)
- pulmonary hypertension (PH): groups 1 and 4 from PH classification

Immune deficiencies

- common variable immunodeficiency (CVID)
- undefined primary antibody deficiency on immunoglobulin (or eligible for Ig)
- hyper-IgM syndromes
- Good’s syndrome (thymoma plus B-cell deficiency)
- severe combined immunodeficiency (SCID)

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- autoimmune polyglandular syndromes or autoimmune polyendocrinopathy, candidiasis, ectodermal dystrophy (APECED syndrome)
- primary immunodeficiency associated with impaired type I interferon signalling
- x-linked agammaglobulinaemia (and other primary agammaglobulinaemias)
- any person with secondary immunodeficiency receiving, or eligible for, immunoglobulin replacement therapy

HIV/AIDS

- people with high levels of immune suppression, have uncontrolled or untreated HIV (high viral load) or present acutely with an AIDS defining diagnosis
- people on treatment for HIV with CD4 less than 350 cells per mm^3 and stable on HIV treatment or CD4 greater than 350 cells per mm^3 and additional risk factors (for example, age, diabetes, obesity, cardiovascular, liver or renal disease, homeless, alcoholic dependency)

Neurological disorders

- Conditions associated with neuromuscular respiratory failure requiring chronic ventilatory support:
    - motor neurone disease
    - Duchenne muscular dystrophy
- Conditions that require use of specific immunotherapies:
    - multiple sclerosis (MS)
    - myasthenia gravis (MG)
    - other immune mediated disorders
- Dementia and neurodegenerative disorders when associated with severe frailty:
    - Alzheimer's disease, vascular disease, Lewy body disease, or frontotemporal atrophy
    - Parkinson's Disease
    - Huntington's disease
    - progressive supranuclear palsy and multiple system atrophy

Box 2: pathway for LFT/PCR positive symptomatic cases aged older than 12 and younger than 18 years, greater than 40kg weight, and clinical concern

Children and young people (CYP) at substantial risk

Complex life-limiting neurodisability with recurrent respiratory infections or compromise.

CYP at significant risk if 2 or more of these risk factors are present

Primary immunodeficiency:

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- primary antibody deficiency on immunoglobulin (or eligible for immunoglobulin replacement)
- hyper-IgM syndromes
- Good's syndrome (thymoma plus B-cell deficiency)
- severe combined immunodeficiency (SCID)
- autoimmune polyglandular syndromes or autoimmune polyendocrinopathy, candidiasis, ectodermal dystrophy (APECED syndrome)
- primary immunodeficiency associated with impaired type I interferon signalling
- x-linked agammaglobulinaemia (and other primary agammaglobulinaemias)

Secondary immunodeficiency:

- HIV CD4 count less than 200 cells per mm^3
- solid organ transplant
- HSCT within 12 months, or with GVHD
- CAR-T therapy in last 24 months
- induction chemotherapy for acute lymphoblastic leukaemia (ALL), non-Hodgkin's lymphoma, chemotherapy for acute myeloid leukaemia (AML), relapsed and/or refractory leukaemia or lymphoma

Immunosuppressive treatment:

- chemotherapy within the last 3 months
- cyclophosphamide within the last 3 months
- corticosteroids greater than 2mg per kg per day for 28 days in last 4 weeks
- B cell depleting treatment in the last 12 months

Other conditions:

- high BMI (greater than 95th Centile)
- severe respiratory disease (for example, cystic fibrosis or bronchiectasis with FEV1 less than 60%)
- tracheostomy or long-term ventilation
- severe asthma (PICU admission in 12 months)
- neurodisability and/or neurodevelopmental disorders
- severe cardiac disease
- severe chronic kidney disease
- severe liver disease
- sickle cell disease or other severe haemoglobinopathy
- trisomy 21

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- complex or chromosomal genetic or metabolic conditions associated with significant comorbidity
- multiple congenital anomalies associated with significant comorbidity
- bronchopulmonary dysplasia - decisions should be made taking in to account degree of prematurity at birth and chronological age
- infants less than 1 year with congenital heart disease (CHD):
    - cyanotic congenital heart disease
    - haemodynamically significant acyanotic CHD and history of prematurity
    - those due for corrective surgery, to avoid complications or delay due to SARS-CoV-2 infection

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