Health and Social Care Board

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Sent via email:
To all GP Practices
GP Out of Hours Providers

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Dear Colleague,

INFORMATION ABOUT COVID-19 TREATMENTS – NEUTRALISING MONOCLONAL ANTIBODIES (nMAB) OR ANTIVIRALS FOR NON-HOSPITALISED PATIENTS WITH COVID-19.

The Board wrote to you on 17 December 2021, regarding the arrangements being put in place by local Trusts for high risk patients identified in the community to access nMAB or antiviral therapies. The highest risk cohorts are as defined in the Interim Clinical Policy developed by the Rapid C-19 policy expert group. A list of the cohort categories is attached to this letter for ease of reference.

Access to these treatments will be directly through Trust-provided, Outpatient COVID-19 Treatment Services (OCTs). A process has been put in place to centrally identify a database of patients potentially eligible for treatment. Dr Margaret O'Brien wrote to you separately outlining the use of GPIP in this regard and arrangements for those practices that do not supply data to GPIP.

Each day the database is matched against the list of patients identified as having a COVID positive test result and OCTs are notified accordingly in order that they may triage patients and administer treatment as appropriate.

General Practice or our-of-hours providers may be contacted by patients querying the availability of these therapies and I wanted to share some additional information on the steps you should take if a patient contacts you.

We have identified three possible reasons that patients may be in contact and the messages / actions required for each group:

1. *Patients who <u>do not</u> have a positive COVID diagnosis but who make contact regarding access to treatment.*

   Advice should be that the treatments are available only to those patients in the identified cohorts and who have a positive COVID diagnosis.

2. *Patients who <u>do</u> have a positive diagnosis of COVID and who have received a text message indicating that their local Trust will be in contact to assess eligibility for treatment*.

   All Trusts have indicated that patients will be contacted irrespective of whether the initial clinical triage suggests that treatment is or is not appropriate. There may be occasions when there is a delay in making contact e.g. at weekends or if the Trust clinician is unable to get through on the phone. It is anticipated that the occasions when contact is not made by the Trust will be rare.

   If you receive contact from a patient on this basis you should provide reassurance that the Trust will be in contact but that this might take a day or two – particularly over a weekend. If you have a particular concern about any patient in this category, Trusts can be contacted by e-mail or phone via the details set out in the Table 1 below. Access is best directed during scheduled hours as this is not an emergency arrangement.

3. *Patients who <u>do</u> have a positive diagnosis of COVID but who have not received a text message about their local Trust contacting them but who are of a view that they are eligible for treatment.*

   The process to centrally identify patients potentially eligible for treatment will be refined as processes develop. The database of patients will be updated regularly with a view to ensuring that as many patients as possible are included and identified for matching against the daily COVID positive test results.

   It will however be difficult to ensure total coverage and there may be occasions when patients with a positive COVID diagnosis but who have not been identified as being potentially eligible make contact with primary care. Again, such occasions should be rare, however, if they arise General Practice or out-of-hours are advised to consider the eligibility and exclusions criteria from the Interim Clinical Policy (see below) and if it is considered that the patient is potentially eligible, make contact via the dedicated inbox in the relevant Trust (set out in Table 1 below) to arrange for the patient to be considered for treatment. If you have a query regarding eligibility Trusts can be

contacted by phone via the details set out in the Table 1 below. Access is best directed during scheduled hours as this is not an emergency arrangement.

- **Eligibility criteria**

Patients must meet all of the eligibility criteria and none of the exclusion criteria. Pre-hospitalised patients are eligible to be considered if:

- SARS-CoV-2 infection is confirmed by polymerase chain reaction (PCR) testing within the last 5 days; AND
- Onset of symptoms of COVID-19 within the last 5 days; AND
- A member of a 'highest' risk group (as defined in Appendix 1 of NHS Clinical Commissioning Policy).

- **Exclusion criteria**

Patients are not eligible for nMAB treatment if they meet any of the following:

- Require hospitalisation for COVID-19; OR
- Require NEW supplemental oxygen specifically for the management of Covid19; OR
- Children weighing less than 40kg; OR
- Children aged under 12 years

Table 1 below set out the details for each Trust should you need to make contact regarding a patient.

Table 1

Trust	OCT Email Address	Phone Number
Belfast	ACCnMABS@belfasttrust.hscni.net	02896 155034
North	Outpatientcovidtreatment@northerntrust.hscni.net	02894 424000 ext 331361
South East	SETrust.CovidTreatment@setrust.hscni.net	02891 475116
Southern	urgent.centre@southerntrust.hscni.net	02837 560601
West	WHSCTrust.CovidTreatment@westerntrust.hscni.net	02871 610816

Please note that the Board is conscious that the preferred method of communication between primary and secondary care is via the clinical communications gateway (CCG). The arrangements above are intended as an interim approach pending discussions in the new-year on developing CCG arrangements.

Should you have a query with regard to this letter please contact your Practice Support Manager in the first instance.

Yours sincerely,

Louise McMahon
Director of Integrated Care

Cc
Sharon Gallagher
Aidan Dawson
Dr Stephen Bergin
PHA Duty Room
Dr Margaret O'Brien
Dr Windsor Murdock
Joe Brogan
Paul Cavanagh
Teresa Magirr
Paul Cunningham
Eddie Ritson
Linda McIlroy
Pat Brolly

Appendix 1: Patient cohorts considered at highest risk from COVID-19 and to be prioritised for treatment with nMABs

The following patient cohorts were determined by an independent advisory group commissioned by the Department of Health and Social Care (DHSC)[7].

Cohort	Description
Down's syndrome	All patients with Down's syndrome
Sickle cell disease	All patients with a diagnosis of sickle cell disease
Patients with a solid cancer	• Active metastatic cancer and active solid cancers (at any stage) • All patients receiving chemotherapy within the last 3 months • Patients receiving group B or C chemotherapy 3-12 months prior • Patients receiving radiotherapy within the last 6 months

Patients with a haematologic malignancy	• Allogeneic haematopoietic stem cell transplant (HSCT) recipients in the last 12 months or active graft vs host disease (GVHD) regardless of time from transplant
	• Autologous HSCT recipients in the last 12 months
	• Individuals with haematological malignancies who have
	  ○ received chimaeric antigen receptor (CAR)-T cell therapy in the last 24 months, or
	  ○ anti-CD20 monoclonal antibody therapy in the last 12 months
	• Individuals with chronic B-cell lymphoproliferative disorders receiving systemic treatment or radiotherapy within the last 3 months
	• Individuals with chronic B-cell lymphoproliferative disorders with hypogammaglobulinaemia or reduced peripheral B cell counts
	• Individuals with acute leukaemias and clinically aggressive lymphomas who are receiving chemotherapy or within 3 months of completion at the time of vaccination

[7] For paediatric/adolescent patients (aged 12-17 years inclusive), paediatric multi-disciplinary team (MDT) assessment should be used to determine clinical capacity to benefit from the treatment

	• Individuals with haematological malignancies who have received anti-CD38 monoclonal antibody or B-cell maturation agent (BCMA) targeted therapy in the last 6 months • Individuals with chronic B-cell lymphoproliferative disorders not otherwise described above

Patients with renal disease	• Renal transplant recipients (including those with failed transplants within the past 12 months), particularly those who:
	  ○ Received B cell depleting therapy within the past 12 months (including alemtuzumab, rituximab [anti-CD20], anti-thymocyte globulin)
	  ○ Have an additional substantial risk factor which would in isolation make them eligible for nMABs or oral antivirals
	  ○ Not been vaccinated prior to transplantation
	• Non-transplant patients who have received a comparable level of immunosuppression
	• Patients with chronic kidney stage (CKD) 4 or 5 (an eGFR less than 30 ml/min/1.73m2) without immunosuppression

Patients with liver disease	• Patients with cirrhosis Child's-Pugh class B and C (decompensated liver disease). • Patients with a liver transplant • Liver patients on immune suppressive therapy (including patients with and without liver cirrhosis) • Patients with cirrhosis Child's-Pugh class A who are not on immune suppressive therapy (compensated liver disease)
Patients with immune-mediated inflammatory disorders (IMID)	• IMID treated with rituximab or other B cell depleting therapy in the last 12 months • IMID with active/unstable disease on corticosteroids, cyclophosphamide, tacrolimus, cyclosporin or mycophenolate. • IMID with stable disease on either corticosteroids, cyclophosphamide, tacrolimus, cyclosporin or mycophenolate. • IMID patients with active/unstable disease including those on biological monotherapy and on combination biologicals with thiopurine or methotrexate
Primary 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)

	• Autoimmune polyglandular syndromes/autoimmune polyendocrinopathy, candidiasis, ectodermal dystrophy (APECED syndrome) • Primary immunodeficiency associated with impaired type I interferon signalling • X-linked agammaglobulinaemia (and other primary agammaglobulinaemias)
HIV/AIDS	• Patients with high levels of immune suppression, have uncontrolled/untreated HIV (high viral load) or present acutely with an AIDS defining diagnosis • On treatment for HIV with CD4 <350 cells/mm3 and stable on HIV treatment or CD4>350 cells/mm3 and additional risk factors (e.g. age, diabetes, obesity, cardiovascular, liver or renal disease, homeless, those with alcohol-dependence)
Solid organ transplant recipients	All recipients of solid organ transplants not otherwise specified above
Rare neurological conditions	• Multiple sclerosis • Motor neurone disease • Myasthenia gravis • Huntington's disease