Chief Medical Officer Directorate

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Registered care home providers (adults)
Copied to
Executive Nurse Directors and Community Nurse Directors
Chief Executives Local Authorities
Chief Officers Health and Social Care Partnerships
Chief Social Work Officers
Directors of Public Health
Scottish Care, CCPS, Care Inspectorate, COSLA

31 December 2021

Dear Colleague,

TARGETED DEPLOYMENT OF COVID-19 MEDICINES FOR NON-HOSPITALISED PATIENTS

This letter provides information, for awareness, on new treatment options, for selected groups of people with coronavirus who are thought to be at greater risk. To be most effective, these treatments need to be administered as soon as practically possible after receiving a positive PCR test and symptom onset. These treatments are in addition to vaccinations, which still remain the best way to protect everyone.

New Treatments

Neutralising monoclonal antibodies (nMABs) work by binding to the spike protein on the outside of the COVID-19 virus; this in turn prevents the virus from attaching to and entering human cells, so that it cannot replicate in the body. Neutralising monoclonal antibodies are typically administered by intravenous infusion.

Antivirals work by interfering with replication of the virus. They are most effective when administered early in infection by preventing progression to more severe, or even critical, symptoms. In November, the MHRA granted a conditional marketing authorisation to the first oral antiviral for COVID-19, molnupiravir. A treatment course is four capsules every 12 hours for 5 days.

Access Arrangements

As set out in more detail below, there are two access routes to receive COVID-19 community treatments this winter, both with different eligibility criteria and access arrangements.

Direct Access to COVID-19 Treatments for Eligible High Risk Individuals

Individuals identified as being at very high risk of deterioration, hospitalisation or death from COVID-19 will be able to access new COVID-19 therapies via the NHS.

Adults and children (aged 12 years and above) are eligible to be assessed for treatment if they;

- Have received a positive PCR test for COVID-19 in the last **five** days; and
- Have symptoms of COVID-19 that started in the last **five** days; and
- Are a member of one of the patient groups considered at high risk from coronavirus and with a clinical condition prioritised for treatment. The list of eligible conditions is set out at Appendix 1.

The list of eligible individuals was developed by an independent expert working group based on detailed clinical evidence and is designed to support targeting those higher risk patients who have the potential to both be least likely to generate a material immune response to vaccines and be at highest risk of disease progression, hospitalisation and death.

Each Health Board has established a single point of contact telephone number for eligible high-risk individuals to contact for an assessment of their suitability for treatment. The single point of contact telephone numbers for each health board can be found on NHS Inform (www.nhsinform.scot/covid19treatments) and are also set out in Appendix 2. Care home staff, or any healthcare professional responsible for care, may also contact this number on behalf of someone living in a care home to discuss suitability for treatment. Normal good practice around consent to treatment, taking capacity into consideration, and involving appropriate others such as welfare power of attorney, should take place.

If an individual is assessed as being eligible for treatment, this may involve travelling to a day clinic at a hospital to receive a monoclonal antibody treatment. Alternatively, an antiviral treatment to be taken orally may be recommneded instead.

PANORAMIC National Study

In parallel to the direct access arrangements for eligible high risk individuals, COVID-19 oral antivirals are being evaluated through a new national study called PANORAMIC, run by the University of Oxford. It is an open-label randomised control trial; 50% of patients will be randomised to receive an antiviral and 50% will receive the current standard of care. The national study will enable collection of additional data to address limitations in the company-sponsored trial, for example the effectiveness of the treatments in vaccinated patients. The participants in the company-sponsored clinical trial were unvaccinated.

The study is open to individuals who have received a positive PCR test for COVID-19 with symptoms of COVID-19 that started in the last five days; and are either aged 50+ years old ***or*** are aged 18-49 years old with an underlying medical condition that can increase the chance of having severe COVID-19.

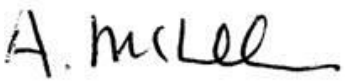
Patients are assessed remotely and where a patient is randomised to receive an oral antiviral, these will be home delivered via a central pharmacy. To participate, individuals will be asked to agree to complete a daily diary for 28 days, or receive a phone call from the trial team on days 7, 14 and 28 to discuss their symptoms. More information is available on the study website (www.panoramictrial.org).

Where an individual meets the eligibility criteria for both the national study and for direct access to COVID-19 treatments, they should be supported to access the direct access arrangements.

There is potential for the access arrangements to antivirals to be broadened in 2022, subject to the findings from the national study.

I hope this information is helpful and I would be grateful for your help in supporting residents to access these treatments in the event that they start experiencing symptoms and receive a positive PCR test. More information is available at: www.nhsinform.scot/covid19treatments

Yours sincerely,



Professor Gregor Smith	Professor Alex McMahon	Professor Alison Strath
Chief Medical Officer	**Chief Nursing Officer**	**Chief Pharmaceutical Officer**

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 Department of Health and Social Care (DHSC) commissioned group of clinical experts using the best available evidence on outcomes in COVID-19.

Cohort	Description
Down's syndrome	All patients with Down's syndrome
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 (cancer of the blood) and stem cell transplant recipients	• Allogeneic haematopoietic stem cell transplant (HSCT) recipients in the last 12 months or active graft vs 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 chimaeric antigen receptor (CAR)-T cell therapy in the last 24 months, or • radiotherapy in the last 6 monthsIndividuals with haematological malignancies receiving systemic anti-cancer treatment (SACT) within the last 12 months except patients with chronic phase chronic myeloid leukaemia (CML) in molecular response or first or second line tyrosine kinase inhibitors (TKI). • All patients with myeloma (excluding MGUS) or chronic B-cell lymphoproliferative disorders (e.g. chronic lymphocytic leukaemia, follicular lymphoma) or myelodysplastic syndrome (MDS) who do not fit the criteria above. • All patients with sickle cell disease. • Individuals with non-malignant haematological disorder (e.g. aplastic anaemia or paroxysmal nocturnal haemoglobinuria) receiving B-cell depleting systemic treatment (e.g. anti-CD20, anti-thymocyte globulin [ATG] and alemtzumab) within the last 12 months
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

***Group B chemotherapy (10-50% risk of grade 3/4 febrile neutropenia or lymphopenia):** • Etoposide based regimens • CMF • Irinotecan and Oxaliplatin based regimens • Cabazitaxel • Gemcitabine • Chlorambucil • Temozolomide • Daratumumab • Rituximab • Obinutuzumab • Pentostatin • Proteosome inhibitors • IMIDs • PI3Kinase inhibitors • BTK inhibitors • JAK inhibitors • Venetoclax • Trastuzumab-emtansine • Anthracycline-based regimens • Fluorouracil, epirubicin and cyclophosphamide (FEC) • Methotrexate, vinblastine, adriamycin/doxorubicin, cisplatin (MVAC) • Adriamycin/doxorubicin, bleomycin, vinblastine, dacarbazine (ABVD) • Cyclophosphamide, doxorubicin, vincristine, prednisolone (CHOP) • Bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine and prednisolone (BEACOPP) • Liposomal doxorubicin • Taxane – 3-weekly • Nab-paclitaxel • Carboplatin-based regimens • Ifosphamide-based regimens • Bendamustine • Cladrabine • Topotecan •Cyclophosphamide/Fludarabine combinations • Ifosphamide, carboplatin, etoposide (ICE) • Gemcitabine, dexamethasone, cisplatin (GDP) • Isatuximab • Polatuzumab • Acalabrutinib • Dexamethasone, cytarabine, cisplatin (DHAP) • Etoposide, methylprednisolone, cytarabine, cisplatin (ESHAP) • Cyclophosphamide, vincristine, doxorubicin, dexamethasone (CVAD) • Dacarbazine-based regimens • Lomustine • Magalizumab • Brentuximab vedotin • Asparaginase-based regimens

****Group C chemotherapy (>50% risk of grade 3/4 febrile neutropenia or lymphopenia):** • All acute myeloid leukaemia/acute lymphocytic regimens • Bleomycin, etoposide and platinum • Highly immunosuppressive chemotherapy (e.g. FluDAP, high dose Methotrexate & • Cytarabine) • Trifluradine/ Tipiracil • KTE-X19 • Gilteritinib

Ref: Interim Clinical Commissioning Policy: Neutralising monoclonal antibodies or antivirals for non-hospitalised patients with COVID-19 (24 December 2021)

Appendix 2: Board Single Points of Contact for Referral

The table below provides a single point of contact in each Health Board that individuals can contact following a positive PCR test result if they believe they meet the eligibility criteria. Lines may be operated as an answering machine and call-back service so must **not** be used for general queries or to seek urgent medical advice.

Health Board Area	Single Point of Contact
NHS Ayrshire & Arran	01563 825610
NHS Borders	01896 827015
NHS Dumfries & Galloway	01387 241959
NHS Fife	01592 729799
NHS Forth Valley	01786 434036
NHS Grampian	01224 553555
NHS Greater Glasgow & Clyde	0800 121 7072
NHS Highland	0800 085 1558
NHS Lanarkshire	01355 58 5145
NHS Lothian	0300 790 6769
NHS Orkney	01856 888259
NHS Shetland	01595 743393
NHS Tayside	01382 919477
NHS Western Isles	01851 601151