From the Chief Medical Officer
Professor Sir Michael McBride

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

Tel: 028 9052 0563
Email: Michael.McBride@health-ni.gov.uk

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FOR ACTION
Chief Executives, Public Health Agency/HSC Trusts/NIAS
Deputy Secretary SPPG
GP Medical Advisers, SPPG
All General Practitioners and GP Locums (for onward distribution to practice staff)
OOHs Medical Managers (for onward distribution to staff)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

COVID-19 THERAPEUTIC ALERT: ANTIVIRALS OR NEUTRALISING MONOCLONAL ANTIBODIES (nMABs) FOR NON HOSPITALISED PATIENTS WITH COVID-19

This letter supersedes HSS(MD) 12/2022

The published UK-wide interim clinical commissioning policy for use of antivirals or nMABs for non-hospitalised patients with COVID-19 has been updated, **effective from 13 June 2022**, to link to the published report of the Independent Advisory Group commissioned by the Department of Health and Social Care (DHSC) to advise on the groups of patients likely to be at highest risk of deterioration, hospitalisation or death from a COVID infection. The report confirms the groups of patients who are potentially eligible for community based COVID treatments under this policy. Clinicians are asked to note that figure 1 of the report refers to adults (aged 18 years and over) and figure 2 refers to children (aged 12-17 years).

The updated policy also now confirms that nirmatrelvir/ritonavir (Paxlovid) may be considered as a treatment choice for patients with stage 3 chronic kidney disease (CKD 3), subject to adequate arrangements for dose adjustment.

There are no other material changes to the policy.

Actions required

HSC Trusts commissioned to provide Outpatient COVID-19 Treatment Services (OCTs) are asked to:

1. **Consider prescribing an antiviral or neutralising monoclonal antibody to non-hospitalised patients eligible under the published policy, noting that the groups of adult and paediatric patients potentially eligible under the policy are defined within the published Independent Advisory Group report.**

   Children aged 12-17 years may only be considered for treatment with sotrovimab (as a licensed treatment option) or remdesivir (as an off-label use). 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.

2. Nirmatrelvir/ritonavir (Paxlovid), and molnupiravir, are **not recommended during pregnancy**. All individuals of childbearing potential who are prescribed molnupiravir should be advised to use effective contraception for the duration of treatment and for 4 days after the last dose of molnupiravir. The use of ritonavir may reduce the efficacy of combined hormonal contraceptives. Patients using combined hormonal contraceptives should be advised to use an effective alternative contraceptive method or an additional barrier method of contraception during treatment and until after one complete menstrual cycle after stopping nirmatrelvir/ritonavir (Paxlovid).

3. Ensure that any patients who receive a COVID antiviral while pregnant are advised to report to the UK COVID-19 antivirals in pregnancy registry on 0344 892 0909 (available 9:00am to 5:00pm, Monday to Friday, excluding bank holidays) so that they can be followed up. For more information, go to https://www.medicinesinpregnancy.org/COVID-19-Antivirals-Pregnancy-Registry/.

4. **Noting the important role of surveillance, treating clinicians are asked to support testing and/or data requirements as recommended under country specific or UK wide surveillance programmes, where laboratory capacity and resourcing allows.** Sequencing is an important part of surveillance activities to monitor for the development of new variants and drug resistance. Genotype results do not form part of the eligibility criteria for any treatment under this policy and treatment should not be delayed pending these results.

5. Ensure clinicians prescribing remdesivir for individuals aged 12-17 years, as an off-label product, follow HSC Trust governance procedures in relation to the prescribing of off-label medicines

   Further guidance on the prescribing of off-label medicines can be found below:

   - https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities

- https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines
- https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Prescribing%20competency%20framework/prescribing-competency-framework.pdf

6. Ensure adequate arrangements are in place to support dosing adjustment where nirmatrelvir/ritonavir (Paxlovid) is prescribed for patients with stage 3 chronic kidney disease (CKD 3). This will typically require dispensing pharmacies to remove tablets from packs and ensure clear explanatory advice is provided to the patient.

7. Discharge letters to primary care should explicitly record the treatment that has been given, together with the dose and date of administration.

8. Adhere to the guidance which has been developed by the Specialist Pharmacy Service (SPS) to support the administration of antivirals and monoclonal antibodies.

9. Provide regular updates on the stock position to HSC Trust Heads of Pharmacy and Medicines Management, pharmacy procurement leads and the Regional Pharmaceutical Procurement Service. Hospitals should enter the product onto stock control and prescribing systems as described below:

    - Paxlovid, nirmatrelvir (150mg tablets) plus ritonavir (100mg tablets), 30 tablet pack
    - Remdesivir 100mg powder for concentrate for solution for infusion
    - Sotrovimab 500mg/8ml solution for infusion vials
    - Molnupiravir 200mg capsules, 40 capsules

The Strategic Planning and Performance Group is asked to:

10. Continue to work with HSC Trusts and the Regional Pharmaceutical Procurement Service to monitor uptake of treatment, pending consideration for routine commissioning in line with extant Managed Entry arrangements.

Summary

The published policy has been updated, effective from **13 June 2022**, to link to the published report of the Independent Advisory Group commissioned by the Department of Health and Social Care (DHSC) to advise on the groups of patients most likely to be at highest risk of deterioration, hospitalisation or death from a COVID infection. The report confirms the groups of patients who are potentially eligible for community based COVID treatments under this policy. Clinicians are asked to note that figure 1 of the report refers to adults (aged 18 years and over) and figure 2 refers to children (aged 12-17 years).

Revised advice is also now provided to confirm that nirmatrelvir/ritonavir (Paxlovid) may be considered for individuals with stage 3 chronic kidney disease (CKD 3) **subject to the prescribing clinician being assured that the necessary dosing adjustment can be managed safely.**

There are no other material changes to the policy.

In summary, available treatment options under the policy for eligible patients are:

- First-line: nirmatrelvir/ritonavir (Paxlovid), (antiviral) OR sotrovimab (neutralising monoclonal antibody (nMAB)), as clinically indicated
- Second-line: remdesivir (antiviral)
- Third-line: molnupiravir (antiviral)

Non-hospitalised patients are eligible for treatment under the policy with any one of the four medicines if:

- SARS-CoV-2 infection is confirmed by either:
    - Lateral flow test (registered via gov.uk or NHS 119)

    OR

    - Polymerase chain reaction (PCR) testing

  AND

- They are symptomatic with COVID-19 and are showing no signs of clinical recovery

  AND

- The patient is a member of a 'highest' risk group (as defined in the Department of Health and Social Care commissioned Independent Advisory Group Report)

Further details, including medicine specific guidance, may be found in the clinical policy. Further information on selecting the most appropriate treatment can be found in the accompanying clinical guide.

Co-Administration

For further information please visit the University of Liverpool COVID-19 Drug Interactions website (https://www.covid19-druginteractions.org/checker).

Monitoring, tracking and follow-up

All handovers of clinical care (including between hospitals if patients are transferred, between levels of care and clinical teams within hospitals, and between hospitals and primary care) should explicitly record that an antiviral or monoclonal antibody has been given, together with the dose and date of administration.

Healthcare professionals are asked to 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

Further enquiries should in the first instance be directed to your hospital pharmacy team

Yours sincerely

PROFESSOR SIR MICHAEL McBRIDE
Chief Medical Officer

MRS CATHY HARRISON
Chief Pharmaceutical Officer

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