Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 1
From:	Sir Frank Atherton, Chief Medical Officer
Date:	1 June 2022
Reference:	CEM/CMO/2022/010
Category:	Immediate (cascade within 6 hours)
Title:	Updated clinical policy- Antivirals or Neutralising Antibodies for Non-Hospitalised Patients with COVID-19
What is this about:	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 non-hospitalised patients who are potentially eligible for COVID treatments under this policy.
Why has it been sent:	**For your awareness and to aid signposting patients appropriately**

Antivirals or Neutralising Antibodies for Non-Hospitalised Patients with COVID-19

Dear Colleagues,

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 non-hospitalised patients who are potentially eligible for 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 (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:

o Lateral flow test (registered via gov.uk or NHS 119)

OR

o 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.

Action

Health Boards 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, 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.

3. Ensure that any patients who receive a COVID antiviral while pregnant are reported 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 local 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/resources/frameworks/prescribing-competency-framework/competency-framework

6. Ensure adequate arrangements are in place to support dosing adjustment where nirmatrelvir/ritonavir 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. Ensure discharge letters to primary care 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 or monoclonal antibodies.

9. Provide regular stock updates to the nationalprocurement lead pharmacist. Providers should enter the products 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

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.

Enquiries

Enquiries should in the first instance be directed to the health board's Chief Pharmacist who will escalate issues to the Pharmacy and Prescribing Team at Welsh Government if required. Enquiries to the Welsh Government should be directed to: COVID-19.Pharmacy.Prescribing@gov.wales.

Yours sincerely

SIR FRANK ATHERTON

Appendix 1:

To: NHS Wales Shared Services Partnership to forward to:

All General Practitioners - please ensure this message is seen by all practice nurses and non-principals working in your practice and retain a copy in your 'locum information pack'.
All Community Pharmacists
Deputising services
HB Chief Pharmacists
HB Prescribing Advisers
Independent/Private clinics and Hospitals and Hospices throughout Wales

To: Health Boards and NHS Trusts:

Chief Executives
Medical Directors
Nurse Directors
Directors of Public Health
Hospital Principals and Chief Pharmacists
Onward distribution to:
Immunisation Leads,
Infectious Disease Departments
Acute medical units
Microbiologists

To: Public Health Wales:

Chief Executive
Director of Public Health Services
Consultants in Communicable Disease Control
Microbiologists
Consultant Epidemiologists
Vaccine Preventable Disease Programme

Cc:

NHS Direct Wales
British Medical Association
Royal College of GPs
Royal College of Nursing
Royal College of Midwives
Royal Pharmaceutical Society
Community Pharmacy Wales
Royal College of Paediatrics and Child Health Wales