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8th July 2022

Circular 020/22

Re: Update from Medicines Management Programme -Paxlovid™ (PF-07321332 + ritonavir)

Dear Doctor,

Please find enclosed update from the Medicines Management Programme on **Paxlovid™** as approved by Dr Colm Henry, Chief Clinical Officer of the HSE.

Information for patients and the public is available on the HSE website: https://www2.hse.ie/conditions/paxlovid/.

Yours faithfully,

Shaun Flanagan
Primary Care Reimbursement Service

Re: Paxlovid™ (PF-07321332 + ritonavir)

8th July 2022

Dear Colleagues,

As you are aware, Paxlovid™ (PF-07321332+ritonavir) became available for use in Ireland, in specific circumstances in April 2022 (later referred to as Paxlovid™).

The purpose of this correspondence is to update you on two additional recommendations from the HSE COVID-19 Therapeutic Advisory group (TAG) and HSE clinical prioritisation subgroup due to the current high levels of community transmission of COVID-19:

1. **changes to the testing requirements to confirm a positive diagnosis of COVID-19 infection prior to consideration of prescribing Paxlovid™ and**
2. **the inclusion of an additional patient tier (Tier 3) where Paxlovid™ use is now recommended.**

As outlined in my previous correspondence, patients should have COVID-19 confirmed with a positive PCR. However, during periods of high levels of community transmission of COVID-19, as we are currently experiencing, **a positive self-administered antigen test** is considered sufficient for consideration of prescribing Paxlovid™, in a patient who the GP considers to be at high risk, following clinical assessment.

The HSE COVID-19 TAG has now also recommended the use of Paxlovid™ for:

- **Vaccinated adult patients at high risk of severe disease (adults aged over 75 years or adults aged over 65 years with additional risks*).** Vaccinated adult patients in this tier, who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation should be prioritised for treatment. (Please refer to Tier 3 as defined in Appendix 2 of the HSE Interim Guidance for the Pharmacological Management of Patients with COVID-19 v4.1 (later referred to as HSE Interim Guidance)

* Additional risks include obesity (BMI over 35), diabetes mellitus, hypertension, cardiovascular disease, chronic lung disease as defined in Appendix 2 of the HSE Interim Guidance

Please note, the HSE Interim Guidance v4.1 (currently available at the above link) is being updated to reflect these changes, but this letter is being issued in advance of these published updates due to the time sensitive nature of the information.

This change is in addition to the patient tiers that the HSE COVID-19 TAG previously recommended the use of Paxlovid™ for:

- unvaccinated adult patients at risk of progressing to severe COVID-19 infection not requiring supplemental oxygen (Tier 1 and Tier 2 as defined in Appendix 2 of the HSE Interim Guidance) or
- immunocompromised adult patients at risk of progressing to severe COVID-19 infection not requiring supplemental oxygen who, despite vaccination, are unlikely to have generated protective immunity (Tier 1 as defined in Appendix 2 and 3 of the HSE Interim Guidance).

In response to enquiries received, I would also like to outline details in relation to the prescribing of Paxlovid™.

Prescriptions for Paxlovid™ should be sent by *Healthmail* to the community pharmacy of the patient's choice. Until practice IT systems have been updated, a prescription for Paxlovid™ may need to be typed or written manually and scanned, including all patient and prescriber details and identifiers.

On receipt of a prescription, the community pharmacy will order Paxlovid™ from the wholesaler. If the product is ordered by 5pm, it will be delivered to the community pharmacy by 5pm the next day. Pharmacies will not hold a stock of Paxlovid™. There is a weekend/bank holiday ordering service available for pharmacies; for information in relation to weekend/bank holiday deliveries the community pharmacy should be contacted.

To facilitate monitoring and stewardship of Paxlovid™ in the Irish context, the HSE-Medicines Management Programme (MMP) has been requested to gather outcome data following the use of Paxlovid™. In the coming weeks, the MMP will be contacting an initial sample of prescribers for data relating to patients where Paxlovid™ was dispensed in the community setting.

I would also like to remind you of the drug-drug interactions associated with this medicine. Paxlovid™ is a potent inhibitor of cytochrome P450 3A (CYP3A) due to ritonavir and may lead to an increase in the plasma concentration of a wide range of commonly prescribed medicines. Due to the risk of drug-drug interactions a full review of patient medication history and interaction risk is required prior to initiating a prescription. More detailed information on prescribing issues, particularly drug-drug interactions is outlined in my previous correspondence Circular 012/22.

If a GP wishes to avail of assistance specifically relating to the potential for drug-drug interactions associated with Paxlovid™, the National Medicines Information Centre (NMIC) is available through their enquiry answering service. Drug-drug interaction enquiries should be emailed to the NMIC (nmic@stjames.ie) via secure email (e.g. Healthmail) with the patient's list of current medicines using the NMIC Template which is available on the HSE-MMP's website; please provide your telephone contact number on the form.

Full prescribing information is available in the Summary of Product Characteristics for Paxlovid™ (PF-07321332+ritonavir) and additional information is available in previous correspondence issued - Circular 012/22 and Circular 014/22.

With best wishes,

Michael Barry.

Professor Michael Barry, National Clinical Lead, Medicines Management Programme www.hse.ie/yourmedicines