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Clinical Programme Implementation &
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Date: 25th November 2022

Circular Number: NCO-18-2022

Dear Doctor,

As you will be aware the Public Health approach to the management of COVID 19 is now moving from a response based on extensive case finding and tracing of infection to reduce transmission towards a response focused on mitigation of the severe impacts of COVID-19 for those most vulnerable to the disease, and those with risk factors who may benefit from specific interventions. In line with this approach COVID 19 will be managed in a similar way to other respiratory diseases, however as wide spread testing of the population ceases there will be a continued strengthening of public health capacity in respect to disease surveillance, modelling and biostatistical analysis. Capacity will be maintained to respond to any increase in confirmed cases through a surge response plan that will see the National Ambulance Service providing additional testing capacity, and an emergency response plan that will scale up testing and tracing teams.

Cessation of certain fees introduced as an emergency measure in March 2020

As the strategy for managing COVID is now shifting to the mitigation phase, and in line with Government policy it is our intention to discontinue those fees, which was introduced as an emergency measure in March 2020. The discontinuation of the fees as set out below will take place on the 9th of December 2022 (ie the last eligible consultations will take place on Thursday 8th December).

- The payment of €30 for remote consultation for assessment and referral for testing will cease from 9th December 2022
- The payment of €75 for COVID respiratory clinics will cease from 9th December 2022

As the strategy for managing of COVID 19 is now moving to mitigation phase in line with Government policy the Department of Health have confirmed that this change will mean that patients accessing GP services on a private basis will no longer have their consultations paid for by the State and will revert to the normal private fee arrangements with their GPs. Standard arrangements will also apply in respect of patients holding Medical or GP Visit cards.

Ongoing GP Supports in relation to Novel Therapeutic Agents – Paxlovid

Within the new model, General practice will continue to play a valuable clinical role, including assessing the suitability of patients who are in one of the relevant risk groups (as outlined hereunder) for prescribing of a course of Paxlovid anti-viral medication in context of treating COVID-19 infection. Testing will only occur based on a clinical assessment where a clinician requires the result to contribute to the diagnosis and management of an individual patient

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Treatment for COVID-19 is currently recommended for people who are at the highest risk of becoming seriously ill from COVID-19.

The following patient groups have been identified as at the highest risk from COVID-19:

- are immunocompromised and have a weak immune system
- have not been fully vaccinated and are aged 65 or over
- have not been fully vaccinated and have additional risk factors

Patients may also be considered for Paxlovid if they are:

- vaccinated and aged 75 or over
- vaccinated and aged 65 or over with additional risk factors

I am attaching correspondence from CCO dated June 2022 previously circulated which includes a link to summary guidance and a decision making aid that is available to assist prescribers in determining eligibility and suitability for treatment with Paxlovid. Full guidance can be found in the *HSE Interim Guidance for the Pharmacological Management of Patients with COVID-19,* at the following link:

https://www.hse.ie/eng/about/who/acute-hospitals-division/drugs-management-programme/hse-interim-guidance-for-the-pharmacological-management-of-patients-hospitalised-with-covid-19.pdf

The HSE and the Department of Health acknowledge the valuable role that General Practice has and will continue to have in relation to the above cohort of patients in determining whether to prescribe Paxlovid, where clinically appropriate, prescribing same and monitoring the population of patients who are prescribed Paxlovid for the duration of their treatment with it. When the therapeutic initiative was commenced earlier this year interim arrangements were agreed which allowed time to learn and adapt to the new therapies. Now, as the arrangements are well established it is intended to put matters on a firm footing and to formalise the fee arrangements as follows:

Approval has been received from the Department of Health to introduce a new fee in respect of vulnerable patients who are being assessed to determine if they would benefit from the prescription of COVID antiviral medicines. Patients in respect of whom this fee will be paid will be identified in line with HSE guidelines (referenced earlier). The fee will be set at €55 and will commence on Friday 9th December 2022. The code to be used for these claims is CP. Claims prior to this date under the previous interim arrangements can also be claimed using the same code CP. The fee may only be claimed in respect of patients which fall into the relevant risk groups (as outlined above). The fees above are composite fees and no other claims or fees (including those under the General Medical Services Scheme) apply in respect of services provided under this scheme.

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In line with established practices, and for the relevant patients only, the GP can assess and consult on the prescribing of Paxlovid. Either a PCR or Antigen (including self-administered) test can be used in making that clinical decision.

To support General Practitioners in the assessment and diagnosis of patients within the relevant risk groups, in line with the *HSE Interim Guidance for the Pharmacological Management of Patients with COVID-19*, a supply of both PCR test kits and Rapid Antigen Test kits will be made available to order via the DMS system as per the current PPE ordering portal. The PCR kits will include all the required packaging for sample transport, and completed samples should be sent to the local hospital through existing local arrangements for sample transportation, from where they will be collected and brought to the NVRL.

Where a PCR test has been carried out, this should be entered by the GP into Healthlink through an amended version of the current referral process (to be advised at a later date). PCR test results will be returned to the GP through Healthlink, as per the current process, and to the individual by SMS.

Further guidance on ordering, packaging and recording PCR tests will be made available to GP practices. For any queries relating to any aspect of the service, GPs will be able to contact a dedicated support line on 1800 807113.

I would like once again to express the sincere gratitude of the HSE to General Practitioners and their teams for their contribution to date and continued support in the management of COVID-19.

Yours sincerely,

Pat Healy
National Director
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BY EMAIL ONLY

Date: 22nd June 2022

Re: Therapeutic Agents for COVID-19

Dear Colleagues,

We have recently seen a sharp rise in the number of COVID-19 cases and this has been accompanied by an increase in the number of hospital cases. You will be aware that we have had a number of novel therapeutic agents become available for treatment of COVID-19 over the last number of months, including Paxlovid™. I would encourage you to make the best use of this therapeutic agent in protecting those most at risk of severe disease and improving their outcomes in the event that they acquire COVID-19. I would also like to remind you of the clinical pathways and the resources available to you to support the appropriate prescribing of this therapeutic.

Clinical Guidance and Eligibility Criteria

The Therapeutic Advisory Group (TAG) have developed clinical guidance for the currently available COVID-19 therapeutic agents including, but not limited to, Paxlovid™. This letter relates to use of Paxlovid™.

The HSE COVID-19 TAG recommend the use of Paxlovid™ for:

(a) ***unvaccinated adult patients*** at risk of progressing to severe COVID-19 infection (Tier 1 and Tier 2 as defined in Appendix 2 of the **'HSE Interim Guidance for the Pharmacological Management of Patients with COVID-19' v4.1**), *i.e. those over 65 or those under 65 with additional risk factors*

(b) ***immunocompromised adult patients*** at risk of progressing to severe COVID-19 infection who, despite vaccination, are unlikely to have protective immunity (Tier 1 as defined in Appendix 2 and 3 of the 'HSE Interim Guidance for the Pharmacological Management of Patients with COVID-19' **v4.1**).

To be considered for treatment with Paxlovid™, patients should have their COVID-19 diagnosis confirmed (PCR test, or professionally administered, HSE-supplied antigen test) **within the last 5 days** and also have symptom onset within the past 5 days.

Clinical Pathways

There are two pathways established for the prescribing oral anti-viral Paxlovid™;

1. Community pathway
   Paxlovid™ is available for GPs to prescribe for community patients who do not require admission to hospital. In the case of community patients, dispensing of Paxlovid™ occurs in community pharmacies. On receipt of a prescription, the community pharmacy will order directly from the wholesaler. If the product is ordered by 4pm, it will be delivered before 5pm the next day. Pharmacies will not hold a stock of the medicine. This time needs to be considered in planning patient care to get first dose taken within 5 days of symptom onset.
2. Hospital inpatient pathway
   Paxlovid™ may also be prescribed by hospital clinicians. In the case of in-patients, it will be dispensed by the hospital pharmacy. In the case of community patients (including where the hospital clinicians have been contacted directly by those usually under their care), dispensing of

Paxlovid™ occurs in the community pharmacy local to the patient to which the prescription will have been sent directly.

Prescribing supports and resources available

As part of the rollout of operational pathways associated with the availability of Paxlovid™ a number of resources were made available to prescribers including;

1. A summary guidance and a decision making aid that is available to assist prescribers in determining eligibility and suitability for treatment with Paxlovid™. This can be found in 'Interim Guidance - Treatment for Covid-19 Infection with Paxlovid™ '.

2. The National Medicines Information Centre (NMIC) issued a letter when Paxlovid™ first became available to update GPs on the imminent availability of the COVID-19 antiviral treatment Paxlovid™ and to highlight prescribing issues (particularly drug-drug interactions) associated with this medicine, this is a useful resource for prescribers and is available here.

3. The NMIC is also available to assist prescribers with drug-drug interaction enquiries specific to the prescribing of Paxlovid™. The support service builds on the NMIC's current model; which is an established, trusted and robust source for medicines information. The NMIC enquiry service is available Monday-Friday 9.00am – 5.00pm and a weekend service will be available for email enquiries specific to Paxlovid™ from 10.00am – 1.00pm on Saturday and Sunday (and bank holidays) from April 11th 2022. The full details of this service and links to the relevant templates can be found in 'Interim Guidance - Treatment for Covid-19 Infection with Paxlovid™'. The HSE is recommending that when GPs seek support from NMIC that they copy in the patient's pharmacy so that all involved can be provided with relevant information.

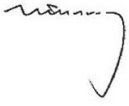
Patient Engagement

Due to the risk of drug-drug interactions with Paxlovid™ work is ongoing with advocacy and patient groups to support patients in compiling a list of their medications to support any prescribing discussions. There is also information available for the public and patients regarding Paxlovid™ on the HSE website.

Conclusion

We now have access to medication for those most at risk of severe COVID-19 and I thank you for your continuing support as these therapeutics have been rolled out in recent months. Current trends show a sharp rise in hospitalisations with those who are unvaccinated or who have not received their booster disproportionately represented. There are a number of resources and supports available to prescribers to support the appropriate prescribing of Paxlovid™ and I would encourage you to utilise them so that Paxlovid™ is made available to eligible patients.

Yours sincerely



Dr Colm Henry
Chief Clinical Officer