PAXLOVID® (PF-07321332 (nirmatrelvir)/ritonavir) Guidance for Adult Hospitalised COVID-19 Patients

NHS Tayside

FOR ALL INPATIENTS ELIGIBILITY ASSESSMENT MUST BE COMPLETED

CONSIDER PAXLOVID in hospitalised patients if ALL the following criteria apply:

- ✓ SARS-CoV-2 infection is confirmed by polymerase chain reaction (PCR) testing or lateral flow test (LFT)
- ✓ Onset of symptoms* of COVID-19 within the last 5 days (off label extension up to a maximum of 7 days if clinically indicated)
  (*feverish, chills, sore throat, cough, shortness of breath or difficulty breathing, nausea, vomiting diarrhoea, headache, red or watery eyes, body aches, loss of taste or smell, fatigue, loss of appetite, confusion, dizziness, pressure or tight chest, chest pain, stomach ache, rash, sneezing, sputum or phlegm, runny nose)
- ✓ Hospitalised for indication other than management of acute symptoms of COVID-19 and is not requiring new supplemental oxygen specifically for management of COVID-19 symptoms
- ✓ Patient showing no evidence of clinical recovery
- ✓ A member of a 'highest' risk group (as defined on previous page)
- ✓ Aged 18 or older
- ✓ Patient does not have a history of advanced decompensated liver cirrhosis
- ✓ Patient is not pregnant and not at risk of pregnancy
- ✓ Patient has been deemed safe for Paxlovid treatment after pharmacist review of potential drug interactions/dose adjustments and discussion with patient specialty team as necessary
- ✓ No known hypersensitivity reaction to the active substance or to any of the excipients

CONSIDER THE FOLLOWING CAUTIONS: See SmPC for more details.

- **Drug interactions:** which may lead to:
  - severe, life threatening or fatal events from greater exposures of concomitant medicines
  - clinically significant adverse reactions from greater exposure to Paxlovid
  - loss of therapeutic effect for Paxlovid and possible development of viral resistance
- **Hepatic disease:** liver enzyme elevations, clinical hepatitis and jaundice have occurred in patients receiving ritonavir. Caution should be exercised when administering Paxlovid in patients with pre-existing liver diseases, LFT abnormalities or hepatitis. This should be balanced against the short duration of treatment.
- **Pregnancy/Contraception:** there are no data for the use of nirmatrelvir in pregnancy therefore Paxlovid is **not recommended** during pregnancy and in patients of childbearing potential not using effective contraception. Ritonavir may reduce efficacy of combined hormonal contraceptives and patients should be advised to use an effective alternative method or additional barrier method during treatment and until one complete menstrual cycle after stopping Paxlovid. All healthcare professionals must 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 so that they can be followed up. For more information go to http://www.uktis.org/.
- **Breast feeding:** is not recommended during treatment and for 7 days after the last dose. There is no human data on the use of Paxlovid in breast feeding.

DOSAGE/DURATION/REVIEW:

- The recommended dose in **normal or mild renal impairment** (eGFR ≥60ml/min (CrCl if >75 years)). Patient information leaflet
  - **PF-07321332 (nirmatrelvir) 300mg (2 x 150mg pink tablets) taken orally every 12 hours for 5 days**
    PLUS
  - **Ritonavir 100mg (1 x 100mg white tablet) taken orally every 12 hours for 5 days**
- The recommended dose in **moderate renal impairment** (eGFR 30-59ml/min (CrCl if >75 years)). Patient information leaflet
  - **PF-07321332 (nirmatrelvir) 150mg (1 x 150mg pink tablet) taken orally every 12 hours for 5 days**
    PLUS
  - **Ritonavir 100mg (1 x 100mg white tablet) taken orally every 12 hours for 5 days**
- The recommended dose in **severe renal impairment** (eGFR < 30ml/min (CrCl if > 75 years)) or dialysis patients ≥ 40kg (given after dialysis). Patient information leaflet
  - **PF-07321332 (nirmatrelvir) 300mg (2 x 150mg pink tablets) and Ritonavir 100mg (1 x 100mg white tablet) on DAY 1, followed by PF-07321332 (nirmatrelvir) 150mg (1 x 150mg pink tablet) AND Ritonavir 100mg (1 x 100mg white tablet) every 24 hours for a further 4 days.**
- The recommended dose in dialysis patients < 40kg (given after dialysis).
  - **PF-07321332 (nirmatrelvir) 150mg (1 x 150mg pink tablets) and Ritonavir 100mg (1 x 100mg white tablet) on DAY 1, followed by PF-07321332 (nirmatrelvir) 150mg (1 x 150mg pink tablet) AND Ritonavir 100mg (1 x 100mg white tablet) on DAY 3 & DAY 5**

- **See guidance on how to prescribe on TPAR**
- **To prescribe on HEPMA - click 'add drug' and in 'Treatment search' panel click on 'Protocol' tab and search 'Paxlovid' - take care to select correct protocol enter correct doses for nirmatrelivir and ritonavir as per guidance above**
- Treatment must not be extended beyond 5 days
- Paxlovid should be commenced as soon as possible after diagnosis of COVID-19 is made and within maximum 7 days of symptom onset.
- The most common adverse reactions are generally mild and can include dysgeusia (taste disturbance), diarrhoea, hypertension, myalgia, vomiting and headache.
- If patient requires hospital based care due to severe or critical COVID-19 after starting treatment, the patient should complete the full 5-day treatment course at the discretion of their clinician.

ADMINISTRATION / PATIENT COUNSELLING:

Advise patient/staff member for inpatients:

- There are 2 different tablets in each pack: PF-07321332 (nirmatrelvir) pink oval tablets and ritonavir white capsule shaped tablets
- The tablets should ideally be swallowed whole with a sufficient amount of fluid (e.g. a glass of water). See here for guidance in patients with swallowing difficulties.
- Tablets can be taken with or without food.
- To reduce the possibility of emerging resistance, patients should be advised to **complete the whole course** of treatment even if their symptoms improve and/or they feel better.
- See information above re advice to give about contraception in patients of child bearing potential
- If dose missed by >8 hours, do not take missed dose but instead take next dose at regularly scheduled time

SUPPLIES/RECORDING:

- Stock is kept in NW and PRI Pharmacy only
- **Prescriber to communicate treatment details to primary care using portal discharge document**
- Report any adverse reactions MHRA Yellow Card Scheme

References: Overview | COVID-19 rapid guideline: managing COVID-19 | Guidance | NICE

Developed by: K Hill/A Shaw Approved by: Resp/ID/Team and AMG/ ADTC
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