FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR PAXLOVID

https://www.fda.gov/media/155050/download

Paxlovid EUA Approved !! — (nirmatrelvir co-packaged with ritonavir)

PAXLOVID may only be used by healthcare providers to **treat mild-to-moderate COVID-19** in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are **at high risk for progression to severe COVID-19**, including hospitalization or death;

Limitations on Authorized Use

• PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.6

• PAXLOVID is not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19.

• PAXLOVID is not authorized for use for longer than 5 consecutive days

- Nirmatrelvir inhibits SARS-CoV-2-3CL protease, and thereby inhibits viral replication at the proteolysis stage (ie, before viral RNA replication
- Nirmatrelvir is boosted with low-dose ritonavir to slow its metabolism and provide higher systemic exposure
- Nirmatrelvir must be co-administered with ritonavir. (2.1)
    - Initiate PAXLOVID treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset. (2.1)
    - Administer orally with or without food. (2.1)
    - Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.
    - Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days. (2.2)
    - PAXLOVID is not recommended in patients with severe renal impairment (eGFR

<30 mL/min). (2.2, 8.6)

- PAXLOVID is not recommend in patients with severe hepatic impairment (Child-Pugh Class C). (2.3, 8.7)

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