Paxlovid EUA Approved Today!! — (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)

EUA 105 Pfizer Paxlovid LOA (12222021) (fda.gov)

FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR PAXLOVID (fda.gov)

Omicron

Omicron is much more contagious than Delta. It is probably similar to measles, which was, until now, probably the most contagious virus in the world.

Nationwide, the COVID Omicron variant went from 0.3% of infections to 12% and now 73% over 3 weeks. In Colorado, Omicron has grown from 0.5% to 1.22% and is now 9.75% of infections.

Modeling shows it is doubling every 1.5-3 days. It will be the dominant strain in Colorado and Nationwide.

Vaccines

The vaccine efficacy for the Omicron variant is much less compared to the Delta variant. From what I have read, vaccine efficacy against Omicron is estimated to be about 70% for Pfizer/Moderna IF we include the booster dose. It prevents 30-40% of infections. Without the booster (only 2 doses), it is estimated that the Pfizer/Moderna vaccine efficacy is reduced to about 40% against Omicron.

You will see breakthrough COVID cases among staff and residents.

Monocloncal Antibody

Sotrovimab is the only Monocloncal Antibody that is expected to have good efficacy against the Omicron variant. It has an EUA for mild to moderate COVID in those without new onset hypoxia and who are not hospitalized.

We still have a lot of Delta around so the other Monoclonal Antibodies still have efficacy at this time but I would expect that to change.

"Providers should prescribe and/or administer monoclonal antibodies to all eligible patients both to benefit the

patients and preserve Colorado's hospital capacity. Omicron variant is increasing rapidly in Colorado, but a substantial proportion of cases are still due to Delta. All monoclonal antibodies authorized for treatment of

COVID-19 (bamlanivimab/etesevimab, casirivimab/imdevimab (REGEN-COV), and sotrovimab) are effective against Delta."

Currently, 42% of available ICU beds are in use in Colorado.

Omicron is the Predominant COVID Strain in U.S. – 73% of cases

The orange is Delta across the U.S.. The purple is Omicron.

Colorado Omicron 9.75% of COVID cases and growing rapidly (exponential growth).