State of New Jersey
Department of Human Services
Division of Medical Assistance & Health Services
New Jersey Drug Utilization Review Board

NEWSLETTER

Volume 32 No. 25 **October 2022**

TO: Physicians, Nurse Practitioners, Independent Clinics, Federally Qualified Health Centers- **For Action**
Providers of Pharmaceutical Services, Health Maintenance Organizations – **For Information Only**

SUBJECT: **Clinical News from the New Jersey Drug Utilization Review Board (DURB)**

PURPOSE: To provide practitioners useful clinical information that the DURB has determined may be helpful in prescribing prescription drugs

BACKGROUND: The DURB serves as an advisory board to the New Jersey Department of Human Services and the New Jersey Department of Health and Senior Services. The Board's responsibilities include recommending clinical standards based, in part, on the evaluation of prescription drug use by participants in the State's prescription drug programs. The Board is also responsible for disseminating information that the Board has determined would encourage appropriate drug utilization.

ACTION: Attached is a bulletin regarding oral COVID therapy. This bulletin may also be viewed online at:
http://www.state.nj.us/humanservices/dmahs/boards/durb/newsletters/.

The DURB welcomes your comments regarding the information shared in the bulletin. These comments may be sent to: semenike@gainwelltechnologies.com. When submitting comments, please include the phrase "DURB Comments" in the subject area of the email.

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ORAL COVID THERAPY

What You Need To Know About Oral COVID Therapy

On December 22, 2021, the FDA granted Emergency Use Authorization (EUA) to Pfizer for the COVID-19 oral antiviral drug product, Paxlovid®. Paxlovid® is a combination of two drugs, nirmatrelvir and ritonavir. On December 23, 2021, the FDA also granted an EUA to Merck for the COVID-19 oral antiviral drug product, molnupiravir (now referred to by its brand name Lagevrio®).

Who is eligible for these medications?

Paxlovid® and Lagevrio® are both available by prescription only. These drugs are used for the treatment of patients meeting certain criteria, differing by age and weight as indicated below:

- ✓ Have tested positive for COVID-19
- ✓ Have mild to moderate symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, etc.)
- ✓ Are at high risk of progression to severe COVID-19, including hospitalization or death
- ✓ Are 12 years of age or older and weigh at least 40kg (80lb) for Paxlovid®
- ✓ Are 18 years of age or older for Lagevrio®

How do these medications combat COVID-19?

Nirmatrelvir renders the virus incapable of processing polyprotein precursors, thereby preventing viral replication. Ritonavir does not have antiviral activity against COVID-19, but instead is used as an enhancer to increase plasma concentrations of nirmatrelvir.
Molnupiravir works by introducing errors into the virus' genetic code, making the virus incapable of replicating properly.

How should my patients take these medications?

Paxlovid® is co-packaged and orally administered consisting of two (2) tablets of nirmatrelvir (150mg) and one (1) tablet of ritonavir (100mg) to be taken concurrently twice daily for five (5) days.

Initiate treatment as soon as possible after COVID-19 diagnosis and within 5 days of symptom onset.

Lagevrio® is also orally administered as four (4) 200mg capsules twice daily for five (5) days.

Completion of the full 5-day treatment course and continued isolation in accordance with CDC's public health recommendations are important to maximize viral clearance and minimize transmission of COVID-19.

What are possible adverse reactions to oral Covid therapy?

Potential side effects include, but are not limited to:

- Impaired sense of taste
- Diarrhea
- Nausea
- Muscle aches

Please check package inserts for additional information.

What are limitations of the use of these medications?

- They are not authorized for the initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19 infection.
- They are not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- They are not authorized for use longer than five (5) consecutive days.
- Prescribers are encouraged to check drug-drug interactions with Paxlovid®.

Can COVID-19 Symptoms Come Back After Using Paxlovid®?

A number of patients have reported testing positive for COVID-19 after taking a five-day treatment course of the drug. According to the FDA, these reports, do not change the conclusions from the Paxlovid® clinical trial which demonstrated a marked reduction in hospitalization and death. However, they are continuing to review data from clinical trials and will provide additional information as it becomes available.

Sources for Additional Reading:

1. CDC's COVID-19 Treatments and Medications https://www.cdc.gov/coronavirus/2019-ncov/your-health/treatments-for-severe-illness.html
2. FDA's EUA for Paxlovid® https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19
3. FDA's EUA for molnupiravir (updated) https://www.fda.gov/media/155053/download
4. FDA Updates on Paxlovid® for Health Care Providers. US Food and Drug Administration. May 4, 2022. https://www.fda.gov/drugs/news-events-human-drugs/fda-updates-paxlovid-health-care-providers Accessed: May 19, 2022.