

NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

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March 11, 2024

## Updated COVID-19 Treatment Provider Memo:

### EUA-Labeled Paxlovid No Longer Authorized for Use

#### PAXCESS Provides Affordable Access to Paxlovid for All Patients

Staying up to date with vaccines and timely access to treatment are the best ways to reduce hospitalization and death due to ongoing circulation of COVID-19. This memo provides [key messages](#), [how to provide treatment to your patients](#), and an [overview of treatment options](#) to healthcare providers for outpatient treatment of COVID-19.

#### **Background/Key Messages:**

- **EUA-labeled Paxlovid no longer authorized for use**
  - As of March 9<sup>th</sup>, 2024, EUA-labeled Paxlovid is [no longer authorized for emergency use](#), regardless of its labeled or extended expiration date. Only [FDA approved Paxlovid](#), also referred to as NDA-labeled Paxlovid, can be dispensed moving forward.
  - All remaining inventory of EUA-labeled Paxlovid must be returned to the manufacturer or disposed of in accordance with all federal, state and local regulations.
  - Paxlovid remains FDA *approved* for treatment of mild-to-moderate COVID-19 in high-risk patients ages 18 and older. An [Emergency Use Authorization \(EUA\)](#) allowing for treatment of mild-to-moderate COVID-19 in high-risk patients ages 12 and older with NDA-labeled Paxlovid also remains in place.
  
- **[PAXCESS provides affordable access to Paxlovid for all patients.](#)**
  - No patient, regardless of insurance status, should pay hundreds of dollars for their Paxlovid prescription. **All patients can continue to have access to Paxlovid at little to no cost** via the PAXCESS Patient Support Program.
    - Through the **Co-pay Savings Program**, commercially insured individuals pay as little as \$0 for their Paxlovid prescription.
    - The **USG Patient Assistance Program (USG PAP)** covers the entire cost of therapy for individuals who participate in Medicare, Medicaid, or are uninsured.
    - Information on both programs is available at [Treatment-PDF\\_PAXCESS-Brochure.pdf \(cdc.gov\)](#)
  - Medicaid and some Medicare Part D recipients can access free Paxlovid through their routine pharmacy pathway without enrolling in the USG PAP. If issues arise while

processing through Medicaid or Medicare Part D plans, then the USG PAP should be used to ensure \$0 cost for these patients.

- For more information and to enroll patients, visit the [PAXCESS Patient Portal](#) or call 1-877-C19-PACK. Patients, caregivers, providers, and pharmacists can all use this simple form to start the enrollment process in either program.
- **COVID-19 treatments are safe, effective, and widely available.**
  - Data shows that using antiviral treatments reduces the risk of hospitalization and death for those at risk of severe COVID-19.
  - [Preliminary data](#) supports the benefit of treatment is associated with reduced risk of Long-COVID.
  - All currently authorized and approved treatments are expected to retain effectiveness against currently circulating variants.
  - There are no supply constraints limiting providers' ability to prescribe treatment.
- **A large proportion of the North Carolina population is considered high risk based on age or underlying conditions.**
  - Individuals who are likely to get very sick from COVID-19 include older adults (age 50 or greater), those who are unvaccinated, and those with underlying conditions including, but not limited to, compromised immune system, heart disease, overweight or obesity (BMI 25 or greater), asthma, diabetes, or depression. More information on who is considered high risk is available [here](#).
  - Providers should discuss a [COVID-19 Plan](#) in advance with high-risk and immunocompromised patients in case of infection.
  - Anyone with a COVID-19 diagnosis who has one or more high-risk health conditions should be carefully evaluated and prescribed COVID-19 treatment as clinically appropriate.
- **Treatment must be started early, even if symptoms are mild.**
  - Oral antivirals (Paxlovid and Lagevrio) must be started within 5 days of symptom onset.
  - IV Veklury must be started within 7 days of symptom onset.

## **How to Provide COVID-19 Treatment to Your Patients:**

### Oral Antivirals (Paxlovid and Lagevrio)

Any prescribing provider in North Carolina can **send a prescription for oral antiviral drugs to the nearest pharmacy** that has drug in stock.

- To ensure patients pay as little as \$0 for Paxlovid, regardless of insurance status, prescribers can enroll their patients in PAXCESS during their visit by going to [paxlovid.iassist.com](https://paxlovid.iassist.com) or by calling 1-877-C19-PACK.
- The Merck Patient Assistance Program offers free Lagevrio to eligible patients. Visit [MerckHelps.com/LAGEVRIO](https://MerckHelps.com/LAGEVRIO) or call 1-800-727-5400 for more information.

### IV Veklury

Veklury is available in hospitals and infusion centers statewide through standard commercial channels.

- Non-hospitals can contact AmerisourceBergen Specialty Distribution or Cardinal Specialty for ordering:
  - AmerisourceBergen Specialty: 1-800-746-6273 or [C19therapies@AmerisourceBergen.com](mailto:C19therapies@AmerisourceBergen.com)

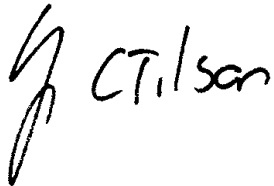
- Cardinal Specialty: 1-855-855-0708 or [GMB-SPD-CSORDERENTRY@cardinalhealth.com](mailto:GMB-SPD-CSORDERENTRY@cardinalhealth.com)
- Patient support is available at [Gilead's Advancing Access](#).

**Overview of Treatment Options:**

The antiviral drugs Paxlovid (ritonavir-boosted nirmatrelvir) and Veklury (remdesivir) are the preferred outpatient treatments for patients at high-risk for progression to severe COVID-19. Lagevrio (molnupiravir) is an alternative treatment option for use only when Paxlovid or Veklury are not accessible or clinically appropriate. For a detailed overview of outpatient COVID-19 treatment options, visit CDC's [Interim Clinical Considerations for COVID-19 Treatment in Outpatients](#) and the [National Institute of Health \(NIH\) COVID-19 Treatment Guidelines](#).

For additional information or questions related to COVID-19 Therapeutics, visit [NCDHHS Therapeutics Information for Providers](#) or contact us at [covid19testingandtreatments@dhhs.nc.gov](mailto:covid19testingandtreatments@dhhs.nc.gov).

Sincerely,

A handwritten signature in black ink that reads "E. Cuervo Tilson". The signature is stylized and appears to be written with a pen or marker.

Elizabeth Cuervo Tilson, MD, MPH  
State Health Director  
Chief Medical Officer  
North Carolina Department of Health and Human Services