STATE OF WISCONSIN
Department of Health Services
Division of Public Health

1 West Wilson Street
PO Box 2659
Madison WI 53701-2659

Telephone: 608-267-9003
Fax: 608-261-4976
TTY: 888-701-1253

Date: May 6, 2022 BCD 2022-07

To: Wisconsin Local Health Departments, Tribal Health Agencies, Infection Preventionists, Division of Quality Assurance, Wisconsin DON Council, Wisconsin LTC Medical Directors Association, Wisconsin Health Care Association, LeadingAge Wisconsin, Wisconsin Assisted Living Association, Pharmacy Society of Wisconsin

From: Ryan Westergaard, MD, PhD, MPH
Chief Medical Officer and State Epidemiologist for Communicable Diseases

Jon Meiman, MD
Chief Medical Officer and State Epidemiologist for Environmental and Occupational Health

COVID-19 Oral Antivirals Medications for Long-Term Care Residents

PLEASE DISTRIBUTE WIDELY

Summary

This memo is intended as guidance to medical and administrative staff of long-term care facilities (LTCFs), including skilled nursing facilities (SNFs), community-based residential facilities (CBRFs), and residential care apartment complexes (RCACs), in Wisconsin. In December 2021, The Food and Drug Administration (FDA) issued emergency use authorizations for two COVID-19 oral antivirals, Paxlovid and Lagevrio. The United States government purchased supplies for distribution to states, and the Wisconsin Department of Health Services (DHS) began distributing these medications to health care facilities in January 2022. While supplies were initially limited, Paxlovid and Lagevrio are now available in sufficient quantities to treat LTCF residents with COVID-19 who are at risk for progression to severe disease.

The purpose of this memo is to provide an overview of Paxlovid and Lagevrio, outline requirements for maintaining a contingency supply in SNFs, and to describe the medication ordering process for long-term care (LTC) pharmacies. Clinical guidance about the use of COVID-19 therapeutics changes frequently. Links to federal guidance are provided throughout this memo, and clinicians are encouraged to consult these resources for the most up-to-date information.

Oral Antiviral Medications for LTCF Patients with COVID-19

Patient eligibility criteria for Paxlovid and Lagevrio are briefly summarized in the table below.

Patient Eligibility Criteria	
Paxlovid	**Lagevrio**
Paxlovid is authorized for treatment of mild-to-moderate COVID-19 among adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of SARS-CoV-2 testing and: • Who are at high risk for progressing to severe COVID-19; and • Symptom onset is **within five days** of initiating treatment. Paxlovid is **not** authorized for: • Treatment in patients requiring hospitalization due to COVID-19 • Pre-exposure or post-exposure prophylaxis for prevention of COVID-19 • Pediatric patients younger than 12 or who weigh less than 40 kg. • Use for longer than five consecutive days	Lagevrio is authorized for treatment of mild-to-moderate COVID-19 among adults aged 18 years and older with positive results of SARS-CoV-2 testing and: • Who are at high risk for progressing to severe COVID-19; • Symptom onset is **within five days** of initiating treatment; and • **Alternative treatment options are not accessible or appropriate** Lagevrio is **not** authorized for: • Treatment in patients requiring hospitalization due to COVID-19. • Pre-exposure or post-exposure prophylaxis for prevention of COVID-19 • Patients younger than 18 years • Use for longer than five consecutive days

Patients at **high risk for severe disease** include those with medical conditions such as cancer, chronic kidney and lung disease, dementia, diabetes, overweight and obesity, and heart disease. For more information, see the Centers for Disease Control and Prevention's list of health conditions associated with risks for developing severe COVID-19. Note that other medical conditions not included in CDC's list may still place a patient at high risk for disease progression.

Warnings, Precautions, and Contraindications

Paxlovid may result in significant drug-drug interactions. Co-administration with drugs highly dependent on CYP3A for clearance may result in serious and/or life-threatening reactions. Providers should consult the FDA Fact Sheet prior to treatment and be familiar with medications for which co-administration is contraindicated (e.g., simvastatin, midazolam, carbamazepine). The National Institutes of Health (NIH) has also developed a concise guide to assist clinicians in assessing the potential for drug-drug interactions. Paxlovid also requires dose adjustment for patients with moderate renal impairment (eGFR ≥30 to <60 mL/min) and is not recommended for patients with severe renal impairment (eGFR <30 mL/min). Assessment of renal function may be required prior to initiating therapy for patients with impaired renal function or for patients without a recent serum creatinine.

Lagevrio is not recommended for use during pregnancy or while breastfeeding. Males of reproductive potential who are sexually active should use a reliable method of contraception during treatment and for at least three months after the last dose. Clinicians should consult the FDA Fact Sheet for full prescribing information.

Preferred therapies

As of April 8, 2022, the NIH recommends Paxlovid as the first line treatment for patients with COVID-19 who are at high risk of progression to severe disease, with remdesivir as the preferred alternative. When Paxlovid or remdesivir are not available, feasible, or clinically appropriate, clinicians can consider

use of bebtelovimab or Lagevrio. The U.S. Department of Health and Human Services (HHS) has developed a clinical decision aid that facilities may use when developing therapeutics protocols.

Contingency Supplies for SNFs

Skilled nursing facilities may choose to maintain a contingency supply of COVID-19 oral antiviral medications. Contingency supplies may reduce treatment delays following a diagnosis of COVID-19. Currently, Wis. Admin. Code ch. DHS 132.65(5)(a) limits contingency supplies to 10 units of a specific medication. A five-day treatment course of Paxlovid or Lagevrio exceeds 10 units, therefore SNF's that wish to have a contingency supply of COVID-19 oral antivirals may request a waiver or request a modification of a current waiver. Please follow the procedures outlined on the DHS website to request a waiver. The waiver or variance request form (F-02536) can be completed and emailed to Elizabeth Laubenstein.

Ordering Process for COVID-19 Oral Antivirals

HHS is partnering with LTC pharmacies for direct receipt of oral antivirals. LTC pharmacies may also obtain antivirals by partnering with DHS, which also provides direct customer assistance. Regardless of whether LTC pharmacies partner with HHS or DHS, pharmacies must first establish an account in the Health Partner Ordering Portal (HPOP). Pharmacies that have a pandemic vaccine PIN should email DHSOperations@wisconsin.gov with the pharmacy name, email address, and PIN. This will begin the HPOP registration process.

Pharmacies that do **not** have a pandemic vaccine PIN should email the following information to DHSOperations@wisconsin.gov

- Site Name
- Full Address (no PO Boxes)
- Pharmacy License
- License Expiration Date
- Primary Contact Name
- Primary Contact Email Address
- Primary Contact Phone Number

Once DHS creates an HPOP account, the primary pharmacy contact will receive a registration email from vpop-no-reply@cdc.gov. The email contains instructions for creating a password and using two-factor authentication. The registration email is only valid for 72 hours. Pharmacy representatives should email DHSOperations@wisconsin.gov if this 72-hour window has lapsed.

HPOP uses two-factor authentication, so the primary contact will need a smart phone or tablet with an authentication app, such as the Google Authenticator. Once the primary contact has created a password and logs in, the contact must provide the 10-digit NPI and verify the pharmacy's license, receiving address, and receiving hours.

Requests for antivirals and reporting of usage and inventory are managed within HPOP. A user guide will be provided upon registration. Antivirals requests can be made at any time, and orders will be placed as allocation allows on Mondays after 3pm.

For more information, contact DHSOperations@wisconsin.gov