COVID-19 Therapeutics:

Toolkit for Health Systems, Hospitals, and Clinics

WISCONSIN DEPARTMENT of HEALTH SERVICES

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Background

Most people who get COVID-19 experience mild illness and can recover at home. A combination of rest, hydration, and over-the-counter medications can help relieve symptoms. But some people with severe illness may need medical care and treatment to get better. There are medications approved or authorized by the U.S. Food and Drug Administration (FDA) for those who are at risk of developing severe COVID-19. These medications – oral antiviral pills – have proven highly effective at keeping people from becoming very ill, being hospitalized, or dying from COVID-19.

The federal government currently provides allocations of these medications to states for distribution to retail pharmacies, health systems, community health clinics, and Test to Treat sites. The Wisconsin Department of Health Services (DHS) distributes COVID-19 oral antiviral treatments to health systems, clinics, and pharmacies throughout the state. These entities can then prescribe and administer the medications for people with COVID-19.

This toolkit contains resources to support prescribing entities in ordering and prescribing these life-saving medications. For additional resources related to public communication, please see the companion toolkit COVID-19 Therapeutics: Toolkit for Communicating Public Health Recommendations.

All information in this toolkit is current as of the publication date.

Clinician Prescribing Information

The following are links to COVID-19 therapeutics prescribing guidelines, FAQs, and other helpful tools for finding and prescribing these therapeutics for providers, health systems, and community health organizations.

Patient Eligibility Requirements

Patient Eligibility Criteria	
Paxlovid	**Lagevrio**
Paxlovid is authorized for treatment of mild-to-moderate COVID-19 symptoms among adults and pediatric patients (12 years of age and older weighing at least 40 kg) who: • Are at high risk for progressing to severe COVID-19. • Have symptom onset **within 5 days** of initiating treatment.	Lagevrio is authorized for treatment of mild-to-moderate COVID-19 symptoms among adults aged 18 years and older who: • Are at high risk for progressing to severe COVID-19. • Have symptom onset **within 5 days** of initiating treatment. • **Are not appropriate for alternative treatment options.**
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 5 consecutive days.	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 5 consecutive days.

FDA Guidance:

Type of Therapeutic	**Name**	**Resources**
Oral Antivirals	Paxlovid	Health Care Provider Resources - Provider fact sheet - EUA FAQ - Patient eligibility checklist tool - - DHS memo on oral antivirals for long-term care residents Patient Resources - Patient fact sheet
	Lagevrio	Health Care Provider Resources - Provider fact sheet - EUA FAQ - Patient eligibility checklist tool - DHS memo on oral antivirals for long-term care residents

		Patient Resources - Patient Fact Sheet

National Institutes of Health (NIH) Guidance

- COVID-19 clinical management summary
- Paxlovid drug-drug interactions
- Lagevrio treatment guidelines
- NIH preferred treatments

Therapeutics Locator Tools

- DHS maps
- U.S. Health and Human Services (HHS) maps

Other Useful Tools

- Liverpool drug interaction checker
- Liverpool Flowchart for use of Paxlovid
- HHS COVID-19 therapeutics decision aid
- Nirmatrelvir/Ritonavir (Paxlovid): What Prescribers and Pharmacists Need to Know (COVID-19 Science Advisory Table)

Myths and Facts about COVID-19 Treatments

The following statements represent common misconceptions regarding COVID-19 treatments. Use this information to train staff within your organization.

Misinformation	**Fact**
Oral antiviral medications have emergency use authorization (EUA) only – they are not FDA approved – therefore, they are not considered an effective treatment.	An EUA is a tool the U.S. Food and Drug Administration (FDA) can use to expedite the availability of medical products, including drugs and vaccines, during a public health emergency. An EUA can only be granted when no adequate, approved, available alternatives exist, and when the known and potential benefits outweigh the potential risks. It is the FDA's job to ensure medical products meet rigorous safety and efficacy standards, a process that can take years for full approval. Though that timeline is condensed when an EUA is granted, the FDA still upholds its strict standards. There is data showing that the oral antiviral pills are highly effective. Physicians should not avoid prescribing these treatments because they have FDA emergency use authorization.
Patient is not sick enough to qualify for treatment. OR Wait-and-see how illness progresses, instead of seeking immediate treatment within the five-day eligibility window	The current treatments are authorized for use in patients with mild to moderate symptoms of COVID-19 who are at risk of progressing to severe illness. Both the National Institutes of Health and the FDA recommend initiating treatment **as soon as possible after a COVID-19 symptom onset.** There is no threshold of sick enough included in the EUA or other prescribing guidelines. There is no recommendation to wait-and-see before starting treatment. The purpose of the medication is to prevent the most severe complications of COVID-19, including hospitalization and death. It is authorized to be given while patients are still in mild to moderate stages of illness.
Not enough supply to merit a prescription since patient is not a severe case.	There is no longer a limited supply of oral antiviral pills. The goal is to prevent patients from progressing to severe illness.
There is a significant risk of rebound following treatment with Paxlovid.	Some patients have reported rebound illness after taking Paxlovid, which may occur between two and eight days after initial recovery. Rebound is characterized by a recurrence of COVID-19 symptoms or a new positive viral test after having tested negative. These cases are infrequent and appear to occur at the same rate for people who have not been treated with oral antiviral medication for COVID-19 as those who were treated with Paxlovid. Per CDC, there is no evidence that additional treatment for COVID-19 is needed for rebound, and there are no reports of severe disease among patients with rebound.

Health System and Clinical Practice Guidance

The following items are intended for health systems, pharmacists, and other providers to describe how to place and receive orders for COVID-19 therapeutics, how to join the Test to Treat program, and how to find information about the medications utilization in your region, or in the state.

Ordering Through the Health Partner Ordering Portal

The Health Partner Ordering Portal (HPOP) is a web-based tool provided by HHS for ordering and reporting COVID-19 therapeutics.

To order COVID-19 therapeutics, your organization needs to have a HPOP account. This free account can be set up by providing DHS with some basic site information along with the pharmacy licenses, the site's National Provider Identification number, and a primary contact. To get started send an email to DHSOperations@wisconsin.gov asking for an HPOP account and you will receive detailed instructions.

Once an account is created and orders can be placed, the order is reviewed by DHS staff and is approved if the state's allocation permits. If the allocation is limited, order quantities maybe reduced or cancelled. The order status is available in HPOP.

Once you have received therapeutics, you will need to update your federally allocated inventory on Mondays and Thursdays by 11:59 pm CT. Your site will be listed on the HHS and DHS locator maps.

Distribution

Weekly, DHS emails all agencies eligible to order therapeutics describing the timeline to place orders in HPOP. Only federal partners who receive direct allocations from HHS don't have to place orders through HPOP.

DHS approves the orders in HPOP and product ships directly to the pharmacy the next day, with no deliveries on weekends.

Once a pharmacy receives product, they are expected to report administered product in HPOP twice a week, Mondays and Thursdays by 11:59 PM CDT. If nothing has been administered, you can report weekly. Please continue to report your inventory of the legacy monoclonal therapies in TeleTracking or EMResource.

Test to Treat Sites

DHS is partnering with the federal government on the Test to Treat program as part of the National COVID-19 Preparedness Plan. The therapeutics locator map shows Test to Treat locations. If your pharmacy, clinic, or organization is interested in becoming a Test to Treat site, please review this checklist to see if you meet eligibility requirements.

Utilization Dashboard

DHS publishes a weekly summary of data on the Wisconsin Partner Communication and Alerting Portal (PCA Portal) for the following medications on a COVID-19 Therapeutic Utilization Dashboard. Below is a table of the information you can access to see current therapeutics utilization. The PCA Portal requires members to enter through the Wisconsin Logon Management System (WILMS). Please email DHSPCAPortal@wi.gov for detailed instructions.

Users of the PCA Portal - COVID-19 Therapeutics dashboard should be aware that metrics are based on data reported to the federal government. DHS works to ensure data quality from the federally-maintained Health and Human Services Protect Tiberius Database.

Users may view data for one medication at a time by selecting from the radio buttons in the upper right of the module. View data for a single HERC region by clicking the region name in the lower part of the module. Multiple regions may be selected and viewed as a group by performing a Ctrl + click action on the desired region names.

Monoclonal Antibodies	Oral Antivirals
Evusheld **	Lagevrio (molnupiravir)
	Paxlovid
	Renal Paxlovid

Reported metrics for each medication include:

ID	Metric	Reported Time Period	Definition
1	Courses Distributed	All Time*	The number of courses delivered to healthcare providers.
2	Courses Dispensed	All Time* and Weekly	The number of courses administered to patients.
3	Utilization Rate	All Time*	*Courses Dispensed* divided by *Courses Distributed*.
4	Courses Dispensed per 1,000 Population by HERC Region	All Time*	The number of courses administered per 1,000 residents within each of the seven HERC regions.

**All Time* refers to the period beginning Dec. 17, 2021 (the date of first therapeutic availability) through the date of the report.

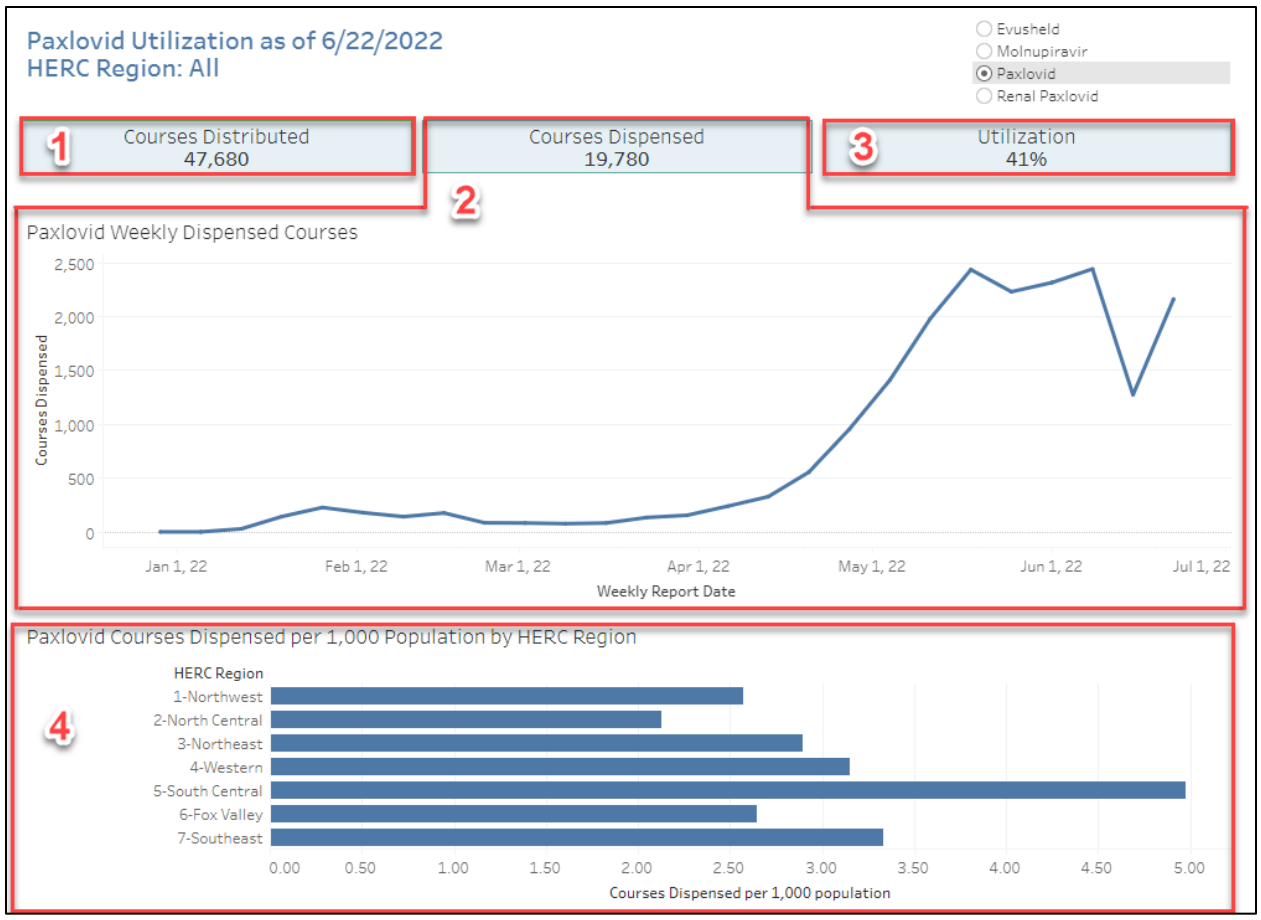

Image 1: <Example of COVID-19 Therapeutics Utilization Dashboard>

** On January 26, 2023, the FDA revoked the EUA for Evusheld, but DHS does not plan to remove Evusheld from the dashboard since this information has historical tracking value.

Talking Points

The following talking points can be used by health systems, pharmacists, and other providers to communicate about COVID-19 medications with the public.

- **If you have symptoms of COVID-19, life-saving, effective treatments are available that can reduce your chances of hospitalization and death.**
    - These treatments have been authorized by the U.S. Food and Drug Administration and are proven to reduce the severity of symptoms and reduce the risk of hospitalization and death from COVID-19.
    - They are recommended for people who are more likely to get very sick from COVID-19, including older adults, people who are unvaccinated, and people with certain medical conditions, including a weakened immune system.
    - There is one type of COVID-19 medication still covered by emergency use authorization: Oral antiviral treatments.
        - Oral antiviral medications are pills you can take at home. Today, two oral antiviral medications called Paxlovid and Lagevrio are authorized.

- **These treatments are widely available across Wisconsin.**
    - Treatments are available by prescription at retail pharmacies, federally qualified health centers, other health clinic locations, and through the free DHS COVID-19 treatment telehealth service. Find where they are available on DHS' website.
    - The cost for treatments may vary. The medications are currently available at no charge, however you may be charged for a clinic visit to receive a prescription.
        - For assistance finding low-cost or free healthcare, dial 211.
        - DHS now offers a free COVID-19 treatment telehealth service.
    - If you don't have health insurance or a primary care doctor to get a prescription, you can also access health care through a community health center. For free, confidential support finding health care and community resources near you, dial 211 or 877-947-2211, or text your ZIP code to 898-211. Find resources online at 211Wisconsin.org.
- **Do not delay: COVID-19 treatments must be started shortly after your symptoms begin.**
    - Paxlovid and Lagevrio must be started within five days of symptom onset.
    - If you feel ill or have been exposed to someone who has tested positive for COVID-19, use an at-home test or visit a community testing site. If you have symptoms of COVID-19, seek a prescription for treatment right away.
- **COVID-19 treatments are not a substitute for COVID-19 vaccinations and boosters.**
    - Vaccination and booster continue to provide the best protection against getting sick and experiencing serious illness, hospitalization, and death from COVID-19.
    - The best way to protect yourself, your family and friends, and community from COVID-19 is to:
        - Know the COVID-19 Community Level where you live or are traveling to and follow associated guidelines.
        - Stay up to date on all COVID-19 vaccines and booster doses.
        - Get tested if you experience symptoms or have been exposed to someone with COVID-19. Stay home if you are sick and contact a doctor or clinic to see if you are eligible for COVID-19 treatments.

Sample Protocol and Procedure for Paxlovid Prescribing

Prescribers are encouraged to develop protocols and procedures for the prescription of COVID-19 therapeutics that align with their organization's policies. The following is an example of a Paxlovid prescribing procedure developed by the Barron County Health Department.

Title:	Paxlovid COVID-19 Antiviral Medication Access	
Effective Date:	07/05/2022	
Created By:	Barron County Health Department	Date: 7/1/22
Revision By:		Date:

Policy: Provide access for uninsured individuals to Paxlovid, a COVID-19 antiviral medication, which can reduce the risk of hospitalization or death.

Purpose: Prevent high-risk, uninsured individuals with mild COVID-19 illness from developing severe COVID-19.

Scope: COVID-19 positive uninsured individuals at high risk for developing severe COVID-19. Symptoms must be mild and less than five days in duration to qualify for the oral antiviral medication.

Procedure:

1) Uninsured person with COVID-19 contacts or is identified by Public Health or Federally Qualified Community Health Center. Positive self-reported home COVID tests are acceptable.
2) Public Health Nurse completes:
    a. Paxlovid PHN Patient Eligibility Screening Checklist
    b. Clinic patient registration
    c. Release of Information between Clinic and local health department
3) Request assistance from clinic's volunteer provider. Call or text to confirm availability.
    a. List of providers and their contact info
    b. If no provider is available refer client to the closest Test to Treat Site: The client will need to specify they want to access the Test to Treat program.
4) Share completed PHN Patient Eligibility Checklist with provider via secure email.
5) Provider will:
    a. Call client for Paxlovid Consult

i. If eGFR recommended, provider will request PHN complete lab testing prior to any prescription being issued.
    1. List phone numbers of contacts

b. If indicated, call Paxlovid prescription to the client's preferred pharmacy that stocks Paxlovid.
    i. If possible, share a list of known medications/OTC meds with pharmacy for another review for medication compatibility
    ii. List of current pharmacies stocking Paxlovid may be found at: https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
        1. List known local pharmacies carrying Paxlovid and their phone numbers

c. If Paxlovid is contraindicated, refer client to the closest health system carrying bebtelovimab*.

6) Lab Testing Required-RN Procedure:
    a. Obtain verbal order for eGFR/Serum Creatinine from provider
    b. Complete Creatinine Order Form
    c. Set up appointment to draw serum
    d. Use a red top tube
    e. Spin sample in centrifuge
    f. Refrigerate sample and arrange transport to your Lab ASAP
    g. Include Creatinine Order Form, ROI between Public Health and your clinic, ROI between RLAFC and Cumberland Healthcare
    h. Share eGFR results with provider
7) Copy of all verbal order forms will be mailed to providers for signature, public health will include an addressed and stamped envelope to return forms (may move to an electronic signature format).
8) All forms will be scanned into the client's public health file and sent via secure email to clinic for inclusion in the client's chart.
    a. List email for EMHR administrator.

*Please Note: this protocol was submitted in July 2022. On November 30, 2022, the FDA revoked the EUA for bebtelovimab. Current recommendations are to offer Lagevrio if appropriate in lieu of Paxlovid when Paxlovid is contraindicated.