COVID-19 Therapeutics Information Brief

May 4, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Therapeutics Information Brief will be May 18, 2022.

IMPORTANT/NEW COVID-19 Therapeutics Information

Availability and Use of Treatments for Outpatients with Mild to Moderate COVID-19 Who are at Increased Risk for Severe Outcomes of COVID-19

The Centers for Disease Control and Prevention (CDC) is updating healthcare providers, public health departments, and the public about the availability and use of recommended therapies for COVID-19 and to advise against using unproven treatments that have known or potential harms for outpatients with mild to moderate COVID-19. For patients with mild to moderate COVID-19 who are not hospitalized and who are at increased risk for severe COVID-19 outcomes, several treatment options are now widely available and accessible.

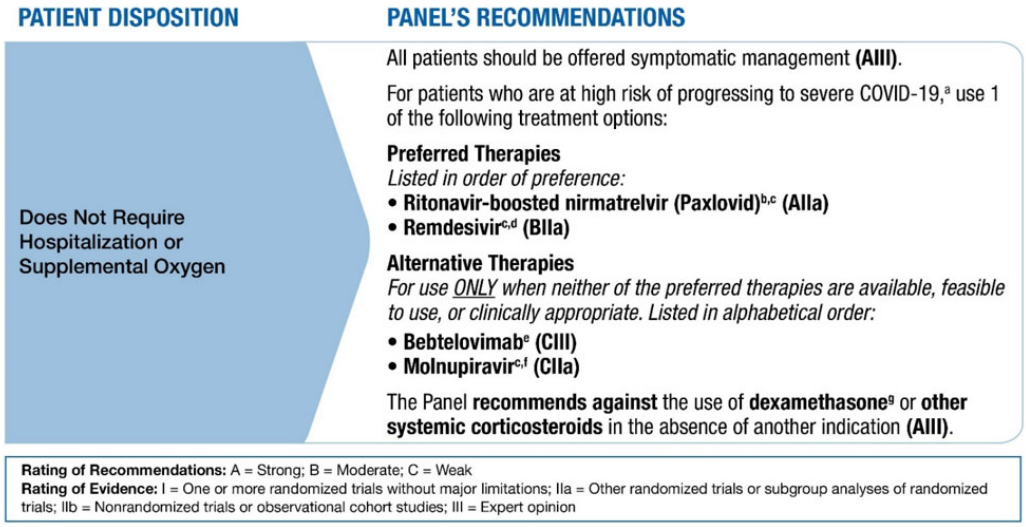
- Systemic corticosteroids are not recommended to treat patients with mild to moderate COVID-19 who do not require supplemental oxygen;
- Patients who are receiving dexamethasone or another corticosteroid for other indications should continue therapy for their underlying conditions as directed by their healthcare providers.
- Antibacterial therapy is not recommended for the treatment of COVID-19 in the absence of another indication.
- Staying up to date with COVID-19 vaccination is still the best way to prevent serious outcomes of COVID-19, including severe disease, hospitalization, and death.

Therapeutic Management of Nonhospitalized Adults with COVID-19

The National Institutes of Health (NIH) provides COVID-19 Treatment Guidelines. The guidelines panel provides treatment options and recommends against using systemic corticosteroids to treat patients with mild to moderate COVID-19 who do not require supplemental oxygen (Figure). Patients who are receiving dexamethasone or another corticosteroid for other indications should continue therapy for their underlying conditions as directed by their healthcare providers. Systemic corticosteroids are recommended for hospitalized patients with COVID-19 who require supplemental oxygen or higher-level respiratory support.

The guidelines panel also recommends against using antibacterial therapy for COVID-19 in the absence of another indication. Antibacterial drugs have no benefit in treating viral infections and can cause harm.

Figure. Therapeutic Management of Nonhospitalized Adults with COVID-19 (from NIH COVID-19 Treatment Guidelines, last updated: April 8, 2022)



FDA Approves First COVID-19 Treatment for Younger Children

The U.S. Food and Drug Administration expanded the approval of the COVID-19 treatment Veklury (remdesivir) to include pediatric patients 28 days of age and older weighing at least 3 kilograms (about 7 pounds) with positive results of direct SARS-CoV-2 viral testing, who are:

- Hospitalized, or
- Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

This action makes Veklury the first approved COVID-19 treatment for children less than 12 years of age. As a result of today's approval action, the agency also revoked the emergency use authorization for Veklury that previously covered this pediatric population. Before now, Veklury was only approved to treat certain adults and pediatric patients (12 years of age and older who weigh at least 40 kilograms, which is about 88 pounds) with COVID-19.

For additional information, see Coronavirus (COVID-19) Update: FDA Approves First COVID-19 Treatment for Young Children

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Renal Packaging for Paxlovid 150mg; 100mg Dose Pack for Patients with low eGFR

This packaging configuration should be used for patients with moderate renal impairment (eGFR ≥ 30 to < 60 mL/min).

- Each 150 mg; 100 mg Dose Pack includes 5 daily blister cards
- Each blister card contains a morning and evening dose
- Each dose consisting of 150mg nirmatrelvir (one oval, pink 150 mg tablet) and 100mg ritonavir (one white or white to off-white film-coated 100mg tablet uniquely identified by the color, shape and debossing)

The HCP and Pharmacist Instructions are available at: https://www.covid19oralrx-hcp.com/resources

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HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund

The HRSA Uninsured Program has stopped accepting claims for testing and treatment due to lack of sufficient funds. IDPH has received questions regarding billing patients for the administration or dispensing fee. It is important to remember the Provider Agreement outlines the following:

- **Providers may NOT charge the patient directly for the administration or dispensing of an anti-viral.**
- Healthcare organizations must dispense COVID-19 therapeutics regardless of the therapeutic recipient's coverage status or ability to pay for COVID-19 therapeutics dispensing fees.
- Organizations may seek appropriate reimbursement from a program or plan that covers COVID-19 therapeutics dispensing fees for the therapeutics recipient. Organizations may not seek any reimbursement, including through balance billing, from the therapeutic recipient.

- Organizations may not charge an office visit or other fee if dispensing of the COVID-19 therapeutic is the sole medical service provided.
- Organization may not require additional unrelated medical or other services or purchases as a condition precedent to receive the COVID-19 therapeutic. **The Intent is to have no cost sharing for patients.**

For additional information, see COVID-19 Uninsured Program Claims Submission Deadline FAQs.

Test to Treat Program

The Biden-Harris Administration launched a new nationwide Test to Treat initiative in March to give individuals an important way to quickly access free lifesaving treatment for COVID-19. The recently launched Test to Treat program supports this priority effort by creating an additional pathway for fast access to lifesaving COVID-19 treatments.

The federally managed Test to Treat program will focus on Federal Retail Pharmacy Therapeutic Program (FRPTP) partners and associated sites; all other sites will be managed by the state and receive state distributions from the weekly state allocation.

The following considerations should be taken by healthcare providers interested in participating in the Test to Treat Program:

- Provide/offer comprehensive end-to-end test and treat services to support a seamless patient experience:
    - COVID-19 testing on-site (or evaluation of at-home testing)
    - Linkage to a clinical evaluation by licensed healthcare provider after positive result to provide prescription when appropriate
- Co-located or affiliated pharmacy able to readily dispense medication to eligible patient's
    - Provide services to all individuals, regardless of insurance status
    - Accept new patients for priority same-day or next-day visit for COVID-19 services

Healthcare providers interested in participating in the Test to Treat Program should contact the COVID-19 Therapeutics Call Center at: C19Therapeutics@idph.iowa.gov or (515) 281-7317.

Extended Expiration Dates on Sotrovimab and Paxlovid

The shelf life of some lots of Paxlovid and Sotrovimab has been extended. The Food and Drug Administration (FDA) authorized the change for certain lots if they have been stored properly.

Drug Name	Lot Number	Extended Expiration Date
Sotrovimab	658W	08-2022
	XV6W, Y74D, JP9Y, 287F	10-2022
	287X, 432U, 433C, BX3T	11-2022
	9W8S, A39T	03-2023
	BD8F, BC9P, C86N, CC3D, CK9V, D74S	04-2023
	J23C, JJ7J, J67D	06-2023
	MJ8W,ME3Y, MJ8X, ME3Y, NM9X, NM6J, NX3P, PK8J	07-2023
	RM3K, S63E, R97L, S94Y, TE4L	08-2023
Paxlovid	FL4516, FL4517, FR7229	Initial 3 lots were extended from 07/31 to 10/31/2022
	FR9088	4th lot extended from 8/31 to 11/03/2022

Guidelines for Product Return

All therapeutic products are property of the United States Government and must be used in accordance with EUA guidance. Sites of care cannot donate products to entities outside the U.S. or for use outside the U.S. Any returned product will be destroyed, as product integrity cannot be verified. Non-expired products should not be destroyed. Any returned product needs to be quantified by the United States Government.

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
- Long-term utility of authorized mAb products is expected
- After consultation with the IDPH COVID-19 Therapeutics Call Center, if undamaged product needs to be returned, follow the below instructions:
    - For bam and bam/ete, see The Lilly Return Goods Procedure, detailed guidance can be found at: https://www.lillytrade.com/
    - For REGEN-COV, call 844-734-6643
    - Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's standard operating procedures

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Sotrovimab is NO Longer Authorized to Treat COVID-19 in any U.S. Region

As of 04/05/2022, the FDA has updated the Sotrovimab Emergency Use Authorization stating **Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases cases caused by the Omicron BA.2 sub-variant.** FDA will continue to monitor BA.2 in all U.S. regions and will provide follow-up communication when appropriate.

The Centers for Disease Control and Prevention (CDC) Nowcast data from April 5, 2022, estimates that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% in all Health and Human Services (HHS) U.S. regions. Data included in the health care provider fact sheet show the authorized dose of sotrovimab is unlikely to be effective against the BA.2 sub-variant. Due to these data, sotrovimab is not authorized in any U.S. state or territory at this time.

Health care providers should use other approved or authorized products as they choose appropriate treatment options for patients. Currently authorized alternative treatments are available for distribution. These include, Paxlovid (an oral antiviral treatment) and molnupiravir (an alternative oral antiviral for patients for which Paxlovid is not appropriate or accessible). Additionally, bebtelovimab is an alternative monoclonal antibody therapy that is currently authorized and available for distribution. Based on similar in vitro assay data currently available, these products are likely to retain activity against the BA.2 variant.

Healthcare providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody and oral antiviral therapy available under an EUA for details regarding specific variants and resistance. Healthcare providers should also refer to the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html) and information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

- COVID-19 Therapeutics Clinical Decision Aids

Evusheld Fact Sheet Updated

April 1, 2022, the FDA updated the Evusheld (tixagevimab co-packaged with cilgavimab) fact sheet and frequently asked questions with updated dosing information for patients who had already received the previously authorized initial dose (150 mg of tixagevimab and 150 mg of cilgavimab). These patients should receive an additional Evusheld dose as soon as possible, with the dose based on the following criteria:

- If the patient received their initial dose less than or equal to 3 months ago, the patient should receive a dose of 150 mg of tixagevimab and 150 mg of cilgavimab.
- If the patient received their initial dose longer than 3 months ago, the patient should receive a dose of 300 mg of tixagevimab and 300 mg of cilgavimab.

It is important to clinically monitor individuals for one hour following an injection of Evusheld. This guidance applies to patients returning for a booster dose. The FDA Fact Sheet for Healthcare Providers states, "*Clinically monitor individuals after injections and observe for at least 1 hour*."

Return of bam/ete and REGEN-COV NOT Recommended

Product return of bam/ete and REGEN-COV is ***NOT*** recommended as any returned product has to be destroyed. The COVID-19 environment remains dynamic and these products may be effective against future variants. Current supplies of bamlanivimab plus etesevimab and Regeneron's casirivimab plus imdevimab (REGEN-COV) should be retained by healthcare providers for potential use for other COVID variants. If healthcare providers have storage concerns or challenges, consider transferring products to another location/site in the region or health system.

If product must be returned, please follow the guidance below:

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
- For bam/ete, see The Lilly Return Goods Procedure; detailed guidance can be found at: https://www.trade.lilly.com/assets/pdf/lilly-product-return-procedure.pdf
- For REGEN-COV, call 844-734-6643
- Note: Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's SOP

As doses of bam/ete expire, all providers should check with the manufacturer prior to disposing of the product given the possibility of extended expiration dates. After verification, expired doses should be disposed of in accordance with the facility's standard operating procedures on medication disposal.

Allocations Cadence Changes for Monoclonal Antibodies, PReP Treatment and Antivirals

Antivirals will shift to a weekly allocation cycle. This will align with the weekly allocation cadence for monoclonal antibodies (Bebtelovimab and sotrovimab) and the pre-exposure prophylaxis treatment (Evusheld). The ordering cadence will be as follows:

- Allocation Survey Sent - Monday
- Allocation Survey Due Back to IDPH - Tuesday at 4:00pm
- Allocation Ordered in Federal System - Thursday
- Allocation Amount Notification from IDPH to healthcare providers - Thursday

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Therapeutic Reporting Reminder

Sites receiving monoclonal antibodies, pre-exposure prophylaxis treatment, or oral antivirals MUST comply with federal reporting requirements.

Failure to comply with reporting requirements may result in the loss of COVID-19 therapeutic providers status and removal of COVID-19 therapeutic products. **Reporting requirements are as follows:**

- Monoclonal antibodies (REGEN-COV, bamlanivimab/etesevimab, sotrovimab): Report on-hand and usage data **every Wednesday** in NHSN (for long-term care facilities) or Teletracking (for all other sites including hospitals).
- Pre-exposure prophylaxis treatment and oral antivirals (Evusheld, Paxlovid, Molnupiravir and

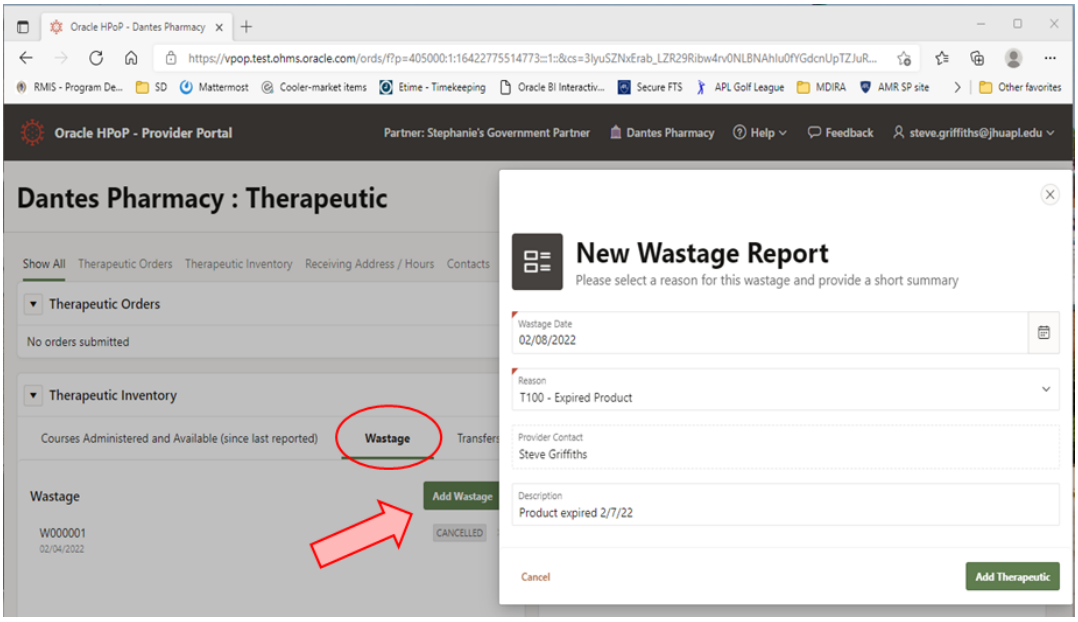
Bebtelovimab): Report on-hand and usage data **daily** in HPoP.

- Reporting should include product doses utilized since the last report date
- Reporting **IS NOT** a cumulative total of all doses utilized to date
- Please contact C19therapeutics@idph.iowa.gov for assistance with HPoP

Reporting Wastage Guidance

In the Provider or Partner Portal, a new tab has been added in the Therapy Inventory section – Wastage. Wastage will be reported for all therapeutic products except Sotrovimab. The following steps outline the reporting of wastage of COVID-19 Therapeutics in HPoP:

- Choose wastage, then select the green "Add Wastage" button. A blank report appears.
- Enter the wastage date, the reason for the wastage (expired, damaged, temp excursion, or other).
    - A provider contact may be chosen, or is predetermined.
    - A description can be added.
- Upon selecting Add Therapeutic, a second window will open allowing details for each line in the wastage report to be entered. Select the therapeutic from drop down, enter the number of courses, a lot number and the lot expiration date.



Allocations Threshold Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

	Iowa Statewide Allocations Threshold Remaining for the week Monday, May 1, 2022 - Sunday, May 8, 2022		
mAbs	Oral AVs		PrEP
Bebtelovimab	Mulnupiravir (Lagevrio)	Paxlovid	EVUSHELD
125 courses	**384 courses**	**860 courses**	**1824 doses** (monthly allocation)

- The minimum order quantity for Molupiravir is 24 courses.
- **Allocations will not include sotrovimab, bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV).**
- **IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Department of Health and Human Services has released a COVID-19 Therapeutics locator.

COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center -** IDPH has established a COVID-19 Therapeutics Call Center. To reach the COVID-19 Therapeutics Call Center, call **515-281-7317**.
- **COVID-19 Therapeutics Email -** IDPH has set up a COVID-19 Therapeutics Email to respond specifically to questions from healthcare providers regarding COVID-19 therapeutics. Therapeutic questions can be emailed to: C19Therapeutics@idph.iowa.gov
    - NOTE: **The COVID-19 Therapeutics Call Center and Email are intended for healthcare providers only.**
- **COVID-19 Therapeutics Table-** IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.