COVID-19 Therapeutics Information Brief

June 15, 2022

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

The next Therapeutics Information Brief will be June 29, 2022.

IMPORTANT/NEW COVID-19 Therapeutics Information

- Fact Sheet: Federal Retail Pharmacy Therapeutics Program
- Paxlovid NDC Update
- Therapeutic Reporting Cadence- UPDATE
- CDC Health Advisory Issued for COVID-19 Rebound After Paxlovid Treatment
- Bebtelovimab Self-Life Extension
- Sotrovimab Shelf-Life Extension - Reminder
- Paxlovid Shelf Life Extension - Reminder
- Renal Packaging for Paxlovid 150mg; 100mg Dose Pack for Patients with low eGFR
- Allocation Cadence Changes for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals
- Allocations Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals
- COVID-19 Therapeutics Information Resources

Fact Sheet: Federal Retail Pharmacy Therapeutics Program (FRPTP)

The Federal Retail Pharmacy Therapeutics Program (FRPTP) for COVID-19 therapeutics is a public-private partnership to increase therapeutics access and equity across the country. The FRPTP is a collaboration between the federal government, state and local health departments, and 20 national and independent pharmacy networks. The pharmacy partners included in the FRPTP receive COVID-19 therapeutic allocations directly from the federal government through the Department of Health and Human Services. The Federal Retail Pharmacy Therapeutics Program Fact Sheet includes additional information regarding this program.

- Federal Retail Pharmacy Therapeutics Program Fact Sheet

Paxlovid NDC Update

Pfizer is the sole manufacturer of Paxlovid. However, the 300mg dose of Paxlovid will have two NDCs due to expansion of Pfizer's manufacturing capacity. Refer to page 29 of the Paxlovid Fact Sheet for additional information.

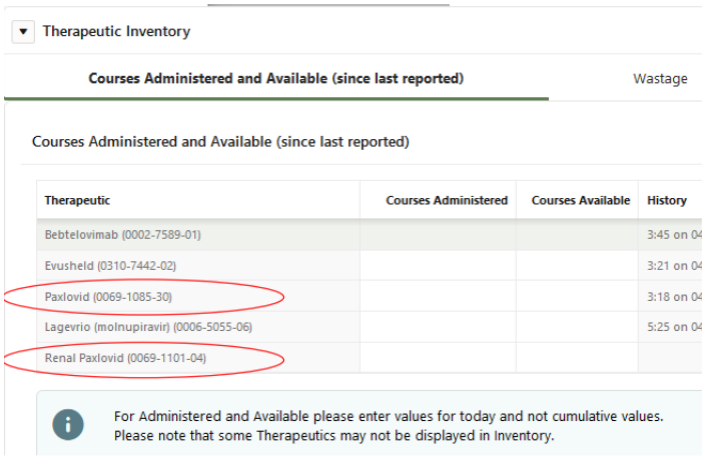
Therapeutic Reporting Cadence- UPDATE

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 **twice per week** in HPoP.
    - **Reporting should be completed by 11:59 pm on MONDAY and THURSDAY**
- 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

Healthcare providers should ensure reporting of the correct Paxlovid or Renal Paxlovid product. Paxlovid (renal) was renamed as Renal Paxlovid and the display order was changed to separate the Paxlovid products.



CDC Health Advisory Issued for COVID-19 Rebound After Paxlovid Treatment

The Centers for Disease Control and Prevention (CDC) issued a Health Alert Network (HAN) Health Advisory to update healthcare providers, public health departments, and the public on the potential for recurrence of COVID-19 or "COVID-19 rebound."

- **Paxlovid continues to be recommended for early-stage treatment of mild to moderate COVID-19 among persons at high risk for progression to severe disease.**
- Paxlovid treatment helps prevent hospitalization and death due to COVID-19. COVID-19 rebound has been reported to occur between 2 and 8 days after initial recovery and is characterized by a recurrence of COVID-19 symptoms or a new positive viral test after having tested negative.

- **A brief return of symptoms may be part of the natural history of SARS-CoV-2 (the virus that causes COVID19) infection in some persons, independent of treatment with Paxlovid and regardless of vaccination status.**
- Limited information currently available from case reports suggests that persons treated with Paxlovid who experience COVID-19 rebound have had mild illness; there are no reports of severe disease.

Bebetelovimab Shelf-Life Extension - May 20, 2022

May 20, 2022, the FDA authorized extension to the shelf-life from 12 months to 18 months for specific lots of the refrigerated Eli Lilly monoclonal antibody, bebtelovimab.

- Some batches may be stored for an additional 6 months from the labeled date of expiry (see Table) and, as required by the emergency use authorization for bebtelovimab, unopened vials of bebtelovimab injection, 175 mg/2 mL, must be stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.
- FDA granted this extension following a thorough review of data submitted by Eli Lilly. This extension applies to all unopened vials of bebtelovimab that have been held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) 111 for bebtelovimab.

Extended Expiry Dating for Bebtelovimab Authorized under EUA 111

Batch Number	Labelled Expiry Date	Extended Expiry Date
D476887	2022-07-11	2023-01-11
D476886	2022-07-13	2023-01-13
D487999	2022-07-13	2023-01-13
D480382	2022-10-27	2023-04-27
D488000	2022-10-27	2023-04-27
D492098	2023-02-16	2023-08-16
D494710	2023-02-16	2023-08-16
D493128	2023-02-17	2023-08-17

Sotrovimab Shelf-Life Extension - Reminder

On September 21, 2021, FDA and ASPR authorized an extension to the shelf-life from 12 months to 18 months for all lots of the refrigerated GSK monoclonal antibody, sotrovimab. Due to the high frequency of the Omicron BA.2 variant, sotrovimab is not currently authorized in any U.S. region. *Therefore, this drug may not be administered for treatment of COVID-19 under the Emergency Use Authorization until further notice by the Agency.*

Extended Expiry Dating for Sotrovimab Authorized under EUA 100

Batch Number	Labeled Expiry Date	Extended Expiry Date
658W	2022-02	2022-08
XV6W	2022-04	2022-10
Y74D	2022-04	2022-10
JP9Y	2022-04	2022-10
287F	2022-04	2022-10
287X	2022-05	2022-11
432U	2022-05	2022-11
433C	2022-05	2022-11

Retained product must be appropriately held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) 100.

Evaluation of future extension of shelf-life for sotrovimab is ongoing. FDA will continue to evaluate the available data and provide updated information as soon as possible. All sotrovimab vials may continue to be retained regardless of the current labeled expiry date or previously provided extension dates, unless otherwise notified by the Agency.

Paxlovid Shelf Life Extension - Reminder

The FDA has authorized the following extended expiry dates for certain lots of Paxlovid.

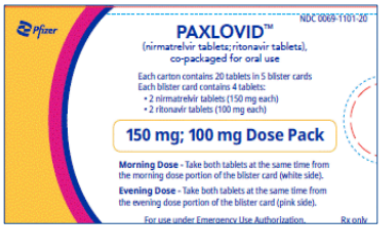
Drug Name	Lot#	Extended Expiry Date
Paxlovid	FL4516, FL4517, FR7229	The initial 3 lots were extended from 7/31 to 10/31/22.
	FR9088	4th lot was extended from 8/31 to 11/30/22

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

FDA updated the Paxlovid EUA to authorize an additional dose pack presentation of Paxlovid with appropriate dosing for patients within the scope of this authorization with **moderate** renal impairment.

- 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



Standard Dose

300 mg nirmatrelvir;100 mg ritonavir: Each carton contains 30 tablets divided in 5 daily dose blister cards. Each blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

Renal Dose

150 mg nirmatrelvir;100 mg ritonavir: Each carton contains 20 tablets divided in 5 daily dose blister cards. Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

If the renal packaging of Paxlovid is not available, healthcare providers may use the standard dose pack of Paxlovid and adjust the dosing per the Dear HCP Letter guidance issued by the FDA for patients with renal impairment.

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

Iowa Statewide Allocations Threshold Remaining for the week Monday, June 13, 2022 - Sunday June 19, 2022				
mAbs	Oral AVs			PrEP
Bebtelovimab	Mulnupiravir (Lagevrio)	Paxlovid	Renal Paxlovid	EVUSHELD
165 courses	**312 courses**	**880 courses**	**80 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 -** To reach the IDPH COVID-19 Therapeutics Call Center, call **515-281-7317**.
- **COVID-19 Therapeutics Email -** Therapeutic questions from healthcare providers can be emailed to: C19Therapeutics@idph.iowa.gov
- **COVID-19 Therapeutics Table-** IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.
- Outpatient Therapeutics Decision Aid
- Side-by-Side Overview Outpatient Therapeutics
- NIH COVID-19 Treatment Guidelines, last updated: April 8, 2022