

# CDPH Therapeutics Update

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# Agenda

- Today's Agenda
  - Test-to-treat Playbook
  - Distribution and Data
  - General updates
  - Pharmacist prescribing update
  - CDPH Resources and Links
  - Q & A



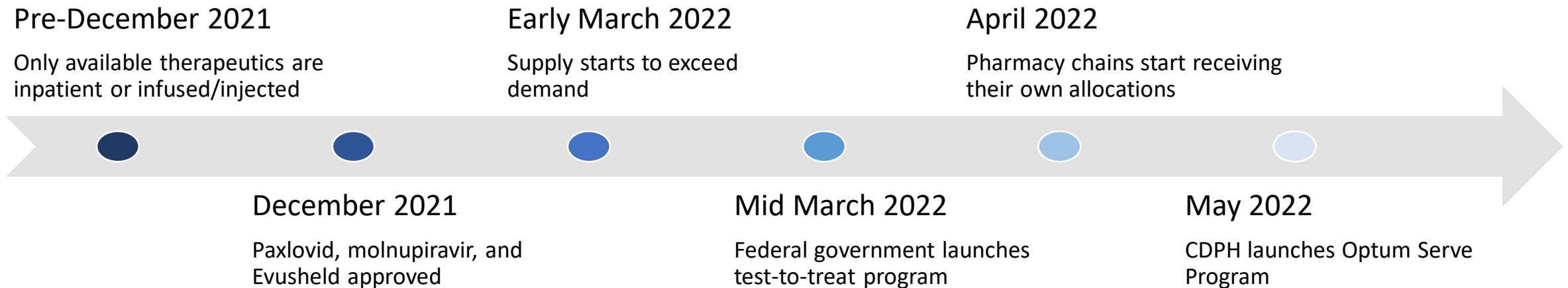
## Currently Available Drugs for COVID-19 Treatment and Pre-exposure Prophylaxis

Drug	Indication	Type	Information
★ → Paxlovid	Treatment	Oral pills	EUA for patients ≥12 y/o; highly effective in reducing deaths/hospitalizations; drug-drug interaction risk; not recommended for severe renal or hepatic impairment
★ → Molnupiravir	Treatment	Oral pills	EUA for patients ≥18 y/o; moderately effective in reducing deaths/hospitalizations; not recommended for pregnant people
Remdesivir	Treatment	IV	FDA-approved for patients ≥12 years; EUA in patients younger than 12; highly effective in reducing deaths/hospitalizations; multi-day treatment
Bebtelovimab	Treatment	IV	EUA for patients ≥12 y/o; real-world effectiveness data pending but likely similar to other mABs; given in single dose
Evusheld	PrEP	Injection	Indicated for immunocompromised individuals who cannot mount an immune response to COVID-19 vaccinations; taken before getting sick or exposed

★ Only drugs currently in T2T pathway (orals)

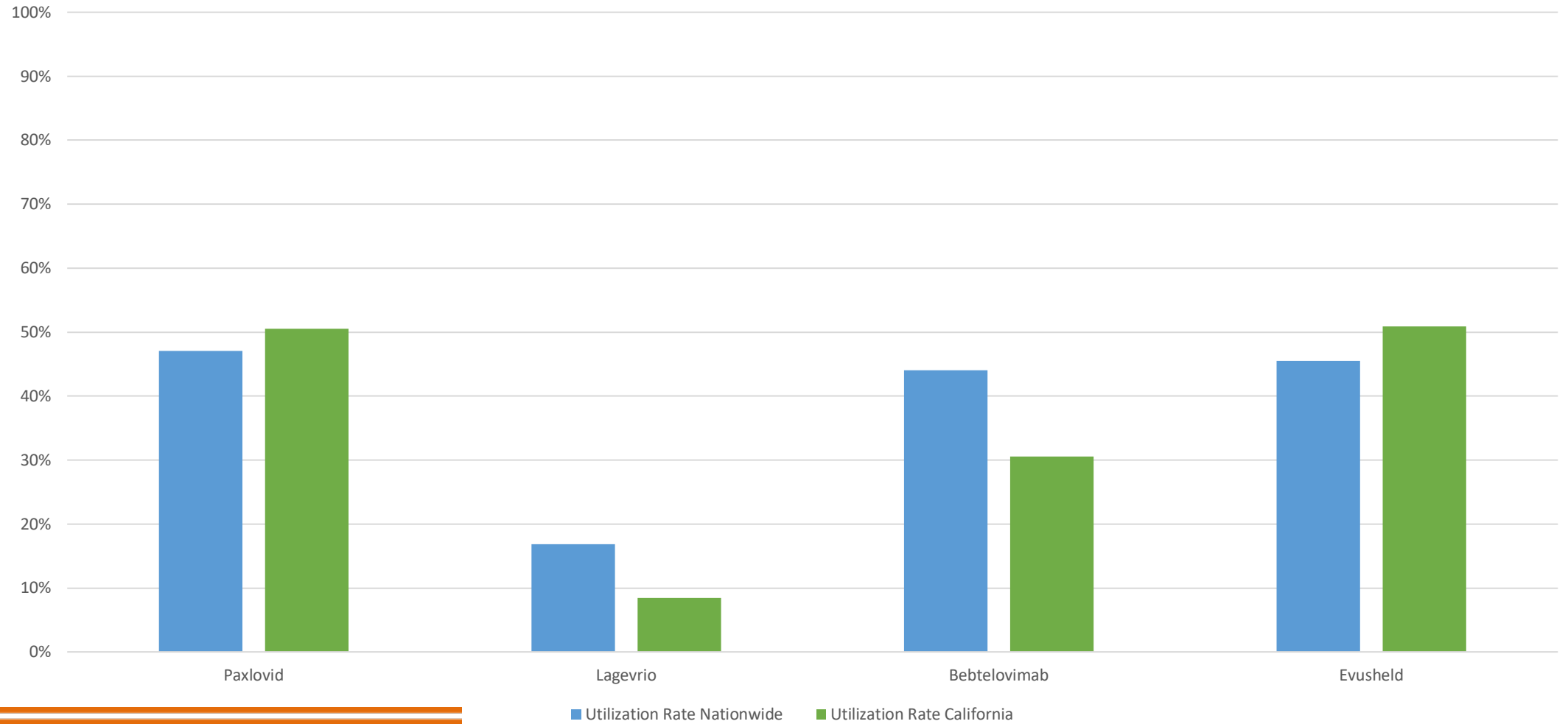
# Test-to-Treat Playbook

- Living document: <http://www.cdph.ca.gov/Test-to-Treat-Playbook>
- Highlights COVID-19 therapeutics as a critical part of pandemic response
  - As of June, 123,000 Paxlovid courses had been administered in CA. CDPH estimates this means:
    - Between 1K and 7K hospitalizations have been averted
    - Between 130 and 1,400K deaths have been averted
- Role of Tx has changed with introduction of Paxlovid



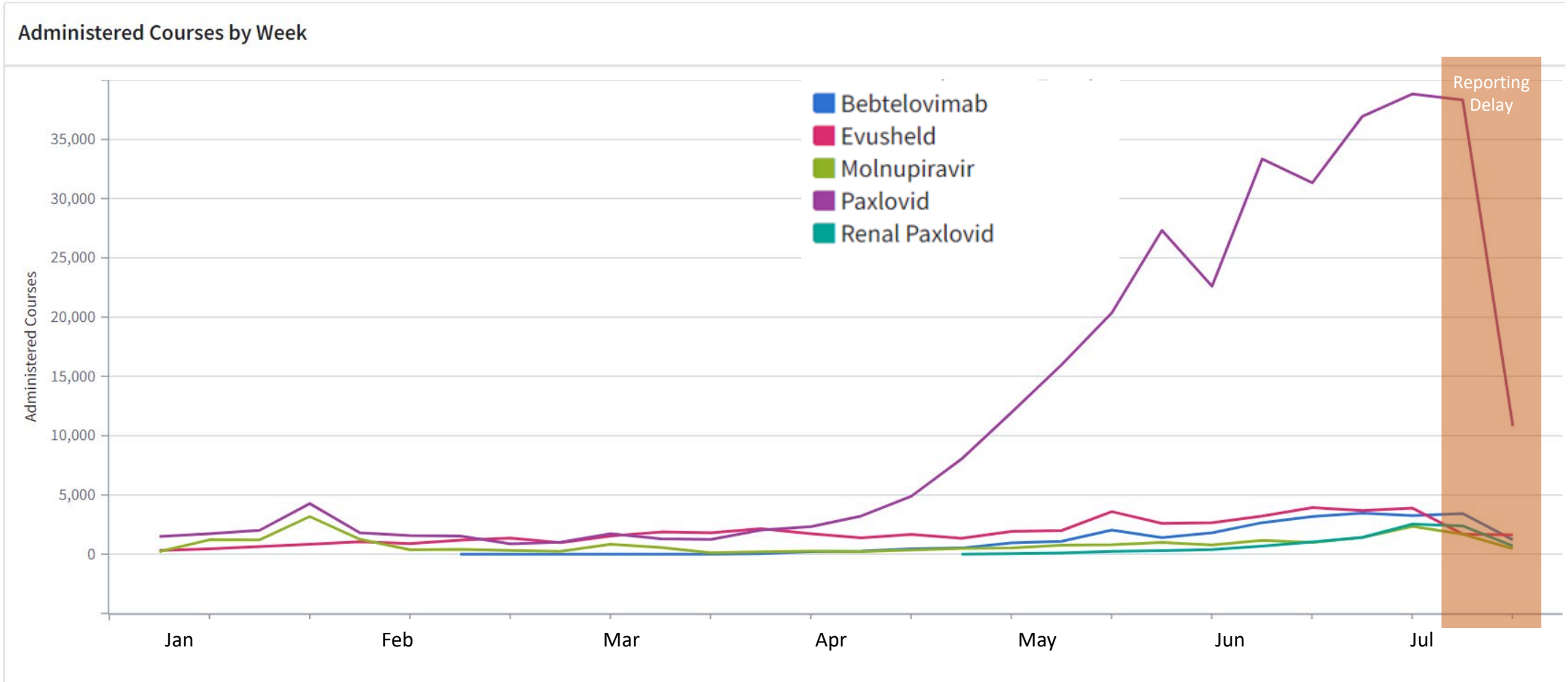
# Distribution & Clinical

Utilization Rates Nationwide vs. CA



■ Utilization Rate Nationwide   ■ Utilization Rate California

# Data Update (Reliant on Reporting Rates)



# General Updates

- FDA revised the [Evusheld Fact Sheet for Healthcare Providers](#) to recommend repeat dosing every 6 months with 300mg tixagevimab + 300 mg cilgavimab (i.e., 2 Evusheld prepackaged doses)
  - Nonclinical data indicate that Evusheld's neutralizing activity decreases ~ 5-fold against the BA.2 and BA.2.12.1 variants, and 33-to 65-fold against BA.4 and BA.5
  - Despite this, pharmacokinetic modeling suggests that sufficient activity against these subvariants may be retained for six months at drug concentrations achieved following 2 Evusheld doses
- \$158M in CA FY22-23 budget for therapeutics to include:
  - Grants to safety net system to facilitate access to therapeutics, including test-to-treat
  - Public media campaign
  - State test-to-treat sites (Optum Serve)



# Pharmacists & Paxlovid Prescribing

- Updated Paxlovid EUA allows state-licensed pharmacist prescribing w/ restrictions. The EUA refers to both regular and renal Paxlovid.
- In order to prescribe and dispense Paxlovid to a patient, pharmacists must have the following:
  - Sufficient info to determine whether the patient has kidney/liver problems, including:
    - Electronic or printed health records <12 months old, including the most recent blood work labs;
    - The results of renal and hepatic function tests; or
    - A consult with the patient's regular health care provider
  - The patient's med list, including OTC medications, from patient health records, a provider consult, or patient self-attestation
- If missing the above info, OR if the patient needs modifications to their current meds, OR if the patient isn't eligible for Paxlovid based on standards in the EUA, the pharmacist should refer patients to a MD, PA, or APRN.



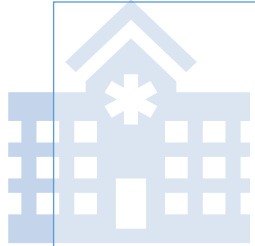
## **FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations: Specific to California**

DCA released a document that waives Business and Professions Code sections 4051, 4052, 4052.1, 4052.2, and 4052.8, to the extent those provisions prohibit pharmacists from independently initiating and furnishing Paxlovid for individual patients, subject to the criteria and conditions laid out in the EUA. Additionally, pharmacists must meet the below criteria:

- The pharmacist is certified in basic cardiopulmonary resuscitation;
- The pharmacist maintains documentation for each patient furnished Paxlovid sufficient to demonstrate compliance with the requirements of the EUA; and,
- The pharmacist complies with all applicable federal and state recordkeeping and reporting requirements, including medication error and adverse event reporting requirements of the EUA.

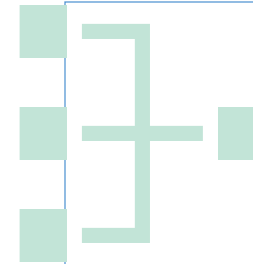
# Pharmacists & Paxlovid Prescribing - Implementation

Due to the restrictions on prescribing, many pharmacies and pharmacists may choose not to offer this service to patients. However, there are a few settings particularly well-suited for this change:



## Skilled Nursing Facilities

- In cases where a physician consult is not quickly available, RNs and other staff in SNFs can submit health records to their long-term care pharmacy (LTCP) partners if a patient tests positive. SNF directors should train their staff in the types of records that should be passed to LTCPs (i.e., renal/hepatic function information and medication lists).



## Health System Pharmacists

- CDPH recommends that large health systems with integrated pharmacies (i.e., Kaiser, the University of California, etc.) train their pharmacist staff in how to prescribe Paxlovid to patients.



## Rural/Remote Locations

- Pharmacist prescribing in remote areas could fill gaps in COVID-19 therapeutics access. While this may not be an option for all patients, especially those without an established health care provider, CDPH recommends that pharmacists use clinician telephone consultations whenever possible to prescribe Paxlovid to patients.



# Pharmacists & Paxlovid Prescribing - Resources

- [Paxlovid EUA Letter of Authorization](#)
- [Frequently Asked Questions on the Emergency Use Authorization for Paxlovid](#)
- [CA DCA Pharmacy Waiver for Paxlovid Prescribing](#)
- [FDA Updates on Paxlovid for Health Care Providers](#)
- [Emergency Use Authorization: Drugs and Non-Vaccine Biological Products](#)
- [Coronavirus Disease](#)
- [Coronavirus Treatment Acceleration Program \(CTAP\)](#)
- [Test to Treat Locator](#)
- [COVID-19 Therapeutics Locator](#)

# CDPH Resources and Links

- [CDPH Therapeutics Resource page](#)
- [LHJ Therapeutics SharePoint](#) (for access email [JEOCUser54@cdph.ca.gov](mailto:JEOCUser54@cdph.ca.gov))
- [Therapeutic Weekly Webinar Files](#) (Meeting Presentations, Recordings, & Q&A)
- [CDPH Weekly Therapeutic Update Webinar](#) (Tuesdays at 1100 hours PST)
- [Therapeutic Weekly Update Newsletter Files](#) (SharePoint)
- [CDPH Snowflake Webinar](#) files (Datasets, Webinar Presentation, and Recording)
- [My Turn](#) (CA COVID-19 Vaccine Scheduling site with link to HHS/ASPR Test-to-Treat locator.)
- [Test-to-Treat Playbook](#) (clinical guidance and tools, distribution and logistics, data applications and availability, and best practices)
- Finding Providers and Test-to-Treat Sites
  - [COVID-19 Therapeutics Locator](#) (arcgis.com)
  - [Test-to-Treat](#) (hhs.gov)

# Questions and Answers

