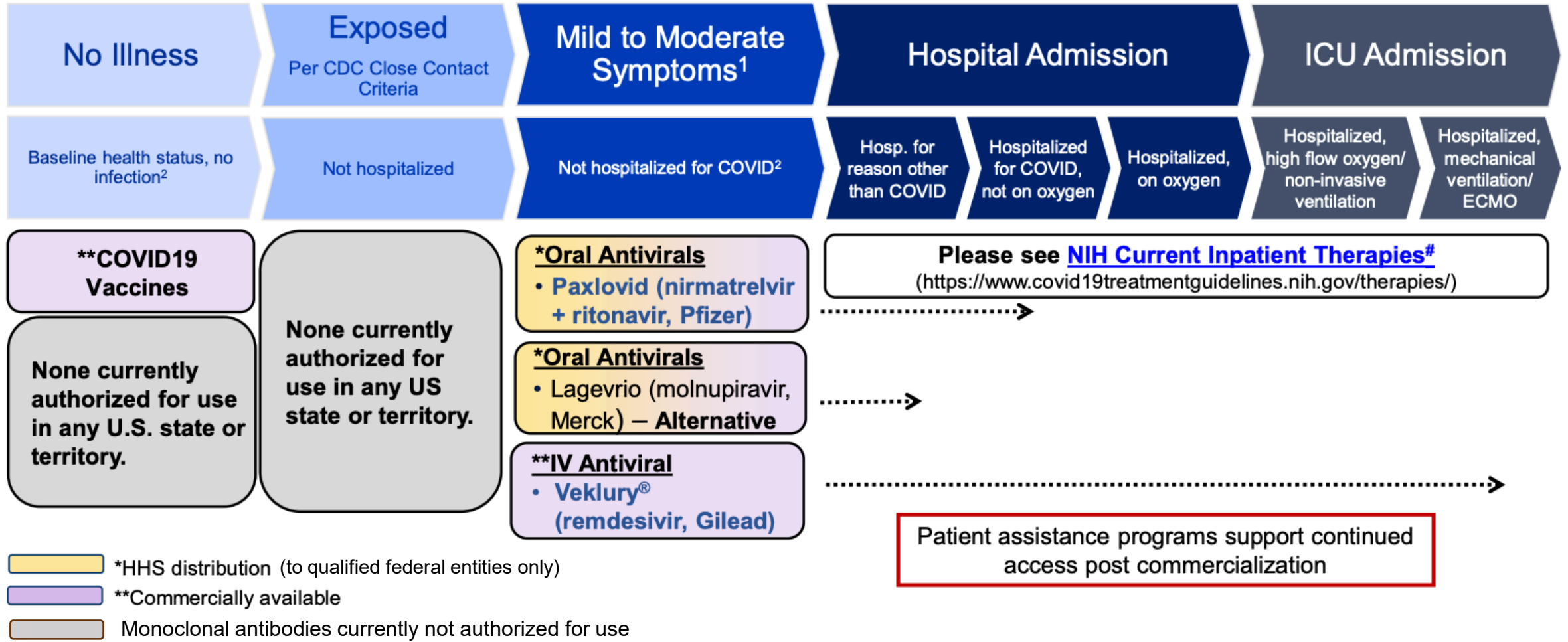# COVID-19 Therapeutics Updates

Jessica de Jarnette, MD, CDPH

Therapeutics Activity Against Emerging Variants

- Paxlovid (nirmatrelvir co-packaged with ritonavir), Veklury (remdesivir), and Lagevrio (molnupiravir) are expected to retain activity against all circulating variants based on current data.

- mAbs currently not authorized for use (Regen-COV, bam/ete, sotrovimab, bebtelovimab, Evusheld) are routinely tested against newly emerging variants.

Summary of COVID-19 Preventative Agents & Treatments

No Illness	Exposed Per CDC Close Contact Criteria	Mild to Moderate Symptoms[1]	Hospital Admission			ICU Admission	
Baseline health status, no infection[2]	Not hospitalized	Not hospitalized for COVID[2]	Hosp. for reason other than COVID	Hospitalized for COVID, not on oxygen	Hospitalized, on oxygen	Hospitalized, high flow oxygen/ non-invasive ventilation	Hospitalized, mechanical ventilation/ ECMO

**COVID19 Vaccines

None currently authorized for use in any U.S. state or territory.

None currently authorized for use in any US state or territory.

*Oral Antivirals
- **Paxlovid (nirmatrelvir + ritonavir, Pfizer)**

*Oral Antivirals
- **Lagevrio (molnupiravir, Merck) — Alternative**

**IV Antiviral
- **Veklury® (remdesivir, Gilead)**

Please see NIH Current Inpatient Therapies#
(https://www.covid19treatmentguidelines.nih.gov/therapies/)

Patient assistance programs support continued access post commercialization

*HHS distribution (to qualified federal entities only)

**Commercially available

Monoclonal antibodies currently not authorized for use

Therapies | COVID-19 Treatment Guidelines (nih.gov)

CDPH

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COVID-19 Medical Coverage Changes
Following End of Federal Public Health Emergency

	Vaccines	Treatment	Testing
Medi-Cal Fee-for-Service	**Free** COVID-19 vaccines.[1]	**Free** COVID-19 treatment and related doctor visits is guaranteed at least until September 30, 2024.[2]	**Free** COVID-19 testing if ordered by a doctor. Eight **free** at-home test kits per month are guaranteed at least until September 30, 2024.[2]
Medi-Cal Managed Care	**Free** COVID-19 vaccines.[3]	**Free** COVID-19 treatment and related doctor appointments.[3]	**Free** COVID-19 testing, including eight free at-home test kits per month.
Medicare	**Free** COVID-19 vaccines with in-network providers.[4]	**Free** COVID-19 oral medications. COVID-19 hospital visits and doctor visits with in-network providers are covered, but cost-sharing varies by plan.[5]	**Free** COVID-19 testing if ordered by a doctor. The cost of at-home test kits for people with Medicare Advantage will vary by plan and might be free in some plans. Some Medicare Advantage plans may still provide free at-home COVID-19 tests.[4] Medicare – Dual coverage also known as Medi-Medi where Medicare does not provide coverage for over-the-counter (OTC) COVID tests, Medi-Cal will provide coverage for the OTC COVID antigen tests through the Medi-Cal Rx benefit.
California Regulated Private Plans	**Free** COVID-19 vaccines, treatment, and testing with in-network providers,[3] including eight at-home test kits per month via SB510. Using out-of-network providers may result in costs such as co-pays.		
Uninsured	**Until December 31, 2024 through the Bridge Access Program (BAP)**[6]: Low-cost or free COVID-19 health care provider visits at FQHCs and free clinics. Free COVID-19 vaccines at BAP pharmacies, community organizations, clinics and FQHCs. See more resources at the CDC Bridge Access program and Vaccines for Children.[5] COVID-19 oral antivirals (OAV) will remain no cost until the government procured product is depleted. Once government procured product is no longer available, uninsured patients will have access to free OAV through the manufacturer's patient assistance programs. Learn more: testinglocator.cdc.gov.[7]		

COVID-19 Coverage Change Table (ca.gov)

Medi-Cal Rx Coverage (Contract Drug List)

Both COVID-19 oral antivirals are covered on the Medi-Cal contract drug list and should have $0 copay.

Molnupiravir *	Capsules	200 mg	ea	QL	* Restricted to a maximum quantity of 40 capsules per dispensing.

Nirmatrelvir/ Ritonavir *	Tablets	150 mg/100 mg	ea	QL	* Restricted to a maximum quantity of 30 tablets per dispensing.

Update on Billing for Pharmacists Prescribing Paxlovid

- Business and Professions Code 4052.04 states a pharmacist may furnish COVID-19 oral therapeutics following a positive test for SARS-CoV-2.

- Department of Healthcare Services (DHCS) will reimburse pharmacists for the prescribing (consultation and assessment of need for treatment) of all Paxlovid products.

- DHCS is extending the temporary allowance to allow billing with these CPT codes from the end of the PHE (May 11, 2023) through September 30, 2024.

Commercial Paxlovid™ Reimbursement and Update on Billing for Pharmacists Prescribing Paxlovid
January 17, 2024

Background

The Department of Health Care Services (DHCS) is providing the following policy update and billing guidance to pharmacy providers about Paxlovid™ (nirmatrelvir and ritonavir tablets), approved or authorized by the U.S. Food and Drug Administration (FDA) for the treatment of COVID-19 when independently initiated and furnished by a pharmacist, and about the commercialization of Paxlovid.

What Pharmacy Providers Need to Know

On May 25, 2023, the FDA approved the use of Paxlovid for the treatment of adults at high risk of progression to severe COVID-19. Paxlovid is still available through an FDA Emergency Use Authorization (EUA) for the treatment of mild-to-moderate COVID-19 in non-hospitalized adolescents from 12 to 17 years of age and weighing ≥40 kg.

Commercialization

On October 13, 2023, Pfizer, the manufacturer of Paxlovid, reached an agreement with the federal government on a timeline to transition Paxlovid from government-managed EUA-Paxlovid distribution to traditional commercial distribution. The commercial transition began on November 1, 2023, as the federal government began to discontinue the distribution of Pfizer's EUA-Paxlovid. Pfizer provided New Drug Application (NDA)-labeled commercial supply to all channels by the end of 2023.

Commercial NDA-labeled Paxlovid is now a covered Medi-Cal Rx benefit for claims with dates of service (DOS) on or after November 1, 2023. Pharmacy providers are encouraged to submit retroactive claims if applicable.

Pharmacy providers will be reimbursed the ingredient cost for commercialized products. The professional dispensing fee will be reimbursed for both NDA and EUA-labeled products. Claims for the dispensing fee and ingredient cost should be billed to Medi-Cal Rx.

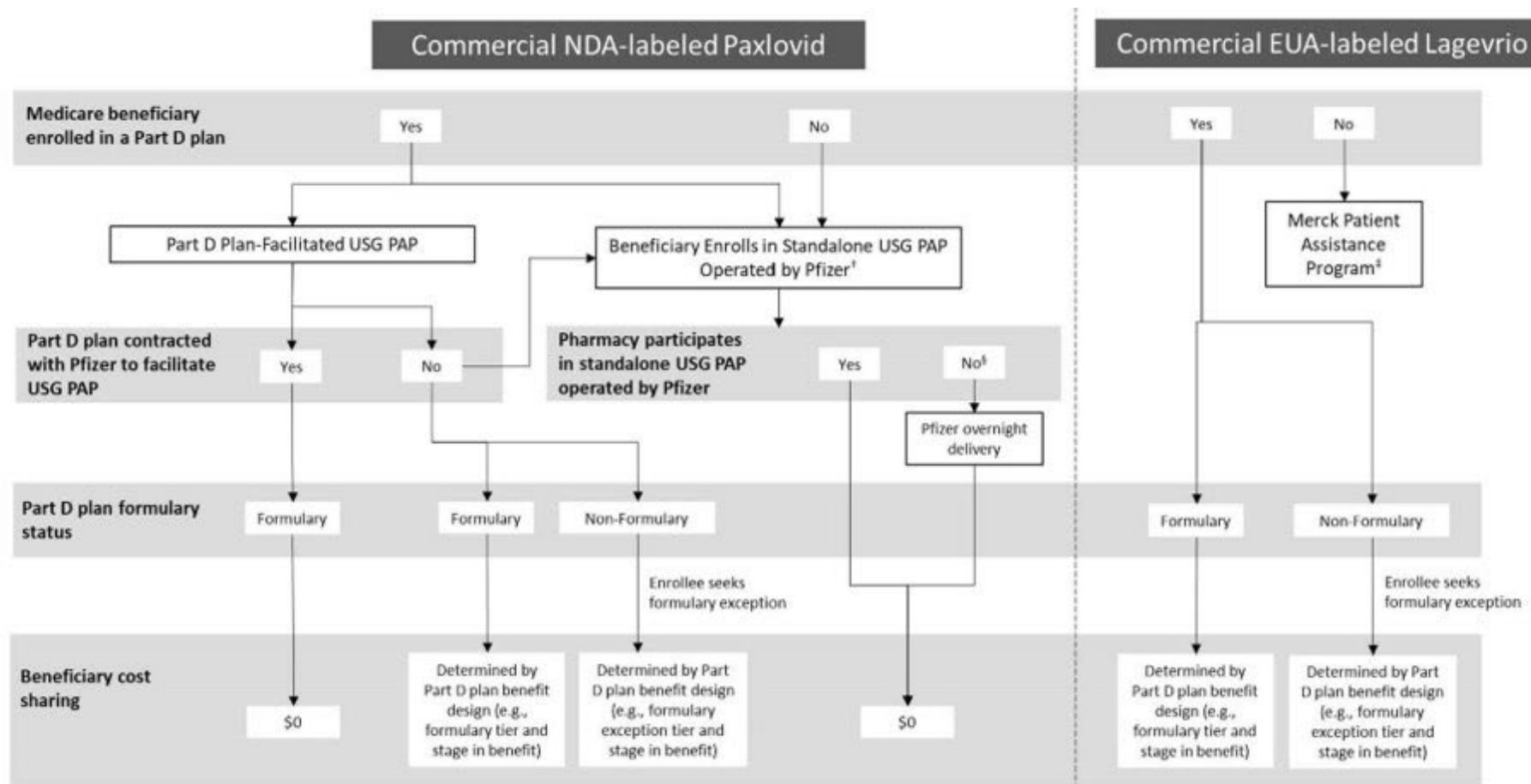Commercial Paxlovid™ Reimbursement and Update on Billing for Pharmacists Prescribing Paxlovid
01/17/2024

CMS Guidance for Oral Antivirals

- Oral antivirals for COVID-19 that meet the statutory requirements at section 1860D-2(e) of the Social Security Act and are not otherwise excluded from coverage **must be covered** by Part D plans, either as a formulary product or through the formulary exception process consistent with 42 CFR § 423.578(b).

- Consistent with the November 4, 2022, memorandum CMS continues to encourage Part D sponsors to add at least one oral antiviral for COVID-19 that meets the definition of a Part D drug to their Contract Year (CY) 2024 formulary on a preferred or $0 cost-sharing tier, as available in the plan benefit structure.

CMS Guidance for Oral Antivirals (cont.)
Pathway for Medicare Beneficiaries

Programs for Uninsured and Underinsured Individuals

Product	Programs	Description and Additional Information
Lagevrio	Patient Assistance Program	**Website**: Merck Programs to Help Those in Need - Product (merckhelps.com) **Tel**: **888-727-8180**
Paxlovid	Co-Pay Savings Program	Co-Pay Savings Program will be available for eligible **commercially insured patients**
Paxlovid	US Government Patient Assistance Program operated by Pfizer (USG PAP)	**Website:** PAXCESS™ | PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets) **Tel**: **1-877-219-7225** (1-877-C19-PACK) Through December 31, 2024: Anyone uninsured or covered by federal programs, such as Medicare or Medicaid, can receive USG-procured, NDA-labeled Paxlovid at no cost through the USG PAP operated by Pfizer. Through this program, participating PAP dispensing sites will be reimbursed for any product dispensed, along with a dispensing fee. For retail pharmacies that would like to learn more about participating in the U.S. Government PAP, please contact the program vendor at **PharmacyNetworkContract102101@assistrx.com**. Starting January 1, 2025: Eligible uninsured and underinsured patients can receive USG procured, NDA-labeled Paxlovid at no cost. Through this program, participating PAP dispensing sites will be reimbursed for any product dispensed, along with a dispensing fee.

Overview: PAXCESS Patient Support

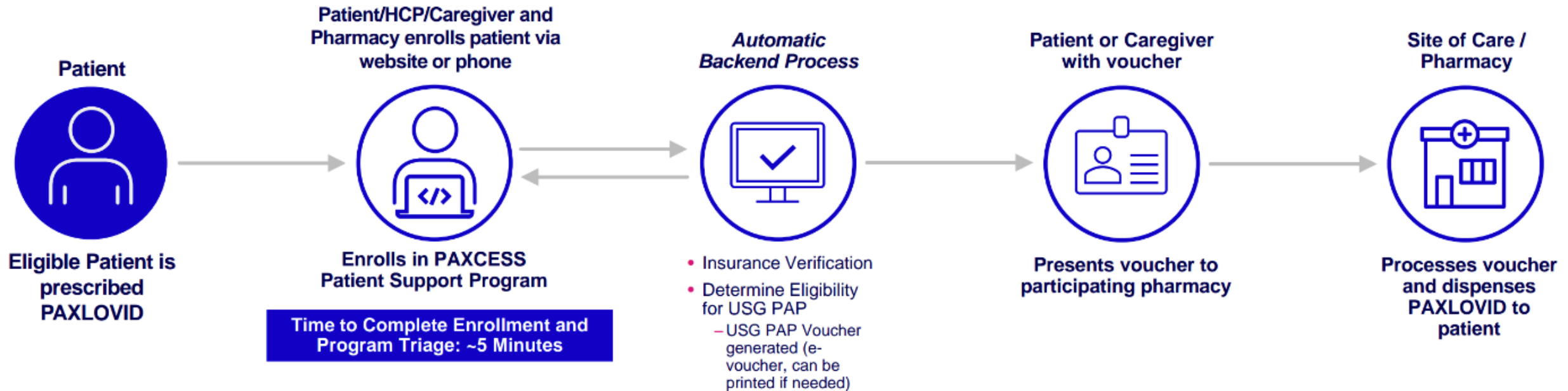**Supporting Patients Prescribed PAXLOVID through 2 Distinct Offerings**

PAXCESS
Patient Support Program

Now Available

Now Available

Pfizer PAXCESS Co-Pay Savings Program

U.S. Government Patient Assistance Program (USG PAP)*:
Operated by Pfizer

Commercially Insured

Medicare **Medicaid**

Uninsured

- PAXLOVID reimbursement through traditional healthcare system
- Out-of-pocket costs determined by insurer and PBM
- Through Co-Pay Program, eligible patients pay as little as $0*

- 2024: PAXLOVID remains free of charge for patients eligible for USG PAP

Details found at PAXLOVID.com and PAXLOVID.pfizerpro.com

*Eligible commercially insured patients can save up to $1,500 per prescription. Maximum annual savings up to $1,500. Terms and conditions apply. Please visit www.PAXLOVID.com/paxcess-terms-and-conditions for full terms and conditions.

*USG PAP eligibility also includes patients insured through TRICARE and the VA Community Care Network

1
2

Please see full Prescribing Information including BOXED WARNING at this presentation or at www.paxlovid.pfizerpro.com

Pfizer | Paxlovid [nirmatrelvir 150 mg tablets | ritonavir 100 mg tablets]

Retail Pharmacy Participating in USG PAP
(operated by Pfizer)

Patient

Eligible Patient is prescribed PAXLOVID

Patient/HCP/Caregiver and Pharmacy enrolls patient via website or phone

Enrolls in PAXCESS Patient Support Program

Time to Complete Enrollment and Program Triage: ~5 Minutes

Automatic Backend Process

- Insurance Verification
- Determine Eligibility for USG PAP
  - USG PAP Voucher generated (e-voucher, can be printed if needed)

Patient or Caregiver with voucher

Presents voucher to participating pharmacy

Site of Care / Pharmacy

Processes voucher and dispenses PAXLOVID to patient
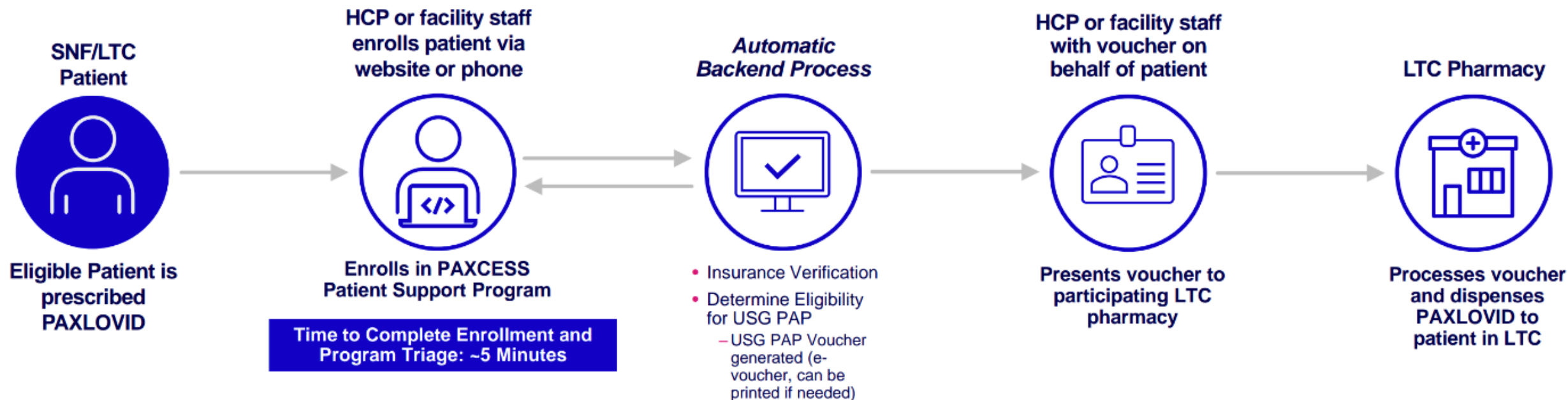
Pharmacies can participate by sending email to:
PharmacyNetworkContract102101@assistrx.com

LTC Pharmacy Participating in USG PAP
(operated by Pfizer)

SNF/LTC Patient

Eligible Patient is prescribed PAXLOVID

HCP or facility staff enrolls patient via website or phone

Enrolls in PAXCESS Patient Support Program

Time to Complete Enrollment and Program Triage: ~5 Minutes

Automatic Backend Process

- Insurance Verification
- Determine Eligibility for USG PAP
  - USG PAP Voucher generated (e-voucher, can be printed if needed)

HCP or facility staff with voucher on behalf of patient

Presents voucher to participating LTC pharmacy

LTC Pharmacy

Processes voucher and dispenses PAXLOVID to patient in LTC

Pharmacies can participate by sending email to:
PharmacyNetworkContract102101@assistrx.com

Continued Access for Lagevrio

- The **Merck Patient Assistance Program (a 501c3 non-profit organization)** provides Lagevrio free of charge to patients who meet its eligibility criteria and who, without assistance, could not otherwise afford the product.
  - This product is ONLY available through an URGENT NEED request. Your Health Care Provider must call 800-727-5400 and tell the program representative that they are making an Urgent Need Request for LAGEVRIO. The program representative will provide necessary instructions. Your Health Care Provider must follow the program representative's instructions to make your request. You may also check your eligibility on MerckHelps.

- In addition, USG-procured Lagevrio will continue to be distributed to certain federal entities, including HRSA-supported health centers, Indian Health Service, and others until USG supply is depleted.

So…how do we know which pharmacies are participating in the PAP program?

Currently combining T2T locator + therapeutics locator + participating PAP locator in one site, but not available yet

Currently most Walgreens are participating, CVS pending, independent pharmacies—it depends

Only way to find out currently which pharmacies are participating is to a) call pharmacy to ask; b) call number on Paxcess website; or c) patient to go ahead and enroll on Pfizer site for Paxcess program

Resources

- Any questions: cdphtherapeutics@cdph.ca.gov

- Therapies | COVID-19 Treatment Guidelines (nih.gov)
- COVID-19 Coverage Change Table (ca.gov)
- Medi-Cal Rx Contract Drugs List - DHCS
- Commercial Paxlovid™ Reimbursement and Update on Billing for Pharmacists Prescribing Paxlovid (ca.gov) - DHCS
- Commercial COVID-19 Oral Antivirals Memo (cms.gov)
- PAXCESS™ | PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets)
- Merck Programs to Help Those in Need - Product (merckhelps.com)