

## Provider and Health System Access to Commercially Available JYNNEOS Vaccine in California

### Background:

The purpose of this document is to share information with California health care providers about offering JYNNEOS vaccine through the commercial market to persons at risk for mpox. JYNNEOS is approved by the U.S. Food and Drug Administration (FDA) for prevention of smallpox and mpox disease in adults 18 years and older at high risk for infection, and it is currently on the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) routine immunization schedule for certain individuals at risk for mpox.

### CDC ACIP recommendations for mpox vaccination

As of October 2023, ACIP recommends vaccination with the 2-dose JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox, which includes the following:

1. Gay, bisexual, and other men who have sex with men, transgender people, or nonbinary people who, in the past 6 months, have had one of the following:
  - New diagnosis of  $\geq 1$  sexually transmitted disease
  - More than one sex partner
  - Sex at a commercial venue
  - Sex in association with a large public event in a geographic area where mpox transmission is occurring.
2. Sexual partners of persons with the risks described above
3. Persons who anticipate experiencing any of the above
4. Persons at risk for occupational exposure to orthopoxviruses:
  - a. Research laboratory personnel working with orthopoxviruses
  - b. Clinical laboratory personnel performing diagnostic testing for orthopoxviruses
  - c. Orthopoxvirus and health care worker response teams designated by appropriate public health and antiterror authorities.

In addition, CDC also recommends vaccination for people traveling to countries with [clade I outbreaks](#) who anticipate any sexual activity, regardless of gender identity or sexual orientation.

Any person at risk for mpox infection should receive the 2-dose series, 28 days apart. People who received only one vaccine dose (and were never diagnosed with mpox), should receive the 2nd dose at 28 days or as soon as possible thereafter, regardless of the amount of time that has lapsed since the first dose; the series should not be restarted.

**Most people who meet the above criteria and have health insurance should have access to JYNNEOS vaccine for free.** In addition, appointments are now available at several pharmacy chains (e.g., [CVS](#), [Rite Aid](#), [Walgreens](#)) in California. Check with your local pharmacy to inquire about JYNNEOS vaccine availability. Some pharmacies may be willing to stock JYNNEOS if there is enough demand for the vaccine. Further details about coverage for insured persons and options for uninsured or underinsured persons are below.

### **JYNNEOS Administration in Children <18 Years of Age**

JYNNEOS is also available for use as post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) for children and adolescents under 18 years determined to be at high risk for mpox infection under the [Emergency Use Authorization \(EUA\)](#) issued by the US Food and Drug Administration on August 9, 2022. [CDC clinical considerations for mpox in children and adolescents in the U.S.](#) are available. For more information about vaccination, please visit: [Mpox Vaccine Considerations](#). Check with the health insurer about reimbursement status.

## **Coverage Options for JYNNEOS Vaccine for Providers & Health Systems**

### **For Insured Individuals**

#### **Private Insurance**

Individual and employer-sponsored private health plans subject to the Affordable Care Act's preventive services coverage standards must provide coverage for individuals to receive vaccines that ACIP recommends without charging a copayment or coinsurance when provided by an in-network provider, even for patients who have not met their yearly deductible. When ACIP recommends a new vaccine, there is a one-year lag for when the coverage requirement starts for that vaccine. Since ACIP recommended the JYNNEOS vaccine for mpox in October 2023, health plans must update their coverage policies once a new plan year starts after October 2024. However, many health insurers have already started covering JYNNEOS vaccine without cost sharing, and as of September 2024, the California Department of Public Health was unaware of denials to cover the JYNNEOS vaccine. In the individual market, coverage would be required beginning January 1, 2025.

### **Medi-Cal**

Medi-Cal covers the mpox vaccine (JYNNEOS) for Medi-Cal members 18 years of age and older. For more information, see the [Medi-Cal Rx Contract Drug List](#) and [Commercial JYNNEOS Reimbursement Update](#).

JYNNEOS and any other vaccine covered by Medi-Cal can be billed either as a pharmacy benefit or as a medical benefit, per this California Department of Health Care Services chart on the [Medi-Cal Rx Pharmacy Carve Out](#) (chart #2, page 2).

### **Children's Health Insurance Program (CHIP)**

CHIP covers ACIP-recommended vaccines for individuals for whom ACIP recommends the vaccination.

### **Medicare**

Medicare Part D: People with Medicare prescription drug coverage receiving the vaccine preventatively, as pre-exposure prophylaxis, in accordance with the ACIP recommendation pay nothing out of pocket for the vaccine.

Medicare Part B: Medicare Part B will cover JYNNEOS for the purpose of treatment or post-exposure prophylaxis. There is no Medicare Part B coverage of JYNNEOS for preventive care, i.e., in the absence of a need for treatment due to a diagnosis, direct exposure, or other treatment need. When JYNNEOS is given as treatment or post-exposure prophylaxis, people with Medicare are responsible for paying the Part B deductible and 20% coinsurance for both the vaccine and its administration.

When using the generic vaccine administration codes (90460 and 90471), reimbursement for vaccine administration is about \$17 dollars depending on the setting, plus an additional geographic adjustment when appropriate.

### **Veteran Affairs (VA) Health Care**

JYNNEOS is available to veterans enrolled in VA health care with a provider recommendation.

### **Military**

People serving in the military or who are a military dependent are eligible for TRICARE. Under TRICARE, [vaccines are covered according to the CDC recommended schedule](#).

TRICARE is a health program for Uniformed Service members and their families, National Guard/Reserve members and their families, survivors, former spouses, Medal of Honor recipients and their families, and others registered in the Defense Enrollment Eligibility Reporting System (DEERS). Eligible persons must [enroll](#) and purchase a plan to participate.

## For Uninsured and Underinsured Individuals

### [Pre-Exposure Prophylaxis Assistance Program PrEP-AP](#)

The Pre-Exposure Prophylaxis Assistance Program (PrEP-AP) works to increase PrEP accessibility and uptake for eligible Californians and ensures underserved, at-risk Californians have access to medical care and services to prevent new human immunodeficiency virus (HIV) infections. JYNNEOS is on the PrEP-AP formulary.

Clinical providers and clinics can enroll in the PrEP-AP provider network. Enrolling allows for reimbursement for services provided such as in-clinic administration of the JYNNEOS vaccine. Interested clinical providers can reach out to [PrEP.Support@cdph.ca.gov](mailto:PrEP.Support@cdph.ca.gov) to request a copy of the PrEP-AP Clinical Provider Application. To be a PrEP-AP clinical provider, the facility must be Medi-Cal and 340B affiliated, and some exceptions apply. Please see [PrEP-AP Clinical Provider Questions](#) for additional details. This application process may take weeks to months.

### [AIDS Drug Assistance Program \(ADAP\)](#)

AIDS Drug Assistance Program (ADAP) helps ensure that people living with HIV and AIDS in California, who are uninsured or under-insured, have access to medication. ADAP pays the prescription costs for medication on the [ADAP Formulary](#) for eligible individuals. JYNNEOS is on the ADAP formulary.

[ADAP enrollment sites](#) must be approved and certified through the Office of AIDS. Certified ADAP enrollment sites are limited to community-based non-profit organizations, clinics, medical providers, and case management service providers. To inquire about becoming an ADAP clinical site, please contact the ADAP call center at (844) 421-7050. Call center staff are available Monday-Friday, 8AM – 5PM (excluding holidays).

### [California Vaccines for Children \(VFC\) Program](#)

The Vaccines for Children (VFC) Program helps families by providing vaccines at no cost to providers who serve eligible children (Medi-Cal, American Indian/Alaskan Native, uninsured, and underinsured) from birth through 18 years of age. However, because JYNNEOS is currently only recommended for adults 18 years and older, only persons 18 years old who meet the eligibility criteria under ACIP can receive JYNNEOS through VFC.

VFC Program requirements are summarized in the annual [Program Participation Requirements at a Glance](#) and defined in the [VFC Provider Agreement](#) (federal agreement) and California VFC Program [Provider Agreement Addendum](#).

Some requirements for participation include having a vaccine management plan, key practice staff such as a vaccine coordinator, staff trainings, and more. Enrollment information can be found at [VFC site enrollment](#).

### **[340B Prime Vendor Program \(PVP\)](#)**

Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b) lists [eligible organizations](#) that can participate in and purchase discounted drugs under the 340B Program.

JYNNEOS and other vaccines are not covered in the 340B Drug Pricing Program, and so the 340B Prime Vendor Program, managed by Apexus, has partnered with vaccine manufacturers and distributors to provide discounts on these products.

Organizations can perform a [340B covered entities search](#) to see if they are already enrolled and can be covered under 340B PVP. Providers and health care groups can check with the 340B Prime Vendor or any other group purchasing organization they might participate in to ask about discounted pricing on vaccines.

### **Bavarian Nordic Patient Assistance Program for JYNNEOS**

There is currently no patient assistance program available through Bavarian Nordic.

If a provider is seeing a high cost for JYNNEOS, a representative from Bavarian Nordic may be able to work with the distributor to correct the pricing (Sara Flubacher, [SARF@bavarian-nordic.com](mailto:SARF@bavarian-nordic.com)).

**Table 1: JYNNEOS Vaccine Coverage Options for Providers & Health Systems for Uninsured or Underinsured Individuals**

Program	Pre-Exposure Prophylaxis Assistance Program (PrEP-AP)	AIDS Drug Assistance Program (ADAP)	340B Prime Vendor Program (PVP)	Vaccines for Children (VFC)
<b>Enrollment Criteria</b>	To be a PrEP-AP clinical provider, the facility must be Medi-Cal and 340B affiliated, and some exceptions apply. Please see <a href="#">PrEP-AP Clinical Provider Questions</a> for additional details.	Certified ADAP enrollment sites are limited to community-based non-profit organizations, clinics, medical providers, and case management service providers.	The <a href="#">PVP</a> is a voluntary program for participating 340B covered entities to obtain lower drug pricing on non-340B items, such as vaccines and medical supplies.	VFC Program requirements are summarized in the annual <a href="#">Program Participation Requirements at a Glance</a> and defined in the <a href="#">VFC Provider Agreement</a> (federal agreement) and California VFC Program <a href="#">Provider Agreement Addendum</a> .
<b>Enrollment Steps</b>	Email <a href="mailto:PrEP.Support@cdph.ca.gov">PrEP.Support@cdph.ca.gov</a> to request a copy of the PrEP-AP Clinical Provider Application. This application process may take weeks to months.	Contact the ADAP call center at (844) 421-7050. Call center staff are available Monday-Friday, 8AM – 5PM (excluding holidays).	340B covered entities can enroll the PVP for free by completing the <a href="#">enrollment form</a> . <i>Organizations interested in becoming a 340B covered entity can visit the <a href="#">340B eligibility webpage</a>.</i>	Enrollment information can be found at <a href="#">VFC site enrollment</a> .
<b>JYNNEOS Covered</b>	Yes	Yes	Yes	Only age 18