### **DHCS COVID-19 Vaccine Administration FAQs**

### December 24, 2020

With the recent federal approval of COVID-19 vaccines, the Department of Health Care Services (DHCS) is seeking federal approval to help support delivery of the vaccine to all Medi-Cal beneficiaries. The vaccine will be provided at no cost to all Californians.

DHCS will follow <u>California's COVID-19 vaccination plan</u>, which was approved by the California Department of Public Health (CDPH). It calls for implementation in several phases: Pre-vaccine; limited doses available; larger number of doses available; and sufficient supply of doses available for the entire population. For further information on the state's vaccination planning efforts please visit <u>https://covid19.ca.gov/vaccines/</u>.

California is leveraging its existing immunization framework and emergency response infrastructure to coordinate efforts among state, local, and territorial authorities to administer the vaccine. Throughout this effort, DHCS will share appropriate information with you and our providers, health plan partners, counties, other key stakeholders, and beneficiaries.

Consistent with the approach being taken by Medicare through Medicare Advantage Plans, DHCS will carve out the COVID-19 vaccine from Medi-Cal managed care health plans and will reimburse providers under the Fee-for-Service (FFS) delivery system for both medical and pharmacy claims. This approach will ease program administration, eliminate challenges with out-of-network provider reimbursements, and keep vaccine administration fee rates consistent for providers regardless of delivery system.

Medi-Cal proposes to reimburse the associated COVID-19 vaccine administration fee at the allowable Medicare rate for all claims (medical, outpatient, and pharmacy), based on the number of required doses. As the federal government will pay for the initial vaccines, there is no Medi-Cal provider reimbursement for the COVID-19 vaccine itself. Providers will bill for administration of the COVID-19 vaccine on medical, outpatient, or pharmacy claims, based on current policy. The Medicare administration rate DHCS is seeking differs from the current Medi-Call pharmacy administration fee today. DHCS is also seeking federal approval to cover the cost of the vaccine administration for Medi-Cal beneficiaries who are in restricted scope coverage, the COVID-19 Uninsured population and enrollees of the Family Planning, Access, Care, and Treatment (Family PACT) program.

Additionally, DHCS is seeking <u>federal approval</u> to pay Federally Qualified Health Centers, Rural Health Centers, and Tribal 638 clinics for the vaccine administration fee outside of their current Prospective Payment System or All Inclusive Rate.

DHCS submitted all federal waiver requests on December 18, 2020 to the federal Centers for Medicare and Medicaid Services (CMS) and has issued <u>initial policy guidance</u> on COVID-19 vaccine administration and our reimbursement policy. Policy and reimbursement guidance will be updated upon additional CMS guidance and/or approvals of requested waivers.

To address potential provider, beneficiary and stakeholder inquiries regarding the plan, these Frequently Asked Questions (FAQs) have been developed.

For further information on the state's vaccination planning efforts please visit <u>https://covid19.ca.gov/vaccines/</u>.

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- 11. How many shots will be needed?
- 12. If I have already had COVID-19 and recovered, do I still need to get vaccinated with the vaccine?
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- 29. What billing codes should be used?
- 30. How will vaccine information be disseminated?
- 31. What is the best way to ensure that patients return for their second shot?
- 32. Where can healthcare providers enroll to become a vaccinator?
- 33. What information should be given to patients upon vaccination?

#### 1. Will individuals have to pay for the vaccine?

A. No. The vaccine is being purchased by the federal government and will be provided to individuals at no cost.

#### 2. Where can individuals get the vaccine?

A. Pharmacies, retail clinics, providers (including those enrolled in managed care plans), and any other sites of care receiving and administering COVID-19 vaccinations. Due to supply constraints, the vaccine will initially be rolled out in phases that include certain defined populations. Updated information can be found on the CDPH website:

https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/COVID-19Vaccine.aspx

#### 3. When can individuals get the vaccine?

A. Initially, vaccine supply will be very limited. California is making sure that these supplies are distributed and administered efficiently and equitably. At first, vaccines will be provided to health care workers and long-term care residents in accordance with the <u>CDPH Allocation Guidelines for COVID-19 Vaccine During Phase 1A.</u>

#### 4. Is the vaccine safe?

A. COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offer protection to people of different ages, races, and ethnicities, as well as those with different medical conditions.

The Food and Drug Administration (FDA) has reviewed the vaccines for their safety and effectiveness before granting Emergency Use Authorization (EUA) for their use. The U.S. Centers for Disease Control (CDC) and its Advisory Committee for Immunizations (ACIP) has also reviewed the safety information of the approved vaccines.

In addition, California formed a <u>Scientific Safety Review Work Group</u> to independently review the safety and efficacy of the vaccines. Based on all these reviews, the vaccine is considered safe for use in Californians. Please refer to the <u>CDPH COVID 19 Questions and Answers</u> page for additional details.

FDA and CDC will continue to monitor the safety of COVID-19 vaccines to make sure even very rare side effects are identified. Health care providers are required to report certain adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

CDC is also implementing a new smartphone-based tool called v-safe to check in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a v-safe information sheet telling you how to enroll in v-safe. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

#### 5. What does Emergency Use Authorization mean for a vaccine?

A. In certain types of emergencies, such as with the current public health emergency, the FDA can issue an emergency use authorization, or EUA, to provide more timely access to critical medical products that may help during the emergency when there are no adequate, approved, and available alternative options. Please refer to the <u>CDPH COVID-19</u>: Information for Laboratories for additional information.

Under the EUA authority, the FDA evaluates requests for authorization very quickly using the evidence that is available, carefully balancing the risks and benefits of the product as we know them, in addition to evaluating other criteria. EUAs are in effect until the emergency declaration ends but can be revised or revoked as needs change during the emergency, or as products meet the criteria to become approved, cleared, or licensed by the FDA.

#### 6. How will safety be tracked once a COVID-19 vaccine is made available to the public?

A. After a vaccine is approved for use via Emergency Use Authorization (EUA), scientists and health professionals will continue to carefully monitor its use. The <u>Vaccine Safety Datalink</u> in the United States, which monitors many immunizations in California, is designed to report a safety problem in

near real time so the public can be informed quickly of possible risks. Health care providers are required to report certain adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

When you receive your vaccine, you will also receive an information sheet telling you how to enroll in a program called v-safe that allows you to report problems or adverse reactions you have after receiving a COVID-19 vaccine to the Centers For Disease Control (CDC). Additionally, the Food and Drug Administration (FDA) and CDC will continue to carefully monitor the safety of COVID-19 vaccines to make sure that even very rare side effects are identified as early as possible. These are some of the ways that will help detect previously undetected issues related to the vaccines as early as possible.

# 7. Is the vaccine helpful? I heard getting COVID-19 gives you better and longer immunity than the protection a vaccine can give. Can it actually make my illness worse if I do end up getting COVID-19?

A. COVID-19 vaccines prevent you from getting sick from COVID-19. If you get COVID-19, you risk becoming very sick and giving it to loved ones who may get very sick. Getting a COVID-19 vaccine is a safer choice.

The ability of COVID-19 vaccines to protect us from spreading the virus to others is not yet known but is being studied carefully.

More detailed questions should be directed to your health care provider.

Even after being vaccinated, people will still need to practice other precautions, like wearing a mask, social distancing, handwashing, and other hygiene measures, until public health officials say otherwise.

Additional information can be found here: https://covid19.ca.gov/vaccines/

#### 8. Are there side effects associated with the vaccine?

A. Most people do not have serious problems after being vaccinated for COVID-19. Any minor symptoms usually go away on their own within a week. Providers will provide information and explain any potential side effects that can be expected with vaccination.

#### 9. Can the vaccine give me COVID-19?

A. No, the vaccine cannot give you COVID-19 because it does not contain infectious virus. Additional information can be found here: <u>https://covid19.ca.gov/vaccines/</u>.

#### 10. Will there be any long-term side effects?

A. COVID-19 vaccines are being tested in large clinical trials to assess their safety. However, it does take time, and more people will need to be vaccinated before we learn about very rare or long-term side effects. That is why safety monitoring will continue. The CDC has an independent group of experts that reviews all the safety data and provides regular safety updates. If a safety issue is detected, immediate action will be taken to determine if the issue is related to the COVID-19 vaccine and determine the best course of action.

#### 11. How many shots will be needed?

A. Most COVID-19 vaccines require two shots. While the first shot starts building protection, everyone has to come back a few weeks later for the second one to get the most protection the vaccine can offer. Your health care provider will advise you when you should return for the second shot, as it varies by type of vaccine.

# 12. If I have already had COVID-19 and recovered, do I still need to get vaccinated with the vaccine?

A. Yes. There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, and more studies are ongoing. Available evidence from clinical studies shows that the vaccine is safe in persons who have had prior COVID-19 infection or who have tested positive for it.

## 13. Do I need to wear a mask and avoid close contact with others if I have received 2 doses of the vaccine?

A. Yes, refer to the <u>covid19.ca.gov</u> site. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it remains important for everyone to continue using all the tools available to help stop the spread of COVID-19, including covering your mouth and nose with a mask, washing hands often, staying at least 6 feet away from others and avoiding crowded places.

#### 14. I have heard about herd immunity. What is it?

A. <u>Herd immunity</u> is a term used to describe when enough people within a population have protection—either from previous infection or vaccination—that disease spread slows and eventually stops within that population. As a result, everyone within the community is protected even if some people don't have any protection themselves.

#### 15. What percentage of the population needs to get vaccinated to have herd immunity to COVID-19?

A. Experts do not know what percentage of people would need to get vaccinated to achieve herd immunity to COVID-19. The percentage of people who need to have protection in order to achieve herd immunity varies by disease. At this time during the pandemic, we cannot rely on herd immunity to protect us from getting COVID.

#### 16. What is the risk of children getting sick with COVID-19?

A. Children can be infected and get sick with COVID-19. Most children with COVID-19 have mild symptoms, or they may have no symptoms at all, which is known as being asymptomatic.

Fewer children have been sick with COVID-19 compared to adults. However, infants (children less than 1 year old) and children with certain underlying medical conditions might be at increased risk for COVID-19. For further information, please consult your child's health care provider.

#### 17. How will vaccinations work for children? Can my child get a COVID-19 vaccine?

A. The Advisory Committee on Immunization Practices (ACIP) recommends that 1) health care personnel and 2) residents of long-term care facilities be offered vaccination in the initial phase of the COVID-19 vaccination program. COVID-19 vaccination will be made available for children later in the vaccine roll-out process. The Pfizer-BioNTech COVID-19 vaccine has Emergency Use Approval

(EUA) approval for ages 16 and above. In early clinical trials for various COVID-19 vaccines, only non-pregnant adults participated. However, clinical trials continue to expand those recruited to participate. The groups recommended to receive the vaccines could change in the future.

#### 18. Can I take the COVID vaccine and the flu vaccine (or another vaccine) at the same time?

A. It is currently recommended that you not get any other vaccination for a minimum of 14 days prior to or after getting the COVID-19 vaccine. Please discuss this further with your health care provider.

#### 19. How long does it take to be protected after vaccination?

A. Although protection from the vaccine is not immediate, the first shot starts building protection. Currently available vaccines require a two dose series, and it will take one-to-two weeks following the second dose to get the most protection the vaccine can offer.

#### 20. If I have previously tested positive for COVID-19, can I still get the vaccine?

A. People who have previously tested positive for or been sick with COVID-19 but have now recovered may still benefit from getting vaccinated.

People are advised to get a COVID-19 vaccine even if they have been sick with COVID-19 before. This is because re-infection with COVID-19 is possible. Those who had a diagnosis in the past three months should consider deferring vaccination for three months to allow other people to get vaccinated first (since natural immunity almost surely provides at least three months of protection).

At this time, we do not know how long someone is protected from getting sick again after recovering from COVID-19. Please consult your health care provider for additional guidance.

#### 21. Who can I contact for more information?

A. If you receive your care from a Medi-Cal health plan and have questions, please call your managed care plan.

For clinical questions please contact your provider.

For all other questions please contact the Medi-Cal Member Help Line: (800) 541-5555; TTY (800) 430-7077), Monday through Friday, 8 a.m. to 5 p.m. You may also call the Medi-Nurse Advice Line: (877) 409-9052.

#### 22. Where do I find general California guidance on COVID-19?

A. There are two California websites that offer general guidance on COVID-19. These are the California Coronavirus Response website and the California Department of Public Health website. Check both websites frequently, as resources are regularly updated and added. Below are the web addresses of each.

- The California Coronavirus Response website is: <u>covid19.ca.gov</u>.
- The California Department of Public Health website is: <a href="mailto:cdph.ca.gov/COVID19">cdph.ca.gov/COVID19</a>

#### 23. When will the vaccine become available?

A. The FDA approved the EUA for Pfizer's COVID-19 vaccine on December 11, 2020, and for Moderna's COVID-19 vaccine on December 18, 2020. The Advisory Committee on Immunization

Practices (ACIP) recommends that 1) health care personnel and 2) residents of long-term care facilities be offered vaccination in the initial phase of the COVID-19 vaccination program.

Updated information can be found at: <u>CDPH Allocation Guidelines for COVID-19 Vaccine During</u> <u>Phase 1A</u>.

#### 24. Who will be covering the vaccine immunization cost?

A. The initial supply of COVID-19 immunizations will be federally purchased, meaning DHCS will not provide Medi-Cal reimbursement for the vaccine itself. Please refer to the question below for information on the vaccine administration fee.

#### 25. Who can healthcare providers give the vaccination to?

A. All providers must vaccinate individuals regardless of existing health coverage or the type of coverage. Providers are prohibited from balance billing or otherwise charging vaccine recipients.

#### 26. How will it work if healthcare providers are not contracted/credentialed with DHCS?

A. The vaccine provider must be enrolled in Medi-Cal for purposes of obtaining reimbursement from DHCS for the vaccine administration fee. Medi-Cal providers who administer the vaccine to Medi-Cal beneficiaries will be reimbursed at the Medicare rate for the administration fee. More information on Medi-Cal provider enrollment can be found here: https://www.dhcs.ca.gov/provgovpart/Pages/PED.aspx

#### 27. Will the vaccine administration fee be covered for all patients on Medi-Cal?

A. Yes. The vaccine administration fee will be covered for all Medi-Cal beneficiaries who have fullscope Medi-Cal. DHCS is seeking federal approval to cover the administration fee for Medi-Cal beneficiaries with restricted scope coverage, the COVID-19 Uninsured population and enrollees Family Planning, Access, Care, and Treatment (FPACT) program.

Payment for the COVID-19 vaccine administration fee will be through the Medi-Cal Fee-for-Service delivery system for all covered populations, including those in Medi-Cal managed care plans.

Medi-Cal proposes to reimburse the associated COVID-19 vaccine administration fee at the allowable Medicare rate for all claims, medical and pharmacy, based on the number of required doses.

#### 28. Will immunization coverage apply to restricted scope group?

A. Yes. All vaccination providers must provide the vaccine regardless of coverage. DHCS is working on obtaining federal approval for immunization coverage for Medi-Cal beneficiaries in restricted scope coverage, individuals in the COVID-19 Uninsured program and individuals enrolled in the FPACT program.

#### 29. What billing codes should be used?

A. DHCS will be using the American Medical Association Current Procedural Terminology or CPT® codes for reporting of immunizations for COVID-19. These CPT® codes are unique for each COVID-19 vaccine.

Vaccine Name	Vaccine Code/Description	CPT® Vaccine Administration Code
Pfizer-BioNTech	91300	0001A (1st dose)
		0002A (2nd dose)
Moderna	91301	0011A (1st dose)
		0012A (2nd dose)
Oxford–AstraZeneca	91302	0021A (1st dose)
		0022A (2nd dose)

#### 30. How will vaccine information be disseminated?

A. DHCS will communicate updated immunization information to providers, stakeholders, health plans, county partners, and the community through strategies, such as:

- Developing written guidance for health plans, including All Plan Letters, as it relates to immunization distribution and reimbursement rates
- Provider notices/bulletins on the Medi-Cal website

#### 31. What is the best way to ensure that patients return for their second shot?

A. Providers are encouraged to explain the health benefits and outcomes associated with second shot administration. Before the patient leaves the office after their first dose, ensure they schedule an appointment for their second dose.

#### 32. Where can healthcare providers enroll to become a vaccinator?

A. Pharmacies, retail clinics, providers, and any other sites of care must sign an agreement with the U.S. government to receive free supplies of the COVID-19 vaccine(s).

Under the agreement, all providers must vaccinate individuals regardless of existing health coverage or the type of coverage. Providers are prohibited from balance billing or otherwise charging vaccine recipients.

Provider enrollment for vaccinators will occur in phases and local health departments will invite providers to enroll based on CDPH Allocation Guideline phases and vaccine availability.

Enrollment is limited at this time to providers authorized by their <u>local health department</u> (LHD). Others may enroll later in January as vaccine supply increases.

Before enrolling, obtain your immunization information system (IIS) ID here: CAIR2.

Once you've been invited by your LHD <u>and</u> have your IIS ID, make sure that you meet all <u>requirements</u> before enrolling.

Providers with questions about enrolling in the California COVID-19 Vaccination Program can email <u>COVIDCallCenter@cdph.ca.gov</u> or call (833) 502-1245, Monday through Friday, from 9 a.m. to 5 p.m.

#### 33. What information should be given to patients upon vaccination?

A. Before receiving the vaccine, patients must be provided with an Emergency Use Authorization fact sheet about the vaccine. After receiving the vaccine, patients must receive a vaccination card that

identifies the brand of vaccine administered and the date their second vaccination (if applicable) is due.

#### Additional Resources:

https://www.cdc.gov/vaccines/covid-19/hcp/answeringguestions.html?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fhcp%2Fcovidconversations%2Fanswering-questions.html

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim Playbook.pdf

https://www.cdc.gov/vaccines/covid-19/index.html

https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/COVID-19Vaccine.aspx

https://files.medi-cal.ca.gov/pubsdoco/COVID19\_response.aspx