Welcome to Provider Office Hours

Thank you for joining our call. Please stand by; we will begin momentarily. During the session, please use the Q&A panel to comment or ask a question:

Q&A Panel

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Housekeeping

Reminder to Panelists:

Please mute yourself when not speaking.

Please monitor the Q & A panel for questions you may be able to answer.

Reminder to Participants:

Please access today's slides and archived presentations at: https://eziz.org/covid/education/



Agenda

| No. | Item | Speaker | Time (AM) | |
|---------------------------|--|--|---------------|--|
| 1 | Welcome & Announcements | Leslie Amani (Facilitator) | 9:00 - 9:05 | |
| 2 | Reimbursement & Billing | Dr. Hisham Rana & Cynthia Garrett, Department of Health Care Services | 9:05 – 9:15 | |
| 3 | Administration & Allocation | Amy Pine (CDPH) | 9:15-9:20 | |
| 4 | Allocations | Jeff Merritt, Third Party Administrator (TPA) | 9:20 - 9:25 | |
| 5 | My Turn Update | James Regan (CDPH) | 9:25 - 9:30 | |
| | Q&A for Reimbursement & Billing / TPA/ My Turn | | | |
| 6 | Provider Call Center | Brenton Louie (CDPH) | 9:45 - 9:50 | |
| 7 | myCAvax Update | Nisha Gandhi (CDPH) | 9:50 - 9:55 | |
| 8 | CDC COVID-19 Provider Visits | Nisha Gandhi (CDPH) | 9:55 - 10:00 | |
| 9 | Clinical Update | Louise McNitt, MD (CDPH) | 10:00 - 10:05 | |
| 10 | Storage & Handling | Kate McHugh (CDPH) | 10:05 - 10:10 | |
| 11 | Wrap-Up & Feedback Poll | Leslie Amani (Facilitator) | 10:10 | |
| Q&A for myCAvax / General | | | | |



Announcements



Stay informed! **Provider Resources on** eziz.org/covid

Frequent Content Updates:

- Alerts
- Program Enrollment
- My Turn Onboarding
- **Reporting Requirements**
- Patient Resources
- Archived Communications
- Education & Support **Materials**
- More to explore!



Program Updates

Program Enrollment

My Turn Onboarding

Vaccine Management

Vaccine Administration

Reporting Requirements

Archived Communications

Provider Support

Patient Resources

COVID Call Center Email: For Program Info

Phone: (833) 502-1245

myCAvax Help Desk

Phone: (833) 502-1245,

Manufacturer Contacts

Email: For Onboarding,

Third Party Administrator

Technical Support Help Desk: (415) 621-9494

Sun-Sat, 7AM-7PM

Email: For Allocations,

TPA Agreement,

General Questions

option 2

Vaccines

My Turn

Hours: Mon-Fri, 8AM-8PM

Email: For Technical Support

Program Updates

The state of California signed a Third Party Administrator (TPA) contract with Blue Shield of California to help the state optimize and accelerate COVID-19 vaccine allocation and distribution equitably, efficiently, and safely throughout the state. The TPA is working closely with local health departments to identify facilities that have the capacity to properly maintain COVID-19 vaccine and meet additional federal and state requirements.

Providers currently enrolled or in the process of enrolling in the California COVID-19 Vaccination Program can access program-related resources and communications on this website.

Vaccinate ALL 58 Together we can end the pandemic

Program Education and Support

- Provider Office Hours and myCAvax Training Sessions
- COVID Call Center and Vaccine Manufacturers' Contact Info
- Guide to Other COVID-19 Vaccine Related Websites Frequently Asked Questions Updated 4/25

Alerts:

Resume Use of Johnson & Johnson COVID-19 Vaccine:

- Johnson & Johnson Vaccine and Thrombosis with Thrombocytopenia Syndrome (TTS): CDC Update for Clinicians 4/27
- CDPH Press Release | Fact Sheet 4/24
- Western States Scientific Safety Review Workgroup statement 4/24
- Joint FDA and CDC statement 4/23

Never Refuse Vaccine Shipments:

1. Accept, 2. Verify shipment & contents, 3. Store in appropriate units, 4. Report any discrepancies immediately. Refer to Reporting Shipment Incidents job aid.

COVID-19 Vaccination Record Cards:

Please remember to ask patients to verify their information and keep their card as an official record of vaccination.

TPA Information

- TPA-Direct Allocation Process and Cadence
 - TPA and My Turn Presentations at Provider Office Hours
 - Coming Soon: Third Party Administrator (TPA) Site-Level Direct Allocation Process 3/26

New Resources:

- VanishPoint® Syringe video
- COVID-19 Vaccine Product Information Guide



ENHANCED BY Google





Provider FAQs

- Answers to questions on the hottest topics
- Updated weekly: Last updated 04.29.2021
- Currently in its 17th iteration!

Q: Can California COVID-19 Vaccine Providers charge a vaccine recipient for the cost of vaccine administration or related services?

A: No. California COVID-19 Vaccination Program Providers shall not under any circumstances bill, charge, collect a deposit from, impose a surcharge on, directly or indirectly seek compensation, remuneration or reimbursement from, or have any recourse against any vaccine recipient for the cost of vaccine administration or related services.

Q: Can Providers send mass notifications to patients through My Turn?

A: My Turn offers three options for Providers to send mass notifications: Self-service, Requested and Automated. Each category offers Providers the opportunity to send mass emails and SMS messaging through the My Turn system. Providers can find detailed information at <u>My Turn Email and SME Notifications</u>.

🥙 Q: How can a Provider find information for the status of their TPA agreement?

A: If a Provider sends an inquiry directly to <u>CovidVaccineNetwork@blueshieldca.com</u>, their question has reached the TPA Network Contracting team. Because the TPA is processing a high volume of requests, the TPA asks Providers to wait, at least, an additional two weeks after submission before inquiring about their status.

California COVID-19 Vaccination Program Provider FAQs

For Prospective, Newly Enrolled, and Current California COVID-19 Vaccine Providers. Providers may also visit <u>California COVID-19 Vaccination Program</u> for information and updates.

Directions: Click on a category to be directed to related FAQs.

Contents

| New and Updated FAQs | 2 |
|-----------------------------|----|
| Vaccine Program Management | 3 |
| Provider Enrollment | 5 |
| Allocation | 7 |
| Ordering | 9 |
| Distribution/Redistribution | 11 |
| Vaccine Storage & Handling | 12 |
| Phases & Tiers | 13 |
| Vaccine Administration | 13 |
| Inventory | 17 |
| Reporting | |
| Costs & Reimbursement | 21 |
| Communication Resources | 21 |



We Appreciate Your Feedback!

We will have a short, 1-question poll at the end of our agenda items.

Please complete our poll!





COVID-19 Vaccine Reimbursement & Billing

Dr. Hisham Rana & Cynthia Garrett

Department of Health Care Services (DHCS)



DHCS COVID-19 Vaccine Administration

- Department of Health Care Services (DHCS) is seeking federal approval to help support delivery of the vaccine to all Medi-Cal beneficiaries at no cost to all Californians.
- Reimbursement for vaccine administration is exclusively through the fee-for-service (FFS) delivery system and carved out from all managed care contracts.
 - $_{\odot}\,$ Ease program administration.
 - o Eliminate challenges with out-of-network provider reimbursements.
 - Keep vaccine administration fee rates consistent for providers.
- 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 Family Planning, Access, Care and Treatment (FPACT) program.



Current Fee-for-Service COVID-19 Medi-Cal Billing Policy

- Vaccines should be billed using CPT® administration codes.
- Additional policy elements:

| CPT® Administrati on Code | NDC | NCPDP D.0/NCPDP 1.2/RTIP Submission Clarification Code | Also Known As | Max. Allowable Reimbursement for DOS before or on 3/14/2021 | Max. Allowable Reimbursement for DOS on or after 3/15/2021 | Effective Date |
|---------------------------------|-------------|---|-----------------------------------|--|---|-------------------|
| 0001A | 59267100001 | 2 | Pfizer- <u>BioNTech</u> Dose 1 | \$16.94 | \$40 | 12/11/2020 |
| 0002A | 59267100001 | 6 | Pfizer- <u>BioNTech</u> Dose 2 | \$28.39 | \$40 | 12/11/2020 |
| 0011A | 80777027310 | 2 | Moderna Dose 1 | \$16.94 | \$40 | 12/18/2020 |
| 0012A | 80777027310 | 6 | Moderna Dose 2 | \$28.39 | \$40 | 12/18/2020 |
| 0031A | 59676058005 | 2 | Janssen | \$28.39 | \$40 | 2/27/2021 |



Current FQHC, RHC and IHS-MOA COVID-19 Medi-Cal Billing Policy

- FQHC and RHC Providers:
 - $_{\odot}$ Vaccines may only be administered as part of a billable face-to-face office visit.
 - $_{\odot}$ The administration of a COVID-19 vaccine is not separately reimbursable in these visits.
 - $_{\odot}$ The CPT® administration codes should be included as informational line items when billing for the visit.
 - $_{\odot}$ The visit will be reimbursed at the Prospective Payment System (PPS) rate.
 - Pending State Plan Amendment (SPA) to allow reimbursement for vaccine administration fee for vaccine-only visits.

• IHS-MOA Providers:

 Vaccines may be administered as part of a billable face-to-face office visit OR as a vaccine-only visit.

 $_{\odot}$ Vaccine-only visits allow for reimbursement at the fee-for-service reimbursement.



COVID-19 vs. Childhood/Adult Vaccine

• COVID-19 Vaccine:

- $_{\odot}$ Carved out of managed care.
- \circ Since the vaccines are purchased by the federal government, providers must not bill for the cost of the vaccine.
- $_{\odot}$ DHCS is only reimbursing for the administration fee.
- Childhood/Adult Vaccine:
 - $_{\odot}$ Covered by managed care and fee-for-service.
 - Reimbursement is determined by the cost of the immunization, plus the physician's administration fee.
 - Medi-Cal only reimburses a provider for the cost of administering Vaccines For Children (VFC) supplied doses, since VFC program supplies vaccine at no cost to the provider.



Information on Childhood/Adult Immunizations

- 2020 Updates to Immunization Guidelines:
 - <u>https://files.medi-cal.ca.gov/pubsdoco/medsupply/Medi-Cal_coverage_immunizations_faq.aspx.</u>
- Medi-Cal Coverage of Immunizations:
 - <u>https://files.medi-cal.ca.gov/pubsdoco/medsupply/Medi-Cal_coverage_immunizations_faq.aspx</u>.
- Medi-Cal reimbursement rates
 - <u>https://files.medi-</u> cal.ca.gov/Rates/Rates_information.aspx?num=21&first=87850&last=94772
- Medi-Cal immunization billing guidelines

 <u>https://files.medi-cal.ca.gov/pubsdoco/publications/masters-</u> <u>mtp/part2/immun.pdf</u>



Resources for Medi-Cal

 For current COVID-19 Medi-Cal policy, see the COVID-19 Medi-Cal Response page on the Medi-Cal Provider website here:

https://files.medi-cal.ca.gov/pubsdoco/COVID19_response.aspx

- For current Medi-Cal policy on the respective COVID-19 vaccines see the following web pages:
 - Pfizer-BioNTech: <u>https://files.medi-cal.ca.gov/pubsdoco/Pfizer_BioNTech_COVID19_Vaccine.aspx</u>
 - Moderna: <u>https://files.medi-cal.ca.gov/pubsdoco/Moderna_COVID19_Vaccine.aspx</u>
 - o Janssen: https://files.medi-cal.ca.gov/pubsdoco/Janssen_COVID19_Vaccine.aspx
- For general claim submission instructions for Medi-Cal providers, refer to the appropriate Medi-Cal Provider Manual:
 - <u>https://files.medi-cal.ca.gov/pubsdoco/manuals_menu.aspx</u>
- For other ways to contact Medi-Cal with questions, refer to the Medi-Cal Contact page on the Medi-Cal Provider website:
 - o <u>https://files.medi-cal.ca.gov/pubsdoco/contact.aspx</u>
- Provider billing questions: (800) 541-5555 (8AM 5PM M-F, excluding holidays)



Administration & Allocation

Amy Pine, CDPH



Doses Administered to Date (4/28/2021)

29,262,215 doses administered!

58.1% of 16+ population has
received at least one dose!

38.1% of 16+ population is fully protected.

20.6% of all doses administered in lowest California Healthy Places Index (HPI) quartile.





California's Allocations (as of 4/28)

| Vaccine (week of 4/26) | Doses | Boxes | | |
|--|-----------|-------|--|--|
| Janssen | 87,800 | 1,740 | | |
| Moderna | 428,600 | 4,286 | | |
| Pfizer | 575,640 | 492 | | |
| Total | 1,092,040 | 6,518 | | |
| Cumulative 37,500,880 Total Doses Delivered! | | | | |



| Dose/Allocation Source | Program State or Pharmacy | Doses Shipped | Doses Delivered |
|---------------------------|----------------------------|---------------|-----------------|
| Direct Federal Allocation | Dialysis Partnership | 10,530 | 10,530 |
| Direct Federal Allocation | FEMA | 818,610 | 818,610 |
| Direct Federal Allocation | HRSA-Funded Health Centers | 2,452,310 | 2,452,110 |
| Direct Federal Allocation | Pharmacy Partnership | 7,912,550 | 7,602,590 |
| Federal Doses | Federal Entity | 1,070,660 | 1,061,470 |
| State Allocation | Jurisdiction | 26,701,535 | 26,617,040 |
| Totals | | 38,966,195 | 38,562,350 |
| Totals Minus Fed | | 37,895,535 | 37,500,880 |

Posted on <u>COVID19.CA.Gov/Vaccine</u> Dashboard Website:

✓ Overview of vaccine administration

✓ <u>Vaccination progress by group</u>

Vaccinating equitably across groups



Allocations

Jeff Merritt, Third Party Administrator (TPA)





My Turn Update James Regan (CDPH) Provider Office Hours April 30, 2021

Today's Special Topics:

- Increasing Clinic Traffic
- In-Home Vaccinations and Transportation Assistance
- Second Dose Notifications









Increasing Clinic Traffic

Proposed "Walk-Ins Welcome" or "Bring a Friend"

• Appointments recommended, not required

Utilize (Short Message Service) SMS Standby Functionality

• 10M+ SMS messages sent by zip code for appointment availability awareness

Canvassing Strategy for Vaccine Scheduling

- Communications and media campaigns via the <u>COVID site</u> include several on the ground outreach partners
- The "Let's Get to Immunity" campaign drives users to the My Turn site

Leverage Overbooking to Avoid Waste

- Use Salesforce reports to understand no-shows
- Follow the week-by-week overbooking methodology

Master Code Use

- Master Codes can be provided for coded clinics for simplified booking
- Instead of sharing unique codes to individuals, Local Health Jurisdictions (LHJs)/Providers can share one code for a clinic that residents can use to book their appointment



<Clinic Name> <Clinic Address>

You do not need a government issued ID to receive a vaccine. However, please bring an acceptable form of documentation with your name on it. The name should match the name on your appointment confirmation. Msg&data rates may apply. Reply STOP to cancel or HELP for more info. Questions? <u>chat.myturn.ca.gov/?id=15</u>





• Pulling CAIR data to see how many people are due/overdue for a 2nd dose.

| People Partially Vaccinated | Total | Pfizer | Moderna | |
|---------------------------------|-------|------------------------|------------------------|--|
| Due to Vax (within window) | | 710,469 | 354,366 | |
| Due to Vax (within window) | | Between 21 and 42 days | Between 28 and 42 days | |
| Overdue to Vax (outside window) | | 573,207 | 596,549 | |

• CAIR will provide information to the My Turn team to send SMS messages reminding them to come in for their second dose.





Residents can request in-home vaccinations and/or transit assistance to get vaccinated by registering in My Turn or by calling the CDPH COVID-19 Call Center at 1-833-422-4255.

Medical Transportation Assistance:

The CDPH Call Center can book medical transportation for patients who need specialized assistance to get to their vaccination appointment

In-Home Patient:

- The CDPH Call Center will verify medical need for in-home vaccination and gather relevant information (address, # in household, etc.) and share with LHJ
- LHJ will track home vaccinations by creating a "Walk-in" clinic in My Turn for data entry
- As needed, LHJ can request ambulance strike teams via the Medical and Health Operational Area Coordinator and the Emergency Medical Services Authority

Non-Medical Transportation Assistance: (All residents are eligible)

The CDPH Call Center can book non-medical transportation for residents who need assistance getting to their vaccine appointment



Provider Office Hours Q&A

Please use the Q&A panel to comment or ask a question:

Q&A Panel





Provider Call Center

Brenton Louie, CDPH



Calls of the Week

- myCAvax Username Change
 - Phase 3 (Last Names Q-Z) started Tuesday, April 27th and now complete!
 - $_{\odot}$ Password reset not required, unless it has expired
- Vaccination capacity form
 - $_{\odot}$ Due every Monday by 4 PM
 - $_{\odot}$ Whether you want 0 doses or 1,000 doses, you will need to fill this out
 - \circ Maximize inventory lines by combining lot numbers with the same expiration date in the same field
- Sending/Accepting Transfers
 - Vaccine Inventory > Transfer/Redistribution complete all fields
 - $_{\odot}$ Visit myCAvax for training video and job aid on how to send/accept
 - Follow transport guidelines on <u>eziz.org/covid</u>



Provider Call Center: Contact Us!

COVID-19 Provider Call Center

Email: covidcallcenter@cdph.ca.gov

Phone: (833) 502-1245, M-F 8 AM-8 PM

For questions from providers/local health jurisdictions (LHJs) regarding the COVID-19 Vaccine Program





myCAvax

Nisha Gandhi, CDPH



myCAvax Reminders



Training Sessions for Providers in the TPA Network

Please join us to learn more about the TPA creating and managing an equitable and efficient statewide vaccine provider network.



TPA Provider Network Training Sessions

- Topics Covered: TPA Overview and myCAvax demonstration
- Date and Time:
 Monday 10:00 AM PST <u>Click here to join</u>
 <u>session!</u>

Please join us for the **TPA Question & Answer (Q&A**) Session. Capacity reports are due every Monday at 4 PM Pacific time. The TPA Q&A Session will help you complete your capacity report.

TPA Q&A Sessions



- **Topics Covered:** Vaccination Capacity
- Form and Vaccine Forecasts
- Date and Time:
- Monday at 10:00 AM PST <u>Click here</u> to join session!
- Wednesday at 10:00 AM PST <u>Click</u> <u>here to join session!</u>



myCAvax Reminders



Don't Forget:

Release 8 myCAvax Training Job Aids Available 05-03-21:

Release 8 training job aids will be published and available on the myCAvax website within the myTrailhead learning experience platform.



Release 8 myCAvax Release Notes Available 05-03-21:

We will distribute the Release 8 Release Notes via email as well as post on EZIZ.

Release 8 myCAvax New Functionality Training Videos Available 05-05-21:

Release 8 training videos will be published and available on the myCAvax website within the myTrailhead learning experience platform.



CDC COVID-19 Site Visits

Nisha Gandhi, CDPH



CDC COVID-19 Provider Visits

- CDC is conducting COVID-19 Vaccination Site Assessments of high-throughput vaccine administration sites and depots nationwide.
- Visit Objectives:
 - Ensure appropriate COVID-19 vaccine program implementation
 - o Documentation of lessons learned, best practices, and challenges for program improvement efforts
 - Demonstrate site visits assessment tools developed by CDC to support the implementation of a COVID-19 Provider Site Visit program.
- Site Visit Selection:
 - \circ Vaccination sites accounting for the top 10% of doses distributed.
 - 8-10 high-throughput vaccination sites in CA in the San Francisco Bay Area, LA, and Southern California Regions
 - Visits will be conducted from Thursday, April 29 through Friday, May 7, 2021
 - Selected sites are being notified directly by CDPH about dates and times of visits.



CA COVID-19 Vaccination Program Provider Oversight

• Planning is underway!

- Recipients of COVID-19 vaccination January 2021 Supplemental funding from CDC must conduct a quality assurance site visit to all COVID-19 Vaccination Program provider locations enrolled by the jurisdiction.
- Site visits must be conducted within 24-months of enrollment and must include any location that has received COVID-19 Vaccine, except for temporary or pop-up clinics.
- Jurisdictions must conduct site visits with a minimum of 25% of their enrolled provider locations with COVID-19 vaccine inventory on site by December 31, 2021.
- Jurisdictions are NOT required to visit Providers receiving direct vaccine allocations from the federal government.
- COVID-19 Vaccination Program site visits can't be combined with VFC site visits if the provider is dually-enrolled.



Clinical Update

Louise McNitt, MD, CDPH



FDA and CDC Lift Recommended Pause on Janssen COVID-19 Vaccine Use Following Thorough Safety Review (<u>Press Release</u>)

- Use of the Janssen COVID-19 Vaccine should be resumed in the United States.
- The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- The available data show that the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.
- At this time, the available data suggest that the chance of thrombosis with thrombocytopenia syndrome (TTS) occurring is very low, but investigation will continue.
- Health care providers administering the vaccine and vaccine recipients, or caregivers should review revised fact sheets.



Reporting rates of TTS after Janssen COVID-19 vaccine

- 7.98 million vaccine doses administered^{*} and 15 confirmed TTS cases[†] as of April 21, 2021
 - Some age- and sex-specific doses administered data were imputed
 - Additional potential TTS cases under review, including potential male cases

| | Females | | | Males | | |
|-----------------|--------------|-------------|-----------------------------|--------------|-------------|-----------------------------|
| Age group | TTS cases | Doses admin | Reporting rate [‡] | TTS cases | Doses admin | Reporting rate [‡] |
| 18-49 years old | 13 | 1,866,294 | 7.0 per million | 0 | 1,977,330 | 0 per million |
| 50+ years old | 2 | 2,125,239 | 0.9 per million | 0 | 2,010,144 | 0 per million |

* Source of doses administered: <u>https://covid.cdc.gov/covid-data-tracker/#vaccinations</u>; * One case was excluded from the final analysis: a female aged <50 years who had concurrent diagnosis of COVID-19 and TTS following receipt of Janssen vaccine; * Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

Summary of population-level risks and benefits by recommendation, all scenarios

- Recommendation for all persons
 aged 18+
 - Risks: Expect 26-45 TTS cases depending on uptake
 - Benefits: Depend on uptake, amount of transmission
 - > 800-3,500 fewer ICU admissions
 - ≻ 600-1,400 fewer deaths

- Recommendation for all persons
 aged 50+
 - Risks: Expect 2-3 TTS cases depending on uptake
 - Benefits: Depend on uptake, amount of transmission
 - ➤ 300-1,000 fewer ICU admissions
 - > 40-250 fewer deaths

Note: Benefits of vaccination apply to the whole population over a 6-month period, and result from direct and indirect effects.


Risks and benefits females, by age group

For every **1 million** doses of vaccine given with current US exposure risk¹



* Deaths, ICU admissions, and deaths due to COVID-19 Acronyms: Thrombosis with Thrombocytopenia Syndrome (TTS)

Summary

- TTS is a rare, but clinically serious and potentially life-threatening adverse event that has been observed in association with the Janssen COVID-19 vaccine
- Symptom onset appears to occur at least several days after vaccination, typically around 1–2 weeks after vaccination
- The clinical features of TTS following Janssen COVID-19 vaccine appear similar to what is being observed following the AstraZeneca COVID-19 vaccine in Europe
- It is important to recognize TTS early and initiate appropriate treatment
 - Do not treat TTS with heparin, unless HIT testing is negative
- The U.S. vaccine safety monitoring system is able to rapidly detect rare adverse events following immunization and quickly assess safety signals
- Safety surveillance and research on TTS continues
- CDC is committed to open and transparent communication of vaccine safety information

Addition to EUA Fact Sheet

https://www.fda.gov/media/146305/

Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks following vaccination. Most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.



Resources

FACT SHEET: Johnson & Johnson COVID-19 Vaccine Benefits and Risks

Understand the risks and benefits of receiving the single-dose Johnson & Johnson COVID-19 vaccine, which may prevent you from getting COVID-19. It is your choice to receive this vaccine. Talk to the vaccination provider if you have questions.

- Johnson & Johnson COVID-19
 Vaccine Fact Sheet
- Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Janssen COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers 04232021 (fda.gov)

About this Vaccine

Like all COVID-19 vaccines, this vaccine has been authorized by the FDA for emergency use given the severity of the COVID-19 pandemic. This vaccine is a single dose injected into the muscle.

Before Getting the Vaccine

Tell the vaccination provider about all your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant, breastfeeding, or plan to become pregnant
- have received another COVID-19 vaccine

You Should Not Get this Vaccine if:

You had a severe allergic reaction to any ingredient of this vaccine: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-COV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropylβ-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

Benefits of this Vaccine

In an ongoing clinical trial, this vaccine has been shown to prevent illness, hospitalization or death from COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

Risks Associated with this Vaccine

- General Side Effects: Side effects reported with this vaccine include injection site reactions and headache, feeling very tired, muscle aches, nausea, and fever.
- Severe Allergic Reaction: There is a remote chance the vaccine could cause a severe allergic reaction (difficulty breathing, swelling of face and throat, fast heartbeat, bad rash all over your body, dizziness, weakness), which would usually occur a few minutes to one hour after getting the dose.
- Blood Clots: Blood clots involving blood vessels in the brain, abdomen, and legs; along with low levels of blood cells that help your body stop bleeding, have occurred rarely in some people who have received the Johnson & Johnson COVID-19 vaccine. In people who developed these blood clots, symptoms began approximately 1–2 weeks after vaccination and most were women under 50 years of age. You should seek medical attention right away if you have any of the following symptoms several days after receiving the vaccine: shortness of breath, chest pain, leg swelling persistent abdominal pain, severe headaches or blurred vision, easy bruising or tiny blood spots under the skin beyond the site of the injection.

If you Experience Side Effects

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Other Options to Prevent COVID-19

It is your choice to receive this vaccine and not getting it will not change your standard medical care. Other vaccines to prevent COVID-19 are available.

More Information

Visit <u>www.janssencovid19vaccine.com</u> or <u>www.cdc.gov/coronavirus</u>



Adapted from FDA Fact Sheet for Recipients and Caregivers



Resources

- Report all adverse events to Vaccine Adverse Event Reporting System (<u>VAERS</u>)
- ACIP: <u>ACIP Meetings Information | CDC</u>
- CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines
 Currently Authorized in the United States
- CDC MMWR: <u>Updated Recommendations on Use of Janssen</u> <u>COVID-19 Vaccine</u>
- CDC COCA Calls: <u>Home | Clinician Outreach and Communication</u> <u>Activity (COCA) (cdc.gov)</u>
- American Society of Hematology (ASH): <u>Thrombosis with</u> <u>Thrombocytopenia Syndrome - Hematology.org</u>



Storage & Handling

Kate McHugh, CDPH



Moderna Update

- The federal government is allocating the "13 to 15" dose vials as 14 dose vials.
- Shipment of the new vials will begin with the federal pharmacy program. Those shipments will start arriving week of May 3rd.
- State allocation next week will include the new National Drug Code (NDC), with shipments arriving the week of May 10.
- Federal government will allocate both NDCs for about three weeks.
- Allocations should transition to be exclusively the new NDC by the end of May.
- Old carton NDC (10/11 dose vials): 80777-273-99
 Vial NDC: 80777-273-10
- New carton NDC (13 to 15 dose vials): 80777-273-98
 Vial NDC: 80777-273-15



Moderna: New Ancillary Kits

- The Moderna vaccine will be shipped with ancillary kits kitted for 140 doses. This includes the normal 5% surplus in the kits to account for damage or wastage of ancillary supplies.
 - $_{\odot}$ If providers are able to draw 15 doses out of the vials, they will need to use their own supplies
 - The kits will include some low dead volume needles/syringes, but will not be exclusively low dead volume
- Cartons and vials are the same size, the vials are just filled to a higher volume



Moderna Vial Labels

- Make sure all staff are aware of the new Moderna National Drug Code (NDC) coming!
 - Keep them organized and labeled in your storage units
 - Vials will be clearly labeled as either a maximum of 11 or maximum of 15 doses
 - The maximum 15 dose vial will have blue shading on the bottom half of the label
 - The new carton for the new NDC will also have blue shading







Moderna Wastage Table

| Manufacturer | Dose | Was the dose extracted in full? | Is it counted as waste? |
|-----------------------|-----------------------|------------------------------------|----------------------------|
| Moderna 6.3mL vial | 10 th dose | Yes | No |
| | | No | Yes |
| | 11 th dose | Yes | No |
| | | No | No |
| | | | |
| Moderna 8mL vial | 13 th dose | Yes | No |
| | | No | Yes |
| | 14 th dose | Yes | No |
| | | No | Yes |
| | 15 th dose | Yes | No |
| | | No | No |
| | | | |

If you cannot pull 15 doses in the new vials, it does not need to be reported as waste. If you pull a full 10 doses from the old NDC, or a full 13 or 14 doses from the new NDC, but do not administer them, you do need to report that as waste.



Your Feedback is Important to Us

Poll: How helpful was today's Provider Office Hours to your work?

- A. Very helpful
- B. Helpful
- C. Somewhat helpful
- D. Slightly helpful
- E. Not helpful at all







Vaccinate ALL 58

Where can I go for additional help?

| Type of Support | Description Updated 4/6/21 |
|--|--|
| Signing the TPA | Send an email to the TPA Network Contracting team if you are interested in signing a TPA provider agreement to join the enhanced COVID-19 Vaccine Network. The team is working through a high volume of requests and will continue doing so during the next several weeks. They will contact you at their first opportunity to walk you through the agreement. Email: <u>CovidVaccineNetwork@blueshieldca.com</u> |
| Allocation process | This email box is being managed by a TPA team that is partnering with the State to set up the new site-level direct allocation process. They will obtain answers for you and respond to you. If you are representing an LHJ/County, it will be forwarded directly to your TPA representative for your LHJ/County, who will respond to you. Email: <u>TPA_allocations@blueshieldca.com</u> . (Note the underscore "_" between TPA and allocations.) |
| → myCAvax help → desk | Dedicated staff provides up-to-date information and technical support through myCAvax help desk: <u>myCAvax.HD@Accenture.com</u> or (833)-502-1245, option 2. "411" myCAvax webinar training sessions are currently being scheduled each week. Send an email to the above address to |
| | inquire about the session schedule and invitation. |
| My Turn / My Clinic help desk | For Onboarding (those in process of onboarding): <u>myturnonboarding@cdph.ca.gov</u> For Technical Support: <u>MyTurn.Clinic.HD@Accenture.com</u>; (415) 621-9494 (Sunday through Saturday from 7AM–7PM) For job aids and demo and training opportunities: <u>https://eziz.org/covid/myturn/</u> |
| COVID-19 Call Center for Providers/LHJs | The COVID-19 Call Center for Providers is dedicated to medical providers in California and their COVID-19 response, specifically addressing questions about State program requirements, enrollment, and vaccine distribution. Email: <u>covidcallcenter@cdph.ca.gov</u> Phone: (833) 502-1245 (Monday through Friday from 8AM–8PM) |
| TPA general inquiry | This email box is being managed by a team at the TPA who will either respond to you directly with an answer to your general question or forward your question/request to the specialized team managing the information you are seeking, so that team can respond to you directly. Email: <u>TPA_Inquiry@blueshieldca.com</u> (Note the underscore "_" between TPA and inquiry.) |
| Source: TPA Vaccine Task Force | |

Provider Office Hours Q&A

Please use the Q&A panel to comment or ask a question:

Q&A Panel





Thank you!



Next Monday:

Next Friday:

My Turn & myCAvax Office Hours

Monday, May 3rd 12:00 PM

Audio Conference: 415-655-0001 Access Code: 145 995 8782 Session Number: 145 995 8782 Session Password: Immunize2020! Provider Office Hours Friday, May 7th 9:00 AM

