

COVID-19 Vaccine updates

Pfizer-BioNTech COVID-19 vaccine: approved

- Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) for use in age ≥ 16 years.
- Advisory Committee on Immunization Practices (ACIP) recommends use.
- Western States Scientific Safety Review Workgroup (CA, NV, OR, and WA) recommends use.
- mRNA vaccine
 - Encodes spike protein of SARS-CoV-2 virus
 - Requires 2 doses administered 3 weeks (21 days) apart

Moderna COVID-19 vaccine: under review

- FDA and ACIP meetings planned this week
 - mRNA vaccine
 - Encodes spike protein of SARS-CoV-2 virus
 - Requires 2 doses administered 4 weeks (28 days) apart
- *not interchangeable with Pfizer-BioNTech vaccine

Vaccination starting in CA

- Initial COVID-19 vaccination in Phase 1a is being offered to:
 - 1. Healthcare personnel**
 - and**
 - 2. Residents of long-term care facilities (LTCFs)**
- LTCFs can plan for COVID-19 vaccination by:
 - A) Working with local health department or affiliated hospital
 - or**
 - B) CDC-Pharmacy Partnership Program with CVS and Walgreens
 - Signup has closed.

CDC Pharmacy Partnership for LTCF Program

- CVS and Walgreens to provide on-site vaccination at facilities
 - LTCF residents
 - LTCF staff not already vaccinated through local health department and other clinics
 - Pharmacies handle end-to-end vaccination
 - Coordinate directly with facilities, 3 visits over 2 months
 - Manage cold chain, vaccines, and ancillary supplies
 - Meet all COVID-19 staff testing and vaccine reporting requirements

Pre-vaccination

- FDA requires Vaccine Fact Sheet for recipients.
- Informed consent is not required by federal law.
 - CVS and Walgreens will use consent forms.
- All persons regardless of prior history of COVID-19 infection are recommended for COVID-19 vaccine.
 - Testing is not recommended for vaccine decision-making.
- Screening for precautions and contraindications (next slide)

MAY PROCEED WITH VACCINATION**PRECAUTION TO VACCINATION****CONTRAINDICATION TO VACCINATION****CONDITIONS****CONDITIONS**

- Immunocompromising conditions
- Pregnancy
- Lactation

ACTIONS

- Additional information provided*
- 15 minute observation period

CONDITIONS

- Moderate/severe acute illness

ACTIONS

- Risk assessment
- Potential deferral of vaccination
- 15 minute observation period if vaccinated

CONDITIONS

- None

ACTIONS

- N/A

ALLERGIES**ALLERGIES**

- History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies
- History of allergy to oral medications (including the oral equivalent of an injectable medication)
- Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis)
- Family history of anaphylaxis
- Any other history of anaphylaxis that is not related to a vaccine or injectable therapy

ACTIONS

- 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause
- 15 minute observation period: Persons with allergic reaction, but not anaphylaxis

ALLERGIES

- History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine)
- History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy

ACTIONS:

- Risk assessment
- Potential deferral of vaccination
- 30 minute observation period if vaccinated

ALLERGIES

- History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine

ACTIONS

- Do not vaccinate

Post-vaccination

- Systemic signs and symptoms following COVID-19 vaccination can include fever, fatigue, headache, chills, myalgia, and arthralgia. Most are
 - mild to moderate in severity
 - occur within the first 3 days of vaccination
 - resolve within 1-2 days of onset
- Systemic adverse reactions were more commonly reported after the second dose than after the first dose and were generally more frequent and severe in persons aged 18–55 years than in those aged >55 years.*
- Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms.

* <https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm>

Infection control considerations

- symptoms
- Healthcare personnel (HCP)
- Residents

https://emergency.cdc.gov/coca/ppt/2020/COCA-Call-Slides_12-14-2020.pdf

-slides 27-44

HCP

Suggested approaches to evaluating and managing new-onset systemic post-vaccination signs and symptoms

- Approaches apply to HCP who
 - have received COVID-19 vaccination in the prior 3 days (including day of vaccination, which is considered day 1) and
 - are not known to have had unprotected exposure to SARS-CoV-2 in the previous 14 days.
- Ultimately, clinical judgement should determine the likelihood of infection versus post-vaccination symptoms.

HCP

Signs and symptoms unlikely to be from COVID-19 vaccination

- Signs and Symptoms
 - Presence of ANY systemic signs and symptoms consistent with SARS-CoV-2 infection (e.g., cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell) or another infectious etiology that are not typical for post-vaccination signs and symptoms.
- Suggested approach
 - Exclude from work pending evaluation for possible etiologies, including SARS-CoV-2 infection, as appropriate.
 - Criteria for return to work depends on the suspected or confirmed diagnosis.

HCP

Signs and symptoms that may be from either COVID-19 vaccination, SARS-CoV-2 infection, or another infection

- Signs and Symptoms
 - Presence of ANY systemic signs and symptoms (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) that are consistent with a post-vaccination reaction, SARS-CoV-2 infection, or another infectious etiology.
- Suggested approach
 - HCP who meet the following criteria may be considered for return to work without viral testing for SARS-CoV-2:
 - Feel well enough and are willing to work, and
 - Are afebrile, and
 - Systemic signs and symptoms are limited only to those observed following vaccination.

HCP

- Suggested approach
 - If symptomatic HCP return to work and symptoms are not improving or persist for more than 2 days
 - Exclude from work, pending evaluation, and consider viral testing
 - HCP with fever should, ideally, be excluded from work pending further evaluation, including consideration for SARS-CoV-2 testing.
 - If an infectious etiology is not suspected or confirmed as the source of their fever, they may return to work when they feel well enough.
 - When critical staffing shortages are anticipated or occurring, HCP with fever and systemic signs and symptoms limited only to those observed following vaccination could be considered for work if they feel well enough and are willing.
 - HCP should be re-evaluated, and viral testing for SARS-CoV-2 considered, if fever does not resolve within 2 days.

Infection control considerations for residents

Residents

Suggested approaches to evaluating and managing systemic new onset post-vaccination signs and symptoms for residents in long-term care facilities

- Approaches apply to residents who have received COVID-19 vaccination in the prior 3 days (including day of vaccination, which is considered day 1).
- Approaches should be tailored to fit the characteristics of each case.

Residents

Signs and symptoms *unlikely* to be from COVID-19 vaccination

- Signs and Symptoms
 - Presence of **ANY** systemic signs and symptoms consistent with SARS-CoV-2 (e.g., cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell) or another infectious etiology that are **not** typical for post-vaccination signs and symptoms.
- Suggested approach
 - Evaluate for possible infectious etiologies, including testing for SARS-CoV-2 and/or other pathogens, as appropriate.
 - Pending evaluation, these residents should be placed in a single person room (if available) and cared for by HCP wearing appropriate Personal Protective Equipment (PPE) recommended for residents with suspected or confirmed SARS-CoV-2 infection. They should **not** be cohorted with residents with confirmed SARS-CoV-2 infection **unless** they are also confirmed to have SARS-CoV-2 infection through testing.
 - Criteria for when Transmission-Based Precautions may be discontinued depend on the results of the evaluation.

Residents

Signs and symptoms *that may be* from either COVID-19 vaccination, SARS-CoV-2 infection, or another infection

- Signs and Symptoms
 - Presence of ANY systemic signs and symptoms (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) that are consistent with post-vaccination signs and symptoms, SARS-CoV-2 infection, or another infectious etiology (e.g., influenza).
- Suggested approach
 - Evaluate the resident
 - These residents should be restricted to their current room (except for medically necessary procedures) and closely monitored until:
 - Fever (if present) resolves and
 - Symptoms improve

Residents

- Suggested approach
 - HCP caring for these residents should wear all PPE recommended for residents with suspected or confirmed SARS-CoV-2 infection while evaluating the cause of these symptoms.
 - If the resident's symptoms resolve within 2 days, precautions can be discontinued.
 - Fever, if present, should have resolved for at least 24 hours before discontinuing precautions.
 - Viral testing for SARS-CoV-2 should be considered for residents if their symptoms are not improving or persist for longer than 2 days.
 - Residents residing in facilities with active transmission, or who have had prolonged close contact with someone with SARS-CoV-2 infection in the prior 14 days, should be tested for SARS-CoV-2 infection.

Resources and information

- For facilities who signed up for CDC Pharmacy Partnership for LTCF Program, CVS and Walgreens will reach out directly to your facility to coordinate.

CVS

- Website: <https://www.omnicare.com/covid-19-vaccine-resource>
- Webinar: <https://cvsh-tv.qumucloud.com/view/B6DiTH0xfjc#/>
- Email: CovidVaccineClinicsLTCF@CVSHealth.com

Walgreens

- Website: <https://www.walgreens.com/covidvaccine>
- Webinar: <https://wba.qumucloud.com/view/oDAT0v8obvH#/>
- Email: immunizeltc@walgreens.com

COVID Vaccine Long Term Care Facility Resources

- CDC: Importance of COVID-19 Vaccination for Residents of Long-Term Care Facilities
www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/LTCF-residents.html
- CDC: Pharmacy Partnership for Long-Term Care FAQs
www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships-faqs.html
- CDC: Post Vaccine Considerations for Residents
www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html
- CDC: Post Vaccine Considerations for Healthcare Personnel
www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html
- CDC: What Every Clinician Should Know about COVID-19 Vaccine Safety and Infection Control
https://emergency.cdc.gov/coca/ppt/2020/COCA-Call-Slides_12-14-2020.pdf
- CDC: Use of Pfizer-BioNTech COVID-19 Vaccine: Clinical Considerations
www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-12/COVID-03-Mbaeyi.pdf
www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-manufacturer%2Fpfizer%2Fclinical-considerations.html

Questions?

COVID vaccine call center

- email COVIDCallCenter@cdph.ca.gov

or

- call (833) 502-1245, Monday through Friday from 9 am to 5 pm