

CVS Health® Enterprise COVID-19 Vaccine

Frequently Asked Questions

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What you need to know about the Coronavirus (COVID-19)

CVS Health is actively monitoring the global COVID-19 pandemic, including guidance from trusted sources of clinical information such as the Centers for Disease Control (CDC) and World Health Organization (WHO). Below is information about policies and procedures that CVS Health has implemented that focus on the health and safety of our colleagues, customers, members, and patients. For more information about the virus, please visit the [CDC](#) and/or [WHO websites](#) dedicated to this issue.

****The content below is not intended to be a substitute for professional medical advice, diagnosis or treatment. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding a medical condition.***

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Vaccine for COVID-19

Clinical

1. How would a COVID-19 vaccine work?

As with any vaccine, the goal of a COVID-19 vaccine is to expose the body to an antigen that won't cause disease but will provoke an immune response that can block or kill the virus if a person becomes infected. Vaccines contain either the whole virus or a component. After receiving a vaccine, a person develops immunity to that disease without having to get the disease. The immunity varies based on the type of vaccine you receive. Some vaccines last a year (like the flu vaccine) and others last longer (like the polio vaccine). Current science suggests that the COVID-19 vaccine will be more like the flu vaccine requiring annual dosing, but research will be required to fully answer this question.

2. What are the different technologies being used to develop a COVID-19 vaccine?

Manufacturers are taking different approaches toward developing a COVID-19 vaccine including using portions of the virus, genetic material or other vectors.

Traditional technology

A traditional vaccine technology is to use protein sub-units that can be injected into cells to stimulate a response. Such vaccines usually need adjuvants—or immune-stimulating molecules—delivered in conjunction with the vaccine and may also require multiple doses. Some of the candidates in development using this technique are from Novavax and Sanofi/GSK.

Novel technologies

Viral vector vaccines use another virus that has been engineered to express the S protein to generate an immune response. Some of the candidates in development using this category are from AstraZeneca/Oxford, Johnson & Johnson, Merck and Vaxart.

Nucleic acid vaccines deliver genetic material into the cell which is then translated into a protein – usually the S protein. However, this method – and the way the genetic material (RNA or DNA) is delivered into the cell – requires that these vaccines be stored and transported at ultracold temperatures of -20 to -70 degrees Celsius. Some candidates in development in this category are from BioNTech/Pfizer, Inovio and Moderna.

3. Most vaccines take years to develop. How is vaccine development able to be sped up for COVID-19?

Vaccine development is a lengthy, expensive process and can take up to 15 years. The fastest vaccine ever to be developed until now was for mumps – and that took nearly five years. Because of the cost and high failure rates, developers typically follow a linear sequence of steps, with multiple pauses for data analysis or manufacturing-process checks.

However, with this pandemic, manufacturers have been able to speed up vaccine development. Here's why:

Head start

Data from SARS-CoV-1 and MERS CoV vaccine development saved time and the initial step of exploratory vaccine design was accelerated.

Government involvement

The government invoked emergency authority to enable manufacturing to start alongside clinical trials. Manufacturing is usually scaled substantially after trials have concluded, but Operation Warp Speed has enabled manufacturers to de-risk and build manufacturing alongside clinical trials.

Pandemic recruitment

The higher rates of infection from this virus and more trial participants have enabled manufacturers to recruit participants and demonstrate efficacy more quickly.

Cutting-edge approaches

New manufacturing technologies have helped accelerate vaccine production.

4. What are some of the clinical considerations or uncertainties concerning a potential vaccine?

Given each vaccine will have different clinical profiles, there are a number of important criteria to evaluate as part of overall planning efforts. Understanding these criteria will help the clinical community plan for safe and effective administration of the vaccine. Some of these considerations include:

- Efficacy, safety, age of vaccine recipient, duration of immunity and route of administration (e.g., intramuscular, intradermal injection, oral, other)

- Dosing frequency and tracking (e.g., single dose vs. multiple doses, time between doses)
- Shipping/storage requirements (e.g., room temperature, refrigerated, frozen, deep-frozen)
- Compounding requirements (e.g., reconstitution, ready-to-use)

Most COVID-19 vaccines under development are likely to require a second booster shot a month or so after the initial dose. Providers will need to ensure that individuals who got the first shot receive a second shot of the right vaccine at the right time. Educating the population about the importance of receiving the booster shot will be critical.

5. Is getting the vaccine safe?

CVS Health's COVID-19 vaccination services will be conducted in compliance with Center for Disease Control and Prevention's (CDC) Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines. CVS Health will only be administering vaccines that have been approved for emergency use by the Food & Drug Administration (FDA).

6. Is getting the COVID-19 vaccine similar to getting a flu vaccine?

Yes, the process will be very similar to receiving a flu vaccine, including scheduling an appointment online at CVS.com or through the CVS app. CVS Health has ample experience in safely administering vaccines, including millions of flu shots every year.

7. Will the vaccine need to be given annually?

Current science suggests that the COVID-19 vaccine will be like the flu vaccine, requiring annual dosing, but research will be required to fully answer this question.

Regulatory

8. What is the FDA's Emergency Use Authorization and how does the process work?

In order to help make a vaccine available as soon as possible, the FDA would need to authorize its distribution under an Emergency Use Authorization (EUA). The agency has issued guidance for the criteria that will be used to evaluate any EUA application.

The FDA evaluates the following criteria when determining whether to issue an EUA:

- Safety: Whether the chemical, biological, radiological or nuclear (CBRN) agent can cause a serious or life-threatening disease or condition. The known and potential benefits of the product,

when used to diagnose, prevent or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.

- Efficacy: If the product is determined to be effective in preventing infection by SARS-CoV-2.
- There is no adequate, approved and available alternative to the product for diagnosing, preventing or treating the disease or condition.

Under the EUA, any investigational vaccines developed to prevent COVID-19 will be assessed on a case-by-case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product and the totality of the available scientific evidence relevant to the product. The final guidance specific to EUA for vaccines to prevent COVID-19 can be found [here](#).

Operations

Distribution

9. How will vaccines be handled, distributed and tracked?

Logistics of cold chain shipping

Depending on which vaccines are approved, transporting from manufacturers to distribution facilities, and from there to providers could require refrigeration, freezing or even ultracold storage. For example, one of the vaccine candidates needs to be kept at -70 degrees Celsius, another at -20 degrees Celsius. So, it is essential to ensure the right logistics to maintain the cold chain, such as shipping vaccines in dry ice packs and ensuring facilities have appropriate freezer capacity. The Department of Health and Human Services (HHS) is ensuring that pharmacies that participate in the federal allocation program have the necessary infrastructure to handle the COVID-19 vaccines.¹

Avoiding waste with multi-dose vials

Manufacturers are putting multiple doses into each vial – currently ranging from 5 to 15 doses. Those administering vaccines will need to make sure that once the vaccine is taken out of the freezer, as many doses are used in a specified time frame before spoilage occurs, so waste is minimized.

¹ <https://www.hhs.gov/about/news/2020/11/12/trump-administration-partners-chain-independent-community-pharmacies-increase-access-future-covid-19-vaccines.html>

Dosing, scheduling and tracking

Booster shots are going to be required for nearly all vaccine candidates. A detailed tracking system will be required to make sure we know who received which vaccine and then make sure that at their follow up visit they get the second dose from the same manufacturer.

The latest guidance issued by the Centers for Medicare and Medicaid Services (CMS) states: “Candidate vaccines may be a single-dose vaccination or be part of a two-dose series. States and organizations should proactively address planning for and identifying resources to engage patients for both initial vaccination and then completion of the vaccine series in advance of vaccine receipt.”²

10. Is CVS Health set up to be able to provide appropriate temperature-controlled storage of the vaccine, even if the approved vaccine requires extreme cold storage and cold-chain standards?

Yes. CVS Health will be able to appropriately store vaccine at the manufacturer’s required temperature range.

Timing/Availability

11. Who will get the vaccine first?

Under the Memorandums of Understanding that CVS Health has signed with HHS for COVID 19 vaccination administration for LTC/ALFs, as well as for the general population, we must administer COVID-19 vaccines in full compliance with all requirements, recommendations and other guidance of the CDC and CDC’s Advisory Committee on Immunization Practices (ACIP), including patient prioritization requirements and recommendations. The ACIP prioritization requirements and recommendations have not been finalized yet, and likely will not be until the December 10-12 time period. We are closely monitoring and understand that the prioritization guidelines will be designed to ensure those most at risk, such as health care workers and residents of long term care facilities, receive the vaccine in the first wave, with other vulnerable and at-risk populations prioritized after that, and then the general public.

² <https://www.cms.gov/files/document/COVID-19-toolkit-issuers-MA-plans.pdf>

12. When will CVS Health begin offering the COVID-19 vaccine?

Once a COVID-19 vaccine (or vaccines) is available to CVS Health, CVS Health will work rapidly to make vaccinations available consistent with governmental priorities.

13. How many doses of vaccine will be made available to CVS Health?

The volume to be made available to CVS Health will be determined by the government's allocation methodology.

14. In how many states will CVS Health be able to offer these clinics?

CVS Health is prepared to provide vaccinations in all 50 states, as well as in Washington, D.C. and Puerto Rico.

15. If more than one vaccine is available, which vaccines will be offered?

The type of vaccine made available to CVS Health will be determined by the government's allocation methodology.

Administration

16. What is the role of CVS Health® in administering COVID-19 vaccines?

CVS Health has entered into agreements with the CDC to (1) participate in the Pharmacy Partnership for Long-Term Care Program and (2) act as one of the official COVID-19 Vaccination Program Providers for the community once the vaccine is available for general distribution. Through these partnerships, CVS Health is prepared to play a prominent role in administering COVID-19 vaccinations to priority populations, including health care workers and residents of long-term care facilities, as well the general public. CVS Health also stands ready to provide additional assistance to states in their state-run vaccination programs.

Appropriate personnel under applicable state and federal laws and guidance will administer vaccines to patients. CVS Health immunizers are trained and certified according to company and state specific regulations. These immunizers may include pharmacists, pharmacy interns and trained pharmacy technicians, as well as other qualified healthcare professionals. All CVS Health immunizers are trained in the administration of immunizations and hold an active CPR certification.

17. Who will be administering the vaccines at these clinics? Pharmacists? Pharmacy technicians? Other health care providers?

Appropriate trained personnel under applicable state and federal laws and guidance will administer vaccines to facility patients and employees at the on-site clinics. CVS Health immunizers are trained and certified according to company and state specific regulations. These immunizers may include pharmacists, pharmacy interns, and trained pharmacy technicians, as well as other qualified healthcare professionals. All CVS Health immunizers are trained in the administration of immunizations and hold an active CPR certification.

18. What processes are in place to manage and ensure appropriate booster shot administration (depending on the authorized vaccine)?

Patients will be required to make an appointment for their initial shot online or through the CVS app. Patients scheduling a first dose of a vaccine will be prompted to schedule an appointment for their booster dose at the same time. The scheduling system will automatically prompt patients to schedule the booster dose within the appropriate timeframe, allowing enough time for a potential reschedule of the appointment. The patient will receive follow-up reminders to get the second dose. Upon receiving their first dose, patients will be provided with a mandated vaccine card with all pertinent vaccination information. Detailed reporting will be shared with state, local or territorial public health authorities.

Billing/Payment

19. Will patients be charged for the vaccine?

No. Section 3203 of the CARES Act generally requires issuers offering non-grandfathered group or individual health insurance coverage to cover any qualifying coronavirus preventive service, including a COVID-19 vaccine, without imposing any cost sharing requirements, such as a copay, coinsurance or deductible.

No patient will be charged for the vaccine or its administration. The government will provide the vaccine itself, and the health care providers who administer the vaccine will be reimbursed by the patient's insurance or, in the case of uninsured patients, the Health Resources and Services Administration (HRSA) program for uninsured patients, for the administration of the vaccine. CMS has established the reimbursement rates for administration of the vaccine for patients covered by Medicare and Medicaid as well as those covered by the program for the uninsured.

Aetna

Employer/Plan Sponsor

Click [here](#) for all Aetna Member Frequently Asked Questions.

20. How is Aetna preparing for the roll-out of the COVID-19 vaccine? NEW

Aetna, as part of CVS Health, is committed to supporting our clients and members when a vaccine becomes available for the broader population.

Our steps include:

- Building a robust communications strategy regarding availability of vaccinations and options for receiving the vaccine
- Training staff including service and clinical teams
- Adding the COVID-19 vaccine to our overall pharmacy vaccination program

All retail pharmacies currently participating in CVS Caremark's networks will be offered the opportunity to provide COVID-19 vaccine administration. Those pharmacies approved to administer the COVID-19 vaccine, will utilize NCPDP and CDC guidelines. We will ensure that pharmacy claims adjudicate properly and that these pharmacies are reimbursed appropriately for administration of the vaccine.

For claims from medical providers approved to administer the COVID-19 vaccine, we will ensure that medical claims adjudicate properly and that these medical providers are reimbursed appropriately for administration of the vaccine.

21. Will the COVID-19 vaccine be part of the Aetna vaccine program?

Yes, the COVID-19 vaccine will be part of the Aetna vaccine program. In addition, Aetna's pharmacy benefit partner, CVS Caremark, will offer all retail pharmacies currently participating in CVS Caremark's networks the opportunity to provide COVID-19 vaccine administration.

COVID-19 vaccinations will be available at pharmacies as well as doctors' offices and other clinical sites of care. The vaccine will be covered under the medical or pharmacy benefit, depending on the site of administration. If the vaccine is administered by a pharmacy, it will be covered under the

pharmacy benefit. If the vaccine is administered by a doctor's office or another clinical site of care, it will be covered under the medical benefit. The initial vaccines will require administration in two doses. For example, the vaccine from Pfizer requires an initial dose and then a second dose 21 days later.

During the initial phase of limited vaccine supply, the federal government will purchase all the initial supply of the vaccine and allocate vaccines to the states for prioritized distribution. During this time, the federal government will be covering the ingredient cost of the COVID-19 vaccine. However, insurers and plan sponsors will be required to cover the administration cost, with most plans requiring zero cost share to their plan members.

22. Will Aetna/CVS support on-site workplace vaccination events?

Considering the cold- and ultra-cold storage requirements for many of the vaccines, CVS will only administer the vaccine in CVS Pharmacy locations. As new vaccinations become available, we anticipate possible worksite options.

Billing/Payment

23. Which COVID-19 vaccinations will Aetna cover?

Aetna will cover any COVID-19 vaccine that has received FDA authorization, either through an Emergency Use Authorizations (EUA) or licensed under a Biologics License Application (BLA), at no cost to members.

24. Are Aetna clients expected to pay for the vaccine?

The government has paid for the vaccine itself, and most issuers are required to reimburse providers for administering the vaccine. Aetna will cover the cost of COVID-19 vaccines and their administration without cost sharing for Aetna members in all plans. Our coverage aligns with requirements in the CARES Act and the recent federal regulation. The CARES Act requirement also applies to self-insured plans.

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