

CVS Health® Enterprise COVID-19 Vaccine

Frequently Asked Questions

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About the COVID-19 vaccine and how it works

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.

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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 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 U.S. Food and Drug Administration (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 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](#).

5. 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.

6. 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, and 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 U.S. 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.

Dosing, scheduling and tracking

As discussed previously, 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

¹ U.S. Department of Health and Human Services. [Trump Administration partners with chain and independent community pharmacies to increase access to future COVID-19 vaccines](#). U.S. Department of Health and Human Services website. November 12, 2020. Accessed December 2, 2020.

²The Centers for Medicare & Medicaid Services. [Toolkit on COVID-19 vaccine: Health insurance issuers and Medicare Advantage plans](#). Last updated November 5, 2020. Accessed December 2, 2020.

Access to and payment for the COVID-19 vaccine

7. Who will get the vaccine first?

Under the Memorandums of Understanding that CVS Health has signed with the HHS for COVID-19 vaccination administration for long-term care (LTC) and assisted living facilities (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 Centers for Disease Control and Prevention (CDC) and the 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.

8. During the initial phases, when the vaccine is in limited supply, how can plan sponsors be assured of getting access to the vaccine for their members?

It will be up to each of the states to determine, considering guidelines provided from the federal government, who to prioritize for the initial vaccine administration. To ensure members access the vaccine as it becomes available, plan sponsors should move quickly to cover the COVID-19 vaccine administration within their existing member benefit. Given the recent HHS announcement of the federal government's partnership with large pharmacy chains and community pharmacies to access and administer the vaccines as they become available, we encourage all our PBM clients to cover the COVID-19 vaccine administration fee under their PBM pharmacy benefit.

9. 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 federal 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.

10. Who will pay for vaccine administration?

Medicare, Medicaid and the vast majority of commercial health insurance will pay for vaccine administration for covered individuals with no cost sharing. On October 28, 2020, CMS [released](#) an [Interim Final Rule with Comment Period \(IFC\)](#) regarding COVID-19 vaccines. The IFC:

- Establishes that any vaccine receiving FDA authorization, either through an EUA or licensed under a Biologics License Application (BLA), will be covered under Medicare and Medicare Advantage (MA) at no cost to beneficiaries ([fact sheet](#)). It implements the CARES Act provisions requiring Medicare FFS, Medicare Advantage, Medicaid* and most group health plans to cover COVID-19 vaccines and administration fees without cost sharing, both in and out of network.
- Establishes Medicare fee-for-service payment rate for vaccine administration for single-dose vaccine at \$28.39; and, for a COVID-19 vaccine requiring a series of two or more doses, sets the initial dose(s) administration payment rate at \$16.94 and at \$28.39 for the administration of the final dose in the series.
- Provides that vaccines provided to Medicare Advantage enrollees will be paid by Medicare fee-for-service.

Commercial insurance

*Under section 6008(b)(4) of the FFCRA, to receive the temporary FMAP increase, a state or territory must cover COVID-19 testing services and treatments, including vaccines and their administration, specialized equipment, and therapies for Medicaid enrollees without cost sharing. We are not aware of any states or territories not currently claiming this temporary FMAP increase, and CMS has stated that it is not aware of any states or territories that intend to cease claiming it. Accordingly, Medicaid coverage of COVID-19 vaccines and their administration, without cost sharing, is expected to be available for most Medicaid beneficiaries.

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For commercial insurance, the IFC implements the CARES Act requirements for non-grandfathered group health plans and health insurance issuers to cover COVID-19 vaccines and administration fees without cost sharing, both in and out of network. In addition, the rule implements the provision requiring coverage of vaccines 15 days after the ACIP makes a recommendation. The IFC also provides that out-of-network rates cannot be unreasonably low, and references CMS's Medicare reimbursement rates for vaccine administration as a potential guideline for insurance companies.

Medicaid

For Medicaid, the IFC confirms that states must cover an approved COVID-19 vaccine for Medicaid beneficiaries without cost sharing through the end of the public health emergency in order to receive the temporary Federal Medical Assistance Percentages rate (FMAP) increase authorized by the Families First Coronavirus Response Act.³

Tool kits to increase access to vaccines for Medicare and Medicaid beneficiaries

Along with the IFC, CMS issued three tool kits aimed at state Medicaid agencies, providers who will administer the vaccine and health insurance plans. According to CMS, together, these tool kits will help ensure the health care system is prepared to successfully administer a safe and effective vaccine by addressing issues related to access, coverage, billing and payment and Medicare payment rates.

Billing and payment

Under the PBM pharmacy benefit: Given that the HHS has announced partnership with retail pharmacies to administer the COVID-19 vaccine, we strongly encourage all plan sponsors to cover the COVID-19 vaccine administration under the PBM pharmacy benefit. The PBM has created a simple process for our clients to contract for COVID-19 vaccine administration, details of which were issued via the COVID-19 e-flyer communication on November 23, 2020. All retail pharmacies currently participating in CVS Caremark® networks will be offered the opportunity to provide COVID-19 vaccine administration. Participating retail pharmacies will utilize National Council for Prescription Drug Programs (NCPDP) and CDC guidelines when administering the COVID-19 vaccine, and the client will be invoiced for COVID-19 vaccine administration on the standard PBM services invoice.

Under the medical benefit: CMS and the American Medical Association have issued Current Procedural Terminology codes for the first vaccines, as well as specific vaccine administration codes for each dose for those vaccines, to allow providers and insurance companies to bill for and track vaccinations for the different vaccines that are provided to their enrollees. States and other payors are strongly encouraged to use a uniform billing standard for vaccine claims (e.g., the NCPDP standard for pharmacy billings).

³The Centers for Medicare & Medicaid Services. [Families First Coronavirus Response Act – Increased FMAP FAQs](#). Last updated April 13, 2020. Accessed December 2, 2020.

11. What steps can issuers take to ensure their providers are equipped to provide COVID-19 vaccines?

Issuers should:

- Ensure that providers in your network know how to become vaccinators for the COVID-19 vaccine.
- Ensure that providers are aware of their reporting requirements for the vaccination. Providers must record details of the vaccination into their system of record within 24 hours, and into the applicable public health system within 72 hours.⁴
- For vaccines that require multiple doses, encourage providers to communicate to their patients to get both doses of the same vaccine.
- Provide a website with FAQs for providers on COVID-19 vaccine administration and reimbursement, including any specific coding instructions.
- Consider how to engage with non-traditional providers, such as local health departments, mobile clinics and mass vaccination sites, so that they are able to bill issuers for vaccine administration.

The role of CVS Health®

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

CVS Pharmacy® 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 Pharmacy 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 Pharmacy 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

⁴Centers for Disease Control and Prevention (CDC). [COVID-19 vaccination program interim playbook for jurisdiction operations](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf). October 29, 2020. Accessed December 2, 2020. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

trained pharmacy technicians, as well as other qualified health care professionals. All CVS Health immunizers are trained in the administration of immunizations and hold active CPR certifications.

Long-term care facilities-specific questions

13. How is CVS Health working with the CDC to make the COVID-19 vaccine available to residents and staff of long-term care facilities?

As announced by the HHS and U.S. Department of Defense, CVS Health has entered into a contract with the CDC to be one of the official COVID-19 Vaccination Program Providers in the Pharmacy Partnership for Long-Term Care Program. As a result, once a COVID-19 vaccine is approved and available, the U.S. government will make a supply of the publicly funded vaccine available to CVS Health to provide on-site vaccination clinic services to residents and staff of long-term care facilities.

14. Who is eligible to receive the COVID-19 vaccination under this contract?

Under this contract, CVS Health will receive a supply of the publicly funded COVID-19 vaccine and necessary supplies for administration once the vaccine is approved and available. This supply of vaccine will be used to provide vaccinations to residents and staff of long-term care facilities.

15. When will CVS Pharmacy begin offering the COVID-19 vaccine?

Once a COVID-19 vaccine (or vaccines) is available, CVS Health will work rapidly to make vaccinations available to staff and residents of long-term care facilities, consistent with governmental priorities.

16. 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.

17. How many clinics does CVS Pharmacy plan to coordinate under this contract?

The number of clinics will be determined by the number of long-term care facilities that select CVS Health as their vaccine partner through the CDC survey process. As of November 18, over 25,000 sites have selected CVS Health to provide vaccinations in their facilities.

18. How will CVS Health identify/select the long-term care facilities that it will support through this vaccination program?

CVS Health will not select facilities. Rather, facilities will select their preferred pharmacy partner through the CDC's survey process. The CDC will then provide a list of facilities to CVS Health where on-site clinics will be scheduled and conducted.

19. In how many states will CVS Pharmacy be able to offer these clinics?

CVS Health is prepared to provide vaccination clinics for long-term care facilities in all 50 states.

20. Where will the vaccinations take place? Will they take place at CVS Pharmacy locations or on-site at the selected long-term care facilities?

For this specific program, CVS Health will coordinate and schedule a series of vaccination clinics on-site at the identified long-term care facilities.

21. Will you be vaccinating both residents and staff members at these long-term care facilities?

Yes. Through this program, we will be vaccinating both residents and staff members at identified long-term care facilities.

22. Will CVS Pharmacy only coordinate these vaccination clinics at long-term care facilities affiliated with CVS Health's Omnicare® business?

No. CVS Health will provide vaccination clinics to any long-term care facility that chooses to utilize CVS Health as their preferred vaccination provider. CVS Health is not limited to Omnicare customers. CVS Health's program is available to any long-term care facility throughout the country.

23. 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 health care professionals. All CVS Health immunizers are trained in the administration of immunizations and hold active CPR certifications.

24. Is CVS Pharmacy 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 Pharmacy will be able to appropriately store vaccines at the manufacturers' required temperature ranges.

25. Will CVS Health be able to use the COVID-19 vaccine provided through this program for other populations outside of long-term care facility settings?

Under the Pharmacy Partnership for Long-Term Care Program, the federal government will supply vaccines for use only to vaccinate residents and staff of long-term care facilities. Under the separate agreement CVS Health has entered into with HHS, CVS Pharmacies will receive vaccine supplies to administer vaccines in our retail locations in accordance with the government's prioritization guidelines.

26. Does CVS Health plan to work with the United States government to help vaccinate other populations beyond long-term care facilities?

Yes. As announced on November 12, CVS Health has entered into a partnership with the HHS to provide access across the country to COVID-19 vaccines, once available. Through this partnership, CVS Pharmacy locations will receive vaccine supplies to administer the vaccine in accordance with federal prioritization guidelines. CVS Health will play a vital role in providing access to COVID-19 vaccines once they become available.

Aetna-specific questions

27. Will Aetna cover the cost of vaccination for COVID-19?

Yes, 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 requirement also applies to self-insured plans.

28. 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.

29. What CPT codes should I be aware of related to vaccinations for COVID-19? (content taken from CMS site)

After the Emergency Use Authorization (EUA) or licensure of each COVID-19 vaccine product by FDA, CMS will identify the specific vaccine code(s), by dose if necessary, and specific vaccine administration code(s) for each dose for Medicare payment. Visit the [CMS website](#) for more information.

30. When a COVID-19 vaccine is available, how should providers bill for the vaccine and its administration?

Per [guidance provided by CMS](#), Medicare beneficiaries enrolled in Medicare Advantage plans will be able to access the COVID-19 vaccine, without cost sharing, at any Fee for Service provider or supplier participating in Medicare and eligible to bill under Part B for vaccine administration, including those enrolled in Medicare as a mass immunizer or a physician, non-physician

practitioner, hospital, clinic or group practice. Providers should submit claims for administration of the COVID-19 vaccine to the CMS Medicare Administrative Contractor (MAC) for payment.

31. 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.

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

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

33. How can Aetna clients be prepared for a COVID-19 vaccine?

Clients should continue to encourage their members and/or employees to obtain the flu vaccine. Additionally, Aetna is preparing a set of educational materials in the form of a tool kit that can be used to educate your members on the effectiveness and safety of the COVID-19 vaccine and where to obtain the vaccine. It is likely that the vaccine will be administered primarily at retail pharmacies as it initially becomes available to the public.

Additional commercial health care vertical questions

34. What type of communication assets can Aetna/CVS Health provide to help plan sponsors communicate vaccination availability and eligibility criteria?

Aetna and CVS Health are in the process of building a broader workforce communication tool kit to help plan sponsors promote timely and relevant content about the vaccines and resources to get vaccinated. We will share the timing and details of this communication strategy as soon as possible and as broader vaccine rollouts become clear.

35. How will Aetna communicate COVID-19 vaccination guidelines directly to my employees (your members) broadly, and for those who meet target eligibility vaccination criteria?

Aetna and CVS Health are in the process of building a broader member communication strategy to help all members with broad awareness, understanding of the vaccines and approved network partners to administer and targeted eligibility and highest-risk members, where appropriate. We will share the details of this communication strategy as soon as possible and as broader vaccine rollouts become clear.

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