

COVID-19 Vaccine Overview and Frequently Asked Questions

On November 5, 2020, the Centers for Medicare & Medicaid Services (CMS) released a set of toolkits for providers, states and issuers to help the healthcare system prepare to swiftly administer the COVID-19 vaccine.

Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) specifies that a COVID-19 vaccine and its administration will be covered under Medicare Part B, and therefore would be excluded from Part D coverage. For calendar years (CY) 2020 and 2021, Medicare payment for the COVID-19 vaccine and its administration for beneficiaries enrolled in Medicare Advantage plans will be made through the original fee-for-service Medicare program.

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 copays, coinsurance, or deductibles.

- A qualifying coronavirus preventive service means an item, service or immunization that is intended to prevent or mitigate COVID-19 and that is, with respect to the individual involved, (1) an evidence-based item or service that has in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF) or (2) an immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) regardless of whether the immunization is recommended for routine use.
- This coverage under section 3203 of the CARES Act must be provided no later than 15 business days after the date that ACIP or the USPSTF makes an applicable recommendation relating to the qualifying coronavirus preventive service. To ensure maximum rapid public take-up of the vaccine, we encourage all issuers to prepare to cover administration of the COVID-19 vaccine immediately upon ACIP’s recommendation. Coverage does not depend on the type of FDA approval (EUA vs BLA) or authorization.
- These coverage requirements do not apply to a plan or coverage that is not required to provide coverage of preventive services without cost sharing under section 2713 of the Public Health Service Act, such as grandfathered health plans, excepted benefits or short-term limited duration insurance, though we encourage all such plans to provide this coverage to all enrollees without cost sharing.

On December 11, 2020, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) allowing the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the U.S. The Advisory Committee on Immunization Practices (ACIP) recommended, as interim guidance, that both 1) health care personnel and 2) residents of long-term care facilities be offered COVID-19 vaccine in the initial phase of the vaccination program. Elixir is planning for configuration and network readiness to ensure that, when the vaccine is distributed to vaccinators, the vaccinators are able to provide and properly record the administration of the vaccine. The vaccine itself will be paid for through funding authorized by the CARES Act, but administration of the vaccine by a pharmacy is paid for by the payer.

Pharmacy Network Communication

1. Pharmacies received an [initial email communication](#) from Elixir on Dec. 11 with information on how to become vaccinators.
 - Elixir will include links to the National Council for Prescription Drug Programs (NCPDP) Emergency Preparedness Guidance and the CMS provider toolkit for pharmacies to ensure awareness of their reporting requirements and how to become vaccinators for the COVID-19 vaccine.
2. Vaccine administration fees will be configured for the COVID-19 vaccine at the CMS standard payment rates of:
 - **Single-dose vaccines:** \$28.39
 - **Vaccines with a series of two or more doses:** \$16.94 for the initial dose(s) and \$28.39 for the final dose in the series

3. No later than Dec. 18, 2020, pharmacies will receive a follow-up communication with additional information on policies for submission of vaccine administration, deployment date, availability of the vaccines and the above administration fees.
4. The Pharmacy Provider Manual will be updated by December 18, 2020 with this information.
5. Elixir Customer Care Center will receive training to be able to respond to pharmacy calls and answer questions on the policies and guidelines to support them in advance of vaccine distribution.

Claim System Configuration

1. Claims system configuration is currently available to accept in-network and out-of-network pharmacy submissions for vaccine administration for non-Medicare plan sponsors.
2. For Medicare plans, claims for the vaccine will reject A5 (Not Covered Under Part D Law) with additional messaging, "Bill to Medicare B FFS."
3. Members will NOT be charged any cost share for the vaccine or its administration.
4. The vaccine will be covered for all non-Medicare plans. Plans that are not required to provide coverage of preventive services without cost sharing under section 2713 of the Public Health Service Act, such as grandfathered health plans, excepted benefits or short-term limited duration insurance must notify your Elixir account manager if an exception is requested to this configuration, and wish to exclude the vaccine. Exceptions are not recommended.

FAQs

Q: Will members be able to get the COVID-19 vaccine at network pharmacies?

A: Yes. Once the vaccine is available to network pharmacies, claims for the administration of the vaccine for non-Medicare members will process through Elixir at \$0 member copay. Claims submitted for Medicare members will reject with special messaging to the pharmacy to bill Medicare B FFS. Now that the FDA has granted EUA to the Pfizer-BioNTech vaccine, it should become available to high-risk populations first based on guidance from the CDC. In Phase 1, the available vaccine will be allocated to states by the CDC. State governments will make the determination as to how those doses are distributed. In Phase 1, COVID vaccinations will likely be focused on healthcare workers and long-term care facilities and people over 65 with chronic health conditions. ***In Phase 1, the vaccine will not be widely available to the general public.*** To receive free supplies of COVID-19 vaccine(s), pharmacies, retail clinics, providers and any other site of care receiving and administering COVID-19 vaccines must sign an agreement with the U.S. government. As supply of the vaccine increases, broader access will become available.

Elixir will allow in-network and out-of-network vaccinator pharmacies to process the administration fee for all non-Medicare plans.

Q: What is the guidance from the CDC for distribution?

A: Currently, the CDC has recommended that healthcare personnel and seniors living in long-term care facilities be prioritized for the first phase. Additional guidance is expected as vaccines become available. Additional information, including the [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#), can be found [here](#).

Q: Will the vaccine be restricted to certain pharmacies?

A: Yes. To receive free supplies of the COVID-19 vaccine(s), pharmacies, retail clinics, providers, and any other site of care receiving and administering COVID-19 vaccines must sign an agreement with the U.S. government. They must also administer the vaccine in accordance with CDC and ACIP requirements and must meet storage and recordkeeping requirements, including recording the administration of the vaccine to patients in their own systems within 24 hours and reporting to public health data systems as soon as practical, and within 72 hours.

Pharmacies that are not contracted with Elixir or who have been removed from the network for OIG sanctions, FWA or other concerns will be handled on a case by case basis.

Q: What will the COVID-19 vaccine cost?

A: The vaccine itself will be paid for through funding authorized by the CARES Act, but administration of the vaccine by a provider will be paid for by the payer (for example, the private insurance company, Medicare in the case of a Medicare Advantage plan or the Provider Relief Fund). Pharmacies, retail clinics, providers, and any other site of care receiving and administering COVID-19 vaccines must sign an agreement with the U.S. government. Under the agreement, all providers must vaccinate individuals regardless of whether they have health insurance coverage or what type of coverage they have and are prohibited from balance billing or otherwise charging vaccine recipients. The federal government has purchased the initial supply of vaccines.

- **Medicare Advantage Coverage and Reimbursement:** For calendar years (CY) 2020 and 2021, Medicare payment for the COVID-19 vaccine and its administration for beneficiaries enrolled in Medicare Advantage plans will be made through the original fee-for-service Medicare program.
- **Non-Medicare plans** will be responsible for paying administration fees.

Q: How will the price differ for out-of-network (OON) pharmacies?

A: The administration fees will be the same for all pharmacies who are enrolled to be vaccinators.

Q: How will the vaccination process work?

A: Now that the FDA has granted EUA to the Pfizer-BioNTech vaccine, it should become available to high-risk populations first based on guidance from the CDC. Another vaccine is in the final phases of FDA review, and it, as well as Pfizer's, both require two doses to be administered at different intervals.

Q: Will pharmacies bill separately for the second dosage?

A: Yes. Each dose will be billed separately. Based on the current vaccines in the pipeline, up to two doses of the vaccine will be available for each member. Elixir will evaluate and comply with ongoing NCPDP recommendations and other regulatory guidance updates.

Q: Will COVID-19 vaccines be covered by Medicare?

A: Yes. For beneficiaries enrolled in Medicare Advantage plans during CY 2020 and 2021, payment for the COVID-19 vaccine and its administration will be made through the original fee-for-service Medicare program. Medicare Advantage plans should inform their contracted providers about this coverage policy and direct them to submit claims for administering the COVID-19 vaccine to the CMS Medicare Administrative Contractor (MAC) using product-specific codes for each vaccine approved. More

information is available in the [CMS Toolkit on COVID-19 Vaccine](#). Elixir will provide the pharmacy network with this information in two waves, beginning Dec. 11, 2020.

According to [guidance from the National Council for Prescription Drug Programs](#), the reject messaging for Medicare Part D BIN/PCN (PDP or MAPD), will be A5 (not covered under Part D law) with additional messaging to bill Medicare Part B FFS.

Q: Will members be able to submit a Direct Member Reimbursement (DMR) if they are required to pay the pharmacy for the administration fee?

A: Since members will receive the vaccine at no copay/cost share or deductible, there is no need for a DMR.

Q: Will Elixir be charging a separate per-claim COVID vaccine transaction processing fee?

A: Elixir will charge the fee to administer the vaccine in addition to any per-claim administrative fee as provided for in the PBM contract.

Q: Can a pharmacy obtain the vaccine and submit a claim if they have not been granted approval by the government?

A: Pharmacies must receive approval from the government to receive and administer the vaccine. Elixir does not monitor the approval pathway for pharmacies to obtain the vaccine and will allow claims to process if submitted for the vaccine and administration, assuming the pharmacy has the vaccine in hand.

Q: How will COVID-19 vaccines work?

A: COVID-19 vaccines will work like other vaccines, which expose recipients to antigens. These antigens help those who are vaccinated to develop an immune response that will be able to block or kill the virus if a person becomes infected. Although some vaccines can provide long-lasting immunity, we do not yet have enough information to evaluate the duration of protection from the COVID-19 vaccine. Scientist will continue to collect long-term immunity data to determine if changes to the COVID-19 vaccine are needed and to determine long-term dosing requirements.

Q. Will the COVID-19 vaccine be like the flu vaccine and require annual dosing?

A: At this time there is not enough data to evaluate a long-term dosing schedule. Although some vaccines can provide long-lasting immunity, we do not yet have enough information to evaluate the duration of protection from the COVID-19 vaccine. Scientist will continue to collect long-term immunity data to determine if changes to the COVID-19 vaccine are needed and to determine long-term dosing requirements.

Q: Most vaccines take years to develop. How have we been able to speed up development for a COVID-19 vaccine and has that affected its safety?

A: It's correct that vaccine development typically takes years. However, in this case, developers were able to speed up the process, in part because of efforts that had been underway on previously known coronaviruses (SARS-CoV-1 and MERS CoV). In addition, the U.S. government aided the process by invoking emergency authority to enable manufacturing to start while the clinical trials were ongoing. Data collected from thousands of participants in clinical trials help the FDA determine the

safety of the vaccine. Currently, the vaccines that have filed with the FDA for emergency use authorization have been shown to be safe and effective.

Q: What is emergency use authorization?

A: An EUA is a way to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies. Under an EUA, the FDA may allow unapproved medical products, or unapproved uses of approved medical products, in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions.

Q: What are some of the clinical considerations or uncertainties concerning a potential vaccine?

A: The vaccines currently being considered will have different clinical profiles, but both the Pfizer-BioNTech and Moderna options are messenger RNA vaccines, or mRNA vaccines. These utilize a new approach to protecting against infectious diseases and will be the first of their kind to be licensed in the United States.

The Pfizer-BioNTech vaccine is authorized for those aged 16 and older and is contraindicated for individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to vaccine components. Side effects of the vaccine typically resolve within 1-2 days and commonly include things like: injection site reactions, fatigue, headache, muscle pain, chills, joint pain, and fever.

The Pfizer vaccine series consists of two doses (30 µg, 0.3 ml each) administered intramuscularly, three weeks apart. According to interim CDC clinical considerations, doses administered within a grace period of ≤4 days (i.e., between day 17 and 21) are considered valid; however, if the second dose is administered earlier than day 17, it does not need to be repeated. If more than 21 days have elapsed since the first dose, the second dose should be given at the earliest opportunity; the series does not need to be repeated.

The CDC advises that vaccine providers should observe patients with a history of allergic reactions (due to any cause) for 30 minutes after vaccination. All other persons should be observed for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions. The CDC also states that appropriate medical treatment must be immediately available to treat a patient who experiences a severe allergic reaction to the vaccine.

Q: Will COVID-19 vaccines be available at Rite Aid locations?

A: Yes. **In Phase 2**, vaccines will be distributed to Rite Aid and other Vaccination Program Providers by the CDC. Rite Aid is staged and ready to distribute a vaccine to our customers (aged 18 and up) immediately upon receipt of the vaccine.