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.

In December 2020, the U.S. Food and Drug Administration (FDA) issued emergency use authorizations (EUAs) allowing the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine to be distributed in the U.S. In late February 2021, the FDA issued an EUA for the Johnson & Johnson COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson. See the table at the end of this document for more information about these authorizations.

On April 13, 2021, the Centers for Disease Control and Prevention (CDC) and the FDA recommended a pause in the use of the Johnson & Johnson COVID-19 vaccine out of an abundance of caution while reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the Johnson & Johnson vaccine. The CDC convened a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday, April 14, to further review these cases and assess their potential significance; however, the committee determined that more information is needed and plans to reconvene in the next week to 10 days. The FDA will review that analysis as it also investigates these cases. Elixir continues to monitor the situation and will provide updates in this FAQ document and via other channels, as appropriate, as new information emerges.

Initially, ACIP recommended, as interim guidance, that both 1) health care personnel and 2) residents of long-term care facilities be offered COVID-19 vaccines in the initial phase of the vaccination program (Phase 1a). See ACIP's current vaccine allocation recommendations here. 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 December 11 and another email communication on December 17 with information on how to become vaccinators and how to submit claims.
    - Elixir included 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 are configured for the COVID-19 vaccine at the CMS standard payment rates. CMS updated the standard payment rates on March 15, 2021.

    For COVID-19 vaccine administration services furnished before March 15, 2021, the Medicare payment rate for a single-dose vaccine or for the final dose in a series is $28.39. For a COVID-19 vaccine requiring a series of two or more doses, the payment rate is $16.94 for the initial dose(s) in the series and $28.39 for the final dose in the series.

    For COVID-19 vaccine administration services furnished on or after March 15, 2021, the Medicare payment rate for each dose of a COVID-19 vaccine is $40.
3. Elixir has updated the Pharmacy Provider Manual with this information.
4. Elixir Customer Care Center staff is receiving training to be able to respond to pharmacy and member calls and answer questions on the policies and guidelines.

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 three vaccines, the vaccinations 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-19 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 that are enrolled to be vaccinators.

Q: What will the vaccination process be?

A: Now that the FDA has granted EUA to these vaccines, the vaccinations should become available to high-risk populations first based on guidance from the CDC. One of the vaccines, the administration of which is currently paused, requires a single dose while the other two vaccines require two doses to be administered at different intervals. The two-dose vaccines are not interchangeable; both required doses have to be the same vaccine.

Q: For the vaccines that require a second dose, will pharmacies bill separately for the second dosage?

A: Yes. Each dose will be billed separately. 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 provided this information to the pharmacy network.

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-19 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. Scientists 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: The need for and timing of booster doses for COVID-19 vaccines has not been established. No additional doses beyond the primary single or two-dose series are recommended at this time. However, scientists will continue to collect data to determine if changes are needed.

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 available vaccines have been proved by the FDA to be safe and effective. The safety and efficacy of available vaccines is the top priority for the federal government, and all adverse events reported following COVID-19 vaccine administration are taken very seriously by the FDA.

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 these vaccines?

A: Two of the currently offered vaccines 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 third vaccine is manufactured using adenovirus type 26 (Ad26) to deliver a piece of the DNA, or genetic material, that is used to make the distinctive "spike" protein of the SARS-CoV-2 virus.

Vaccine	Population	Common Side Effects	Dosing[1,2]
Pfizer-BioNTech	Authorized for use in those aged 16 and older and contraindicated for individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any vaccine component	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, nausea, feeling unwell, swollen lymph nodes and fever.	Series of two doses (30 mcg, 0.3 mL each) administered intramuscularly, three weeks apart
Moderna	Authorized for use in those aged 18 and older and contraindicated for individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any vaccine component	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, nausea and vomiting and fever.	Series of two doses (100 mcg, 0.5 mL each) administered intramuscularly, one month apart
Johnson & Johnson/ Janssen[3]	Authorized for use in those aged 18 and older and contraindicated for individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any vaccine component	Side effects of the vaccine typically resolve within 1-2 days and commonly include things like injection site reactions, fatigue, headache, muscle pain, and nausea.	Single dose (0.5 mL each) administered intramuscularly

1. According to interim CDC clinical considerations, doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated. The second dose should be administered as close to the recommended interval as possible. However, there is no maximum interval between the first and second dose of either vaccine.

2. Both doses of the two-dose series should be completed with the same product. However, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.

3. Out of an abundance of caution, the CDC and FDA recommended a pause in the use of the Johnson & Johnson COVID-19 vaccine.

The CDC advises that vaccine providers 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.

If any recipients of the Johnson & Johnson vaccine develop severe headache, abdominal pain, leg pain or shortness of breath within three weeks after vaccination, they should contact their health care providers. Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at https://vaers.hhs.gov/reportevent.html.

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

A: Yes. For updated information on vaccine eligibility in your area and for scheduling appointments at Rite Aid, view the Eligibility Guide. Vaccine doses are extremely limited, and availability is updated daily. Store and pharmacy associates are not able to schedule appointments.

Q: Which vaccines is Rite Aid administering?

A: Rite Aid is following the April 13, 2021 recommendation and guidance issued by the federal government to temporarily pause all Johnson & Johnson COVID-19 vaccinations. Rite Aid will continue administering the Pfizer-BioNTech and Moderna

vaccines across its various locations; however, each store will only provide one type of vaccine at a time. Rite Aid is working to provide additional administering locations for increased vaccination capability. Visit Rite Aid's website to learn more.