

Latest information on COVID-19 vaccines

Frequently Asked Questions



For OptumRx Pharmacy Plans

Updated Dec. 14, 2020

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This Optum COVID-19 Vaccine Q&A document is designed to provide up-to-date developments regarding COVID-19 vaccine clinical data, FDA review, allocation, distribution and reimbursement, and to try to answer some of the most commonly raised questions relative to these areas.

The COVID-19 vaccine landscape remains highly dynamic and fluid, with new information and new data emerging almost daily. As such, it is important to note the information provided here summarizes the most up-to-date information at our disposal at the point in time this document was issued. The information contained within is subject to change as new information is brought forth. Any projections/assumptions contained here are based upon current market conditions and data available within the public domain.

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We will update this document as new information emerges.

The COVID-19 vaccines will be an important way to slow the spread of the disease. Helping our clients and members find vaccine information and get vaccines is our top priority. This FAQ is designed to help keep our clients and partners informed of the latest information related to the COVID-19 vaccines.

Key points of information related to the COVID-19 vaccines

- The FDA has a review process to issue Emergency Use Authorizations (EUA) before vaccines are authorized for use by the general public.
- There are several COVID-19 vaccines in late-stage trials. The Pfizer vaccine received Emergency Use Authorization (EUA) from the FDA on Dec. 12, and the FDA is expected to announce a second EUA for Moderna with an FDA Advisory Committee hearing scheduled for Dec. 17.

- Once FDA-authorized COVID-19 vaccines are publicly available, members will have **\$0 cost-share (copayment, coinsurance or deductible)**, as outlined below, including when two doses are required.
- At this time, the cost for the vaccine itself will be covered by the federal government via funding authorized by the Coronavirus Aid, Relief, and Economic Security (CARES) Act.
- Health plans and self-insured plans will be required to pay for the administration of the COVID-19 vaccine. Administration fees for Medicare plans will be covered by Medicare Fee-for-Service.
 - Administration cost for the two-dose vaccine: first dose \$16.94/second dose \$28.39
 - Administration cost for a single-dose vaccine: \$28.39
- There may be a limited supply of FDA-authorized COVID-19 vaccines available initially. The [CDC](#) and state health agencies will manage distribution and provide prioritization on which groups of people should receive the vaccines first.
- OptumRx is equipped to support our clients who wish to cover the cost of the COVID-19 vaccine under the pharmacy benefit.
- OptumRx is monitoring federal and state agency activities and updating COVID-19 policies and communications as appropriate.

Frequently Asked Questions

Vaccine overview

1. What do we know today about COVID-19 vaccine approvals and timing, including Emergency Use Authorization (EUA)?

There are several COVID-19 vaccines in late stage clinical development in the U.S. and globally. One product, Pfizer's Messenger RNA vaccine, was approved by the Food and Drug Administration (FDA) for EUA on Dec. 11, 2020. One other product, Moderna's Messenger RNA vaccine, has also been filed with the FDA for EUA and others are expected to follow in early 2021. The FDA has a review process to issue emergency use authorizations before vaccines are authorized for use by the general public. Since the COVID-19 vaccine situation is changing quickly, the [CDC website](#) is the best resource for COVID-19 information.

Regarding the Pfizer EUA approval, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) convened a meeting on Sat., Dec. 12, 2020 to further discuss the Pfizer vaccine and offered an interim recommendation. The ACIP voted 11 – 0 (with 3 recusals) in favor of the use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years for the prevention of COVID-19.

Following is the high-level status of approvals and timing for the current leading vaccine candidates. For a detailed view of all leading vaccines and their status, see the Pipeline Vaccine Candidates section of the [COVID-19 November Update](#).

Vaccine Type	Manufacturer	Status of Trials	FDA Approval Status
Messenger RNA	Pfizer	Phase 3 completed	FDA Approved for EUA in patients 16 years of age or older.
Messenger RNA	Moderna	Phase 3 completed	Submitted for EUA
Viral Vector	Astra Zeneca	Phase 3 in process	Expected in early 2021
Viral Vector	Janssen	Phase 3 in process	Expected in Q1 2021
Protein Sub-unit	Novavax	Phase 3 in process	Expected in 2021
Protein Sub-unit	Sanofi/GSK	Phase 1/2 results expected in December 2020	Expected in late 2021

2. How soon after FDA Authorization will the vaccines be available for administration?

Federal health officials indicate initial doses will be shipped within 24 hours of FDA authorization and immunizations could begin within about 48 hours.

3. With the EUA approval for the Pfizer vaccine, has the vaccine been shipped? To which locations?

Yes. Pfizer has begun shipping vaccines. The quantity of the vaccine and the shipping locations are being determined at the state level.

4. Are the leading vaccines safe? What do we know about the safety of the vaccines given the fast track process?

While the development of COVID-19 vaccines has been fast tracked via Operation Warp Speed, the FDA has reinforced that no safety precautions or criteria have been compromised. The FDA is expected to convene a meeting of the Vaccine and Related Products Advisory Committee (VRBPAC) prior to any approval. The VRBPAC is an advisory committee to the FDA and is comprised of independent experts in the fields of vaccine safety and infectious disease.

Based on Phase 3 trials, both Pfizer and Moderna have reported positive safety outcomes. The Pfizer trial reported side effects of fatigue and headache in only 3.8% and 2% of participants respectively. The Moderna trial reported injection site pain at 2.7%, and after the second dose included fatigue (9.7%), muscle pain (8.9%), joint pain (5.2%), headache (4.5%) and redness at the injection site (2.0%).

5. How effective are the leading vaccines in preventing the coronavirus?

Both Moderna and Pfizer have reported Phase 3 trial efficacy at ~95%. This represents the degree to which the vaccines prevent the occurrence of symptomatic COVID-19 disease. The FDA requires >50% efficacy for approval. Both report that efficacy was consistent across age, gender, race and ethnicity demographics.

6. How many doses are required for the leading vaccines?

Of the leading vaccine candidates, most require two doses including the Pfizer and Moderna vaccines. Only the Janssen vaccine is a one-dose vaccine.

7. What is the timing between the first and second doses of the vaccine?

The timing between the first and second dose varies by vaccine. For the two leading vaccines, the doses are separated by 28 days for the Moderna vaccine and 21 days for the Pfizer vaccine.

8. How long after the vaccine is given is it effective and protecting the individual?

The CDC states that it typically takes a few weeks for the body to build immunity after vaccination. This means it is possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection.

Vaccine launches and availability

9. Will the vaccines be approved for everyone or just select groups? Who will be the first to get the vaccines?

The [Centers for Disease Control and Prevention \(CDC\)](#) is making COVID-19 vaccine allocation recommendations based upon input from its advisory committee, the Advisory Committee on Immunization

Practices (ACIP), which is holding regular meetings to discuss the key criteria for prioritizing who should receive COVID-19 vaccines if the supply is limited. ACIP has issued recommendations for which groups should receive the vaccine during the initial phase when vaccine supply is expected to be limited.

ACIP Recommendation (as of Dec. 1, 2020):

When a COVID-19 vaccine is authorized by the FDA and recommended by ACIP, health care personnel¹ and residents of long-term care facilities² should be offered vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a).

The vaccine has not been studied in pregnant women or children. Children <18 years were purposely excluded from initial clinical trials to date. This is typically the standard protocol for vaccine development until safety and efficacy can be adequately assessed in adults first. However, more will be known when a vaccine has been authorized by the FDA for use, and the ACIP has had a chance to review the available information and make a recommendation about vaccinating these populations.

ACIP will make additional recommendations once a vaccine is authorized for use by the FDA.

¹ Health care personnel are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials.

² Long-term care facility residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.

10. Where will the vaccines be administered and will there be optimal locations for the different vaccines? Are there challenges with cold storage/distribution of the Pfizer and Moderna vaccines?

The federal government has indicated allocations will be determined based on the provider (1) size and reach, (2) capability to store vaccines and ensure cold chain management, (3) ability to meet data reporting requirements to jurisdictions and the CDC, and (4) estimated daily number of doses each facility is able to administer. Pharmacies may also register to receive vaccines through their local jurisdictions.

The Pfizer vaccine will be distributed by Pfizer itself without a wholesaler due to the cold chain shipping storage requirements necessary to preserve the vaccine, which require extreme cold temperatures. Likely the Pfizer vaccine will be administered within certain health care facilities, including long-term care facilities, with the ability to vaccinate large numbers of individuals quickly, due to the storage requirements.

The Moderna vaccine remains stable at refrigerated conditions, which allows for storage at most pharmacies in addition to hospitals and physicians' offices. If approved, Moderna plans to distribute the vaccines via McKesson, the federally contracted distributor.

11. Will the government be tracking who gets the vaccine?

Yes. The CDC and local jurisdictions have already highlighted the reporting requirements for vaccine providers in the Operation Warp Speed Playbook.

Vaccine supply chain

12. If Pfizer and Moderna vaccines are cleared by the FDA via EUA in December, what type of supply do we anticipate relative to their production and supply to U.S. citizens in the first quarter of 2021 and beyond?

If approved, Pfizer has stated they will be able to provide 40 million doses by the end of 2020. The U.S. government has an agreement for 100 million doses of Pfizer's vaccine with an option to purchase 500 million more. Similarly, Moderna has an agreement with the U.S. government to supply 100 million doses, with 20 million doses available by the end of 2020.

The U.S. expects to have enough Pfizer and Moderna doses to vaccinate 20 million Americans in December and 25 million more in January, per STAT. Moderna CEO Stéphane Bancel told the *Times* the company is on track to produce 500 million to a billion doses of the two-dose vaccine in 2021.

With over 300 million individuals in the U.S., and each vaccine requiring two doses, such a limited initial supply will need to be prioritized until the manufacturing capabilities can ramp up and other vaccines gain approval to meet the demand of the entire population.

13. Will the supplies that are produced by these companies only be available to those in the U.S., or will they be allocated worldwide?

Supplies produced by these manufacturers will be made available to countries around the world. The United States, several European countries and others have already placed sizable advanced orders for vaccine, and the World Health Organization (WHO) has established the COVID-19 Vaccines Global Access (COVAX) Facility to try and ensure equitable distribution of vaccine to all countries, rich and poor.

14. Do we anticipate there will be enough supply of vaccine to properly vaccinate everyone in the U.S.? If so, by when?

The initial supply as indicated by Pfizer and Moderna will not be enough to vaccinate everyone in the U.S. Distribution will need to be prioritized for those most in need until manufacturing capabilities can ramp up and additional manufacturer vaccines are approved to meet the demand of the entire population.

Early in the response, the federal government invested in select vaccine manufacturers to help them increase their ability to quickly make and distribute a large amount of COVID-19 vaccine. This will allow the United States to start with as much vaccine as possible and continually increase the supply in the weeks and months to follow. The goal is for everyone to be able to easily get a COVID-19 vaccine as soon as large quantities are available. Several thousand vaccination providers will be available, including doctors' offices, retail pharmacies, hospitals, and federally qualified health centers.

15. Will there be quantity limits or age edits applied to these vaccines to manage supply?

Quantity limits will be implemented to prevent no more than the recommended number of doses from being administered based on the EUA. Age limits are being considered to ensure appropriate use in the defined age group stated in the EUA.

Retail pharmacy administration

16. When do we anticipate our retail pharmacies will begin to access and administer vaccines?

At this time, it is not known when retail pharmacies will be able to administer vaccines in store locations, in line with the prioritized group / early vaccination phased approach. OptumRx will continue to monitor federal guidance and our pharmacy network for updates on in-store availability.

17. Are all network chains prepared to administer vaccine? What about independent pharmacies?

While all network pharmacies and independent pharmacies will be able to administer the vaccine, pharmacies will make their own determination on whether they will administer the vaccine, and if so, must enroll in the federal COVID-19 Vaccination Program.

18. Do we know which retail chains are planning on stocking which vaccines? Do we anticipate all chains to be enrolled?

At this time, OptumRx's retail providers are not aware which vaccines will be received through the initial phase of vaccine distribution in partnership with the federal government.

As of the Nov. 12, 2020 press release from HHS, the following pharmacy providers and pharmacy provider networks have signed on to participate in the federal allocation program:

Albertsons Companies, Inc. (incl., Osco, Jewel-Osco, Albertsons, Albertsons Market, Safeway, Tom Thumb, Star Market, Shaws, Haggen, Acme, Randalls, Carrs, Market Street, United, Vons, Pavilions, Amigos, Lucky's, Pak n Save, Sav-On); Costco Wholesale Corp.; CPESN USA, LLC; CVS Pharmacy, Inc. (incl. Long's); Good Neighbor Pharmacy and AmerisourceBergen Drug Corporation's PSAO, Elevate Provider; Health Mart Systems, Inc.; H-E-B, LP; Hy-Vee, Inc.; LeaderNET and Medicine Shoppe, Cardinal Health's PSAOs; Managed Health Care Associates (MHA); Meijer Inc.; Publix Super Markets, Inc.; Retail Business Services, LLC (incl., Food Lion, Giant Food, The Giant Company, Hannaford Bros Co, Stop & Shop); Rite Aid Corp.; The Kroger Co. (incl., Kroger, Harris Teeter, Fred Meyer, Frys, Ralphs, King Soopers, Smiths, City Market, Dillons, Marianos, Pick-n-Save, Copps, Metro Market); Topco Associates, LLC (incl. Big-Y Pharmacy and Wellness Center, Brookshire's Pharmacy, Super One Pharmacy, FRESH by Brookshire's Pharmacy, Coborn's Pharmacy, Cash Wise Pharmacy, MarketPlace Pharmacy, Hartig Drug Company, King Kullen, Food City Pharmacy, Ingles Pharmacy, Raley's, Bel Air, Nob Hill Pharmacies, Save Mart Pharmacies, Lucky Pharmacies, SpartanNash, Price Chopper, Market 32, Tops Friendly Markets, ShopRite, Wegmans, Weis Markets, Acme Fresh Markets); Walgreens (incl. Duane Reade); Walmart, Inc. (incl. Sam's Club); and Winn-Dixie Stores Inc. (incl. Winn-Dixie, Harveys, Fresco Y Mas)

19. Will each state's board of pharmacy determine if a pharmacist can administer COVID-19 vaccine? Do pharmacists have to be specially trained and certified to administer vaccines? Can pharmacy technicians administer vaccines?

The HHS has provided authority for pharmacists to order and administer COVID-19 vaccines during the Emergency Period and allows interns and technicians, with acceptable credentialing, to administer vaccines under the authority of a pharmacist.

To administer COVID-19 vaccines, providers must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction's immunization program. Each state jurisdiction will provide credentialing requirements for immunizers and during the Emergency Period only enrolled immunizers will have access to COVID-19 vaccines. The program requires daily reporting of vaccine administration activities to the CDC and the local jurisdiction managing the vaccine distributions and allocations.

20. Will members be able to obtain the vaccine at out-of-network pharmacies?

Yes. Members will be able to obtain the vaccine at both in-network and out-of-network pharmacies. This is federally mandated.

21. What network/provider communications are being planned around COVID-19 vaccine billing and coverage for Commercial, Exchange and Medicare members?

OptumRx is planning to send communications to our pharmacy network on Dec. 18 to ensure all pharmacy providers are aware of claim submission protocols and coverage determination procedures. While we expect some providers in the network will not ultimately provide COVID-19 vaccines, our plan is to communicate to the entire network and enable visibility.

22. Will Optum Infusion sites be providing the vaccine?

Optum Infusion sites are not planning to administer the COVID-19 vaccine at this time.

Cost and benefit administration

23. What is the cost of the vaccine to plan sponsors? Will all vaccine costs be covered by the federal government?

At this time the federal government will cover the cost of the COVID-19 vaccine through funding authorized by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. We are not able to speculate for how long.

Medicare will cover the costs and administration fees through the Medicare Fee-for-Service (FFS) program until the MA capitation rates take the new significant cost into account. Contracted providers should be directed to submit claims for administration of the COVID-19 vaccine to the CMS Medicare Administrative Contractor (MAC) for payment.

Fully insured and self-insured plans will be required to pay for the administration of the vaccine.

24. What is the anticipated cost for the vaccine administration?

CMS has set administration costs for the vaccine as follows:

- Administration cost for two doses: first dose \$16.94/second dose \$28.39
- Administration cost for a single dose: \$28.39

Fully insured and self-insured plans will be required to pay for the administration of the vaccine. Administration fees for Medicare plans will be covered by Medicare Fee-for-Service.

25. How was the administration cost of the vaccine determined by CMS?

Per the CMS website, the rates recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the vaccine.

26. What will the member cost-share be? Is this set by HHS or can plan sponsors set the member cost-share?

As established in the CARES Act, patients will receive the vaccine at no out-of-pocket cost and no deductible regardless of where they get the vaccine. State Medicaid and CHIP agencies must provide COVID-19 vaccinations at no cost-sharing for beneficiaries and CMS is requiring that private health plans and insurers cover the COVID-19 vaccine administration with no cost-sharing as outlined in questions 27-29.

27. Will vaccines be covered under Medicare Part D?

No. The COVID-19 vaccines will not be covered under Medicare Part D. Medicare guidance has stated that the Part B Fee-for-Service (FFS) benefit administered by the federal government will be the only coverage channel for COVID-19 vaccines. Though Medicare organizations are not prohibited from covering the product, the capitation payments that these organizations receive will not include funding for COVID-19 vaccines at least through the end of 2021. The guidance encourages Medicare Advantage organizations to coordinate with their local providers to confirm their readiness to issue vaccines under the FFS program.

28. Is coverage of the vaccine administered under the medical benefit or pharmacy benefit?

The COVID-19 vaccine will be managed in a similar manner to other preventative vaccines, with administration of the vaccine primarily through physicians' offices and pharmacies, typically under the medical benefit.

Clients may choose to provide coverage of the COVID-19 vaccine under the pharmacy benefit.

Medicare: Coverage for the COVID-19 vaccine for plans with Part D will be administered under Medicare Part B under the medical benefit. Medicare guidance has stated the Part B Fee-for-Service (FFS) benefit administered by the federal government will be the primary coverage channel for COVID-19 vaccines. Though Medicare Advantage (MA) organizations are not excluded from covering the product, the capitation payments that these organizations receive will not include funding for COVID-19 vaccines until the end of 2021. The guidance encourages MA organizations to coordinate with their local providers to confirm their readiness to issue vaccines under the FFS program.

Medicaid: CMS has mandated that States must cover COVID-19 vaccine administration fees at \$0 cost- share. CMS recommends alignment to CMS reimbursements; however, State agencies have not yet advised how they will cover this benefit or their reimbursement strategy.

29. What is the process to get COVID-19 vaccine coverage under the pharmacy benefit?

OptumRx clients will have the option to cover vaccines under the pharmacy benefit if they choose. Speak to your OptumRx account executive for more information.

Claims adjudication

30. Will there be any claims edits in place to ensure the first dose was administered prior to the second dose?

OptumRx will rely on the Submission Clarification Code submitted by the pharmacy in the event the first dose was not submitted through the same benefit. The first and second dose is likely to be the same NDC.

31. Will vaccine claims be processed as brand medications? Generics? Other?

There are currently two NDCs for vaccines to facilitate immediate distribution of COVID-19 vaccines; these will adjudicate as brand medications.

32. The CARES Act, after ACIP recommendations are announced, has indicated plans would have only 15 days to implement \$0 coverage versus the normal one year. How is OptumRx preparing to handle coding, client notifications, etc. in this timeframe?

OptumRx is working diligently with NCPDP to set-up benefits and process claims under the pharmacy benefit that meet the NCPDP guidelines, which are anticipated to be published in the NCPDP Emergency Preparedness Guidelines in December. Clients will be able to set-up benefits that meet their state and/or federal regulations.

Member services and support

33. Will customer service agents be able to direct members to pharmacies in their area that are administering the vaccine, including in-network and out-of-network pharmacies (if an out-of-network pharmacy is a closer option)?

Customer Service Advocates will assist members in locating both in-network and out-of-network pharmacies located near them. To support members in locating pharmacies where they can get the COVID-19 vaccine, members will be referred to the government's resource, www.vaccinefinder.org.

34. Is OptumRx planning any type of routine member-oriented communications we can use to educate our members and help them make informed decisions?

Yes. As more details are known, OptumRx will support our clients and members with educational information about how to access the vaccine.

35. Is OptumRx doing anything to support adherence to the second vaccine dose? Will we do a patient reminder or outreach?

OptumRx is finalizing plans for refill reminders and will share more information soon.

In addition, our retail pharmacy partners, including Genoa pharmacies are planning communication campaigns that include email, IVR and text messaging to remind members about their 2nd dose appointments. OptumRx is also working to determine the best way to supplement these retail pharmacy processes.

Client financials and reporting

36. Will COVID-19 vaccines be rebate-eligible? Are there pharma rebates provided for these medications?

No. Consistent with our current vaccine strategy, COVID-19 vaccines are not rebate eligible and are not included in the calculation of rebate guarantees.

37. Can OptumRx assist with financial modeling relative to the financial impact of COVID-19 vaccines on pharmacy budgets, expenditures and trend? Does your analytics team have a per population estimate on how many individuals are likely to get the vaccine for 2021 in any given population?

OptumRx is assessing options internally relative to actuarial modeling that might assist clients with an understanding of the financial implications of the COVID-19 vaccine administration costs. As vaccine approval, production, allocation and distribution are all highly fluid issues right now, there are several challenges inherent to the development of such modeling.

Government regulatory and compliance information

38. How will OptumRx monitor and ensure compliance with all State-specific regulations relative to vaccine coverage?

Individual states are required to maintain electronic immunization registries to track which residents have gotten which vaccines, when and from what provider. Most vaccine providers (i.e., pharmacies and physicians' offices) connect their records directly to these state registries. The CDC is also launching a new Vaccine Administration Management System (VMAS) to supplement existing state registries and support providers who may not be electronically connected to existing state registries. The CDC will also require providers administering vaccines to provide dose-level accounting and reporting, so the agency can track where doses of vaccine are at any point in time.

If you would like additional information, please contact your OptumRx representative.



2300 Main Street, Irvine, CA 92614

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