

# **COVID-19 Overview and Frequently Asked Questions**

In December 2020, the U.S. Food and Drug Administration (FDA) issued emergency use authorizations (EUAs) allowing two COVID-19 vaccines to be distributed in the U.S. In late February 2021, the FDA issued an EUA for a third COVID-19 vaccine. In July 2022, a fourth COVID-19 vaccine joined with a FDA issued EUA.

Four COVID-19 vaccinations are currently available. The Johnson & Johnson vaccine requires a single dose while the other three (Pfizer-BioNTech, Moderna, Novavax) require two doses and, for those with compromised immune systems, a third dose (Pfizer-BioNTech or Moderna vaccines only) may be recommended. Funding authorized by the CARES Act covers the cost of these COVID-19 vaccines.

In addition, oral antiviral medications are now available by prescription to treat those with COVID-19. See the oral antiviral medications chart for more details about these treatments. We are continually monitoring for legislative requirements associated with Paxlovid.

Effective January 15, 2022, the federal government is requiring insurance companies and group insurance plans to cover the cost of over-the-counter at-home COVID-19 tests, so people with private health coverage can get them for free. (This directive does not apply to Medicare or Medicaid plans. Individual state Medicaid agencies are providing guidance related to at-home test kits for Medicaid beneficiaries, and CMS has issued separate guidance to allow people with Medicare to access free OTC at-home test kits. Please see question 10 below for details.)

Here is some updated information to help answer questions you may have.

### Over-the-Counter (OTC) COVID-19 Test Kits

#### **FAQs**

#### Q1: Where can I get a test kit at no cost without submitting a reimbursement form?

**A:** Currently, only a few major pharmacy chains, such as Rite Aid (including Bartell's), Walmart (including Sam's Club) and Safeway, are processing no-cost COVID-19 test kits at the pharmacy counter. (This list is subject to change as more pharmacies develop the capability to process these purchases at no cost to you.) There will be no up-front cost and no requirement to submit for reimbursement. Simply go to the pharmacy counter, present your member ID card and ask to have your OTC at-home COVID-19 test kits submitted to your plan for coverage.

OTC COVID-19 tests are also available via mail order from Elixir Pharmacy. You may call Elixir customer care at 866-909-5170 to check availability and place an order. A minimum order of eight tests is required, and up to eight tests per covered member are allowed per month.

#### Q2: Is there a specific test kit that I should get?

**A:** Only FDA-authorized at-home COVID-19 test kits can be covered. Test kits covered by insurance are limited to eight (8) tests per covered member per month.

**PLEASE NOTE:** The Office of the Inspector General (OIG) has issued a warning about scams involving fake and unauthorized at-home COVID-19 test kits. Please encourage members to be sure to purchase FDA-approved



COVID-19 test kits from legitimate providers. More information about COVID-19 scams is available on the OIG website at <a href="https://oig.hhs.gov/fraud/consumer-alerts/fraud-alert-covid-19-scams/">https://oig.hhs.gov/fraud/consumer-alerts/fraud-alert-covid-19-scams/</a>.

Q3: Do I need a prescription to get free at-home OTC test kits to test for COVID-19? A: No. Prescriptions are not required.

#### Q4: Will I have to pay for my test up front?

A: Some pharmacies are not able to process these kits at the pharmacy counter; however, you can purchase FDA-authorized COVID-19 OTC test kits at Rite Aid Pharmacy (including Bartell Drugs), Walmart or Sam's Club Pharmacy, or Safeway Pharmacy. (This list is subject to change as more pharmacies develop the capability to process these purchases at no cost to you.) There will be no up-front cost and no requirement to submit for reimbursement. Simply go to the pharmacy counter, present your member ID card and ask to have your OTC athome COVID-19 test kits submitted to your plan for coverage.

If you purchase the kit and pay out of pocket, you may be reimbursed. Reimbursement from Elixir applies only if athome COVID-19 tests are covered by your pharmacy plan. Some plans may cover the tests under your medical benefit. For more information, please contact your health plan.

Q5: Do I have to purchase these at-home OTC test kits at specific locations to get them for no cost?

A: Starting January 15, 2022, members are encouraged to get at-home test kits at participating in-network pharmacies – where you would typically get prescription medications. If your plan has chosen to use the Elixir network for at-home OTC COVID-19 test kit coverage, all pharmacies will be considered in-network as long as they are contracted with Elixir.

If you purchase kits at non-participating pharmacies or retailers or online, you can submit receipts to Elixir, as long as your plan has chosen to have these kits paid under the pharmacy benefit. If your insurance plan reimburses the receipts under medical benefit, you will have to submit those receipts to your health insurance plan. See instructions below on how to submit a pharmacy claim.

Q6: What if I can't find any network pharmacies that have the at-home COVID-19 test kits in stock?

A: If you purchase kits at non-participating pharmacies or retailers or online, you can submit receipts to Elixir, as long as your plan has chosen to have these kits paid under the pharmacy benefit. If your insurance plan reimburses under the pharmacy benefit, you may be reimbursed at a rate of up to \$12 (or the cost of the test, if less than \$12). See instructions below on how to submit a pharmacy claim.

You may also access free testing in your communities, or tests can be administered by healthcare providers, such as nurses, doctors and pharmacists, without cost-sharing.



#### Q7: How do I get reimbursed if I am not able to get a free test at the pharmacy?

**A:** If your plan has chosen to have these kits paid under the pharmacy benefit, you can submit to Elixir for reimbursement of up to 8 tests per month for each covered person on the plan. For example, a family of four who are all covered under the plan can be reimbursed for as many as 32 tests per month. If you purchase tests at non-participating pharmacies or retailers or online, you may be reimbursed at a rate of up to \$12 (or the cost of the test, if less than \$12).

To ensure timely processing of your reimbursement, please provide the following information with your request:

- Completed Member Reimbursement Form\*
- Itemized receipt of COVID-19 tests showing the date or purchase, location of purchase and cost of tests (TIP: Circle the tests and purchase price on the receipt.)
- Original or photocopy of UPC (Universal Product Code) symbols from purchased products; see sample at right
- Number of tests purchased for each covered person

NOTE: If any of the required documentation listed above is not included with your reimbursement request, your claim will be rejected, indicating that additional information is needed.

You will need to complete separate requests for each covered member. You may submit your requests in one of several ways, depending on the BIN number on your Member ID card.

If the BIN number on the front of your Member ID card is **800004**, follow the directions below to submit your reimbursement request for OTC COVID-19 tests. **Members with all other BIN numbers should follow the instructions starting on page 4**.

- 1. Download the <u>member reimbursement form for BIN number 800004</u>. You can find it in the FORMS AND DOCUMENTS section at <u>elixirsolutions.com/members</u>.
- 2. Complete the top CARDHOLDER-PATIENT INFORMATION section.
- 3. In PRESCRIPTION INFORMATION section:
  - a. Enter date the test(s) were purchased in the DATE FILLED box.
  - b. Enter the number of tests purchased (for the individual named in the CARDHOLDER-PATIENT INFORMATION) in the METRIC QTY. DISPENSED box.
- 4. Submit this form along with copies or images of your receipt(s) and the UPC symbols from your test packages via one of the following methods:

**Email** to keyedclaims@elixirsolutions.com (preferred method)

**Fax** to (866) 552-8939

Mail to Elixir Solutions, PO Box 619, Twinsburg, OH 44087

Please allow up to 30 days for claims processing and payment to be issued.



#### For all other BIN numbers (*NOT* 800004)

You may be able to submit reimbursement requests via your Member Portal account. Refer to the <u>step-by-step</u> guide, available online at elixir.info/otc-guide, for instructions.

Otherwise, download <u>this form</u> from our website at <u>elixirsolutions.com/members</u>. (Scroll to the FORMS AND DOCUMENTS section; then select REIMBURSEMENT FORM.) Please follow the instructions for completing this form for OTC COVID-19 test reimbursement starting on page 3 of this <u>step-by-step guide</u>, available online at <u>elixir.info/otc-guide</u>.

Complete the form and submit it in one of the following ways:

- 1. **Faxed** to: 866-646-1403 Attn: DMR Department
- 2. Mailed to:

Elixir – DMR 8935 Darrow Rd P.O. Box 1208 Twinsburg, OH 44087

#### Q8: When will I receive my reimbursement?

A: Allow up to 30 days for claims processing and payment to be issued.

## Q9: What if I bought and paid for some at-home test kits *before* January 15, 2022. Can I request reimbursement for those?

**A:** Insurance plans are not required by federal law to cover at-home tests acquired before January 15, 2022. You may contact your insurance plan about getting reimbursed for tests purchased before January 15, 2022.

# Q10: Can Medicare or Medicaid/CHIP members also submit for reimbursement of OTC at-home COVID-19 tests?

A: Under a new initiative that is expected to be launched in early spring 2022, Medicare beneficiaries will be able to access up to eight over-the-counter COVID-19 tests per month for free. Tests will be available through eligible pharmacies and other participating entities. More details are available from the Centers for Medicare & Medicaid Services (CMS). People with Medicaid or CHIP coverage should contact their state Medicaid or CHIP agency for information, as coverage rules may vary by state.

#### Q11: Does Elixir Mail Order Pharmacy have free COVID-19 test kits?

**A:** Elixir Pharmacy now has tests available for mail order delivery. You may call Elixir customer care at 866-909-5170 to check availability and place an order. A minimum order of eight tests is required, and up to eight tests per covered member are allowed per month.



#### Q12: Are COVID-19 at-home OTC test kits available at Rite Aid?

**A:** Due to high demand, at-home OTC test kits may have limited availability at some Rite Aid locations. However, as of January 27, 2022, Rite Aid Pharmacy is processing no-cost COVID-19 test kits at the pharmacy counter. To find Rite Aid locations near you and other pharmacies in your network, log in to your Member Portal account in the mobile app or at <a href="elixirsolutions.com">elixirsolutions.com</a> and select the FIND PHARMACIES option. You may also call the customer service number on the back of your member identification card.

#### **Vaccine and Antiviral Medication**

### **FAQs**

#### Q: Will I be able to get the COVID-19 vaccine or the antiviral medication at my network pharmacies?

A: Yes. You can get COVID-19 vaccines and fill prescriptions for the antiviral medication at any network pharmacy.

#### Q: How can I learn more about getting a vaccine in my state?

**A:** We have prepared a state-by-state guide that may help. <u>Click here</u> to view the guideand select your state to learn more.

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

**A:** Yes. If you are enrolled in a Medicare Advantage plan during calendar year 2020 and 2021, payment for the COVID-19 vaccine and its administration will be made through the original fee-for-service Medicare program. This means that you can be vaccinated against COVID-19 with no copay/cost share or deductible. Please present your red, white, and blue Medicare card at the pharmacy at the time of vaccination.

Q: If I am not a Medicare member, will the COVID-19 vaccine be covered by my plan, and what will it cost?

A: Elixir members who are not enrolled in a Medicare Advantage plan can receive all recommended doses of the vaccine at *no copay/cost share or deductible*. The federal government has purchased the initial supply of vaccines, so the vaccine itself will be paid for through funding authorized by the CARES Act. Some pharmacies may charge an administration fee, but that should be paid for by your plan.

#### Q: Will antiviral medications be covered by Medicare?

A: Yes. Antiviral medications will be covered under Medicare Part D.

#### Q: Will vaccine prices be different if I have to go to an out-of-network (OON) pharmacy?

A: No. Members will receive both doses of the vaccine at no copay/cost share or deductible.

#### Q: Will the vaccine or the antiviral medication be available only at certain pharmacies?

**A:** Yes. To receive free supplies of COVID-19 vaccines and/or COVID-19 antiviral medications, pharmacies, retail clinics, providers, and others must sign an agreement with the U.S. government.



### Q: When should the oral antiviral medications be prescribed, and what are some of the clinical considerations?

**A:** Two oral antiviral medications are now available under EUA for the treatment of mild-to-moderate COVID-19 in individuals who have tested positive within five days of symptom onset. These medications are only available by prescription. See the oral antiviral medications chart for additional details.

ORAL ANTIVIRAL MEDICATIONS FOR THE TREATMENT OF COVID-19						
Medication	Population	Common Side Effects	Dosing			
Lagevrio (Molnupiravir)	Authorized for those aged 18 years and older who are at high risk for progression to severe COVID-19.1	Possible side effects include diarrhea, nausea and dizziness. Molnupiravir is <i>not</i> recommended for use during pregnancy because studies showed that molnupiravir may cause fetal harm when administered to pregnant individuals. <sup>2</sup>	Dosed twice daily (four capsules) every 12 hours for five days.			
Paxlovid (nirmatrelvir and ritonavir)	Authorized for those aged 12 years and older weighing at least 40 kg and who are at high risk for progression to severe COVID-19.	Possible side effects include dysgeusia (altered or impaired sense of taste), diarrhea, increased blood pressure and myalgia (muscle aches). Nirmatrelvir and ritonavir, which comprise paxlovid, also interact with other medicines, which may lead to serious or lifethreatening adverse reactions.	Dosed orally twice daily as three tablets (two tablets of nirmatrelvir and one tablet of ritonavir) for five days. A dose reduction is required for those with moderate renal impairment.			

Molnupiravir is not authorized for use in patients younger than 18 years of age because it may affect bone and cartilage growth.

#### 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.

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

**A:** More data is required to determine if COVID-19 vaccines will be needed every year, but may be likely. See the chart below for the latest recommendations on COVID-19 vaccines and boosters.

Recently the FDA approved two new formulations of Moderna and Pfizer -BioNTech Boosters. These boosters are bivalent and have two different antigens unlike the original boosters which targeted one antigen. The hope is to provide better protection against current and future variants of COVID-19. Whether someone qualifies for a booster can be dependent on age, first vaccine received and time since the last received COVID-19 vaccine dose. To find out if you or someone you know

<sup>&</sup>lt;sup>2.</sup> Additional warnings and precautions for those of childbearing age are available in these FAQs from the FDA.



should be getting a booster, you can visit the FDA website at: <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html</a> and click on "Find Out When to Get a Booster".

### UPDATED BIVALENT mRNA and NOVAVAX COVID-19 BOOSTERS

MANUFACTURER	EUA APPROVAL	WHEN CAN IT BE ADMINISTERED	NOTE
Pfizer- BioNTech	For individuals 6 months of age and older as a single booster dose against COVID-19	At least 2 months after either:  • completion of primary vaccination with any authorized or approved monovalent1 COVID-19 vaccine, or  • receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine	Monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals 5 years of age and older  Moderately or severely immunocompromised individuals should refer to specific guidance <sup>1</sup>
Moderna	For individuals 6 months of age of age and older as a single booster dose against COVID-19	For patients 6 months to 5 years (Moderna) and 6 months to 4 years (Pfizer) please refer to the EUA Fact Sheets	
Novavax	For the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older	Administered at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine	A monovalent Novavax booster is available in limited situations <sup>2</sup> While Novavax primary series can be used in those 12 years of age and older, the booster is only indicated for those 18 years of age and older

<sup>1)</sup> Moderately to severely immunocompromised individuals may also have different guidance. please refer to: <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html</a>

2) Novavax may be used in limited situations for a booster, please refer to: https://www.cdc.gov/media/releases/2022/s1019-novavax.html



# Q: Most vaccines take years to develop. How did we speed up development of a COVID-19 vaccine and has that affected its safety?

**A:** It's correct that vaccine development usually 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 allowing 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.

#### Q: What is emergency use authorization?

**A:** An EUA is a way to facilitate the availability and use of medical treatments, 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 details about these vaccines?

**A:** Two of the currently offered vaccines are messenger RNA vaccines, or mRNA vaccines. These use a new approach to protecting against infectious diseases and are the first of their kind to be licensed in the United States. Johnson & Johnson/Janssen's 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. Novavax's vaccine is a protein based with an adjuvant to enhance immune response.

VACCINES TO PROTECT AGAINST COVID-19						
Vaccine	Population	Common Side Effects	Initial/Primary Series <sup>,2, 3, 4, 5, 6, 7</sup>			
Pfizer- BioNTech	Authorized for use in those 6 months of age and older and contraindicated for individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any vaccine component; FDA-approved for the prevention of COVID-19 disease in individuals 16 years of age and older.	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 for those 5 years and older.  Certain immunocompromised patients may receive another dose in primary vaccination series.  For those 6 months through 4 years of age, a three-dose series is required.			
Moderna	Authorized for use in those 6 months of age and older and contraindicated for individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any vaccine	Side effects of the vaccine typically resolve within 1-2 days and commonly include things like injection site reactions, fatigue, headache, muscle	Series of two doses.  Certain immunocompromised patients may receive			



	component. FDA-approved for the prevention of COVID-19 in individuals 18 years of age and older.	pain, chills, joint pain, nausea and vomiting and fever.	another dose in primary vaccination series.
Johnson & Johnson/ Janssen <sup>8</sup>	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
Novavax <sup>9</sup>	Authorized for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 12 years of age and older	Side effects commonly include things like injection site reactions, fatigue, headache, muscle/joint pain, and nausea	Series of two doses

- 1. CDC recommends the second dose of the primary series be 3 weeks after the first dose for Pfizer-BioNTech and Novavax. The second dose should be 4 weeks apart for a primary series with Moderna. In some circumstances, the second dose of the primary series may be given up to 8 weeks after the first dose.
- 2. For moderately to severely immunocompromised, an additional dose of mRNA vaccine may need to be administered after the second primary series dose. Please refer to CDC guidance:

https://www.cdc.gov/coronavirus/2019-

ncov/vaccines/recommendations/immuno.html#:~:text=Who%20Is%20Moderately%20or%20Severely,or%20cancers%20of%20the%20blood

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.

#### Q: Does Elixir Mail Order Pharmacy have the vaccine?

**A:** No. As a mail order pharmacy, Elixir Pharmacy is unable to administer the vaccine directly to members.

#### 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, visit Rite Aid's <u>COVID-19 page</u>. Vaccine doses are limited, and availability is updated daily. Store and pharmacy associates are not able to schedule appointments.