

FDA Approves License for Pfizer-BioNTech COVID-19 Vaccine



August 23, 2021

Today, the U.S. Food and Drug Administration (FDA) approved the license for the Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 disease in individuals 16 years of age and older. The Pfizer COVID-19 vaccine continues to be available under emergency use authorization (EUA) for those 12 through 15 years old and for a third dose in certain immunocompromised individuals. The licensing approval was made after another thorough evaluation of safety and effectiveness data by a panel of scientific and medical experts. FDA-approved vaccines undergo the agency's standard process for reviewing the quality, safety and effectiveness of medical products.

We are grateful to the many scientists and researchers who have worked tirelessly to develop and evaluate the vaccines during the most challenging public health crisis of our lifetime. We are also grateful to the FDA for their thoughtful analyses and review processes to ensure that we can have the highest confidence that the vaccine is safe and effective.

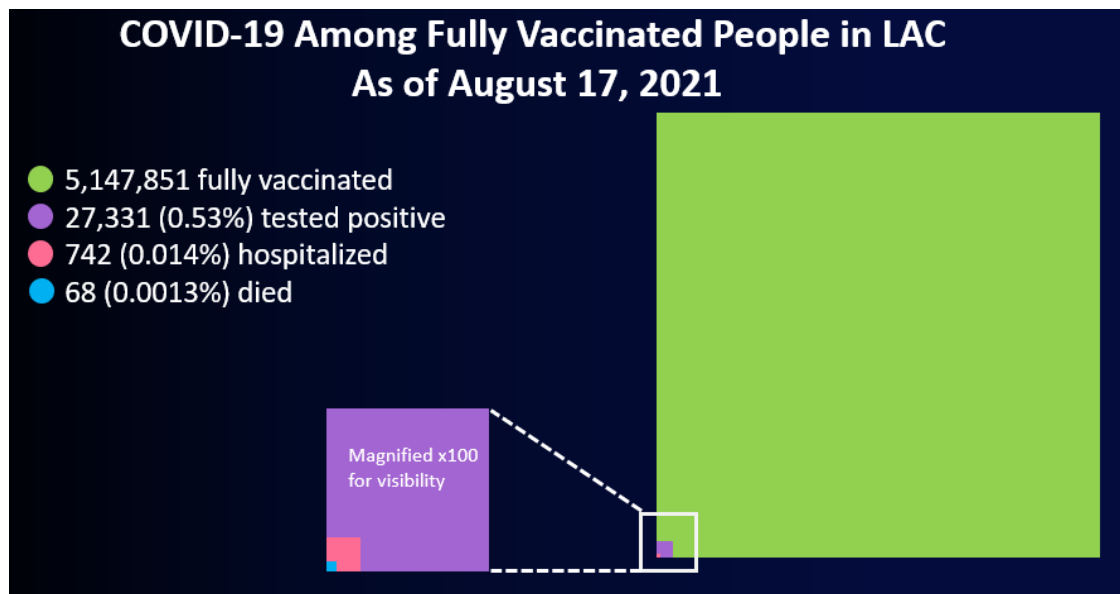
The COVID-19 vaccine remains the most powerful tool we have to both lower our risk of infection and protect against serious illness and death from COVID-19. We encourage everyone who is eligible to get vaccinated – it is the most important step you can take to protect yourself, your loved ones, and our LA County community and to ultimately end this pandemic. If you still need to get vaccinated, Public Health can help. Visit [VaccinateLACounty.com](https://www.vaccinatelacounty.com) to find a vaccination site near you.

COVID-19 Update

Given the increased evidence that fully vaccinated people can test positive for COVID-19, it is important to track the information about the effectiveness of the vaccines and how they keep ourselves and others safe.

To date, more than 5.1 million residents are fully vaccinated in LA County, represented by the big green box. The tiny purple box in the left lower corner of the green box below represents the 27,331 fully vaccinated people who tested positive for COVID as of August 17th, 2021, representing less than 1% of those fully vaccinated.

Of those who were fully vaccinated and tested positive, 0.014% were hospitalized and only 0.0013% died.



This data should provide significant reassurance that fully vaccinated people remain at relatively low risk for becoming infected with COVID-19 and even lower risk for having a bad outcome if they are infected.

Getting vaccinated has never been easier, as there are more than 700 vaccination sites throughout Los Angeles County, most of which do not require an appointment.

Visit [VaccinateLACounty.com](https://vaccinatelacounty.com) for more information about the COVID-19 vaccine or to [find a vaccination site near you](#).

Additional Third Dose for Certain Immunocompromised People & Boosters

Federal officials announced changes to vaccination strategies aimed at increasing the protection afforded to people by vaccines. With emerging data indicating that certain populations will need more support to be protected, the CDC's Advisory Committee on Immunization Practices on August 13th recommended a third dose of mRNA vaccines for immunocompromised people, including transplant recipients, people with advanced or untreated HIV infection, people actively receiving cancer treatment, and people taking immunosuppressive medications. Third doses have been available to eligible individuals at vaccination sites across the county since Saturday.

Here is a quick rundown on third doses for immunocompromised:

Who is eligible for a third dose of the COVID-19 Vaccine?

People who received organ transplant, people undergoing cancer treatment, people with advanced or untreated HIV and those on certain immunosuppressive medications can get a third dose of the Pfizer or Moderna vaccine.

There is evidence that individuals who are severely immunocompromised are not fully protected after receiving two doses and this small, vulnerable group may benefit from a third dose.

How do I know if I am eligible to receive a third dose?

You are eligible for a third dose if you are:

- Receiving active cancer treatment for tumors or cancers of the blood;
- Received an organ transplant and am taking medicine to suppress my immune system;
- Received a stem cell transplant within the last 2 years or am taking medicine to suppress the immune system;
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome);
- Advanced or untreated HIV infection;
- Active treatment with high-dose corticosteroids or other drugs that suppress my immune response

Why is third dose of the COVID-19 Vaccine needed?

Although the Pfizer and Moderna vaccines work very well in the majority of individuals, there is evidence that individuals who are severely immunocompromised are not fully protected after receiving two doses and this small, vulnerable group may benefit from a third dose. Certain medical conditions or the treatments used for specific conditions may prevent the immune system from responding adequately to two doses of the vaccine and therefore require an additional dose to provide adequate protection from COVID-19.

When can I get the third dose?

At least 28 days after the second dose of the Pfizer or Moderna vaccine. Los Angeles County is administering third doses to those who qualify now.

How do I get my third dose of the COVID-19 vaccine?

Public Health encourages individuals who qualify for a third dose to speak to their healthcare provider to confirm their eligibility and get vaccinated. Third doses of the vaccines will be accessible through vaccination sites that currently offer Pfizer or Moderna vaccines. Eligible individuals will be able to provide a self-attestation that they

have a qualifying medical condition at these sites; there is no medical documentation needed to get the third dose.

What if I received the Johnson and Johnson vaccine?

A follow-up dose is not currently recommended for those who have received a single dose of the Johnson & Johnson vaccine. The FDA is still evaluating data on the effectiveness of the Johnson & Johnson vaccine in immunocompromised individuals.

Additionally, the CDC announced last week that booster doses of Pfizer and Moderna vaccines will be offered to all vaccinated people 8 months after their second dose starting in late September. These boosters are meant to increase antibody levels that have waned after a robust increase in the months after vaccination. Public Health is continuing to work with staff and residents at skilled nursing facilities to prioritize these most vulnerable residents for booster doses to be prepared for administering these as soon as the Food and Drug Administration gives their approval.

Visit Public Health's [How to Get Vaccinated "Doses for Immunocompromised"](#) section for more information.

Masks Required at Outdoor Mega Events

With cases rising, outdoor mega events where a large number of people are around one another can pose a significant risk to spread COVID-19. In an effort to slow the spread, the Los Angeles County [Health Officer Order](#) was modified to require universal masking at outdoor mega events with more than 10,000 people, except when actively eating or drinking, regardless of COVID-19 vaccination status. And after someone finishes eating or drink, they should immediately put the mask back on, whether they are seated at a table, counter, or a ticketed seat.



Outdoor mega events are outdoor events with crowds greater than 10,000 attendees and can include music or food festivals, car shows, large endurance events, marathons, parades, sporting events and concerts.

How to Prevent Outbreaks in the Workplace

LA County is monitoring outbreaks at workplaces, schools and other mixed used gathering places. More than 5,000 outbreaks have been investigated within the county since the beginning of the pandemic and with the rise in the very infectious Delta Variant, outbreaks are more of a concern than ever.

In LA County, more than 3 COVID-19 cases in 24 hours in a workplace or worksite can be considered an outbreak. Outbreak cases must be reported to the Department of Public Health so that an investigation can be done to determine if the outbreak is linked to the workplace. Persons involved in the outbreak should be isolated and tested before [returning to work](#).

Help Prevent Outbreaks in the Workplace

If you have three or more confirmed COVID-19 cases identified at your workplace within 14 days, report to Public Health immediately:

Online: www.redcap.link/covidreport

Phone: 888-397-3993

Employers who don't yet have a plan in place for outbreaks should utilize [DPH resources](#) to build one, as immediate implementation of an exposure management plan after identifying a single case of COVID-19 at any work place can help to contain spread of COVID-19 and prevent a single case from becoming an outbreak.

There are three things to implement in the workplace to avoid outbreaks and the interrupting the flow of work and employees' lives:

1. Rapid reporting. Don't hesitate to report and don't wait to identify other cases. Reporting a single case can help us head off an outbreak before it can even be classified as one. Collaboration with our team should begin early. Cases can multiply faster than people realize. You can report outbreaks by calling 888-397-3993. [Additional guidance is available on our website.](#)
2. Masking in the workplace. With the mask mandate in place, everyone indoors should be wearing one. As a workplace, you can check-in with your employees to make sure they have new, comfortable, and properly fitting masks that are replaced as often as needed to be effective. DPH has a [helpful webpage dedicated to mask information.](#)
3. Vaccination. The COVID-19 vaccine is a great tool to have in any workplace. Please encourage your employees to get vaccinated and consider having a [vaccine event during the workday.](#)

Visit our [Best Practices Webpage](#) for many more ideas on how to keep your employees and co-workers safe.

Traveling to or from LA County?

Here's everything you need to know about quarantining, testing, and safety precautions

With many planning holiday or summer travel, there are certain steps you can take to protect yourself from COVID-19. Whether travel within or outside of California, both the California and [Los Angeles County Departments of Public Health](#) ask that you do the following:

- Do NOT travel if you are sick, you have a recent positive COVID-19 viral test result, or you are waiting for results of a COVID-19 viral test after being exposed to the virus. You could spread the virus to others.
 - If you have COVID-19 symptoms (see ph.lacounty.gov/covidcare), [get tested](#), wait for a negative test result and improvement in your symptoms before you start your trip.
 - *If you are not fully vaccinated against COVID-19, a negative test should not be interpreted as a safety clearance for traveling or engaging in high-risk activities.*
 - For more details on when a person should not travel, see the CDC's [When Not to Travel](#) guidance.
- Delay travel until you're fully vaccinated.
 - If you are [eligible](#), get fully vaccinated against COVID-19. Wait at least two (2) weeks after getting your second dose of the Pfizer or Moderna COVID-19 vaccine or after getting the single dose of the Johnson & Johnson/Janssen COVID-19 vaccine to travel—it takes time for your body to build protection after any vaccination. If you do not wait as described above, you are considered NOT fully vaccinated.
- If you're fully vaccinated, follow the CDC [domestic](#) and [international](#) travel guidance for fully vaccinated people.
- If you're not fully vaccinated, but choose to travel, follow the CDC [domestic](#) and [international](#) travel guidance for unvaccinated people.

- *Note: testing is not recommended if you have recovered from laboratory confirmed COVID-19 in the past 90 days AND you are currently without symptoms. “Recovered from COVID-19” means you had a positive COVID-19 viral test (swab or saliva) result and you have completed your [isolation](#). See LACDPH’s [“When does my home isolation end”](#) webpage for more details.
- Review and follow the CDC [Safer Travel Tips](#), which provides guidance on People You Come into Contact with During Travel, Transportation, Accommodations, Food, Camping, and Additional Resources.
- If you are traveling with children who are not or cannot get vaccinated at this time, follow recommendations for unvaccinated people and choose the [safer travel](#) options.

No matter your vaccination status, wear a mask while on public transportation or in a transportation hub. It is a Federal requirement.

For the latest information, see CDC guidance on [Travel During COVID-19](#):

- Domestic Travel: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-during-covid19.html>
- International Travel: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html>. Be sure to check the [COVID-19 situation in your destination](#).

Additional Resources

The Los Angeles County Department of Public Health has developed a wide array of documents, guidance documents, and resources for the workers, businesses, partners, and the general public on a variety of topics related to COVID-19, including:

- [COVID-19 Vaccine Information and Community Resources](#)

Information for the Public

- [Masks](#)
- [Travel](#)
- [Reducing Risk](#)
- [Public Settings](#)
- [Sick?](#)

- [Workers' Rights Pamphlet](#)

Best Practices for Businesses

- [Food and Beverage](#)
- [Indoor Fitness](#)
- [Large Events](#)
- [Offices](#)
- [Personal Care](#)
- [Request a Mobile Vaccination Clinic](#)

It is recommended you follow @lapublichealth on [Facebook](#), [Twitter](#) or [Instagram](#) for when appointments will be made available.

Always check with trusted sources for the latest accurate information about novel coronavirus:

- Los Angeles County Department of Public Health <http://publichealth.lacounty.gov/media/Coronavirus/>
- California Department of Public Health <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/ncov/2019.aspx>
- Centers for Disease Control and Prevention (CDC) <https://www.cdc.gov/coronavirus/2019-ncov/index.html> Spanish <https://www.cdc.gov/coronavirus/2019-ncov/index-sp.html>
- World Health Organization <https://www.who.int/health-topics/coronavirus>
- LA County residents can also call 2-1-1