Janssen vaccine authorized, soon to be available in Missouri

Today, Dr. Randall Williams, director of the Missouri Department of Health and Senior Services (DHSS) signed the standing order for Janssen Biotech, Inc. COVID-19 vaccine administration after review of preliminary recommendations made today by the Centers for Disease Control and Prevention (CDC).

“We are incredibly appreciative to be receiving additional vaccines in Missouri, and we remain committed to making it available for a variety of vaccinators to get it into arms as efficiently as possible,” said Williams. “The order issued today will authorize approved vaccinators to vaccinate using the Janssen vaccine as soon as they receive it from our federal partners.”

Janssen’s single-dose COVID-19 vaccine was authorized for emergency use for the prevention of COVID-19 in those 18 or older by the U.S. Food and Drug Administration on Feb. 27. It is the third COVID-19 vaccine authorized for use in the United States. Approximately 50,000 doses are expected in Missouri this week.

“During these initial weeks that the Janssen vaccine is available, we will be allocating it across all current delivery channels providing vaccinations for Missourians,” said Governor Mike Parson. “Hospitals, local public health agencies, federally-qualified health centers and mass vaccination clinics will be included in the plan to distribute the Janssen vaccine so local providers can help determine which populations could be best served with a single-dose regimen.”

The effectiveness data to support the Emergency Use Authorization (EUA) include an analysis of 39,321 participants in the ongoing randomized, placebo-controlled study being conducted in South Africa, certain countries in South America, Mexico, and the U.S. who did not have evidence of SARS-CoV-2 infection prior to receiving the vaccine. More than half of the participants in the study received the vaccine. At least 28 days after vaccination, the vaccine was 85% effective in preventing severe or critical COVID-19.

Janssen’s data shows while it is effective against asymptomatic infection, it is even more effective against more severe forms of the disease.

“The best COVID-19 vaccine you can get is the one you are able to get the soonest after becoming eligible,” said Williams. “The scientific evidence shows that the Janssen vaccine does a great job at preventing hospitalizations and deaths which is the main goal for COVID-19 vaccines.”
Different from Pfizer and Moderna’s mRNA vaccines, the Janssen COVID-19 vaccine is manufactured using a specific type of virus called adenovirus type 26 (Ad26). The vaccine uses 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. While adenoviruses are a group of viruses that are relatively common, Ad26, which can cause cold symptoms and pink eye, has been modified for the vaccine so that it cannot replicate in the human body to cause illness. After a person receives this vaccine, the body can temporarily make the spike protein, which does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2.

Reported side effects include pain or redness/swelling at the injection site, tiredness, headache, muscle pain, nausea and fever. Those who should not get the Janssen COVID-19 vaccine are those under age 18 and those who have had a severe allergic reaction to any ingredient of the vaccine.

Ingredients of the Janssen COVID-19 vaccine include recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride. Individuals who question their ability to receive this vaccine should consult with their medical provider.

These precautions and contraindications are subject to change following the impending final release of the Advisory Committee on Immunization Practices and CDC recommendations.

Read DHSS’s full news release here.

Additional Janssen Resources:
- Letter of Authorization
- Fact Sheet for Healthcare Providers Administering Vaccine
- Fact Sheet for Recipients and Caregivers
- Press Release

Tips and reminders

1. Make sure to discard all used and empty vaccine vials in a Bio-Hazzard sharps container.
2. All vaccinators should make sure that the needle is securely attached to the hub of the syringe before vaccinating a patient.

Vaccinator resource webpage

Many resources have been added to this webpage, including many of your frequently asked questions and answers, necessary forms, vaccination guidance and Vaccine Navigator materials.

VaccineFinder

VaccineFinder rolled out a soft launch of its publicly available, searchable inventory. It intends to have a full launch soon (date TBD). A fact sheet for vaccination providers that includes information about onboarding, reporting and public display can be found here.
Note: The expiration date for the Moderna vaccine is not 12.31.2069

Providers must go to the Moderna website, enter the lot number, and receive the correct expiration date to enter into ShowMeVax.

To correct the expiration date in ShowMeVax, go to inventory, vaccines, on hand, click action for the vaccine, then edit, enter correct expiration date and update. This will change the date for all records that have been entered with that lot number.

Vaccine Navigator enrollment for vaccinators

To gain access to Missouri Vaccine Navigator, please complete the Vaccine Navigator Access form on the DHSS website. Demos and fact sheets regarding the use of the program is available on the vaccinator resource page.

Update from CDC on Pfizer-BioNTech COVID-19 Vaccine Cold Chain Changes

On February 25, 2021, the U.S. Food and Drug Administration (FDA) announced that it is allowing undiluted frozen vials of Pfizer-BioNTech COVID-19 Vaccine to be transported and stored at conventional temperatures commonly found in pharmaceutical freezers (-25°C to -15°C; -13°F to 5°F) for a period of two weeks. This reflects an alternative to the recommended storage of undiluted vials in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F).

In brief, undiluted vials maybe stored at the following temperature ranges

- Between -80°C and -60°C (-112°F to -76°F) until the expiration date
- Between -25°C and -15°C (-13°F to 5°F) for up to two weeks
  - Note: These temperatures are within the appropriate range for routinely recommended vaccines, BUT the temperature range for this vaccine is tighter. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.
- Between 2°C and 8°C (35°F to 46°F) for up to 120 hours (5 days)

Additional Background

- This alternative storage option will not change the current shipping procedures for Pfizer-BioNTech COVID-19 Vaccine.
- Orders will still be sent in the thermal shipping containers with dry ice which maintain a temperature range of -90°C to -60°C. Pfizer thermal shipping containers are qualified to maintain ultralow temperatures only; they cannot be used to store/transport vaccine at other temperatures.
- Once received, vials may be stored or transported at -25°C to -15°C (-13°F to 5°F) for a period of two weeks.
- Frozen vials stored or transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). This includes
vials that are held up to two weeks at -25°C to -15°C (-13°F to 5°F), and in risk of not being used in time.

- Any time that the vials are stored or transported at -25°C to -15°C count against the two-week limit.
  - Redistributed vials transported at -25°C to -15°C (-13°F to 5°F) can either be returned to -80°C to -60°C (-112°F to -76°F) and used by the expiration date or maintained at -25°C to -15°C (-13°F to 5°F) and used within two weeks. Time in transit counts as part of the two-week time limit.
- Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed two weeks. CDC is updating Pfizer Beyond-Use Date Labels to track this two-week timeframe.

These changes are further outlined in the FDA’s Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).

What’s Next?

- Pfizer will host training sessions next week to review information and answer questions about the Pfizer-BioNTech COVID-19 Vaccine. Please click on the link below to join the sessions at the designated times. Each training below is the same content.

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- CDC’s product-specific materials and the Storage and Handling Summary will be updated to reflect the updated EUA.

Updated Pfizer vaccine preparation guidance

See the updated do’s and don’ts of diluting Pfizer’s vaccine and withdrawing doses from the vial here.

New equitable vaccine distribution webpage

A NEW webpage has been launched to support the work of our state’s Missouri Advisory Committee on Equitable COVID-19 Vaccine Distribution.

The Equity Advisory Committee was formed in 2020 to work directly with and engage our DHSS’s external partners and stakeholders to inform an equitable distribution of Missouri’s COVID-19 vaccine supply. The Committee’s mission is to solicit stakeholder feedback across the state of Missouri to ensure equitable distribution of the COVID-19 vaccine across all communities with a focus on the disability, aging and underserved and underrepresented minority communities.

A special thank you to our partners who are helping Missouri strategize how to deliver vaccines to those individuals who need them most, inform our State’s process on the COVID-19 vaccine distribution and help expand COVID-19 vaccine awareness, education and promotion.  
www.MOSTopsCovid.com/equity
Clarification of vaccination eligibility

Family caregivers often serve in the role of an unpaid healthcare worker, providing in-home care to those at an increased risk for severe illness as a result of COVID-19. These family and household members serve in a role to meet the daily care needs of an adult unable to complete those tasks independently or for a child with specialized medical needs. As unpaid healthcare providers, these caregivers are currently eligible to receive the vaccine in Phase 1A.

Clergy who minister to those in long-term care/congregate facilities or hospitals are eligible for vaccination now with healthcare workers in Phase 1A.

Vaccine shipments from McKesson

Vaccine shipments to providers are preceded by two emails from McKesson:

1. **An order acknowledgment email** that is sent once the order has been received into the McKesson system
2. **An advance shipment email** that is sent once the order has shipped from the McKesson depot and contains the carrier tracking details

Both of these emails will be sent to the provider (facility) level email address that is transmitted with the order in VTrckS.

Both of these emails will be sent from CDCNotifications@mckesson.com (Note: This is a new email address for emails from McKesson. Awardees should request that providers whitelist this address so that the emails are not blocked. Please do not send correspondence to this mailbox as it is not monitored for incoming emails.

If you have questions, please contact McKesson Specialty Customer Care at (833) 343-2703 Monday – Friday, 7 a.m. - 7 p.m. or COVIDVaccineSupport@McKesson.com.

Updated supply / demand webpage

In an effort to provide further transparency, the State launched a supply and demand webpage on Feb. 19 showing allocations, order requests and distributions. It was updated on Feb. 26. Soon, historical distribution information will be added at MOStopsCovid.com/supply.
### Pfizer Ordering Cadence

<table>
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<th>Deadline for vaccinator to place order</th>
<th>Order Placed by State</th>
<th>Order Received</th>
<th>Order Placed by State</th>
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### Moderna Ordering Cadence

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<th>Deadline for vaccinator to place order</th>
<th>Order Placed by State</th>
<th>Order Received</th>
<th>Order Placed by State</th>
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Need more information?

We continuously update Missouri’s **vaccinator resource hub** with the latest information on the approved vaccines, guidance, Missouri Vaccine Navigator, vaccinator FAQs and training opportunities. Additional resources are also listed below:

- Vaccinator enrollment checklist
- ShowMeVax training videos
- Missouri vaccinator reporting guidance / required data fields

**DHSS contacts by topic area:**

- ShowMeVax enrollment support: Cathy Kennon
- ShowMeVax troubleshooting: vfc-smvsupport@health.mo.gov
- Reporting Dose Administration assistance: ImmunizationHL7Onboarding@health.mo.gov
- Adverse events/clinical assistance: Lana Hudanick
- Vaccine redistribution: covidvaccineredistribution@health.mo.gov
- Ordering and supply management support: covidvaccineorders@health.mo.gov
- Additional PPE and other equipment: Jenn Stockman
- Newsletter/webinars: Lisa Cox
- All other questions: CovidVaccine@health.mo.gov

**Upcoming Meetings**

- Vaccine Call for local public health agencies: every **Monday**, reach out to Tiffany Bayer for more information.
- Vaccinator webinar: Past webinars can be found [here](#).
  The next webinar will be from **3-4 p.m. on Tuesday, March 2.** Click [here to attend](#). Or join by phone: 1-650-479-3207 | Meeting number (access code): 133 183 7153 Meeting password: AtqpY6fi7F5