UNDERSTANDING COVID-19 VACCINES

Helping employers plan their vaccination strategies

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From the onset of the COVID-19 pandemic, Cigna has focused on delivering peace of mind to the people and businesses we serve. With three COVID-19 vaccines having received FDA Emergency Use Authorization (EUA), Cigna is partnering with employers, like you, to help plan for vaccine administration of employees and their dependents, taking into account vaccine availability; how your workforce fits into the phased rollout (e.g., essential workers); and what you can do to prepare. We are pleased to provide answers to your common questions.

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What COVID-19 vaccines are available?

In the United States, there are currently three vaccines to prevent COVID-19 that are FDA-approved for Emergency Use Authorization (EUA). These vaccines are manufactured by Pfizer-BioNTech, Moderna, and Johnson & Johnson (J&J) /Janssen Biotech.

Who is eligible to receive a COVID-19 vaccine and where are they administered? Will vaccine be distributed to primary care physician offices?

Current eligibility for vaccine is dependent upon individual states' roll-out recommendations. Note that in many jurisdictions, broader populations are now able to obtain their vaccinations. Currently, large health systems and medical groups, pharmacies, and county vaccination sites are administering vaccines through appointment processes that follow local current guidelines. The ease of storage and handling of the J&J/Janssen vaccine increased access to smaller facilities, office practices and retail pharmacies.

We recommend employers and individuals contact their local public health department or their own provider regarding their planned COVID-19 vaccination participation. State resources are available at Cigna.com/vaccinesbystate. More details are also available on the CDC website.

Will the COVID vaccine be covered under preventive services (similar to flu vaccine) under Cigna plans now and in the future?

Yes. Any FDA-approved vaccine is covered as a preventive service. As such, a covered individual's out-of-pocket cost for the COVID-19 vaccine will be $0. If other services are provided at the time of vaccine administration, such as a chronic condition evaluation, then cost-share for these services may be applied.

Keep in mind, the federal government is distributing doses of COVID-19 vaccine serum free of cost, and has mandated that non-exempt health plans and ASO employers pay 100% of the cost of administration of the vaccine, whether administered by health care professionals or pharmacists and whether in- or out-of-network.

For all EUA-approved COVID-19 vaccines that are now (and become) available, Cigna's payment for vaccine administration is at the established national CMS rates when billed under the medical benefit.

We are taking a multi-pronged approach working with providers, pharmacy partners, employer onsite clinics, community resources, and other vaccine suppliers to help ensure that individuals get vaccinated when they are eligible.

Can you explain the difference between the vaccines and whether someone should choose one over the other? How will we know that a vaccine is both safe and effective?

The best vaccine choice is the vaccine available at the first available appointment. All three EUA-approved vaccines do an excellent job of preventing moderate to severe disease, hospitalizations and death. Long-term data is needed to learn how long the vaccines remain effective and what the impact of variants might be. People who feel uncomfortable symptoms within three weeks after getting a vaccination should contact their health care provider. Please refer to the CDC website for more details.

DIFFERENT COVID-19 VACCINES

	Pfizer-BioNTech	Moderna	J&J/ Janssen
STORAGE DETAILS[1]	Dry ice freezing	Refrigerator 30 days	Simple refrigeration
DOSING SCHEDULE[1]	2 injections, 3 weeks apart	2 injections, 4 weeks apart	1 injection
AGE GROUP[3]	16+	18+	18+
EFFICACY: PREVENTING MODERATE TO SEVERE DISEASE	95%[1]	94.5%[1]	72%[1,3]
EFFICACY: PREVENTING SEVERE COVID-19 DISEASE	100%[2]	100%[2]	85%[2]
EFFICACY: PREVENTING COVID-19 DEATHS	No deaths[2]	No deaths[2]	No deaths[4]
MECHANISM[1]	mRNA	mRNA	Adenovirus vector
STATUS[1]	FDA Emergency Authorization granted Dec. 11, 2020	FDA Emergency Authorization granted Dec. 18, 2020	FDA Emergency Authorization granted Feb. 27, 2021

1. Zimmer, Carl, et al. “Coronavirus Vaccine Tracker.” The New York Times. Last updated March 1, 2021. 2. Kaplan, Karen. “How the Moderna and Pfizer COVID-19 vaccines compare.” Los Angeles Times. Dec. 15, 2020. 3. Efficacy rate in U.S. trial. 4. Jnj.com. Jan. 29, 2021.

How necessary is the vaccine for employees between the ages of 18 and 49?

It is incredibly important for everyone over the age of 16 to receive a vaccine when it is their turn to get vaccinated. Until there is a large enough portion of the population inoculated, COVID-19 will continue to spread and variants will have room to develop.

Getting vaccinated for COVID-19 will help our country, communities, and families to end this pandemic and bring life back to normal. Getting an available vaccine helps prevent serious illness for those who get infected with COVID-19.

Are there ongoing trials for those under age 16? If so, is there a forecast for FDA approval?

Moderna and Johnson & Johnson (J&J) Janssen Biotech did not include pediatric patients under age 18 and Pfizer-BioNTech did not include patients <16 in the initial clinical trials. There are ongoing vaccine clinical trials for pediatric patients, including children as young as 6 months old. Initial results for children ages 12 to 15 are available. The companies are preparing to submit the results as amendments to their EUA with anticipated approval in mid-summer or later this year.

How long will the vaccine last? Do you need to get an annual shot like the flu shot?

At this time, the answer is unclear. It is anticipated that the currently available vaccines will provide protection for at least one year. The potential need for a booster is being studied, including data based on variants. Ultimately, some of this depends on how many and how quickly variants develop before enough people are vaccinated.

What is Cigna doing to reduce disparities in COVID-19 vaccine administration?

Cigna has recognized and worked to address health disparities for years, including those around vaccination. Examples of our current activities include:

1. Increased emphasis on education about vaccine concerns in our patient communication materials
2. Involving community leaders (city, faith-based, business) in efforts to improve awareness and access
3. Promoting implicit bias training for physicians
4. Broadly driving Social Determinants of Health/Health Disparities initiatives within all of our value-based clinical provider partnerships

Did COVID-19 clinical trials include diverse populations and were the outcomes or side effects different by race or gender?

Yes. Manufacturers provided demographic data for participants in their late-stage clinical trials. Similar vaccine efficacy and safety results were observed across racial and ethnic populations. For more information, see kff.org.

If I am pregnant or breast feeding, is it recommended that I get a COVID-19 vaccine?

Any of the currently authorized COVID-19 vaccines can be offered to people who are pregnant or breastfeeding. If you have questions about getting vaccinated, a conversation with your healthcare provider might help, but may not be necessary.

According to the CDC, pregnant people are at increased risk for severe illness from COVID-19. Although the overall risk of severe illness is low, pregnant people are at an increased risk for severe illness from COVID-19 when compared to non-pregnant people. Severe illness includes illness that results in intensive care admission, mechanical ventilation, or death. Additionally, pregnant people with COVID-19 might be at increased risk of adverse pregnancy outcomes, such as preterm birth, compared with pregnant women without COVID-19.

More information is available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

Can employers buy vaccine to expedite the delivery to their workforce?

Non-healthcare employers do not have access to the vaccines purchased by the federal government. A CDC COVID-19 Vaccination Program Provider Agreement needs to be filed and an application completed on each state's health department portal. Employers interested in onsite vaccine events should work with their client services representative.

What are employers allowed to ask employees about the vaccine? Is the decision to vaccinate a medical decision protected by HIPAA? If not, why?

As the vaccine rollout continues and restrictions are eased, we recognize that some employers are evaluating workplace rules. This requires a thorough discussion with your legal counsel and human resources partner. A number of factors may come into play:

- Can employers ask their employees to say when they've been vaccinated?
    a. HIPAA protects the confidentiality, integrity, and availability of personal health information. Employers may consider offering incentive programs that allow self-disclosure or self-attestation where the release of the health information is part of the consent to participate in the program. Employers cannot request health information to be used for non-care coordination uses such as surveillance, site location opening, or other occupational reasons.

- Can employers require that their employees get the vaccine?
    a. The U.S. Equal Employment Opportunity Commission issued guidance suggesting that employers can mandate COVID-19 vaccines as long as employees don't have a disability and/or a sincerely-held religious belief that would prevent them from getting vaccinated.

b. It's important to remember that COVID-19 vaccines have FDA Emergency Use Authorization approval. Under FDA rules for Emergency Use Authorization, the recipient has the right to either get it or refuse it. Mandating vaccines with EUA is problematic. Once COVID-19 vaccines receive the full Biologics License Application (BLA) approval, policy makers and employers must determine which, if any, populations to which a vaccine mandate should apply. Post BLA, vaccine mandates could be imposed in multiple sectors, each with their own legal and ethical considerations.

It's never too soon to promote the value of getting the vaccine to your workforce. So, talk with your client services representative about our Health Ways to Work℠ program to discuss ways to promote the importance and safety of these vaccines to help encourage employees.

Will Cigna be able to host an onsite office vaccination event? I tell everyone to sign up with their state and local governments for vaccination ASAP and not wait for a company event. Is this the right strategy?

Yes, for now, encouraging your employees to register for vaccine notification when they are eligible is the best approach. Each state decides its priority order of vaccination and how the vaccine will be distributed.

Employees can register with large health systems and medical groups, retail pharmacies, and county vaccination sites that are administering vaccines through appointment processes based on local health department guidelines. On Cigna.com/vaccinesbystate, you'll find links to each state's vaccine registration for an appointment either through state vaccination centers or links to health systems, medical groups, and pharmacies.

We are taking a multi-pronged approach by working with onsite vendors, national retail pharmacy chains, and market providers to assist clients in coordinating onsite COVID-19 vaccine events when local vaccine priorities and available supply allows. Please talk to your client services representative if you are interested so they can add you to the onsite event list. In addition, for clients that have onsite health centers operated by Cigna, we have filed an application with the states to conduct vaccine administration. We are making every effort to obtain the vaccine and offer it to eligible employees.

Will the current vaccines protect against known emerging variants first identified in England, Brazil and South Africa? How many variants will the current vaccines cover?

Each vaccine was designed using the original strain of the virus. Recent statements by both Pfizer-BioNTech and Moderna suggest that their vaccines do protect against emerging strains. J&J/Janssen also conducted a subgroup analysis in the United States, South Africa, and Brazil showing efficacy rates as part of the EUA-approval process.

What are the rates of adverse events for COVID-19 vaccines? Should employees with existing allergic reactions to foods or other vaccines receive the COVID-19 vaccine?

The CDC indicates that while some people don't have any side effects after getting a COVID-19 vaccine, many people will have mild side effects after vaccination. More severe reactions are extremely **rare** and can be treated. Patients are asked to stay for 15 to 30 minutes after getting a vaccine in order to be observed and provided treatment in the rare case it is needed. We encourage customers to discuss concerns with their health care provider.

Common COVID-19 vaccine topics of concern

Concern	Fact*
Speed of development	The vaccines are proven safe and effective, and they were developed quickly because of the worldwide effort. Although developed in record time, they have gone through the same rigorous FDA process as every other vaccine, meeting all safety standards. No steps were skipped.
Impact of RNA	mRNA is simply a message that the body reads. It cannot change your DNA or modify your genes.
Ingredients	mRNA vaccines are free of preservatives and only contain the mRNA, a fatty coating layer to protect the mRNA, PEG (polyethylene glycol), and a combination of salts, sugar and water. Viral vector COVID-19 vaccines use a harmless version of a different virus, called a "vector," to deliver information to the body that helps protect
Long-term data	Hundreds of millions have been vaccinated. Clinical trials have shown us the vaccines are safe, and now we are seeking long-term data to learn how long the vaccines remain effective.

* University of Waterloo School of Pharmacy and UC Davis Health, *Real facts about common COVID-19 vaccine myths*.

What important points can employers share to address vaccine hesitancy?

Be honest with your employees. Provide the facts. Create a positive environment around vaccination. Set the example. Some key points to mention:

- The available vaccines are proven to be safe and effective.
- Although developed in record time, they have gone through the same rigorous FDA process as every other vaccine, meeting all safety standards. Some factors that accelerated approval were funding, prioritization in the FDA pipeline, and high volume of available clinical trial participants. For example, recruiting clinical trial participants can take a long period of time and this was done quickly with COVID-19 vaccines.
- Clinical trials were completed through the usual process. No steps were skipped.
- More severe reactions are extremely rare and can be treated. Out of an abundance of safety after receiving the vaccine, patients are asked to stay 15 to 30 minutes after getting a vaccine in order to be observed and provided treatment in the rare case it is needed. Those who experience uncomfortable symptoms within three weeks after vaccination should contact their health care provider.
- We encourage individuals to talk with their health care provider if they have concerns.

What did the CDC and FDA determine regarding the safety of the J&J/Janssen COVID-19 vaccine?

After a temporary pause of J&J/Janssen COVID-19 vaccinations in the U.S., the Advisory Committee on Immunization Practices (ACIP), the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) recommended that vaccinations with the J&J/Janssen COVID-19 vaccine resume, concluding that the benefits of the Janssen COVID-19 vaccine outweigh its known and potential risks in individuals18 years and older. However, women younger than 50 years old should be aware of the rare but increased risk of thrombosis with thrombocytopenia syndrome (TTS). TTS is a serious condition that involves blood clots with low platelets. There are other COVID-19 vaccine options available for which this risk has not been seen.

The two agencies determined:

- The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- The FDA determined that the available data show that the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.
- At this time, the available data suggest that the chance of thrombosis-thrombocytopenia syndrome (TTS) occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk.

The FDA and CDC conducted extensive outreach to providers and clinicians across the United States to ensure they were made aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots with low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS).

What should my employees who already received or want to get the J&J/Janssen COVID-19 vaccine know about TTS?

According to the CDC website, there is a plausible causal relationship between the J&J/Janssen COVID-19 vaccine and a rare and serious adverse event—blood clots with low platelets (thrombosis with thrombocytopenia syndrome, or TTS). However, after reviewing all available safety data, the CDC and FDA recommended use of this vaccine resume in the United States given that the known and potential benefits outweigh the known and potential risks.

What patients should know:

- TTS is a rare, adverse event, occurring at a rate of about seven per 1 million vaccinated women between 18 and 49 years old. For women 50 years and older and men of all ages, this adverse event is even more rare.
- For three weeks after receiving the vaccine, those vaccinated should be aware of possible symptoms of a blood clot with low platelets. These include:
    - Severe or persistent headaches or blurred vision
    - Shortness of breath
    - Chest pain
    - Leg swelling
    - Persistent abdominal pain
    - Easy bruising or tiny blood spots under the skin beyond the injection site

Patients should seek medical care right away if one or more of these symptoms develop.

- Health care providers administering the vaccine, vaccine recipients, and caregivers should review the J&J/Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers, which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who received the J&J/Janssen COVID-19 vaccine.

What do I ask employees to do now that the CDC has released guidelines for fully vaccinated people?

The CDC has issued interim public health recommendations for fully vaccinated people. For now, fully vaccinated people should continue to take precautions in public. More information is available here. For the most up-to-date recommendations and information, please visit the CDC website regularly.

What happens when you try to register for a second shot and no times are available within 4 to 6 weeks?

The Pfizer-BioNTech and Moderna vaccines require two doses, while the J&J Janssen vaccine requires one. Contacting and working with your provider and local county health department are good approaches if employees are having trouble scheduling second appointments.

According to the CDC, if it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. With vaccine availability opening up, we don't expect this to be an issue in the near future.

Helpful resources for employers

Below are links to important guidance and helpful information from the CDC, FDA, and other sources for your reference.

- CDC COVID-19 Vaccine FAQ
- CDC COVID-19 Vaccines
- CDC COVID-19 Vaccine Planning Guide
- CDC COVID-19 Vaccination Recommendations
- CDC COVID-19 Vaccination Information Regarding Children
- Occupational Safety and Health Administration (OSHA) Regarding COVID-19
- U.S. Equal Employment Opportunity Commission (EEOC) Regarding COVID-19
- Cigna Coronavirus (COVID-19) Resource Center
- CDC Fully Vaccinated Guidance
- CDC Fully Vaccinated

In addition to federal guidelines, state and local health departments have resources to provide further information on COVID-19 vaccines. For state and local health departments, please see Cigna.com/vaccinesbystate.

The CDC also provides a link to accredited State Departments of Health here. The National Association of County and City Health Officials (NACCHO) provides links to local health departments here.

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