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COVID-19 Vaccine FAQ

November 2020



FAQ: COV19 Vaccine

Where do I find COVID-19 vaccine information on the Vizient site?

 Materials and information on COVID-19 vaccine may be found on the <u>Vizient Vaccine Resource</u> Center.

How do I enroll my organization to be a provider of the COVID-19 vaccine?

 According to the <u>CDC COVID-19 Vaccination Program Interim Playbook</u>, provider organization should enroll through their state's individual immunization program. Enrolled providers must agree to the Vaccination Program Provider Agreement detailed in the playbook. Each location that will administer the vaccine must also complete the CDC COVID-19 Vaccination Provider Profile.

Where do I find information on the COVID-19 Vaccines candidates in Phase III trial?

A side-by-side comparison is available on the Vizient COVID-19 Vaccine Resource Center
vizientinc.com/vaccine site here. This document includes a comprehensive summary of the leading
vaccine candidates including information on the manufacturer, vaccine platform technology,
pharmacology, dose, frequency, how the vaccine is supplied, safety considerations, adverse effects,
and Phase III study endpoints. The Vizient COVID-19 vaccine side by side is updated every two
weeks.

Where do I find a summary of the top vaccine candidates?

A vaccine tracker summarizing the top vaccine candidates is available on the Vizient COVID-19
 Vaccine Resource Center vizientinc.com/vaccine site here. This document includes the
 manufacturer(s), phase of development, vaccine platform technology, number of doses ordered, and
 special considerations. The vaccine tracker is updated weekly.

How do we know that the COVID-19 vaccines that will be commercially available are safe?

Currently, clinical trials are evaluating investigational COVID-19 vaccines in thousands of study
participants to generate scientific data and other information for the Food and Drug Administration
(FDA) to determine their safety and effectiveness. These clinical trials are being conducted according
to the rigorous standards set forth by the FDA in their June 2020 guidance document, <u>Development
and Licensure of Vaccines to Prevent COVID-19</u>. An excerpt on the Safety Considerations section of
this document is listed below:

The general safety evaluation of COVID-19 vaccines, including the size of the safety database to support vaccine licensure, should be no different than for other preventive vaccines for infectious diseases. Safety assessments throughout clinical development should include:

 Solicited local and systemic adverse events for at least 7 days after each study vaccination in an adequate number of study participants to characterize reactogenicity (including at least a subset of participants in late phase efficacy trials).

- Unsolicited adverse events in all study participants for at least 21–28 days after each study vaccination.
- Serious and other medically attended adverse events in all study participants for at least 6 months after completion of all study vaccinations. Longer safety monitoring may be warranted for certain vaccine platforms (e.g., those that include novel adjuvants).
- All pregnancies in study participants for which the date of conception is prior to vaccination or within 30 days after vaccination should be followed for pregnancy outcomes, including pregnancy loss, stillbirth, and congenital anomalies.
- Key considerations on post-licensure safety evaluation is also described in the FDA document Development and Licensure of Vaccines to Prevent COVID-19. If the FDA determines that a vaccine meets its safety and effectiveness standards, it can make these vaccines available for use in the United States by approval or emergency use authorization. After the FDA makes its determination, the Advisory Committee on Immunization Practices (ACIP) will review available data before making vaccine recommendations to CDC. Link here to learn more about how the CDC is making COVID-19 vaccine recommendations.

What are the storage requirements for COVID-19 vaccines?

 The Vizient side-by-side comparison, available on the Vizient COVID-19 Vaccine Resource Center vizientinc.com/vaccine site here, details the storage requirement for the leading COVID-19 vaccine candidates. Listed are the anticipated commercial vaccine storage conditions; investigational conditions may differ.

What refrigerator and freezer products do we have on Vizient contract?

Vizient is contracted with Follet, Helmer, Thermo-fisher, and Cardinal to provide freezers and
refrigerators. A document summarizing the cold-chain storage solutions is available on the Vizient
COVID-19 Vaccine Resource Center vizientinc.com/vaccine site here. This document includes the
suppliers and their contact information, contract number, cost range, estimated lead times, and return
policy and warranty information.

Where can I find information on safe handling and storage of dry ice?

Dry ice is frozen carbon dioxide. Unlike most solids, it does not melt into a liquid but instead changes
directly into a gas. A Vizient document detailing the safe handling and storage of dry ice is located on
the Vizient COVID-19 Vaccine Resource Center vizientinc.com/vaccine site here. This document is
sourced from an OSHA blog posting here.

What is the cost of COVID-19 vaccines?

The federal government is committed to providing free or low-cost COVID-19 vaccines. Vaccine doses
purchased with U.S. taxpayer dollars will be given to the American people at no cost. However,
vaccination providers will be able to charge an administration fee for giving the shot to someone. Most

public and private insurance companies will cover that fee, so there is no cost for the person getting vaccinated. In addition, people without health insurance can get COVID-19 vaccines at no cost. Information supporting this is located here and https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.

What information is available on COVID-19 vaccine administration reimbursement?

- Information on reimbursement for uninsured patients is available https://www.hrsa.gov/CovidUninsuredClaim. The COVID-19 reimbursement program, administered by UnitedHealth Group via a contract with the U.S. Department of Health and Human Services' Health Resources and Services Administration (HRSA), will accept claims from health care providers that provide testing, treatment, and vaccine administration for uninsured patients. When an FDA-licensed or authorized vaccine becomes available, the administration fees for the vaccine will be covered.
- Once a COVID-19 vaccine becomes available, all Medicare Part D plans will be required to cover it.
 Information on Coverage and Payment Related to COVID-19 Medicare is located https://www.cms.gov/files/document/03052020-medicare-covid-19-fact-sheet.pdf.

What ancillary supplies do I need to have on hand for vaccine administration?

- According to the <u>COVID-19 Vaccination Program Interim Playbook</u>, ancillary supplies will be packaged
 in kits and will be automatically ordered in amounts to match the quantity of vaccines ordered. Each kit
 will contain supplies to administer 100 doses of vaccine. The following will be included in each kit:
 - √ Needles (various sizes for the population served by the ordering vaccination provider)
 - √ Syringes
 - √ Alcohol prep pads
 - √ 4 surgical masks and 2 face shields for vaccinators
 - ✓ COVID-19 vaccination record cards for vaccine recipients

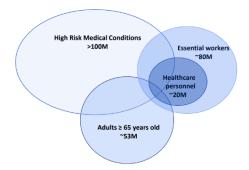
Is there guidance on vaccine administration?

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html

- The <u>Advisory Committee on Immunization Practices (ACIP)</u> has set the following goals for deciding who to recommend COVID-19 vaccines for if supply is limited:
 - ✓ Decrease death and serious disease as much as possible
 - ✓ Preserve functioning of society
 - √ Reduce the extra burden the disease is having on people already facing disparities.
 - ✓ Increase the chance for everyone to enjoy health and well-being
- The ACIP is considering four groups to possibly recommend COVID-19 vaccination:
 - √ Health care personnel (Phase 1a)

- All paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials
- Includes persons not directly involved in patient care but potentially exposed to infectious agents while working in a health care setting
- Examples: Hospitals, long-term care facilities (assisted living facilities and skilled nursing facilities), outpatient, home health care, retail pharmacies, EMS, public health
- √ Workers in essential and critical industries (Phase 1b)
 - Workers who are essential to continue critical infrastructure and maintain the services and functions Americans depend on daily
 - Workers who cannot perform their duties remotely and must work in close proximity to others should be prioritized
 - Sub-categories of essential workers may be prioritized differently in various jurisdictions depending on local needs
 - Examples: Food and Agriculture, Transportation, Education, Energy, Water and Wastewater, Law Enforcement
- ✓ People at high risk for severe COVID-19 disease due to underlying medical conditions (Phase 1b)
 - o Cancer
 - o Chronic kidney disease
 - Chronic obstructive pulmonary disease (COPD)
 - o Immunocompromised state from solid organ transplant
 - Obesity (BMI of 30 or greater)
 - Serious heart conditions (heart failure, coronary artery disease or cardiomyopathies)
 - Sickle cell disease
 - Type 2 diabetes mellitus
- ✓ People 65 years and older (Phase 1b)

The ACIP Phase I allocation for COVID-19 vaccine work group considerations is located <u>here</u> with a graphic below.



The ethical principles for phased allocation of COVID-19 vaccines summarized at the ACIP October 30, 2020 meeting by the ACIP COVID-19 Vaccines Work Group can be found here.

How are long-term care facilities (LTCF) getting access to COVID-19 vaccine?

The U.S. Department of Health and Human Services (HHS) and Department of Defense have
established agreements with CVS and Walgreens to provide and administer COVID-19 vaccines to
residents of long-term care facilities (LTCF) nationwide with no out-of-pocket costs. The Pharmacy
Partnership for Long-Term Care Program will provide complete management of the COVID-19
vaccination process. This program is:

- √ Free of charge to facilities
- ✓ Available for residents in all long-term care settings, including skilled nursing facilities (SNF), nursing homes, assisted living facilities, residential care homes, and adult family homes
- ✓ Available to all remaining LTCF staff members who have not been previously vaccinated for COVID-19 (e.g., through satellite, temporary, or off-site clinics)
- ✓ Available in most rural areas that may not have an easily accessible pharmacy
- Starting October 19, 2020, LTCFs will be able to opt in and indicate which pharmacy partner their
 facility prefers to have on-site. LTCFs are not mandated to participate in this program and can request
 to use their current pharmacy contracts to support COVID-19 vaccination. Nursing homes can sign up
 via the National Healthcare Safety Network, and assisted living facilities can sign up via an online
 survey they will receive. Link here for additional information on this partnership to provide COVID-19
 vaccines to long-term care facilities.

Where can I find COVID-19 vaccine information from federal sources?

- ✓ <u>Strategy for Distributing a COVID-19 Vaccine</u>
- ✓ COVID-19 Vaccination Program Interim Playbook
- ✓ COVID-19 Vaccine Distribution Process Infographic
- ✓ Operation Warp Speed Fact Sheet
- ✓ Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act
- ✓ Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry
- Other documents
 - ✓ CDC COVID-19 Vaccination Provider Agreement
 - ✓ Enforcement Discretion Relating to Certain Pharmacy Billing
 - ✓ CMS COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS)

 Billing
 - ✓ CDC Frequently Asked Questions about COVID-19 Vaccination

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