Pfizer-BioNTech COVID-19 Vaccine

GENERAL INFORMATION

m-RNA – or messenger RNA – is a molecule, composed of nucleotides linked in a unique order to convey genetic information for the cells to produce the proteins or antigens encoded by the mRNA. Once mRNA in a vaccine is inside of the body's cells, the cells use their genetic machinery to translate the genetic information and produce the antigens encoded by the mRNA vaccine. The antigens are then displayed on the cell surface, where they are recognized by the immune system which generates a response, including the production of antibodies against the antigen. In a mid-November 2020 analysis of 36,621 participants randomized 1:1 to vaccine or placebo, the efficacy of Pfizer-BioNTech COVID- 19 in preventing confirmed COVID-19 occurring at least 7 days after the second dose of vaccine was 95.0%.

INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE

The Pfizer BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine. See PHN Protocol 1.170 Community Located Vaccination Clinics.

RECOMMENDED POPULATIONS FOR PFIZER BIONTECH COVID-19 VACCINATION

- All persons aged **12** and older including people who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future
- The vaccine is a 2-dose primary series, spaced 21 days apart. The 2nd dose should be administered as close to the recommended 21day interval as possible, but not earlier than recommended. Second doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated.
- If it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer BioNTech COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. Delay in receiving the second dose does not result in starting the series over
- Vaccination must be with the same vaccine manufacturer for the 2 dose primary series. Vaccine manufacturers are not interchangeable for the 2 dose primary series.
- Additional clinical considerations can be found at: Interim Clinical Considerations for Use of COVID- 19 Vaccines | CDC
- **A Third** primary series dose is recommended for moderately and severely immunocompromised individuals.
    - Third dose should be from the same manufacturer as the 2 dose primary series, if not available, a different mRNA vaccine may be utilized.
    - Third dose should be administered at least 28 days after completion of the 2nd dose of mRNA COVID-19 vaccine.

- Single **booster** dose at least 6 months after completion of a primary series*
    - People 65 years and older and residents in long-term care settings should receive a booster shot
    - People 50-64 years old with underlying medical conditions should receive a booster shot
    - People 18–49 years old with underlying medical conditions may receive a booster shot depending on their individual benefits and risks;
    - People 18-64 who are at increased risk for Covid-19 exposure and transmission because of occupational or institutional setting may receive a booster shot based on their individual benefits and risks.
        - ✓ Examples of underlying medical conditions:
            - Cancer
            - Cerebrovascular disease
            - Chronic kidney disease
            - COPD
            - Diabetes type 1 or type 2
            - Heart conditions (such as heart failure, coronary artery disease or cardiomyopathies)
            - Obesity - BMI ≥ 30 kg/m2
            - Pregnancy or recent pregnancy
            - Smoking, current or former

SPECIAL POPULATIONS

- Pfizer BioNTech Covid-19 vaccine may be given to individuals who have had both symptomatic and asymptomatic recent infection and infection in the past.
- Vaccination of persons with known current COVID infection should be deferred until the person has recovered from the acute illness (if the patient had symptoms) and criteria has been met for them to discontinue isolation. There is no recommended minimum interval between infection and vaccination. Prior infection is NOT a contraindication to receiving vaccine
- Persons with the following should defer vaccination for 90 days after:
    - Receiving passive antibody therapy for COVID-19 before any dose or after the second dose
        - *There is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination*
    - History of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A) should consider delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis and recovered from illness
- Immunocompromised individuals should be advised that their immune response may be blunted and to continue infection protection precautions
- Persons with autoimmune conditions, history of Guillain-Barré or Bell's Palsy, who have no contraindications to vaccination, may receive an mRNA COVID-19 vaccine
- COVID-19 and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 and other vaccines on the same day, as well as co- administration within 14 days
- COVID-19 vaccination should not be delayed because of testing for tuberculosis (TB) infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon release assay (IGRA), can be done before, after, or during the same encounter as COVID-19 vaccination.
- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy): Consideration may be given to vaccination with Janssen COVID-19 vaccine.

*one or more dose of the primary series must be a Pfizer vaccine

People who have received one mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least 28 days after the mRNA vaccine dose to receive Janssen COVID-19 vaccine

PFIZER BIONTECH COVID 19 VACCINE SHOULD NOT BE USED/IS CONTRAINDICATED FOR:

- Children younger than **12** years
- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*

PRECAUTIONS

- Known polysorbate allergy is no longer a contraindication to mRNA vaccination; however, known polysorbate allergy is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.
    - If the patient wishes to pursue COVID19 vaccination,
        - ✓ Consult with the Regional Medical Director or designee for consideration or
        - ✓ Advise patient to consult with their personal healthcare provider
- Observe patients for 30 minutes after vaccination receipt. CDC considers a history of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]) as a precaution but not a contraindication to vaccination.
- People with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction
    - ✓ Specifically, people with a severe allergic reaction (e.g., anaphylaxis) after a previous dose of another type of vaccine or to a component of another type of authorized COVID-19 vaccine have a precaution to the Pfizer mRNA vaccine**
    - ✓ If the patient wishes to pursue COVID19 vaccination,
        - Consult with the Regional Medical Director or designee for consideration or
        - Advise patient to consult with their personal healthcare provider
        - Observe patients for 30 minutes after vaccination receipt

*For the purposes of this guidance, an immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration

**People with a contraindication to one type of the currently authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector). However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions

- Pregnant or lactating women:
    - There is no evidence that any of the COVID-19 vaccines affect current or future fertility
    - COVID-19 vaccines do not cause infection in the pregnant person or the fetus
    - No safety signals in animal studies
    - Reassuring early safety data on mRNA COVID-19 vaccines during pregnancy
    - Early data suggest mRNA COVID-19 vaccines during pregnancy are effective
    - If any questions, refer them to their personal healthcare provider.

COMMON SIDE EFFECTS

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm at the injection site, swelling (hardness and redness)
- General side effects: fatigue, headache, muscle pain, chills, joint pain, fever, nausea and vomiting
- Cough, shortness of breath and loss of the sense of taste and/or smell are **NOT** side effects of the Pfizer BioNTech COVID-19 vaccine.

PLAN

- Ask patient, parent or guardian about contraindications
- Have patient/guardian read Emergency Use Authorization Fact Sheet and sign consent.
- Counsel regarding side effects of vaccine
- Dose preparation:
    - Diluent with 1.8ml of sterile 0.9% Sodium Chloride -do not use any other diluent
    - Equalize vial pressure before removing the needle from the vial by withdrawing 1.8ml air into the empty dilute syringe
    - Gently invert the diluted vial 10 times to mix – Do not shake
- Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off- white suspension. During the visual inspection,
    - Verify the final dosing volume of 0.3 ml
    - Confirm there are no particulates, and that no discoloration is observed- Do not administer if vaccine is discolored or contains particulate matter
- Administer 0.3 ml intramuscularly in the deltoid muscle
- Persons with a history of an **immediate allergic reaction of any severity to a vaccine or injectable therapy and** persons with a **history of anaphylaxis due to any cause** should be observed for **30 minutes.** All other persons should be observed for 15 minutes
- Provide direction to patient, parent, or guardian for scheduling additional doses as appropriate
- Provide the patient the following documents:
    - Completed vaccination card
    - V-Safe information
    - CDC What to Expect after Getting a COVID-19 Vaccine
- Instruct patient/guardian to contact Health Department if adverse reaction occurs
- Document vaccine administration on the immunization clinic record
- Enter information into the TennIIS mass immunization module.
- Report to the Vaccine Adverse Event Reporting System (VAERS) if indicated:
    - vaccine administration errors whether associated with an adverse event,
    - serious adverse events (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and

- cases of COVID-19 that result in hospitalization or death.

REFERRAL INDICATORS:

Patients with a history of an immediate allergic reaction to an other injectable or intravenous medication/vaccine who wish to pursue COVID19 vaccination, should be advised to consult with their healthcare provider or consult with the Regional Medical Director or designee to coordinate vaccination.

REFERENCES

Tennessee COVID-19 Vaccination Plan; Tennessee Department of Health, 10/16/20, V1.0

COVID-19 Vaccine Storage and Handling Guidance; Tennessee Vaccine-Preventable Diseases and Immunization Program, 10/21/20

Tennessee Department of Health Memo #1: COVID-19 vaccine planning; November 16, 2020

Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COIVD-19) 09/22/2021

Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Cornoavirus Disease 2019 (COVID-19) in Individuals 12 Years of Age and Older. 09/22/2021

CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC 09/15/2021

Clinical considerations for use of an additional mRNA COVID-19 vaccine dose after a primary mRNA: COVID-19 vaccine series for immunocompromised people Neela D. Goswami, MD, MPH ACIP Meeting August 13, 2021

This protocol has been approved by CHS Medical Director jill c Obremskey, md, mmhc, FAAP