COVID-19 Vaccine (mRNA) (Lexi-Drugs)

Special Alerts

COVID-19 Vaccine (mRNA): Health Canada Authorizes Use of Moderna Vaccine Under Interim Order December 2020

Health Canada authorized the use of Moderna's COVID-19 Vaccine (mRNA) via an interim order.

Further information may be found at:

Health Canada Product Monograph: https://covid-vaccine.canada.ca/info/pdf/moderna-covid-19-vaccine-pm1.pdf

Health Canada Regulatory Decision Summary: https://covid-vaccine.canada.ca/info/regulatory-decision-summary-detailTwo.html?linkID=RDS00736

Health Canada (Interim Order): https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna/authorization.html

NACI: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-key-populations-early-covid-19-immunization.html

COVID-19 Vaccine (mRNA): FDA Issues Emergency Use Authorization of Moderna Vaccine December 2020

The FDA has issued an emergency use authorization (EUA) for Moderna's investigational coronavirus disease 2019 (COVID-19) vaccine (mRNA) for the prevention of COVID-19 in persons ≥18 years of age. While the safety and effectiveness of this investigational agent for use in the prevention of COVID-19 continues to be evaluated, the vaccine was shown in clinical trials to prevent COVID-19 occurring at least 14 days after the second dose; no significant safety concerns were identified.

Health care provider fact sheet: https://www.fda.gov/media/144637/download

Patient fact sheet: https://www.fda.gov/media/144638/download

Further information may be found at the following links, by scanning the QR code on the fact sheet or vaccine vial label, or by calling 1-866-663-3762:

Emergency Use Authorization letter: https://www.fda.gov/media/144636/download?utm_medium=email&utm_source=govdelivery

FDA: https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid

Moderna vaccine website: https://www.modernatx.com/covid19vaccine-eua

CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html

CDC V-safe: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

COVID-19 Vaccine (mRNA): FDA Issues Emergency Use Authorization of Pfizer-BioNTech Vaccine December 2020

The FDA has issued an emergency use authorization (EUA) for Pfizer-BioNTech's investigational coronavirus disease 2019 (COVID-19) vaccine (mRNA) for the prevention of COVID-19 in persons ≥16 years of age. While the safety and effectiveness of this investigational agent for use in the prevention of COVID-19 continues to be evaluated, the vaccine was shown in clinical trials to prevent COVID-19 occurring at least 7 days after the second dose; no significant safety concerns were identified.

Health care provider fact sheet: https://www.fda.gov/media/144413/download

Patient fact sheet: https://www.fda.gov/media/144414/download

Further information may be found at the following links, by scanning the QR code on the fact sheet or vaccine vial label, or by calling 1-877-829-2619:

Emergency Use Authorization letter: https://www.fda.gov/media/144412/download

FDA: https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

Pfizer-BioNTech vaccine website: https://www.cvdvaccine.com

CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html

CDC V-safe: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

COVID-19 Vaccine (mRNA): Health Canada Authorizes Use of Pfizer-BioNTech Vaccine Under Interim Order December 2020

Health Canada authorized the use of Pfizer-BioNTech's COVID-19 Vaccine (mRNA) via an interim order.

Further information may be found at:

Health Canada Product Monograph: https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf

Health Canada Regulatory Decision Summary: https://covid-vaccine.canada.ca/info/regulatory-decision-summary-detailTwo.html?linkID=RDS00730

Health Canada (Interim Order): https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html#a2.8

NACI: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-key-populations-early-covid-19-immunization.html

Brand Names: US

Moderna COVID-19 Vaccine; Pfizer-BioNTech COVID-19 Vacc

Brand Names: Canada

Moderna COVID-19 Vaccine; Pfizer-BioNTech COVID-19 Vacc

Pharmacologic Category

Vaccine; Vaccine, mRNA

Dosing: Adult

Coronavirus disease 2019 (COVID-19) prevention: Note: Vaccinated individuals should continue to observe effective public health measures (eg, wearing a mask, social distancing, limiting gatherings) due to current unknowns about duration of protection and impact on transmissibility (CDC 2021; Goodman 2020). The same vaccine should be used for both doses in the vaccination series (CDC 2021; FDA 2020a; FDA 2020b; Moderna Canadian product monograph; Pfizer-BioNTech Canadian product monograph); however, if 2 different mRNA COVID-19 vaccines are inadvertently administered, the dose or series does not need to be repeated (CDC 2021).

For both vaccines, the second dose should be administered as close to the recommended interval as possible. However, the second dose administered within ≤4 days from the recommended date of the second dose is considered valid. If the second dose is administered earlier than the 4-day grace period, then it does not need to be repeated. There is no maximum interval between the first and second dose; series does not need to be restarted if the second dose is administered after the recommended timeframe (CDC 2021).

Moderna vaccine: **IM:** 0.5 mL per dose for 2 doses administered 28 days apart (FDA 2020b; Moderna Canadian product monograph).

Pfizer-BioNTech vaccine: **IM:** 0.3 mL per dose for 2 doses administered 21 days apart (FDA 2020a; Pfizer-BioNTech Canadian product monograph).

Dosing: Geriatric

Refer to adult dosing.

Dosing: Renal Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Hepatic Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Pediatric

Coronavirus disease 2019 (COVID-19) prevention:

Note: Vaccinated individuals should continue to observe effective public health measures (eg, wearing a mask, social distancing, limiting gatherings) due to current unknowns about duration of protection and impact on transmissibility (CDC 2020; Goodman 2020). In patients ≥18 years of age, the same vaccine should be used for both doses in the vaccination series (CDC 2020; FDA 2020a; FDA 2020b); however, if 2 different mRNA COVID-19 vaccines are inadvertently administered, the dose or series does not need to be repeated (CDC 2020). For patients <18 years of age, only the Pfizer-BioNTech vaccine should be used.

For both vaccines, the second dose should be administered as close to the recommended interval as possible. However, the second dose administered within ≤4 days from the recommended date is

considered valid. If the second dose is administered earlier than the 4-day grace period, then it does not need to be repeated. There is no maximum interval between the first and second dose (CDC 2020).

Pfizer-BioNTech COVID-19 vaccine: Adolescents ≥16 years of age: IM: 0.3 mL per dose for 2 doses administered 21 days apart (FDA 2020a; Pfizer Canadian product monograph).

Note: The National Advisory Committee on Immunization Practices of Canada provides the following discretionary recommendation: A complete 2-dose series of the Pfizer-BioNTech vaccine may be offered to individuals 12 to 15 years of age who are at very high risk of severe outcomes of COVID-19 (eg, due to a preexisting medical condition known to be associated with increased risk of hospitalization or mortality) **and** are at increased risk of exposure (eg, due to living in a congregate care facility); in these cases, expected benefits must outweigh the potential risks for the individual, and the informed consent discussion must include the insufficiency of evidence on the use of COVID-19 vaccines in this population (Health Canada 2020b).

Moderna COVID-19 vaccine: Adolescents ≥18 years of age: IM: 0.5 mL per dose for 2 doses administered 28 days apart (FDA 2020b; Moderna Canadian product monograph).

Dosing: Renal Impairment: Pediatric

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Hepatic Impairment: Pediatric

There are no dosage adjustments provided in the manufacturer's labeling.

Use: Labeled Indications

See Use: Off Label: Adult.

Use: Off-Label: Adult

Coronavirus disease 2019 (COVID-19) prevention Level of Evidence [A]

Moderna COVID-19 vaccine (mRNA): Data from a phase 3 randomized, placebo-controlled, observer-blinded study support the use of the Moderna vaccine in preventing symptomatic COVID-19 (including severe infection) caused by SARS-CoV-2 virus in persons ≥18 years of age (RefBaden 2020).

Pfizer-BioNTech COVID-19 vaccine (mRNA): Data from a phase 2/3 randomized, placebo-controlled, observer-blinded study support the use of the Pfizer-BioNTech vaccine in preventing symptomatic COVID-19 (including severe infection) caused by SARS-CoV-2 virus in persons ≥16 years of age (RefPolack 2020).

Note: The Pfizer-BioNTech and Moderna COVID-19 vaccines are available under emergency use authorizations (EUA) from the FDA (RefFDA 2020aFDA 2020b) and under interim orders from Health Canada (RefHealth Canada 2020aHealth Canada 2020b).

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine in persons ≥16 years of age (RefCDC/ACIP [Oliver 2020]) and the Moderna COVID-19 vaccine in persons ≥18 years of age to prevent COVID-19 (RefCDC/ACIP [Oliver 2021]).

The ACIP recommends the following allocation of initial supplies of COVID-19 vaccine; refer to state/local health departments for more information.

Phase 1a: Vaccine should be offered to health care personnel (paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials) and residents of long-term care facilities (adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently) (Ref CDC/ACIP [Dooling 2020]).

Phase 1b: Vaccine should be offered to persons ≥75 years of age and non-health care frontline essential workers (the subset of essential workers likely at highest risk for work-related exposure to SARS-CoV-2 because their work-related duties must be performed on-site and involve being in close proximity [<6 feet] to the public or to coworkers) (Ref CDC/ACIP [Dooling 2021]).

The ACIP classifies the following as frontline essential workers:

- First responders (eg, firefighters, police officers)
- Corrections officers
- Food and agricultural workers
- US Postal Service workers
- Manufacturing workers
- Grocery store workers
- Public transit workers
- Teachers and school support staff members
- Childcare workers

Phase 1c: Vaccine should be offered to persons 65 to 74 years of age, persons 16 to 64 years of age with high-risk medical conditions, and essential workers not recommended for vaccination in Phase 1b (Ref CDC/ACIP [Dooling 2021]).

High-risk medical conditions associated with increased risk for severe COVID-19-associated illness include:

- Cancer
- Chronic kidney disease
- Chronic obstructive pulmonary disease
- Heart conditions (eg, heart failure, coronary artery disease, cardiomyopathies)
- Immunocompromised due to solid organ transplant
- Obesity (BMI ≥30 kg/m^2)
- Sickle cell disease

• Smoking

• Type 2 diabetes mellitus

• Pregnancy

In Phase 1c, the ACIP recommends vaccination for the following sectors of essential workers who have not yet been vaccinated:

• Transportation and logistics

• Water and wastewater

• Food service

• Shelter and housing (eg, construction)

• Finance (eg, bank tellers)

• Information technology and communications

• Energy

• Legal

• Media

• Public safety (eg, engineers)

• Public health workers

Phase 2: All persons ≥16 years of age not previously recommended for vaccination ([Ref]CDC/ACIP [Dooling 2021]).

Canadian Guidance: The National Advisory Committee on Immunization (NACI) has also made recommendations for prioritization of initial COVID-19 vaccine supplies and on the use of COVID-19 vaccines; see recommendations for details ([Ref]Health Canada 2020bHealth Canada 2020c).

Level of Evidence Definitions

Level of Evidence Scale

A - Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support the off-label use. Further research is unlikely to change confidence in the estimate of benefit.

B - Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.

C - Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care), unsystematic clinical experience, or from potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.

G - Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

Clinical Practice Guidelines

ACIP, "General Best Practice Guidelines for Immunization"

CDC/ACIP, “The Advisory Committee on Immunization Practices’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020,” 2020

CDC/ACIP, “The Advisory Committee on Immunization Practices’ Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020,” 2020

CDC, "Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States," 2021

IDSA, "Vaccination of the Immunocompromised Host," 2013

NACI, "Recommendations on the Use of COVID-19 Vaccine(s)," 2020

NACI/CATMAT, "Canadian Immunization Guide"

Administration: IM

Administer IM in the deltoid muscle. Do not inject intravascularly, subcutaneously, or intradermally (FDA 2020a; FDA 2020b). Do not routinely administer simultaneously with other vaccines; allow a minimum interval of 14 days before or after other vaccines. If administration of other vaccines is needed and the benefits outweigh the unknown risks (eg, tetanus for wound management, measles or hepatitis A during an outbreak) or to avoid barriers or delays to coronavirus disease 2019 (COVID-19) vaccination, may consider <14-day interval. If administered within 14 days of another vaccine, doses of either vaccine do not need to be repeated (CDC 2021). To prevent syncope-related injuries, adolescents and adults should be vaccinated while seated or lying down (ACIP [Ezeanolue 2020]). US recipients or caregivers should be given a vaccination card with the date when the recipient needs to return for the second dose (FDA 2020a; FDA 2020b).

Moderna vaccine: Prior to use, gently swirl vial; do not shake (FDA 2020b; Moderna Canadian product monograph). Each vial will contain 10 doses of 0.5 mL per dose; an eleventh dose may be obtainable. Do not pool partial doses remaining in vials into a full dose (FDA 2021).

Pfizer-BioNTech vaccine: Must be diluted prior to use; gently invert diluted vial 10 times prior to use; do not shake (FDA 2020a; Pfizer-BioNTech Canadian product monograph). Extract doses from vial preferably using a low dead-volume syringe and/or needle. Each vial will contain up to 6 doses of 0.3 mL per dose; if standard syringes and needles are used, there may be volume sufficient for only 5 doses. Do not pool partial doses remaining in vials into a full dose (FDA 2020a).

For patients at risk of hemorrhage following IM injection, the vaccine should be administered IM if, in the opinion of the physician familiar with the patient's bleeding risk, the vaccine can be administered by this route with reasonable safety. If the patient receives antihemophilia or other similar therapy, IM vaccination can be scheduled shortly after such therapy is administered. A fine needle (23-gauge or smaller) can be used for the vaccination and firm pressure applied to the site (without rubbing) for at

least 2 minutes. The patient should be instructed concerning the risk of hematoma from the injection. Patients on anticoagulant therapy should be considered to have the same bleeding risks and treated as those with clotting factor disorders (ACIP [Ezeanolue 2020]).

Administration: Pediatric

Parenteral: IM: Administer IM in the deltoid muscle (FDA 2020a; FDA 2020b). Do not inject intravascularly, subcutaneously, or intradermally. Do not administer simultaneously with other vaccines; allow a minimum interval of 14 days before or after other vaccines. If administered within 14 days of another vaccine, doses of either vaccine do not need to be repeated (CDC 2020). To prevent syncope-related injuries, adolescents should be vaccinated while seated or lying down (ACIP [Ezeanolue 2020]). US recipients or caregivers should be given a vaccination card with the date when the recipient needs to return for the second dose (FDA 2020a; FDA 2020b).

Pfizer-BioNTech vaccine: Adolescents ≥16 years of age: Must be diluted prior to use; gently invert diluted vial 10 times prior to use; do not shake. Extract doses from vial preferably using a low dead-volume syringe and/or needle. Each vial will contain up to 6 doses of 0.3 mL per dose; if standard syringes and needles are used, there may be volume sufficient for only 5 doses. Do not pool partial doses remaining in vials into a full dose (FDA 2020a).

Moderna vaccine: Adolescents ≥18 years of age: Prior to use, gently swirl vial; do not shake (FDA 2020b).

For patients at risk of hemorrhage following IM injection, the vaccine should be administered IM if, in the opinion of the physician familiar with the patient's bleeding risk, the vaccine can be administered by this route with reasonable safety. If the patient receives antihemophilia or other similar therapy, IM vaccination can be scheduled shortly after such therapy is administered. A fine needle (23-gauge or smaller) can be used for the vaccination and firm pressure applied to the site (without rubbing) for at least 2 minutes. The patient should be instructed concerning the risk of hematoma from the injection. Patients on anticoagulant therapy should be considered to have the same bleeding risks and treated as those with clotting factor disorders (ACIP [Ezeanolue 2020]).

Storage/Stability

Moderna vaccine: Store intact vial frozen at -25°C to -15°C (-13°F to 5°F) in original carton to protect from light. Do not store on dry ice or below -40°C (-40°F). May store under refrigeration at 2°C to 8°C (36°F to 46°F) for up to 30 days or for up to 12 hours at room temperature at 8°C to 25°C (46°F to 77°F) prior to use. After first use, may store for up to 6 hours at 2°C to 25°C (36°F to 77°F). Do not refreeze thawed vials.

Pfizer-BioNTech vaccine: Store intact vial frozen at -80°C to -60°C (-112°F to -76°F) in original carton to protect from light. If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 vaccine arrives may be used as temporary storage when consistently refilled to the top of the container with dry ice; refer to re-icing guidelines in thermal container for more information. May store under refrigeration at 2°C to 8°C (35°F to 46°F) for up to 5 days or at room temperature up to 25°C (77°F) for up to 2 hours. Minimize exposure to room light; avoid exposure to direct sunlight and UV light. Thawed vials can be handled in room light conditions. After dilution, use immediately or may store for up to 6 hours at 2°C to 25°C (35°F to 77°F). Do not refreeze thawed vials.

Preparation for Administration: Adult

Moderna vaccine: Must be thawed prior to administration. Two methods may be used to thaw: To thaw in the refrigerator, transfer to refrigerator (2°C to 8°C [36°F to 46°F]) for 2.5 hours, then allow thawed vial to stand at room temperature for 15 minutes prior to use; or thaw vial at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour. Gently swirl vial after thawing and between each dose withdrawal. Do **not** shake or dilute the vaccine. Liquid should be a white to off-white suspension and may contain white or translucent product-related particles; discard vial if any other discoloration or particulates are present. Use within 6 hours after initial puncture. Each vial will contain 10 doses of 0.5 mL per dose; an eleventh dose may be obtainable. Do not pool partial doses remaining in vials into a full dose (FDA 2021). Do not refreeze thawed vials (FDA 2020b; Moderna Canadian product monograph).

Pfizer-BioNTech vaccine: Must be thawed prior to dilution. To thaw, transfer to refrigerator (2°C to 8°C [35°F to 46°F]); may take 2 or 3 hours for a 25-vial or 195-vial pack, respectively, to thaw. For immediate use, thaw at room temperature up to 25°C (77°F) for 30 minutes. Allow the thawed vial to come to room temperature and gently invert 10 times; do not shake. Dilute with 1.8 mL preservative-free NS only (not supplied in carton); do not add more than 1.8 mL of diluent. Do not use bacteriostatic NS or any other diluent. Gently invert 10 times; do not shake. Discard if particulates or discoloration are present (liquid should be white to off-white and may contain white to off-white opaque amorphous particles) or if not used within 6 hours after dilution. Extract doses from vial, preferably using a low dead-volume syringe and/or needle. Each vial will contain up to 6 doses of 0.3 mL per dose; if standard syringes and needles are used, there may be volume sufficient for only 5 doses. Do not pool partial doses remaining in vials into a full dose. Do not refreeze thawed vials (FDA 2020a; Pfizer-BioNTech Canadian product monograph).

Preparation for Administration: Pediatric

Moderna vaccine: Must be thawed prior to administration. Two methods may be used to thaw: To thaw in the refrigerator, transfer to refrigerator (2°C to 8°C [36°F to 46°F]) for 2.5 hours, then allow thawed vial to stand at room temperature for 15 minutes prior to use; or thaw by setting vial at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour. Gently swirl vial after thawing and between each dose withdrawal. Do not shake or dilute the vaccine. Liquid should be a white to off-white suspension and may contain white or translucent product-related particles; if any other discoloration or particulate are present, discard vial. Use within 6 hours after initial puncture. Do not refreeze thawed vials (FDA 2020b).

Pfizer-BioNTech vaccine: Must be thawed prior to dilution. To thaw, transfer to refrigerator (2°C to 8°C [35°F to 46°F]); may take 2 or 3 hours for a 25-vial or 195-vial pack, respectively, to thaw. For immediate use, thaw at room temperature up to 25°C (77°F) for 30 minutes. Allow the thawed vial to come to room temperature and gently invert 10 times; do not shake. Dilute with 1.8 mL preservative-free NS only (not supplied in carton); do not add more than 1.8 mL of diluent. Do not use bacteriostatic NS or any other diluent. Gently invert 10 times; do not shake. Discard if particulates or discoloration are present (liquid should be white to off-white and may contain white to off-white opaque amorphous particles) or if not used within 6 hours after dilution. Extract doses from vial, preferably using a low dead-volume syringe and/or needle. Each vial will contain up to 6 doses of 0.3 mL per dose; if standard syringes and needles are used, there may be volume sufficient for only 5 doses. Do not pool partial doses remaining in vials into a full dose. Do not refreeze thawed vials (FDA 2020a).

Medication Patient Education with HCAHPS Considerations

Health care provider fact sheet: https://www.fda.gov/media/144413/download

Patient fact sheet: https://www.fda.gov/media/144414/download

Medication Safety Issues

Sound-alike/look-alike issues:

Under the FDA's Emergency Use Authorization (EUA), the various coronavirus disease 2019 (COVID-19) vaccines will not have proprietary brand names which may lead to confusion among products (eg, different dosage volumes, vaccination schedules, storage requirements).

Prescribing and Access Restrictions

The Pfizer-BioNTech and Moderna coronavirus disease 2019 (COVID-19) vaccines are not commercially available; they are available as part of ongoing clinical trials under emergency use authorizations (EUA) from the FDA. The US federal government, in conjunction with state health departments, will allocate a supply of the vaccines to individual sites of care across the United States.

As part of the EUA, fact sheets pertaining to emergency use of the COVID-19 vaccines are required to be provided to health care providers and recipients/caregivers, and certain mandatory requirements for administration under the EUA must be met as outlined in the FDA EUA letter.

Moderna COVID-19 vaccine: The health care provider fact sheet is located at: https://www.fda.gov/media/144637/download. The patient fact sheet is located at: https://www.fda.gov/media/144638/download.

Pfizer-BioNTech COVID-19 vaccine: The health care provider fact sheet is located at: https://www.fda.gov/media/144413/download. The patient fact sheet is located at: https://www.fda.gov/media/144414/download.

The vaccine provider should include vaccination information in the state/local jurisdiction Immunization Information System (IIS) or other designated system and provide a paper record card as a backup.

Additionally, the vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS) (https://vaers.hhs.gov/reportevent.html or 1-800-822-7967):

- vaccine administration errors whether or not associated with an adverse event
- serious adverse events (irrespective of attribution to vaccination)
- cases of multisystem inflammatory syndrome (MIS) in adults and children
- cases of COVID-19 that result in hospitalization or death

The vaccination provider is also responsible for responding to FDA requests for more information. Additional adverse events may be reported to VAERS and the manufacturer. Adverse events related to the Pfizer-BioNTech vaccine may be reported to Pfizer via https://www.pfizersafetyreporting.com, 1-800-438-1985, or via fax at 1-866-635-8337. Adverse events related to the Moderna vaccine may be

reported to ModernaTx, Inc. via ModernaPV@modernatx.com (email), 1-866-663-3762, or via fax at 1-866-599-1342.

Contraindications

Known history of a severe allergic reaction (eg, anaphylaxis) or immediate allergic reaction (regardless of severity and occurring within 4 hours) to coronavirus disease 2019 (COVID-19) mRNA vaccine or any component of the formulation; immediate allergic reaction (regardless of severity) to polysorbate (due to potential cross-reactive hypersensitivity to polyethylene glycol) (CDC 2021).

Warnings/Precautions

Concerns related to adverse effects:

• Anaphylactoid/hypersensitivity reactions: Anaphylaxis has been reported with the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine (mRNA) during vaccination outside of clinical trials. Use the vaccine with caution in persons with history of immediate allergic reaction to any other vaccine or injectable therapy (eg, IM, IV, SubQ vaccines or therapies not related to a component of the mRNA vaccine or polysorbate). A history of allergic reaction (regardless of severity) to noninjectable items other than polyethylene glycol and polysorbate (eg, food, pets, oral medications [including oral equivalents of injectable medications]) is not a contraindication or precaution to using the vaccine (CDC 2021). Immediate treatment (including epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during vaccine use (ACIP [Ezeanolue 2020]; FDA 2020a). Administration of antihistamines prior to vaccination to prevent allergic reactions is not recommended (CDC 2021).

• Shoulder injury related to vaccine administration: Vaccine administration that is too high on the upper arm may cause shoulder injury (eg, shoulder bursitis, tendinopathy) resulting in shoulder pain and reduced range of motion following injection. Use proper injection technique for vaccines administered in the deltoid muscle (eg, injecting in the central, thickest part of the muscle) to reduce the risk of shoulder injury related to vaccine administration (Cross 2016; Foster 2013).

• Syncope: Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (eg, skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination. Procedures should be in place to avoid injuries from falling and to restore cerebral perfusion if syncope occurs (ACIP [Ezeanolue 2020]).

Disease-related concerns:

• Acute illness: The decision to administer or delay vaccination because of current or recent febrile illness depends on the severity of symptoms and the etiology of the disease. In general, it is recommended to defer vaccine administration in patients with moderate or severe acute febrile illness (with or without fever) and to provide vaccination in patients with mild acute illness (with or without fever) (ACIP [Ezeanolue 2020]). Although not included in the Pfizer or Moderna emergency use authorization (EUA) documentation from the FDA, the Canadian product information for the Pfizer vaccine recommends postponing vaccination in patients with acute severe febrile illness (Pfizer-BioNTech Canadian product monograph). In addition, the Canadian product information for the Moderna vaccine states to consider postponing vaccination in patients with acute severe febrile illness or severe acute infection (Moderna Canadian product monograph).

• Bleeding disorders: Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration; if the patient receives antihemophilia or other similar therapy, IM injection can be scheduled shortly after such therapy is administered (ACIP [Ezeanolue 2020]).

• SARS-CoV-2 infection or exposure (CDC 2021):

- *Persons with current or prior history of COVID-19 or asymptomatic SARS-CoV-2 infection:* Based on data from clinical trials, vaccination in persons with evidence of prior SARS-CoV-2 infection is safe. Defer vaccination in persons with known current SARS-CoV-2 infection until the person has recovered from acute illness (if symptomatic) and no longer requires isolation. This applies to those persons who develop SARS-CoV-2 infection before receiving any vaccine doses and also those who develop infection after the first dose but before the second dose. Based on current evidence that reinfection is uncommon within 90 days following initial infection, vaccination may be delayed until near the end of the 90-day period. For vaccinated persons who subsequently develop COVID-19, prior receipt of an mRNA COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.

- *Persons who received passive antibody COVID-19 therapy:* There are currently no data on the safety and efficacy of mRNA COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. As a precaution, it is recommended to defer vaccination (first dose or second dose) for at least 90 days following receipt of COVID-19 convalescent plasma or anti-COVID-19 monoclonal antibody therapy. There is no recommended minimum interval between vaccination and antibody therapies that are not specific to COVID-19.

- *Persons with known SARS-CoV-2 exposure:* Vaccination for outbreak management or postexposure prophylaxis is not currently recommended. Persons with known exposure should wait to seek vaccination until after their quarantine period has ended. For persons in congregate settings (eg, long-term care facilities, correctional facilities, homeless shelters), residents with known exposure may be vaccinated; however, if COVID-19 is strongly suspected and viral testing results are pending, consider deferring vaccination.

Concurrent drug therapy issues:

• Anticoagulant therapy: Use with caution in patients receiving anticoagulant therapy; bleeding/hematoma may occur from IM administration (ACIP [Ezeanolue 2020]).

• Medications for postvaccination adverse reactions: Antipyretic or analgesic medications (eg, acetaminophen, nonsteroidal anti-inflammatory drugs) may be taken for the treatment of postvaccination local/systemic symptoms (if medically appropriate). However, routine prophylactic administration of these medications for the purpose of preventing postvaccination symptoms is not currently recommended; impact on antibody response is unknown (CDC 2021).

• Vaccines: Do not routinely administer simultaneously with other vaccines; allow a minimum interval of 14 days before or after other vaccines. If administration of other vaccines is needed and the benefits outweigh the unknown risks (eg, tetanus for wound management, measles or hepatitis A during an outbreak) or to avoid barriers or delays to COVID-19 vaccination, may consider <14-day interval. If inadvertently administered within 14 days of another vaccine, doses of either vaccine do not need to be

repeated. Safety and efficacy of COVID-19 vaccine (mRNA) administered simultaneously with other vaccines is unknown (CDC 2021).

Dosage form specific issues:

• Interchangeability: There are no data on the interchangeability of COVID-19 vaccines. The second dose should be the same product used for the first dose (CDC 2021; FDA 2020a; FDA 2020b; Moderna Canadian product monograph; Pfizer-BioNTech Canadian product monograph); however, if 2 different mRNA COVID-19 vaccines are inadvertently administered, the dose or series does not need to be repeated (CDC 2021).

• Traceability: The vaccine name and batch number must be recorded for each patient in order to improve traceability (FDA 2020a; FDA 2020b; Moderna Canadian product monograph; Pfizer-BioNTech Canadian product monograph).

Special populations:

• Altered immunocompetence: Immunocompromised persons (including those with HIV or receiving immunosuppressant therapy) may have a diminished immune response to the vaccine (CDC 2021; FDA 2020a; FDA 2020b; Moderna Canadian product monograph; Pfizer-BioNTech Canadian product monograph). Patients with stable HIV infection were included in the clinical trials (FDA 2020a; FDA 2020b). Although data are not currently available to establish vaccine safety and efficacy in immunocompromised persons, the Centers for Disease Control and Prevention (CDC) recommends vaccination of immunocompromised patients if there are no contraindications. Revaccination is not recommended after immune competence is regained for those persons who received vaccination during chemotherapy or other immunosuppressive therapy (CDC 2021).

• Autoimmune conditions: Although data are not currently available to establish vaccine safety and efficacy in patients with autoimmune conditions or inflammatory disorders, the CDC recommends vaccination of patients with autoimmune conditions if there are no contraindications (CDC 2021).

• Guillain-Barré syndrome: Persons with a history of Guillain-Barré syndrome may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination (CDC 2021).

Other warnings/precautions:

• Effective immunity: Vaccination may not result in effective immunity in all patients (FDA 2020a; FDA 2020b; Moderna Canadian product monograph; Pfizer-BioNTech Canadian product monograph). Response depends upon multiple factors (eg, type of vaccine, age of patient) and may be improved by administering the vaccine at the recommended dose, route, and interval (ACIP [Ezeanolue 2020]). There is currently insufficient evidence to support efficacy of COVID-19 mRNA vaccines in preventing death, hospitalization, and asymptomatic infection, or in reducing transmission of SARS-CoV-2; studies are ongoing (Health Canada 2020b). Vaccines may not be effective if administered during periods of altered immune competence (ACIP [Ezeanolue 2020]; CDC 2021).

Reproductive Considerations

Coronavirus disease 2019 (COVID-19) (mRNA) vaccines are investigational vaccines permitted for use under FDA emergency use authorization (EUA). Routine pregnancy testing is not required prior to

vaccination (ACOG 2020; CDC 2021). Based on the mechanism of action, COVID-19 mRNA vaccines are not expected to increase the risk of infertility. Use should not be withheld from individuals planning a pregnancy who meet the criteria for vaccination based on the Advisory Committee on Immunization Practices recommended priority groups. Pregnancy does not need to be delayed following vaccination (ACOG 2020).

Pregnancy Considerations

Coronavirus disease 2019 (COVID-19) (mRNA) vaccines are investigational vaccines permitted for use under FDA emergency use authorization (EUA). Pregnant patients were excluded in the original clinical studies (Jackson 2020; Walsh 2020). Adverse events were not observed in animal reproduction studies using the Moderna COVID-19 vaccine (FDA 2020b); animal reproduction studies using the Pfizer BioNTech product are ongoing (ACOG 2020).

Information following inadvertent administration to patients later determined to be pregnant is limited at this time. Based on available information, mRNA vaccines are not likely to be a risk to pregnancy; however, safety data specific to pregnancy is not yet available. Studies in pregnant patients are planned (ACOG 2020; CDC 2021).

The risk of severe illness from COVID-19 infection is increased in pregnant patients and pregnancy is one of the high-risk medical conditions defined by the Centers for Disease Control and Prevention (CDC). The decision to vaccinate during pregnancy should be individualized, considering the individual risks of infection and severe disease with the available safety information and benefits of the vaccine. Pregnant patients who are otherwise prioritized for vaccination may choose to be vaccinated and the COVID-19 (mRNA) vaccine should not be withheld (ACOG 2020; CDC 2021). If pregnancy occurs after the first dose, the second dose should be administered as otherwise recommended (ACOG 2020). Information related to COVID-19 (mRNA) vaccines continues to emerge; refer to current guidelines for vaccinating pregnant patients.

Data collection to monitor maternal and infant outcomes following exposure to COVID-19 vaccines during pregnancy is ongoing. Health care providers are encouraged to enroll patients exposed to the Moderna COVID-19 vaccine during pregnancy in the Moderna Pregnancy Registry (1-866-663-3762). All patients who become pregnant within 30 days of exposure to a COVID-19 (mRNA) vaccine are encouraged to enroll in the CDC V-SAFE monitoring program (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html) (ACOG 2020). Health care providers are encouraged to enroll pregnant patients exposed to COVID-19 vaccines in the Organization of Teratology Information Specialists (OTIS) pregnancy registry (877-311-8972; https://mothertobaby.org/join-study/).

Breast-Feeding Considerations

Coronavirus disease 2019 (COVID-19) (mRNA) vaccines are investigational vaccines permitted for use under FDA emergency use authorization (EUA). There are no specific data on the effects of mRNA vaccines on the breastfed infant or on milk production/excretion (CDC 2021; FDA 2020a; FDA 2020b).

Based on available information, mRNA vaccines are not likely to be a risk to breastfeeding (CDC 2021). Patients who are breastfeeding and meet the criteria for vaccination based on the Advisory Committee on Immunization Practices recommended priority groups may choose to be vaccinated and should be offered the COVID-19 (mRNA) vaccine (ACOG 2020; CDC 2021). The initiation of breastfeeding does not

need to be avoided and breastfeeding does not need to be discontinued in patients who are vaccinated (ACOG 2020).

Health care providers are encouraged to enroll breastfeeding patients exposed to COVID-19 vaccines in the Organization of Teratology Information Specialists (OTIS) pregnancy registry (877-311-8972; https://mothertobaby.org/join-study/).

Adverse Reactions (Significant): Considerations

Hypersensitivity reactions

Anaphylaxis has been reported with the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine (mRNA) outside of clinical trials ([RefCDC 2020]). During clinical trials, hypersensitivity-related reactions occurred rarely ([RefCDC 2020]).

Risk factors:

• History of severe allergic reactions (eg, anaphylaxis) to any other vaccine or injectable therapy (eg, IM, IV, SubQ) ([RefCDC 2020])

Bell's palsy

Bell's palsy was reported with both the Pfizer-BioNTech and Moderna coronavirus disease 2019 (COVID-19) vaccine (mRNA) during clinical trials (Pfizer: 4 cases, 0 placebo cases; Moderna: 3 cases, 1 placebo case) ([RefFDA 2020aFDA 2020b]). The incidence of Bell's palsy was similar to the general population incidence and data are insufficient to determine a causal relationship at this time ([RefCDC 2020FDA 2020aFDA 2020b]). In the absence of a contraindication to vaccination, patients with a history of Bell's palsy may receive the vaccine ([RefCDC 2020]). Report any occurrence of Bell's palsy following vaccination ([RefCDC 2020]).

Onset: Varied; Pfizer: After dose 1, day 37. After dose 2, day 3, 9, and 48 ([RefFDA 2020a]). Moderna: Day 22, 28, and 32 after vaccination ([RefFDA 2020b]).

Local reactions

Local reactions include **pain at injection site** (most common), and less commonly, **erythema at injection site** and **swelling at injection site**. Injection site pain was reported more frequently in younger patients (18 to 55 years of age) and was more likely to be moderate in severity compared to patients >55 years with the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine (mRNA). Similarly, injection site pain was reported more frequently in younger patients (18 to 64 years of age) with the Moderna (COVID-19) vaccine (mRNA). In general, local reactions were mild to moderate in severity and resolved after a mean duration of ~2.5 days (with some cases resolving after ~30 days). The proportion of local reactions did not increase after the second dose ([RefPolack 2020]). Local **hypersensitivity reaction** (including injection site rash and injection site urticaria) occurred with the Moderna (COVID-19) vaccine (mRNA).

Onset: Varied; within 7 days after either injection ([RefPolack 2020]).

Systemic reactions (excluding hypersensitivity)

The most common systemic reactions include **fatigue** and **headache**. Other systemic reactions include **arthralgia** (new/worsened), **myalgia** (new/worsened), **chills**, **fever**, **diarrhea**, **nausea**, and **vomiting**. Frequency and severity of systemic events were higher in younger patients (18 to 55 years of age) than

patients >55 years with the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine (mRNA); frequency and severity were also higher after the second dose compared to the first dose, except for diarrhea and vomiting (similar regardless of dose). Similarly, the frequency and severity of systemic events was reported more frequently in younger patients (18 to 64 years of age) and after the second dose with the Moderna COVID-19 vaccine (mRNA). In general, systemic reactions were mild to moderate in severity and resolved within 1 to 2 days after vaccination ([RefCDC 2020]). Intractable nausea and vomiting requiring hospitalization occurred in one patient who received the Moderna COVID-19 vaccine (mRNA). This patient had a history of severe headache and nausea. An unsolicited systemic reaction possibly attributed to vaccine was **lymphadenopathy**.

Onset: Rapid; within 3 days after either injection ([RefCDC 2020])

Adverse Reactions

The following adverse reactions and incidences are derived from the FDA issued emergency use authorizations (EUAs) unless otherwise specified. Refer to EUAs for specific vaccines for information regarding reporting adverse reactions (FDA 2020a; FDA 2020b).

>10%:

Gastrointestinal: Diarrhea (Pfizer: 8% to 11% [placebo: 6% to 12%]; higher in younger patients), nausea and vomiting (Moderna: 9% to 21% [placebo: 4% to 8%]; higher in younger patients and with second dose)

Local: Pain at injection site (66% to 90% [placebo: 8% to 19%]; higher in younger patients), swelling at injection site (4% to 13% [placebo: 0.2% to 1.2%])

Nervous system: Chills (Moderna: 5% to 49%; Pfizer: 6% to 35% [placebo: 3% to 6%]; higher in younger patients and with second dose), fatigue (33% to 68% [placebo: 17% to 33%]; higher in younger patients and with second dose), headache (Moderna: 25% to 63%; Pfizer: 25% to 52% [placebo: 18% to 34%]; higher in younger patients and with second dose)

Neuromuscular & skeletal: Arthralgia (Moderna: 16% to 46%; Pfizer: 9% to 22% [placebo: 4% to 12%]; higher in younger patients and with second dose), axillary swelling (Moderna: Including axillary tenderness; 6% to 16% [placebo: 3% to 5%]; higher in younger patients), myalgia (Moderna: 20% to 62%; Pfizer: 14% to 37% [placebo: 5% to 14%]; higher in younger patients and with second dose)

Miscellaneous: Fever (<1% to 16% [placebo: 0.1% to 0.9%]; higher in younger patients and with second dose)

1% to 10%:

Gastrointestinal: Nausea (Pfizer: 1%), vomiting (Pfizer: <1% to 2% [placebo: 0.3% to 1.2%]; higher in younger patients)

Hematologic & oncologic: Lymphadenopathy (≤1% [placebo: <0.1% to 0.6%]; unsolicited) (Polack 2020)

Hypersensitivity: Hypersensitivity reaction (Moderna: Including injection site rash and injection site urticaria; 2% [placebo: 1.1%])

Local: Erythema at injection site (2% to 9% [placebo: 0.4% to 1.1%])

<1%: Nervous system: Malaise (Pfizer)

Frequency not defined:

Dermatologic: Facial swelling (Moderna)

Gastrointestinal: Appendicitis (Pfizer; unsolicited; data insufficient to determine causal relationship)

Hypersensitivity: Anaphylaxis (CDC 2020)

Nervous system: Bell's palsy (unsolicited; data insufficient to determine causal relationship)

Neuromuscular & skeletal: Joint injury (shoulder; unsolicited) (Polack 2020)

Allergy and Idiosyncratic Reactions

- Aluminum Allergy With Vaccines
- Aminoglycoside Allergy

Metabolism/Transport Effects

None known.

Drug Interactions Open Interactions

Acetaminophen: May diminish the therapeutic effect of Vaccines. Management: Consider avoiding routine prophylactic use of acetaminophen before or during vaccine administration when possible. Acetaminophen is still recommended to treat fevers and/or pain that occurs after vaccination. *Risk D: Consider therapy modification*

Bamlanivimab: May diminish the therapeutic effect of COVID-19 Vaccine (mRNA). Management: Postpone administration of the vaccine until at least 90 days after treatment with bamlanivimab to minimize any possible interference with immune response to the vaccine. *Risk D: Consider therapy modification*

Casirivimab and Imdevimab: May diminish the therapeutic effect of COVID-19 Vaccine (mRNA). Management: Postpone administration of the vaccine until at least 90 days after treatment with casirivimab and imdevimab to minimize any possible interference with immune response to the vaccine. *Risk D: Consider therapy modification*

Immunosuppressants: May diminish the therapeutic effect of COVID-19 Vaccine (mRNA). *Risk C: Monitor therapy*

Propacetamol: May diminish the therapeutic effect of Vaccines. Management: Consider avoiding routine prophylactic use of propacetamol before or during vaccine administration when possible. Propacetamol is still recommended to treat fevers and/or pain that occurs after vaccination. *Risk D: Consider therapy modification*

Test Interactions

Coronavirus disease 2019 (COVID-19) vaccine (mRNA) will not affect results of SARS-CoV-2 viral testing (antigen or nucleic acid amplification tests). A test that detects antibody (IgG and/or IgM) to the SARS-

CoV-2 nucleocapsid protein should be used to assess for prior infection in COVID-19 vaccinated individuals. A positive SARS-CoV-2 antibody test that detects antibody (IgG and/or IgM) to the SARS-CoV-2 spike protein may indicate either prior infection or vaccination (CDC 2021).

Inactive vaccines do not interfere with tuberculosis (TB) test results, and there are currently no data regarding the impact of mRNA vaccines on TB tests, including tuberculin skin tests and interferon gamma release assays. If TB testing is required for onboarding or entry into a facility, perform testing first, then vaccinate. If vaccination has already occurred, defer TB testing for 4 weeks following completion of the 2-dose vaccination series. If TB testing is required for other reasons, perform TB symptom screening and test for infection before or at the same time as COVID-19 vaccination; see CDC recommendations (CDC 2021).

Monitoring Parameters

Monitor for hypersensitivity and syncope for 15 minutes following administration (ACIP [Ezeanolue 2020]; CDC 2021). Observe patients with a history of anaphylaxis (due to any cause) or a history of an immediate allergic reaction (regardless of severity; immediate is defined as within 4 hours of administration) to a vaccine or injectable therapy for 30 minutes after vaccination (CDC 2021). If seizure-like activity associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion.

Product Availability

In December 2020, the FDA and Health Canada both authorized the use of the Pfizer-BioNTech COVID-19 vaccine (mRNA) and the Moderna COVID-19 vaccine (mRNA) for use for the COVID-19 pandemic (FDA 2020a; FDA 2020b; Moderna Canadian product monograph; Pfizer-BioNTech Canadian product monograph).

Dosage Forms Considerations

After dilution with sodium chloride 0.9% injection, each vial of Pfizer-BioNTech COVID-19 Vaccine contains at least five 0.3 mL doses.

Dosage Forms: US

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Suspension, Intramuscular:

Pfizer-BioNTech COVID-19 Vacc: 30 mcg/0.3 mL (1.5 mL) [contains 2-((peg)-2000)-n,n-ditetradecylacetamide]

Suspension, Intramuscular [preservative free]:

Moderna COVID-19 Vaccine: 100 mcg/0.5 mL (5 mL) [contains dmg-peg 2000]

Dosage Forms: Canada

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Suspension, Intramuscular:

Generic: 30 mcg/0.3 mL (1.5 mL); 100 mcg/0.5 mL (5 mL)

Generic Available (US)

Yes

Mechanism of Action

Promotes active immunization against coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 virus. The modified messenger RNA (mRNA) in the vaccine is formulated in lipid particles that enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 spike (S) antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the S antigen, which may contribute to protection against COVID-19 disease (FDA 2020a; FDA 2020b).

Efficacy:

Moderna vaccine: Overall, in all patients, 94.1% protective efficacy against symptomatic COVID-19 disease following the 2-dose series; age subgroup analysis: Persons 18 to <65 years of age without prior evidence of SARS-CoV-2 infection ~96% protective efficacy; in persons ≥65 years of age protective efficacy was ~86% following the 2-dose series (FDA 2020b).

Pfizer-BioNTech vaccine: ~95% protective efficacy against symptomatic COVID-19 disease in persons ≥16 years of age without prior evidence of SARS-CoV-2 infection following completion of the 2-dose series (FDA 2020a).

Pharmacodynamics/Kinetics

Onset of action:

Moderna vaccine: The vaccine-efficacy value of 94.1% is based on disease cases occurring 14 days or more after dose 2 (Baden 2020). Virus-neutralizing antibody activity was detected in all patients by day 15 following the second dose (Jackson 2020).

Pfizer-BioNTech vaccine: The vaccine-efficacy value of 95% is based on disease cases occurring 7 days or more after dose 2 (Polack 2020). Virus-neutralizing antibody activity peaked 7 to 14 days following the second dose (Walsh 2020).

Duration: Data are currently insufficient to determine; clinical trials and epidemiologic surveillance are ongoing to evaluate break-through infections in vaccine recipients.

Related Information

- Centers for Disease Control and Prevention (CDC) and Other Links
- Immunization Administration Recommendations

Index Terms

BNT162b2; Coronavirus Disease 2019 Vaccines; COVID-19 Vaccines; CV19 Vaccines; mRNA 1273; mRNA-1273; Pfizer COVID-19 Vaccine; SARS-CoV-2 (mRNA) Vaccines; SARS-CoV-2 Vaccines; Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine; Tozinameran

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