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

Special Alerts

COVID-19 Vaccine (mRNA): FDA Expands Use of Pfizer-BioNTech Vaccine to Patients 12 Years and Older Updated May 2021

The FDA has expanded the use of Pfizer-BioNTech's COVID-19 Vaccine (mRNA) to patients 12 years and older.

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 and https://content.govdelivery.com/accounts/USFDA/bulletins/2d8857e

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 Expands Use of Pfizer-BioNTech Vaccine to Patients 12 Years and Older Updated May 2021

Health Canada has expanded the use of Pfizer-BioNTech's COVID-19 Vaccine (mRNA) to patients 12 years and older.

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 (December 2020): https://covid-vaccine.canada.ca/info/regulatory-decision-summary-detailTwo.html?linkID=RDS00730

Health Canada (Interim Order) (December 2020): 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

COVID-19 Vaccine (mRNA): Updated Storage Information for Pfizer-BioNTech Vaccine February 2021

The FDA has approved alternative storage requirements allowing undiluted frozen vials of the Pfizer-BioNTech COVID-19 Vaccine to be transported and stored at conventional freezer temperatures (−25 to −15°C [−13 to 5°F]) for a period of up to 2 weeks. This is an alternative to the preferred storage of the undiluted vials in an ultra-low temperature freezer between −80 to −60°C (−112 to −76°F). Vials stored at −25 to −15°C (−13 to 5°F) for up to 2 weeks may be returned 1 time to the recommended storage condition of −80 to −60°C (−112 to −76°F). Total cumulative time the vials are stored at −25 to −15°C (−13 to 5°F) should be tracked and should not exceed 2 weeks.

Further information may be found at:

FDA: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer

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

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

Pronunciation

Vm

P

(KO vid nine teen vak SEEN m R N A)

Brand Names: US

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

Brand Names: Canada

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

Pharmacologic Category

Vaccine; Vaccine, mRNA

Dosing: Adult

COVID-19 prevention:

Moderna vaccine: IM: 0.5 mL per dose for 2 doses administered 28 days apart (FDA 2021a; Moderna Canadian product monograph).

Pfizer-BioNTech vaccine: IM: 0.3 mL per dose for 2 doses administered 21 days apart (FDA 2021c; Pfizer-BioNTech Canadian product monograph).

Dosing interval: 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. If unable to adhere to the recommended interval and a delay is unavoidable, may administer the second dose up to 6 weeks (42 days) after the first dose. Series does not need to be restarted if the second dose is administered after the recommended timeframe (CDC 2021c).

Interchangeability: The same vaccine should be used for both doses in the vaccination series (CDC 2021c). If the same mRNA vaccine is temporarily unavailable, then it is preferable to delay the second dose (up to 6 weeks after the first dose) so that the same product can be given. If the first vaccine

product cannot be determined or is unavailable, may administer any available mRNA COVID-19 vaccine at a minimum interval of 28 days between doses. If 2 different mRNA COVID-19 vaccines are administered, the dose or series does not need to be repeated (CDC 2021c). The safety and efficacy of administering the Janssen COVID-19 adenovirus vector vaccine after an mRNA vaccine has not been established; however, the Centers for Disease Control and Prevention (CDC) states that in limited, exceptional situations where a patient's first dose was an mRNA vaccine and they are unable to complete the series with the same or different mRNA vaccine (eg, due to a contraindication), then a single dose of the Janssen COVID-19 adenovirus vector vaccine may be considered at a minimum interval of 28 days from the mRNA vaccine dose. If a non–FDA-authorized COVID-19 vaccine has been administered, allow a minimum interval of 28 days between a non–FDA-authorized vaccine and an FDA-authorized vaccine (CDC 2021c).

Premedication: The CDC does not recommend routine prophylactic administration of antihistamines, antipyretic/analgesic medications (eg, acetaminophen, nonsteroidal anti-inflammatory drugs), or aspirin/anticoagulants for the purpose of preventing postvaccination symptoms. Antihistamines may mask cutaneous symptoms of anaphylaxis, which could delay the diagnosis and management of the reaction. The impact of antipyretic/analgesic medications on antibody response is unknown. Antipyretic/analgesic medications may be taken **after** vaccination for the treatment of postvaccination local/systemic symptoms (if medically appropriate) (CDC 2021c).

Dosing recommendations for deviation in dose preparation or administration: If dose volume was too high, do **not** repeat dose and administer the second dose at the appropriate interval, unless patient experiences significant or prolonged adverse reactions (assess on a case-by-case basis). If dose volume was too low but more than half of the dose was administered, do **not** repeat the dose. If less than half the dose or the amount is unknown, repeat the dose in the opposite arm. If the Pfizer-BioNTech vaccine was undiluted or the wrong diluent volume was used during preparation, do **not** repeat the dose (CDC 2021c).

* See Dosage and Administration in AHFS Essentials for additional information.

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

COVID-19 prevention:

Pfizer-BioNTech COVID-19 Vaccine: Children ≥12 years and Adolescents: IM: 0.3 mL per dose for 2 doses administered 21 days apart (FDA 2021c; Pfizer Canadian product monograph).

Moderna COVID-19 Vaccine: Adolescents ≥18 years of age: IM: 0.5 mL per dose for 2 doses administered 28 days apart (FDA 2021a; Moderna Canadian product monograph). **Note**: If a person 16 or 17 years of age is inadvertently administered Moderna product for first dose, then may also administer as the second dose (CDC 2021c).

Dosing interval: 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. If unable to adhere to the recommended interval and a delay is unavoidable, may administer the second dose up to 6 weeks (42 days) after the first dose. Series does not need to be restarted if the second dose is administered after the recommended timeframe (CDC 2021c).

Interchangeability: The same vaccine should be used for both doses in the vaccination series (CDC 2021c). If the same mRNA vaccine is temporarily unavailable, then it is preferable to delay the second dose (up to 6 weeks after first dose) so that the same product can be given. In patients ≥18 years of age, if the first vaccine product cannot be determined or is unavailable, may administer any available mRNA COVID-19 vaccine at a minimum interval of 28 days between doses. If 2 different mRNA COVID-19 vaccines are administered, the dose or series does not need to be repeated (CDC 2021c). For patients <18 years of age, only the Pfizer-BioNTech vaccine should be used. The safety and efficacy of administering the COVID-19 adenovirus vector vaccine from Janssen after an mRNA vaccine has not been established. However, for patients ≥18 years of age the CDC states that in limited, exceptional situations where a patient's first dose was an mRNA vaccine and they are unable to complete the series with the same or different mRNA vaccine (eg, due to a contraindication), then a single dose of the COVID-19 adenovirus vector vaccine from Janssen may be considered at a minimum interval of 28 days from the mRNA vaccine dose. If a non-FDA authorized COVID-19 vaccine has been administered, allow a minimum interval of 28 days between a non-FDA authorized vaccine and an FDA-authorized vaccine (CDC 2021c).

Premedication: The CDC does not recommend routine prophylactic administration of antihistamines, antipyretic/analgesic medications (eg, acetaminophen, NSAIDs), or aspirin/anticoagulants for the purpose of preventing postvaccination symptoms. Antihistamines may mask cutaneous symptoms of anaphylaxis, which could delay the diagnosis and management of the reaction. The impact of antipyretic/analgesic medications on antibody response is unknown. Antipyretic/analgesic medications may be taken after vaccination for the treatment of postvaccination local/systemic symptoms (if medically appropriate) (CDC 2021c).

Dosing recommendations for deviation in dose preparation or administration: If dose volume was too high, do **not** repeat dose and administer the second dose at the appropriate interval, unless patient experiences significant or prolonged adverse reactions (assess on a case-by-case basis). If dose volume was too low but more than half of the dose was administered, do **not** repeat the dose. If less than half the dose or the amount is unknown, repeat the dose in the opposite arm immediately (no minimum interval). If Pfizer-BioNTech vaccine was administered undiluted or the wrong diluent volume was used during preparation, do **not** repeat the dose (CDC 2021c).

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.

* See Uses in AHFS Essentials for additional information.

Use: Off-Label: Adult

COVID-19 prevention Level of Evidence [A]

Moderna COVID-19 Vaccine (mRNA): Available under an FDA emergency use authorization (EUA) and an interim order from Health Canada for active immunization to prevent COVID-19 in persons ≥18 years of age. 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 ([Ref]).

Pfizer-BioNTech COVID-19 Vaccine (mRNA): Available under an FDA EUA and an interim order from Health Canada for active immunization to prevent COVID-19 in persons ≥12 years of age. 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 ([Ref]).

Advisory Committee on Immunization Practices: The Advisory Committee on Immunization Practices (ACIP) recommends any age-appropriate FDA-authorized COVID-19 vaccine if no contraindications exist; ACIP does not have a preferential recommendation for any COVID-19 vaccine product ([Ref]).

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

Level of Evidence Definitions

Level of Evidence Scale

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 COVID-19 Vaccines Currently Authorized in the United States," 2021

CDC, “Interim Public Health Recommendations for Fully Vaccinated People,” 2021

IDSA, "Vaccination of the Immunocompromised Host," 2013

NACI, “Extended Dose Intervals for COVID-19 Vaccines to Optimize Early Vaccine Rollout and Population Protection in Canada,” 2021

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

NACI/CATMAT, "Canadian Immunization Guide"

WFH/EAHAD/EHC/NHF, “COVID-19 Vaccination Guidance for People with Bleeding Disorders,” 2020

Administration: IM

Administer IM in the deltoid muscle. Use proper injection technique 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). Do not inject intravascularly, subcutaneously, or intradermally (FDA 2021a; FDA 2021c; Moderna Canadian product monograph; Pfizer-BioNTech Canadian product monograph). For persons who developed delayed injection site reactions after the first dose, administer the same vaccine but in the opposite arm for the second dose (CDC 2021c). To prevent syncope-related injuries, adolescents and adults should be vaccinated while seated or lying down (ACIP [Kroger 2021]). US recipients or caregivers should be given a vaccination card with the date when the recipient needs to return for the second dose (FDA 2021a; FDA 2021c).

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, rabies for postexposure prophylaxis) or to avoid barriers or delays to 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 2021c).

Moderna vaccine: Prior to use, gently swirl vial; do not shake (FDA 2021a; Moderna Canadian product monograph). There are 2 vial sizes: 10 to 11 doses per vial and 13 to 15 doses per vial; number of doses (0.5 mL/dose) obtainable from each vial depends on the type of syringe/needle used. Do not pool partial doses remaining in vials into a full dose (FDA 2021a).

Pfizer-BioNTech vaccine+: Must be diluted prior to use; gently invert diluted vial 10 times prior to use; do not shake (FDA 2021c; Pfizer-BioNTech Canadian product monograph). Extract doses from vial preferably using a low dead-volume syringe and/or needle. Each vial will contain 6 doses (possibly 7 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 2021b; FDA 2021c).

Inappropriate administration technique: If administered SubQ or into a muscle other than the deltoid or anterolateral thigh (alternate administration site), do **not** repeat dose. If it was the first dose, administer the second dose at the recommended interval. If this dose was the second dose, the series is considered complete and no additional doses are needed (CDC 2021c).

Patients at risk for hemorrhage: 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 [Kroger 2021]). For patients with bleeding disorders, specific recommendations are available (eg, US National Hemophilia Foundation, World Federation of Hemophilia).

Administration: Pediatric

Parenteral: IM: Administer IM in the deltoid muscle (FDA 2021a; FDA 2021c). Use proper injection technique 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). Do not inject intravascularly, subcutaneously, or intradermally (FDA 2021a; FDA 2021c). For persons who developed delayed injection site reactions after the first dose, administer the same vaccine but in the opposite arm for the second dose (CDC 2021c). To prevent syncope-related injuries, adolescents should be vaccinated while seated or lying down (ACIP [Kroger 2021]). US recipients or caregivers should be given a vaccination card with the date when the recipient needs to return for the second dose (FDA 2021a; FDA 2021c).

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, rabies for postexposure prophylaxis) or to avoid barriers or delays to 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 2021c).

Pfizer-BioNTech vaccine: Children ≥12 years and Adolescents: 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 6 doses (possibly 7 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 2021b; FDA 2021c).

Moderna vaccine: Adolescents ≥18 years of age: Prior to use, gently swirl vial; do not shake (FDA 2021a). There are two vial sizes: 10 to 11 doses per vial and 13 to 15 doses per vial; number of doses (0.5 mL/dose) obtainable from each vial depends on the type of syringe/needle used. Do not pool partial doses remaining in vials into a full dose (FDA 2021a).

Inappropriate administration technique: If administered subcutaneously or into a muscle other than the deltoid or anterolateral thigh, do not repeat dose. If it was the first dose, administer the second dose at the recommended interval. If this dose was the second dose, the series is complete and no additional doses are needed (CDC 2021c).

Patients at risk for hemorrhage: 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 [Kroger 2021]). For patients with bleeding disorders, specific recommendations are available (eg, US National Hemophilia Foundation, World Federation of Hemophilia).

Storage/Stability

Note: Contact the manufacturer for guidance if a dose is administered after improper storage and handling or past the expiration/beyond use date (CDC 2021c). Carton and vial labels may contain different storage information; information in health care provider fact sheet issued as part of emergency use authorization supersedes any information on cartons or vials (FDA 2021c).

Moderna vaccine:

Storage of frozen vials: Store intact vial frozen at −50°C to −15°C (−58°F to 5°F) in original carton to protect from light. Do not store on dry ice or below −50°C (−58°F) (FDA 2021a). **Note:** Canadian product information recommends storage of frozen vials at −25°C to −15°C (−13°F to 5°F) and to avoid storage on dry ice below −40°C (−40°F) (Moderna Canadian product monograph).

Transportation of thawed vials: If it is not feasible to transport vials at −50°C to −15°C (−58°F to 5°F), may transport thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours using shipping containers that will maintain 2°C to 8°C (35°F to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2°C to 8°C (35°F to 46°F), vials should not be refrozen; store at 2°C to 8°C (35°F to 46°F) until use (up to 30 days total at 2°C to 8°C [35°F to 46°F]) (FDA 2021a).

Thawed vials: May store under refrigeration at 2°C to 8°C (36°F to 46°F) for up to 30 days or for a total of 24 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 12 hours at 2°C to 25°C (36°F to 77°F). Thawed vials can be handled in room light conditions. Do not refreeze thawed vials (FDA 2021a). **Note:** Canadian product information recommends storage of thawed vials at 2°C to 8°C (36°F to 46°F) for up to 30 days or for up to 12 hours 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).

Storage of pre-drawn syringes: The manufacturer indicates that vaccine may be pre-drawn in syringes if administered within 6 hours after vial is initially pierced; syringes should be stored refrigerated at 2°C to 8°C (36°F to 46°F) or at room temperature at 15°C to 25°C (59°F to 77°F) and protected from sunlight (data on file [Moderna 2021]). Multidose vials do not contain a preservative.

Pfizer-BioNTech vaccine:

Storage of frozen vials: Store intact vials frozen at −80°C to −60°C (−112°F to −76°F) in original carton to protect from light. Alternatively, may store at −25°C to −15°C (−13°F to 5°F) for up to 2 weeks; vials stored under these conditions may be returned one time to the recommended storage of −80°C to −60°C (−112°F to −76°F); ensure that total cumulative time stored at −25°C to −15°C (−13°F to 5°F) does not exceed 2 weeks (FDA 2021c).

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. Storage between −96°C to −60°C (−141°F to −76°F) is not considered an excursion from the recommended storage condition (FDA 2021c; Pfizer-BioNTech Canadian product monograph).

Transportation of frozen vials: If full cartons cannot be transported at −90°C to −60°C (−130°F to −76°F), may transport at −25°C to −15°C (−13°F to 5°F). Any hours used for transport at this temperature count against the 2-week limit for storage at −25°C to −15°C (−13°F to 5°F). May return vials one time to the recommended storage condition of −80ºC to −60ºC (−112ºF to −76ºF) (FDA 2021c).

Thawed vials prior to dilution: For frozen vials thawed under refrigeration, may store under refrigeration at 2°C to 8°C (35°F to 46°F) for up to 5 days (120 hours). For frozen vials thawed at room temperature, may store 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. If transportation of thawed vials is needed, data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at this temperature range count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F) (FDA 2021c; Pfizer-BioNTech Canadian product monograph).

Vials after dilution: After dilution, use immediately or may store for up to 6 hours at 2°C to 25°C (35°F to 77°F). Minimize exposure to room light; avoid exposure to direct sunlight and UV light. Thawed vials can be handled in room light conditions. Do not refreeze thawed vials (FDA 2021c; Pfizer-BioNTech Canadian product monograph).

*Storage of pre-drawn syringes:*Additional studies performed by the manufacturer indicate that diluted vaccine in vials stored at 2°C to 30°C (36°F to 86°F) for up to a cumulative period of 18 hours or stored in syringes at 2°C to 30°C (36°F to 86°F) for up to 6 hours have been shown to be physically and chemically stable; consider microbiological risk (data on file [Pfizer 2021]). Multidose vials do not contain a preservative.

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 for the maximum 11-dose vial or 3 hours for the maximum 15-dose vial; allow thawed vial to stand at room temperature for 15 minutes prior to use. Alternatively, thaw vial at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour for the maximum 11-dose vial or 1.5 hours for the maximum 15-dose vial. 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. There are 2 vial sizes: 10 to 11 doses per vial and 13 to 15 doses per vial; number of doses (0.5 mL/dose) obtainable from each vial depends on the type of syringe/needle used. Do not pool partial doses remaining in vials into a full dose. Do not refreeze thawed vials (FDA 2021a; 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). Extract doses from vial, preferably using a low dead-volume syringe and/or needle. Each vial will contain 6 doses (possibly 7 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 2021b). Do not refreeze thawed vials (FDA 2021c; 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 for the maximum 11-dose vial or 3 hours for the maximum 15-dose vial; allow thawed vial to stand at room temperature for 15 minutes prior to use. Alternatively, thaw vial at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour for maximum 11-dose vial or 1.5 hours for the maximum 15-dose vial. 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. There are two vial sizes: 10 to 11 doses per vial and 13 to 15 doses per vial; number of doses (0.5 mL/dose) obtainable from each vial depends on the type of syringe/needle used. Do not pool partial doses remaining in vials into a full dose. Do not refreeze thawed vials (FDA 2021a).

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). Extract doses from vial, preferably using a low dead-volume syringe and/or needle. Each vial will contain 6 doses (possibly 7 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 2021b). Do not refreeze thawed vials (FDA 2021c).

Medication Patient Education with HCAHPS Considerations

What is this drug used for?

• It is used to prevent COVID-19.

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

• Pain, redness, or swelling where the injection was given; headache; muscle or joint pain; fever of 100.4°F (38°C) or higher; chills; upset stomach or throwing up; swollen or tender glands; or feeling tired or unwell

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

• Bell's palsy like weak or drooping muscles on one side of your face

• Fast or slow heartbeat, dizziness, passing out, weakness, anxiety, confusion, or change in eyesight or hearing

• Pain, redness, or swelling at the injection site that lasts a few weeks

• Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

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

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

Pfizer-BioNTech vaccine health care provider fact sheet: https://www.fda.gov/media/144413/download

Pfizer-BioNTech vaccine patient fact sheet: https://www.fda.gov/media/144414/download

Note: This is not a comprehensive list of all side effects. Talk to your doctor if you have questions.

Consumer Information Use and Disclaimer: This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a limited summary of general information about the medicine's uses from the patient education leaflet and is not intended to be comprehensive. This limited summary does NOT include all information available about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not intended to provide medical advice, diagnosis or treatment and does not replace information you receive from the healthcare provider. For a more detailed summary of information about the risks and benefits of using this medicine, please speak with your healthcare provider and review the entire patient education leaflet.

Medication Safety Issues

Sound-alike/look-alike issues:

Other safety concerns:

Prescribing and Access Restrictions

The Pfizer-BioNTech and Moderna COVID-19 Vaccines are not commercially available; they are available as part of ongoing clinical trials and 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

History of a severe allergic reaction (eg, anaphylaxis) after a previous dose or to a component of the formulation; history of immediate allergic reaction (regardless of severity and occurring within 4 hours) to a previous dose; known allergy to any component of the formulation (eg, polyethylene glycol) (CDC 2021c).

Warnings/Precautions

Concerns related to adverse effects:

• 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 [Kroger 2021]).

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 [Kroger 2021]). 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 or 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 [Kroger 2021]). For more information on administering the COVID-19 vaccine in patients with bleeding disorders, see society recommendations (eg, US National Hemophilia Foundation, World Federation of Hemophilia).

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

- *Persons with current or prior history of COVID-19 or asymptomatic SARS-CoV-2 infection:* Vaccination should be offered to persons regardless of history of symptomatic or asymptomatic SARS-CoV-2 infection, including those with prolonged symptoms. 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.

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. Vaccination within 90 days after passive antibody therapy does not need to be repeated.

- *Persons who received antibody therapies that are not specific to COVID-19:* There is no recommended minimum interval between vaccination and antibody therapies that are not specific to COVID-19 (eg, IVIG, hepatitis B immune globulin) (CDC 2021c).

- *Vaccinated persons who subsequently develop COVID-19:* Prior receipt of a COVID-19 vaccine should not affect treatment decisions (eg, monoclonal antibodies, convalescent plasma) or timing of such treatments (CDC 2021c). If a person is fully vaccinated and ≥2 weeks postvaccination and tests positive for SARS-CoV-2, the Centers for Disease Control and Prevention (CDC) recommends holding the specimen and contacting the state health department.

- *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 unless they have symptoms consistent with COVID-19.

Concurrent drug therapy issues:

• Anticoagulant or aspirin therapy: Prophylactic administration of aspirin or anticoagulants is not recommended (CDC 2021a). Clinicians administering vaccine should be aware of potential bleeding or hematoma that could occur due to IM administration (ACIP [Kroger 2021]).

• 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 2021c).

• 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, rabies for postexposure prophylaxis) 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 2021c).

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 2021c). If the same mRNA vaccine is temporarily unavailable, then it is preferable to delay the second dose (up to 6 weeks after the first dose) so that the same product can be given. If the first vaccine product cannot be determined or is unavailable, may administer any available mRNA COVID-19 vaccine at a minimum interval of 28 days between doses. If 2 different mRNA COVID-19 vaccines are inadvertently administered, the dose or series does not need to be repeated (CDC 2021c).

• Polyethylene glycol: Some COVID-19 vaccines may contain polyethylene glycol. Hypersensitivity reactions have been reported. Polyethylene glycol and polysorbate are structurally related; cross-reactive hypersensitivity may occur (CDC 2021c).

• Traceability: The vaccine name, batch/lot number, expiration date, and other administration details must be recorded for each patient in order to improve traceability (FDA 2021a; FDA 2021c; 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 2021c; FDA 2021a; FDA 2021c; Moderna Canadian product monograph; Pfizer-BioNTech Canadian product monograph). Patients with stable HIV infection were included in the clinical trials (FDA 2021a; FDA 2021c). Although data are not currently available to establish vaccine safety and efficacy in immunocompromised persons, the CDC recommends vaccination of immunocompromised patients if there are no contraindications. If possible, complete COVID-19 vaccination ≥2 weeks prior to initiation of immunosuppressive therapy. If completion of a whole vaccination series is not possible, persons receiving immunosuppressants can still receive COVID-19 vaccination. Revaccination is not recommended after immune competence is regained for those persons who received vaccination during chemotherapy or other immunosuppressive therapy (CDC 2021c). For more information on administering the COVID-19 vaccine in specific disease states, see society recommendations (eg, American Cancer Society, National Multiple Sclerosis Society).

• 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 2021c).

• Persons who had received dermal fillers: Temporary swelling at or near the site of filler injection has been infrequently reported after COVID-19 (mRNA) vaccination. Persons who develop swelling at or near the site of dermal filler should contact their health care provider for evaluation and possible medical treatment (CDC 2021c).

Other warnings/precautions:

• Effective immunity: Vaccination may not result in effective immunity in all patients (FDA 2021a; FDA 2021c; 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 [Kroger 2021]). 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 2021). Vaccines may not be effective if administered during periods of altered immune competence (ACIP [Kroger 2021]; CDC 2021c).

• Mammograms: Temporary contralateral or ipsilateral lymphadenopathy after a COVID-19 vaccination has been reported. To avoid possible misinterpretation of mammogram screening, mammograms are recommended prior to vaccination or 4 to 6 weeks after the second dose. When this is not possible, the mammogram technologist or radiologist should be informed when and which vaccine was administered,

and what arm the injection was given (ACOG 2021). Imaging needed for acute symptoms, or urgent treatment planning or complications, should not be delayed (Becker 2021).

* See Cautions in AHFS Essentials for additional information.

Reproductive Considerations

COVID-19 (mRNA) vaccines are investigational vaccines permitted for use under FDA emergency use authorization (EUA). Vaccination is encouraged for patients planning a pregnancy and pregnancy does not need to be delayed following vaccination. Routine pregnancy testing is not required prior to vaccination (ACOG 2021; CDC 2021c).

COVID-19 vaccines do not 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 (ACOG 2021).

Current American College of Obstetricians and Gynecologists and CDC recommendations do not have a product preference; any age-appropriate vaccine may be used for patients who may become pregnant and who do not otherwise have contraindications to the vaccine (ACOG 2021; CDC 2021c).

Pregnancy Considerations

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 (ACOG 2021).

Placental transfer of neutralizing antibodies after maternal COVID-19 vaccination has been documented:

- In a case report, a mother received the first dose of the Pfizer-BioNTech Vaccine at 32 6/7 weeks' gestation and her second dose at 35 2/7 weeks' gestation. A SARS-CoV-2 IgG test prior to pregnancy was negative. All SARS-CoV-2 RNA RT-PCR tests conducted at random intervals between 4 3/7 weeks' gestation and 28 2/7 weeks' gestation were negative. Spontaneous delivery occurred at 38 6/7 weeks' gestation; a maternal SARS-CoV-2 RNA RT-PCR was negative at delivery. SARS-CoV-2 IgG tests of maternal and umbilical cord blood at delivery were both positive for neutralizing antibodies, with IgG titers of 1:25,600 (Gill 2021).

- A separate study followed 84 pregnant women who received either the Pfizer-BioNTech COVID-19 Vaccine (n = 41) or the Moderna COVID-19 Vaccine (n = 43) (mean gestational age at first dose: 23.2 weeks). Maternal IgG, IgM, and IgA antibodies were increased with both vaccines. Maternal vaccine response and adverse events were similar in comparison to nonpregnant patients (n = 16). Cord blood was available from 10 pregnancies of mothers vaccinated during the third trimester; 9 received both doses prior to delivery. IgG antibodies were detected in all cord blood samples; the lowest levels occurred in the delivery in which the mother received only 1 dose of the vaccine. The optimal time from vaccination to delivery requires additional study (Gray 2021).

Based on available information, mRNA vaccines are likely to have the same safety and efficacy in pregnant and nonpregnant patients (ACOG 2021; CDC 2021c). Preliminary information is available from data collected between December 14, 2020 and February 28, 2021 using the V-safe Surveillance System and pregnancy registry, and the Vaccine Adverse Event Reporting System (VAERS). Based on the

preliminary data, the COVID-19 (mRNA) vaccines had similar safety outcomes in pregnant and nonpregnant patients:

- Preliminary information from the V-safe surveillance system includes data from 35,691 pregnancies. Patients received the Pfizer-BioNTech Vaccine (53.9%) or the Moderna COVID-19 Vaccine (n = 46.1%) during pregnancy (86.5%) or tested positive for pregnancy after vaccination (13.5%). The most common maternal adverse events (injection-site pain, fatigue, headache) occurred at rates similar to nonpregnant patients and occurred more frequently after the second dose in both pregnant and nonpregnant patients. Maternal temperature ≥38°C was <1% following the first dose and 8% following the second dose and occurred less frequently in patients who were pregnant.

- Using the V-Safe surveillance system, 14.7% of pregnant patients were contacted for inclusion into the V-safe pregnancy registry and 3,958 pregnancies were enrolled. Patients received the Pfizer-BioNTech Vaccine (54%) and Moderna COVID-19 Vaccine (46%). Vaccination occurred primarily during the first (28.6%), second (43.3%), and third trimesters (25.7%). Outcomes were available for 827 completed pregnancies. There were no congenital anomalies reported following vaccination in the first trimester or prior to conception. Other pregnancy outcomes (eg, spontaneous abortion, stillbirth, preterm birth) were similar when compared to the general population.

-Preliminary information from the VAERS includes data from 221 pregnancies following use of the Pfizer-BioNTech Vaccine (58.8%) or Moderna COVID-19 Vaccine (40.7%) in either the first trimester (49.7%), second trimester (32.5%), or third trimester (17.8%). Fatigue, headache, and chills were the most common adverse events following vaccination; no congenital anomalies were reported.

All information included in these surveillance systems is voluntary and self-reported. Information continues to be collected (Shimabukuro 2021b).

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 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. The COVID-19 (mRNA) vaccines should not be withheld from pregnant patients who meet the criteria for vaccination based on the Advisory Committee on Immunization Practices recommended priority groups. Patients who are pregnant may choose to be vaccinated and can be offered the COVID-19 (mRNA) vaccine (ACOG 2021; CDC 2021c).

Vaccination of pregnant patients may be done in any setting authorized to administer the vaccine. If pregnancy occurs after the first dose, the second dose should be administered as otherwise recommended (ACOG 2021).

Current American College of Obstetricians and Gynecologists and CDC recommendations do not have a product preference; any age-appropriate vaccine may be used for patients who are pregnant and who do not otherwise have contraindications to the vaccine (ACOG 2021; CDC 2021c). Information related to COVID-19 vaccines continues to emerge; refer to current guidelines for vaccinating pregnant patients.

Rho(D) immune globulin is not expected to interfere with an immune response to the COVID-19 vaccine. Treatment should not be withheld in patients planning to be vaccinated or who recently received the COVID-19 vaccine. There is no recommended minimum interval between COVID-19 vaccination and Rho(D) immune globulin administration (ACOG 2021; CDC 2021a).

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 Vaccine are encouraged to enroll in the CDC V-SAFE monitoring program (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html) (ACOG 2021).

- Health care providers are encouraged to enroll pregnant patients exposed to COVID-19 vaccines in the Organization of Teratology Information Specialists (OTIS) pregnancy registry (1-877-311-8972; https://mothertobaby.org/join-study/).

Breast-Feeding Considerations

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 COVID-19 vaccines on the breastfed infant or on milk production/excretion (CDC 2021c; FDA 2021a; FDA 2021c).

SARS-CoV-2-specific antibodies are present in breast milk following vaccination. Information is available from 2 studies following administration of the COVID-19 (mRNA) vaccine to lactating women. The first study included 31 lactating patients who received either the Pfizer-BioNTech COVID-19 Vaccine (n = 16) or the Moderna COVID-19 Vaccine (n = 15) ~7 to 11 months after delivery (Gray 2021). The second study included women who received their first dose of the Pfizer-BioNTech COVID-19 Vaccine ~10 months postpartum (n = 84) (Perl 2021). In both studies, SARS-CoV-2-specific IgA and IgG antibodies were present in breast milk following vaccination. Concentrations of IgG antibodies increased (were boosted) following the second dose (Gray 2021; Perl 2021).

Based on available information, mRNA vaccines are not likely to be a risk to the breastfeeding infant (CDC 2021c). The COVID-19 (mRNA) vaccines should not be withheld from patients who are breastfeeding and meet the criteria for vaccination based on the Advisory Committee on Immunization Practices recommended priority groups. Patients who are breastfeeding may choose to be vaccinated and can be offered the COVID-19 (mRNA) vaccine (ACOG 2021; CDC 2021c). The initiation of breastfeeding does not need to be avoided and breastfeeding does not need to be discontinued in patients who are vaccinated (ACOG 2021). Current American College of Obstetricians and Gynecologists and CDC recommendations do not have a product preference; any age-appropriate vaccine may be used for patients who are breastfeeding and who do not otherwise have contraindications to the vaccine (CDC 2021c).

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

Local reactions

Systemic reactions (excluding hypersensitivity)

Bell's palsy

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 2021a; FDA 2021c).

>10%:

Gastrointestinal: Diarrhea (Pfizer: 8% to 11%; higher in younger patients) (See Table 1), nausea and vomiting (Moderna: 5% to 21%; higher in younger patients and with second dose) (See Table 2)

Local: Pain at injection site (66% to 90%; higher in younger patients) (See Table 3), swelling at injection site (4% to 13%) (See Table 4)

Nervous system: Chills (Moderna: 5% to 49%; Pfizer: 6% to 35%; higher in younger patients and with second dose) (See Table 5), fatigue (33% to 68%; higher in younger patients and with second dose) (See Table 6), headache (Moderna: 25% to 63%; Pfizer: 25% to 52%; higher in younger patients and with second dose) (See Table 7)

Neuromuscular & skeletal: Arthralgia (Moderna: 16% to 46%; Pfizer: 9% to 22%; higher in younger patients and with second dose) (See Table 8), axillary swelling (Moderna: Including axillary tenderness; 6% to 16%; higher in younger patients), myalgia (Moderna: 20% to 62%; Pfizer: 14% to 37%; higher in younger patients and with second dose) (See Table 9)

Miscellaneous: Fever (≤17%; higher in younger patients and with second dose) (See Table 10)

1% to 10%:

Gastrointestinal: Nausea (Pfizer: 1%), vomiting (Pfizer: <1% to 2%; higher in younger patients)

Hematologic & oncologic: Lymphadenopathy (≤1%; unsolicited) (See Table 11) (Polack 2020)

Hypersensitivity: Hypersensitivity reaction (Moderna: 2%; including rash at injection site, urticaria at injection site, and severe hypersensitivity reaction) (See Table 12)

Local: Erythema at injection site (2% to 9%), injection site reaction (delayed: 1%)

<1%: Nervous system: Malaise (Pfizer)

Frequency not defined:

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

Local: Local swelling (at or near the site of dermal fillers [eg, face or lips]) (CDC 2021c)

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

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

Post-authorization:

Dermatologic: Pruritus (Shimabukuro 2021a), skin rash (Shimabukuro 2021a), urticaria (Shimabukuro 2021a)

Hypersensitivity: Anaphylaxis, angioedema (Shimabukuro 2021a)

Nervous system: Dizziness (CDC 2021a)

Respiratory: Airway obstruction (Shimabukuro 2021a)

* See Cautions in AHFS Essentials for additional information.

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*

Antihistamines: May enhance the adverse/toxic effect of COVID-19 Vaccine (mRNA). Specifically, the prophylactic use of antihistamines may mask symptoms and delay diagnosis and management of anaphylaxis. Management: Do not administer antihistamines to COVID-19 mRNA vaccine recipients prior to vaccination to prevent allergic reactions. Use may mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis. *Risk D: Consider therapy modification*

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

Dermal Fillers: COVID-19 Vaccine (mRNA) may enhance the adverse/toxic effect of Dermal Fillers. Specifically, the risk for swelling at or near the site of dermal filler injection (usually face or lips) may be increased. *Risk C: Monitor therapy*

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

COVID-19 vaccine 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 2021c).

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 policy (eg, onboarding or entry into a facility), testing may be performed prior to vaccination or at the same encounter. If vaccination has already occurred, defer TB testing for ≥4 weeks following completion of vaccination; if testing cannot be deferred, consider retesting individuals with negative results ≥4 weeks following completion of vaccination. If TB testing is required for medical diagnosis, consider delaying TB testing until ≥4 weeks after completion of COVID-19 vaccination; if testing cannot be delayed, patients with negative results should be considered for retesting ≥4 weeks following completion of vaccination. For more information, see Centers for Disease Control and Prevention recommendations (CDC 2021c).

Monitoring Parameters

Monitor for hypersensitivity and syncope for 15 minutes following administration (ACIP [Kroger 2021]; CDC 2021c). Observe patients for 30 minutes after vaccination in those patients with the following: a history of anaphylaxis (due to any cause); a history of an allergic reaction of any severity within 4 hours of receipt of a vaccine or injectable therapy; or a person with a contraindication to a different type of COVID-19 vaccine (CDC 2021c). If seizure-like activity associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion.

Antibody testing to assess for SARS-CoV-2 immunity following vaccination is not currently recommended (CDC 2021c).

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 2021a; FDA 2021c; Moderna Canadian product monograph; Pfizer-BioNTech Canadian product monograph).

Dosage Forms Considerations

Moderna COVID-19 Vaccine: There are 2 vial sizes; number of doses obtainable from each vial is dependent on the syringes and needles used. For the vial that contains a maximum of 11 doses, each vial will contain 10 to 11 doses of 0.5 mL per dose; for the vial that contains a maximum of 15 doses, each vial will contain 13 to 15 doses of 0.5 mL per dose. Do not pool partial doses remaining in vials into a full dose.

Pfizer-BioNTech COVID-19 Vaccine: After dilution with sodium chloride 0.9% injection, each vial of vaccine contains at least six 0.3 mL doses. Do not pool partial doses remaining in vials into a full dose.

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 (1.8 mL) [contains 2-((peg)-2000)-n,n-ditetradecylacetamide]

Suspension, Intramuscular [preservative free]:

Moderna COVID-19 Vaccine: 100 mcg/0.5 mL (5 mL, 7 mL) [contains dmg-peg 2000]

Dosage Forms: Canada

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

Suspension, Intramuscular:

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

Generic: 30 mcg/0.3 mL (1.8 mL)

Generic Available (US)

Yes

Mechanism of Action

Promotes active immunization against 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 2021a; FDA 2021c).

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 2021a).

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 2021c).

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.

Dental: Local Anesthetic/Vasoconstrictor Precautions

No information available to require special precautions.

Dental: Effects on Dental Treatment

Key adverse event(s) related to dental treatment: Facial swelling (frequency not defined).

Dental: Effects on Bleeding

No information available to require special precautions.

Related Information

- Centers for Disease Control and Prevention (CDC) and Other Links
- COVID-19 Vaccine Tracker
- Immunization Administration Recommendations

Index Terms

BNT162b2; Coronavirus Disease 2019 Vaccines; COVID-19 Vaccines; CV19 Vaccines; Moderna COVID-19 vaccine; 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

FDA Approval Date

December 11, 2020

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