At-a-glance: mRNA COVID-19 Vaccines

Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)
EUA	Issued December 11, 2020	Issued December 18, 2020
Fact sheet	• Health care providers • Recipients/caregivers	• Health care providers • Recipients/caregivers
ACIP	Interim recommendation for use: Persons aged ≥16 years for prevention of COVID-19	Interim recommendation for use: Persons aged ≥18 years for prevention of COVID-19
Dose	30 mcg **(0.3 mL each)**	100 mcg **(0.5 mL each)**
Schedule	**First dose:** Day 0 **Second dose:** Day 21	**First dose:** Day 0 **Second dose:** Day 28
Storage and handling	• **Long-term storage:** -70°C (dry ice) • **Refrigeration:** 2°C–8°C for up to 5 days • **Room temp:** up to 5 hours (unpunctured) **Must be at room temp at least 30 minutes before dilution* • **After first use:** Room temp up to 6 hours	• **Long-term storage:** -20C • **Refrigeration:** 2°C–8°C for up to 30 days • **Room temp:** up to 12 hours (unpunctured) **Thaw in refrigerated conditions for at least 2.5 hours, then let the vial stand at room temp for at least 15 minutes before administering.* • **After first use:** Room temp up to 6 hours
Efficacy	95% efficacy in 43,538 volunteers beginning 7 days after second dose	94.1% in 30,420 volunteers beginning 14 days after second dose
Contraindications	Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine	
Postvaccination symptoms	• **Local:** pain, swelling, erythema at the injection site, localized axillary lymphadenopathy (80%–89% of vaccinated persons*) • **Systemic:** fever, fatigue, headache, chills, myalgia, arthralgia (55%–83% of vaccinated persons*; acetaminophen or ibuprofen may be used) • These symptoms tend to be more common after the second dose and resolve 1–3 days after vaccination. • Anaphylaxis following vaccination was not observed in clinical trials. • Access a comprehensive summary of local reactions, systemic reactions, adverse events, and serious adverse events for the Pfizer or Moderna COVID-19 vaccines. **Depending on the vaccine, age group, and vaccine dose*	
Phase III study	Polack, et al. *NEJM*. 2020.	Baden, et al. *NEJM*. 2020.

Abbreviations used: EUA, emergency use authorization; ACIP; Advisory Committee on Immunization Practices.

Updated January 7, 2021 • Copyright © 2021, American Pharmacists Association. All rights reserved.

At-a-glance: mRNA COVID-19 Vaccines (continued)

Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

Quick Links

- CDC: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States
- CDC: Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine
- CDC: Frequently Asked Questions about COVID-19 Vaccination
- FDA: Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions

Administration

- **Dosing interval:** Second doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated.
- **Doses per vial:** Initially, the Pfizer-BioNTech vaccine was thought to contain 5 doses after dilution, but thanks to pharmacists, the FDA has revised the EUA to state that after dilution, one vial of the Pfizer-BioNTech vaccine contains up to 6 doses of 0.3 mL. Vial labels and cartons may state that the vial contains 5 doses of 0.3 mL, but the FDA's EUA Fact Sheet supersedes this labeling. Since the vials are preservative free, it is critical to note that any further remaining product that does not constitute a full dose should not be pooled from multiple vials to create one dose. The Moderna vaccine contains 10 doses of 0.5 mL.
- **Interchangeability:** NOT interchangeable with other COVID-19 vaccine products; complete the vaccine series with the same product.
  - > If two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.
- **Coadministration with other vaccines:** Administer alone at least 14 days before or after administration of other vaccines.
  - > If inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.
  - > If the patient received another vaccine within 14 days but won't be able to return for the COVID-19 vaccine, do not miss the opportunity to administer the COVID-19 vaccine.
  - > If a live vaccine must be given, administer the COVID-19 vaccine first, then administer the live vaccine 14 days later.
- **Booster doses:** No more than two doses are recommended at this time.

Updated January 7, 2021 • Copyright © 2021, American Pharmacists Association. All rights reserved.

At-a-glance: mRNA COVID-19 Vaccines (continued)

Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

Storage and handling

- Complete storage and handling information can be found in the fact sheets for health care providers in the table above.
- For both vaccines, never refreeze.

Contraindications and precautions

- **Contraindication:** Recommend against use in individuals with known history of severe allergic reaction to any component of the vaccine.
- **Precaution:** Counsel about the unknown risks of developing a severe allergic reaction for patients with a history of severe allergic reaction (anaphylaxis) to any other vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous).
- Vaccine providers should observe patients after vaccination to monitor for immediate adverse reactions:
  - **30 minutes:** Persons with a history of anaphylaxis
  - **15 minutes:** All other persons
- Review CDC's Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites.
- See table below for the ingredients within each vaccine.

Underlying medical conditions

- mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions unless there is a contraindication. Persons with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, were found to have similar safety and efficacy profiles compared to persons without comorbidities in clinical trials.
- Data are limited or not currently available for the following *specific underlying conditions*. Unless there is a contraindication, patients with the following conditions may consider receiving one of the COVID-19 vaccines.
  - **Immunocompromised:** Counsel on the potential for reduced immune response to the vaccine and the need to follow current guidance to protect themselves against COVID-19 (e.g., masks, social distancing)
    - **Note:** Persons with stable HIV infections were included in clinical trials.
  - **Autoimmune conditions:** No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants.

Updated January 7, 2021 • Copyright © 2021, American Pharmacists Association. All rights reserved.

At-a-glance: mRNA COVID-19 Vaccines (continued)

Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

Underlying medical conditions *Continues.*

- **Guillain-Barré syndrome:** No cases have been reported among participants following vaccination.
- **Bell's palsy:** Cases were reported following vaccination in participants in clinical trials; however, FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination.

Pregnancy and lactation

- **Pregnancy:** No data are available on the safety of COVID-19 vaccines in pregnant women; studies are ongoing, and more are planned.
  - Consider risk versus benefit. Issues to consider:
    - Level of COVID-19 community transmission (risk of acquisition)
    - Her personal risk of contracting COVID-19 (by occupation or other activities)
    - Risks of COVID-19 to her and potential risks to the fetus
    - Vaccine efficacy
    - Known adverse effects of the vaccine
    - Lack of data about the vaccine during pregnancy
  - Pregnant women who experience fever following vaccination should be counseled to take acetaminophen, as fever has been associated with adverse pregnancy outcomes.
- **Breastfeeding/lactating women:** No data are available on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or on milk production/excretion.
  - mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant.

Considerations related to SARS-CoV-2 infection

- **Persons with a history of SARS-CoV-2 infection**
  - Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
  - Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision making.

Updated January 7, 2021 • Copyright © 2021, American Pharmacists Association. All rights reserved.

At-a-glance: mRNA COVID-19 Vaccines (continued)

Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

Considerations related to SARS-CoV-2 infection *Continues.*

- **Persons with known current SARS-CoV-2 infection**
  - > Vaccination should be deferred until recovery from acute illness (if person had symptoms) *and* criteria have been met to discontinue isolation.
  - > There is no minimal recommended interval between infection and vaccination.
    - Reinfection is uncommon in the 90 days after initial infection, so persons may defer vaccination until the end of this period, if desired.
- **Persons who previously received passive antibody therapy for COVID-19**
  - > Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.
- **Persons with a known SARS-CoV-2 exposure**
  - > Community or outpatient setting: Defer vaccination until quarantine period has ended.
  - > Residents of congregate health care settings (e.g., long-term care facilities) can be vaccinated. Employ appropriate infection prevention and control procedures.

Impact on SARS-CoV-2 testing

- **Viral tests**
  - > Prior receipt of mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests.
- **Antibody tests**
  - > Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to spike or nucleocapsid proteins.
  - > mRNA COVID-19 vaccine encodes the spike protein; thus, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination.
  - > To evaluate for evidence of prior infection in an individual with a history of mRNA COVID-19 vaccination, use a test specifically evaluating IgM/IgG to the nucleocapsid protein.

Updated January 7, 2021 • Copyright © 2021, American Pharmacists Association. All rights reserved.

At-a-glance: mRNA COVID-19 Vaccines (continued)

Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102 (proprietary to Moderna)
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

Source: Adapted from CDC's Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States; Appendix A.

Disclaimer: *Information related to the COVID-19 pandemic is changing rapidly and continuously. The material and information contained in this publication is believed to be current as of the date included on this document. The American Pharmacists Association assumes no responsibility for the accuracy, timeliness, errors or omission contained herein. Links to any sources do not constitute any endorsement of, validity, or warranty of the information contained on any site. The user of these materials should not under any circumstances solely rely on, or act based on this publication. Pharmacy professionals retain the responsibility for using their own professional judgment and practicing in accordance with all rules, regulations, and laws governing the pharmacy practice within their jurisdiction.*