

COVID-19 mRNA Vaccines



What Clinic Personnel Need to Know



	Pfizer-BioNTech	Moderna
Product	Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)	Moderna COVID-19 Vaccine (mRNA-1273)
Vaccine type	mRNA (messenger RNA)	mRNA (messenger RNA)
Age indication	16 years of age and older	18 years of age and older
Basic information	<p>CDC Resources: Pfizer-BioNTech COVID-19 Overview www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html</p> <p>ACIP Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s_cid=mm6950e2_w</p> <p>Pfizer-BioNTech Resources: Pfizer-BioNTech COVID-19 vaccine website www.cvdvaccine-us.com</p>	<p>CDC Resources: Moderna COVID-19 Overview www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html</p> <p>ACIP Interim Recommendation for Use of Moderna COVID-19 Vaccine www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1_w</p> <p>Moderna Resources: Moderna COVID-19 vaccine website www.modernatx.com/covid19vaccine-eua/providers/</p>
Emergency Use Authorization (EUA) factsheets Required to be given to recipients in place of a Vaccine Information Statement (VIS)	<p>For Providers www.fda.gov/media/144413/download</p> <p>For Recipients and Caregivers <i>English</i> www.fda.gov/media/144414/download <i>Translations</i> www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine</p>	<p>For Providers www.fda.gov/media/144637/download</p> <p>For Recipients and Caregivers <i>English</i> www.fda.gov/media/144638/download <i>Translations</i> www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine</p>
Presentation	<ul style="list-style-type: none"> Frozen liquid concentrate, no preservative Multidose vial, at least 5 doses/vial* * Some syringe types may be able to draw up to 6–7 full doses per vial, which is acceptable. Never combine vaccine from more than 1 vial to make a dose. 	<ul style="list-style-type: none"> Frozen liquid, no preservative Multidose vial, at least 10 doses/vial* * Some syringe types may be able to draw up 11 full doses per vial, which is acceptable. Never combine vaccine from more than 1 vial to make a dose.
Packaging	<ul style="list-style-type: none"> 195 vials/tray (975 doses) 1–5 trays per shipper Each tray: 9" x 9" x 1.6" 	<ul style="list-style-type: none"> 10 vials/carton (100 doses) Each carton: 2" x 2" x 5-3/8"
Minimum shipment	975 doses (195 multidose vials)	100 doses (10 multidose vials)

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	Pfizer-BioNTech	Moderna
Storage and handling	<p>SHIPPING Shipped at -80°C to -60°C (-112°F to -76°F)</p> <p>STORAGE <i>(protect from light during storage)</i></p> <p>Frozen: -80°C to -60°C (-112°F to -76°F) In “ultracold” temperature freezer</p> <ul style="list-style-type: none"> • Up to 6 months <p>In Pfizer thermal shipper with dry ice</p> <ul style="list-style-type: none"> • Up to 30 days if following Pfizer instructions for dry ice replenishment and # of openings allowed/per day <p>Thermal Shipping Container Dry Ice Replenishment Instructions www.cvdvaccine-us.com/images/pdf/DryIceReplenishment.pdf</p> <p>Refrigerated: 2° to 8°C (36° to 46°F)</p> <ul style="list-style-type: none"> • Unopened vial: up to 5 days (120 hours)/ must discard after 120 hours • Unopened vial: up to 2 hours at room temperature (up to 25°C [77°F]) • Punctured vial: up to 6 hours in refrigerator or at room temperature (2° to 25°C [36° to 77°F]) • Thawed vaccine cannot be refrozen <p>.....</p> <p>CDC Resources: Storage and Handling Summary (Pfizer) www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf</p> <p>Ultracold Vaccine Storage Temperature Log</p> <p>CELSIUS www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/temp-log-ultracold-storage-celsius.pdf</p> <p>FAHRENHEIT www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/temp-log-ultracold-storage-fahrenheit.pdf</p> <p>Refrigerator Vaccine Storage Temperature Log</p> <p>CELSIUS www.cdc.gov/vaccines/covid-19/downloads/refrigerator-storage-logger-celsius.pdf</p> <p>FAHRENHEIT www.cdc.gov/vaccines/covid-19/downloads/refrigerator-storage-logger-fahrenheit.pdf</p> <p>Pfizer Resource: Storage and handling guidance www.cvdvaccine-us.com/product-storage-and-dry-ice</p>	<p>SHIPPING Shipped at -25°C to -15°C (-13°F to 5°F)</p> <p>STORAGE <i>(protect from light during storage)</i></p> <p>Frozen: -25°C to -15°C (-13°F to 5°F)</p> <ul style="list-style-type: none"> • Up to 6 months • If storing in freezer with other routinely recommended vaccines, carefully adjust freezer temperature range to THIS vaccine • Do NOT store on dry ice <p>Refrigerated: 2°C to 8°C (36°F to 46°F)</p> <ul style="list-style-type: none"> • Unopened vial: up to 30 days • Unopened vial: up to 12 hours at room temperature (up to 25°C [77°F]) • Punctured vial: up to 6 hours in refrigerator or at room temperature (2° to 25°C [36° to 77°F]) • Thawed vaccine cannot be refrozen <p>.....</p> <p>CDC Resources: Storage and Handling Summary (Moderna) www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf</p> <p>Freezer Vaccine Storage Temperature Log</p> <p>CELSIUS www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/temp-log-freezer-storage-celsius.pdf</p> <p>FAHRENHEIT www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/temp-log-freezer-storage-fahrenheit.pdf</p> <p>Refrigerator Vaccine Storage Temperature Log</p> <p>CELSIUS www.cdc.gov/vaccines/covid-19/downloads/refrigerator-storage-logger-celsius.pdf</p> <p>FAHRENHEIT www.cdc.gov/vaccines/covid-19/downloads/refrigerator-storage-logger-fahrenheit.pdf</p> <p>Moderna Resource: Storage and handling guidance www.modernatx.com/covid19vaccine-eua/providers/storage-handling</p>

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	Pfizer-BioNTech	Moderna
Expiration date	<p>CDC Resource: COVID-19 expiration date tracking tool www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf</p>	<p>CDC Resource: COVID-19 expiration date tracking tool www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf</p> <p>Moderna Resource: Vaccine expiration date look-up tool (Moderna) www.modernatx.com/covid19vaccine-eua/providers/vial-lookup</p>
Preparation and administration		
Thawing	<p>Vaccine may be thawed in refrigerator or at room temperature</p> <p>Refrigerator: 2°C to 8°C (36°F to 46°F)</p> <ul style="list-style-type: none"> • 25–195 vials may take 2 to 3 hours to thaw • Fewer vials will take less time <p>Room temperature: up to 25°C (77°F)</p> <ul style="list-style-type: none"> • Thaw between 30 minutes and 2 hours • Unopened vials may be kept at room temperature for up to 2 hours. Mix with diluent within 2 hours or return to refrigerator • Once diluted, use or discard within 6 hours <p>Thawed vaccine cannot be refrozen</p>	<p>Vaccine may be thawed in refrigerator or at room temperature</p> <p>Refrigerator: 2°C to 8°C (36°F to 46°F)</p> <ul style="list-style-type: none"> • 2.5 hours to thaw <p>Room temperature: 15°C to 25°C (59°F to 77°F)</p> <ul style="list-style-type: none"> • Thaw for 1 hour • Unopened vials may be kept at room temperature for up to 12 hours • Once punctured, use or discard within 6 hours <p>Thawed vaccine cannot be refrozen</p>
Dilution	<p>Dilute vial of vaccine concentrate with 1.8 mL preservative-free* 0.9% sodium chloride (normal saline)</p> <p>*do not use bacteriostatic normal saline</p> <ul style="list-style-type: none"> • Thaw before dilution, invert gently to mix • Do not shake vial (discard if shaken) • Must use diluted vaccine within 6 hours or discard <p>.....</p> <p>CDC Resources: Vaccine preparation: mixing diluent and vaccine www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/diluent-poster.pdf</p>	NONE
Needle gauge and length	22–25 gauge, 1 – 1½"	22–25 gauge, 1 – 1½"
Dose	0.3 mL	0.5 mL
Route	Intramuscular (IM)	Intramuscular (IM)

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	Pfizer-BioNTech	Moderna
Preparation and administration <i>continued</i>		
Dosing regimen	<p>2 doses, separated by 21 days (3 weeks)</p> <ul style="list-style-type: none"> Both doses must be Pfizer-BioNTech vaccine Schedule dose #2 at least 21 days after dose #1. Doses administered up to 4 days early are still considered valid; however, do not routinely schedule at less than 21 days. If dosing interval exceeds 21 days, give ASAP. Do not restart series. <p>.....</p> <p>CDC Resources: Preparation and Administration Summary (Pfizer) www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/prep-and-admin-summary.pdf Standing Orders Template (Pfizer) www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf</p>	<p>2 doses, separated by 28 days (1 month)</p> <ul style="list-style-type: none"> Both doses must be Moderna vaccine Schedule dose #2 at least 28 days after dose #1. Doses administered up to 4 days early are still considered valid; however, do not routinely schedule at less than 28 days. If dosing interval exceeds 28 days, give ASAP. Do not restart series. <p>.....</p> <p>CDC Resources: Preparation and Administration Summary (Moderna) www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/prep-and-admin-summary.pdf Standing Orders Template (Moderna) www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf</p>
Contraindications and precautions	<p>Contraindication:</p> <ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) or any non-severe immediate allergic reaction (e.g., hives, swelling, or wheezing within 4 hours) to a previous dose or any component of the vaccine, including polyethylene glycol (PEG) or polysorbate (a related chemical compound). <p>Precautions:</p> <ul style="list-style-type: none"> An immediate allergic reaction of any severity to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) Moderate to severe illness (defer until recovered) <p>.....</p> <p>CDC Resources: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html APPENDIX A: <i>Triage of persons presenting for mRNA COVID-19 vaccination</i> APPENDIX B: <i>Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines</i> Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html</p>	
Recommended observation time post-vaccination	<p>Persons with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy or a history of anaphylaxis (from any cause) – 30 minutes</p> <p>All other persons – 15 minutes</p>	
Adverse event reporting	<p>General reporting:</p> <ul style="list-style-type: none"> Vaccine Adverse Events Reporting System (VAERS): https://vaers.hhs.gov Under EUA, COVID-19 vaccination providers are required to report: vaccine administration errors, severe adverse events, cases of multisystem inflammatory syndrome (MIS-C), and cases of COVID-19 resulting in hospitalization or death <p>Patient self-reporting (voluntary):</p> <ul style="list-style-type: none"> v-safe (smartphone-based after vaccination health checker): www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html 	

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	Pfizer-BioNTech	Moderna
Post-injection symptoms / adverse events (as reported during clinical trials)	Most symptoms mild-moderate, onset within 1–2 days, and resolve in 1–2 days. Frequency higher for dose 2 and for younger recipients (<i>italics</i> =most commonly observed reactions) Injection site: <i>pain</i> , swelling, redness (80–89% reported one or more) Systemic: <i>fatigue, headache, muscle pain</i> , chills, fever, joint pain (71–83% reported one or more) CDC Resources: Reactions and adverse events (Pfizer-BioNTech) www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html	Most symptoms mild-moderate, onset within 1–2 days, and resolve in 1–2 days. Frequency higher for dose 2 and for younger recipients (<i>italics</i> =most commonly observed reactions) Injection site: <i>pain</i> , swelling, redness (84–91% reported one or more) Systemic: <i>fatigue, headache, muscle pain</i> , joint ache, chills (72–82% reported one or more) CDC Resources: Reactions and adverse events (Moderna) www.cdc.gov/vaccines/covid-19/info-by-product/moderna/reactogenicity.html
Codes		
Product	CPT – 91300* *American Medical Association www.ama-assn.org/system/files/2020-11/covid-19-immunizations-appendix-q-table.pdf NDC 10/11 (dose level/unit of use) 59267-1000-1 59267-1000-01 CVX – 208	CPT – 91301* *American Medical Association www.ama-assn.org/system/files/2020-11/covid-19-immunizations-appendix-q-table.pdf NDC 10/11 (dose level/unit of use) 80777-273-10 80777-0273-10 CVX – 207
Administration	<ul style="list-style-type: none"> • 1st dose: 0001A • 2nd dose: 0002A 	<ul style="list-style-type: none"> • 1st dose: 0011A • 2nd dose: 0012A
Medicare/CMS	Medicare Part B Payment for COVID-19 Vaccines...during the Public Health Emergency www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies	
Frequently Asked Questions	FAQs for Healthcare Professionals (CDC) www.cdc.gov/vaccines/covid-19/hcp/faq.html Ask the Experts (IAC) www.immunize.org/askexperts/experts_cov.asp	
Manufacturer contact (while under EUA)	Main website: www.cvdvaccine.com General product inquiries: 877-829-2619 Medical information: 800-438-1985 www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine Customer service: 800-879-3477	Main website: www.modernatx.com Customer service: 866-MODERNA (866-663-3762)