

# COVID-19 vaccine side-by-side comparison

October 2023



## About this document

This document includes a review of Pfizer-BioNTech, Moderna, and Novavax COVID-19 vaccines. The information contained in the side-by-side comparison is primarily based on product labeling for FDA-approved vaccines, emergency use authorizations (EUAs), and recommendations from the Advisory Committee of Immunization Practices (ACIP), **current as of October 16, 2023**. Updated 2023-24 monovalent omicron XBB.1.5 formulations for Pfizer-BioNTech and Moderna were approved on September 11, 2023. This includes FDA-approval of Pfizer-BioNTech's Comirnaty and Moderna's Spikevax, both indicated for use in patients  $\geq 12$  years of age, as well as EUAs for the use of these vaccines in children 6 months to 11 years of age. The updated XBB.1.5 formulation of the Novavax vaccine was authorized (via EUA) on October 3, 2023 for use in patients  $\geq 12$  years of age. The Janssen COVID-19 vaccine is not included in this side-by-side comparison as this product is no longer available for use in the US.

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## COVID-19 vaccine side-by-side comparison

	Generic name (brand name)		
	COVID-19 vaccine, mRNA (Comirnaty) <sup>1,2</sup>	COVID-19 vaccine, mRNA (Spikevax) <sup>3,4</sup>	COVID-19 vaccine, adjuvanted <sup>5</sup>
<b>Manufacturer</b>	Pfizer-BioNTech	Moderna	Novavax
<b>Original approval date</b>	2021 (monovalent original strain)	2022 (monovalent original strain)	NA
<b>Date on latest EUA / package insert</b>	<ul style="list-style-type: none"> <li>Package insert (Comirnaty): September 11, 2023</li> <li>EUA: September 11, 2023</li> </ul>	<ul style="list-style-type: none"> <li>Package insert (Spikevax): September 11, 2023</li> <li>EUA: September 11, 2023</li> </ul>	EUA: October 3, 2023
<b>AKA</b>	BNT162b2	mRNA 1273	NVX-CoV2373
<b>Vaccine platform technology</b>	mRNA vaccine		Protein subunit vaccine with adjuvant
<b>Valency</b>	Available as monovalent ( <b>Omicron XBB.1.5</b> ) only		Available as monovalent ( <b>Omicron XBB.1.5</b> ) only.
<b>Targeted SARS-CoV-2 antigen</b>	Full-length, prefusion stabilized SARS-CoV-2 spike protein		
<b>Indications for use</b>			
FDA-approved indications	Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals $\geq 12$ y of age	Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals $\geq 12$ y of age	NA - <u>Not</u> FDA approved
EUA indications	Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals $\geq 6$ mo through 11 y of age.	Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals $\geq 6$ mo through 11 y of age.	Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals $\geq 12$ y of age.
<b>Pharmacology</b>	mRNA encoding for the SARS-CoV-2 spike glycoprotein is delivered to cells in a lipid capsule; using this mRNA, cells manufacture the spike protein (antigen), which stimulates the body's immune response and production of antibodies against SARS-CoV-2.		Genetic sequence encoding the antigen (spike protein) is cloned into baculovirus and inserted into Sf9 insect cells, where the antigen is produced and subsequently isolated/extracted. Matrix-M adjuvant boosts immune response and enables vaccine dose-sparing by stimulating entry of antigen-presenting cells into the injection site and enhancing B- and T-cell responses

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<b>Recommended vaccine schedule</b>											
ACIP recommendations and dosing schedule <sup>6,7</sup>	<ul style="list-style-type: none"> <li>ACIP recommends 2023-2024 (monovalent, XBB containing) COVID-19 vaccines as authorized under EUA or approved by BLA in all persons ≥ 6 mo regardless of previous vaccination status.</li> <li>Bivalent mRNA COVID-19 vaccines are <u>no longer</u> recommended in the US.</li> </ul> <p><u>Complete vaccination status criteria:</u></p> <ul style="list-style-type: none"> <li>Everyone ≥ 5 y is recommended to receive 1 dose of the 2023-24 mRNA monovalent (XBB.1.5) COVID-19 vaccine (includes previously vaccinated and unvaccinated individuals).</li> <li>Children aged 6 mo to 4 y are recommended to complete a multi-dose initial series (2 doses of Moderna or 3 doses of Pfizer-BioNTech mRNA COVID-19 vaccine). For children who previously received the recommended number of doses, an additional dose with the 2023-24 mRNA monovalent XBB.1.5 vaccine, from the same manufacturer from which they completed their initial series, is recommended. Children in this age group not previously vaccinated or with incomplete vaccination status should receive the number of recommended doses with a new mRNA monovalent XBB.1.5 vaccine to complete the series.</li> <li>Persons who are moderately or severely immunocompromised should complete a 3-dose initial series as previously recommended. Persons who previously received the recommended number of doses should receive an additional dose with one of the 2023-24 mRNA monovalent XBB.1.5 vaccines. Persons in this group not previously vaccinated or with incomplete vaccination status should receive the number of recommended doses with a new mRNA monovalent XBB.1.5 vaccine. People who are moderately to severely immunocompromised may get additional doses of the 2023–2024 mRNA monovalent XBB.1.5 COVID-19 vaccine.</li> </ul>		<p>ACIP recommends individuals ≥ 12 y receive <i>either</i> the updated 2023-24 mRNA (Moderna, Pfizer-BioNTech) or the updated 2023-24 Novavax vaccine.</p> <p>The updated 2023-24 Novavax vaccine is recommended in individuals ≥ 12 y as follows:</p> <ul style="list-style-type: none"> <li>Initial vaccination (previously unvaccinated): 2 doses of updated 2023-24 Novavax vaccine</li> <li>Previously vaccinated with any Original strain monovalent vaccine or bivalent mRNA vaccine: 1 dose of updated 2023-24 Novavax vaccine</li> <li>Individuals who are moderately or severely immunocompromised may receive ≥ 1 additional updated 2023-24 Novavax vaccine doses</li> </ul>								
Key changes in previous recommendations <sup>6,7</sup>	<table border="1"> <thead> <tr> <th>Previous bivalent mRNA</th> <th>2023-24 mRNA monovalent XBB.1.5</th> </tr> </thead> <tbody> <tr> <td>Single dose recommended in all persons ≥ 6 y</td> <td>Single dose recommended in all persons ≥ 5 y</td> </tr> <tr> <td>2 Moderna dosages authorized for 6 mo to 5 y depending on vaccination history and immune status</td> <td>All Moderna doses in ages 6 mo to 11 y are now 25 mcg</td> </tr> <tr> <td>Optional second bivalent dose for persons ≥ 65 y</td> <td>No additional dose recommended in persons ≥ 65 y at this time</td> </tr> </tbody> </table>		Previous bivalent mRNA	2023-24 mRNA monovalent XBB.1.5	Single dose recommended in all persons ≥ 6 y	Single dose recommended in all persons ≥ 5 y	2 Moderna dosages authorized for 6 mo to 5 y depending on vaccination history and immune status	All Moderna doses in ages 6 mo to 11 y are now 25 mcg	Optional second bivalent dose for persons ≥ 65 y	No additional dose recommended in persons ≥ 65 y at this time	<p>The updated 2023-24 Novavax vaccine is recommended for use individuals ≥ 12 y for both an initial primary series (if previously unvaccinated) and as a booster dose. Previously, a booster dose was authorized for use in individuals ≥ 18 y only. Additionally, the updated 2023-24 Novavax is recommended as an option alongside the updated mRNA vaccines. Previously the monovalent Original strain Novavax vaccine was only recommended in individuals who could not or would not receive the bivalent mRNA vaccine.</p>
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CDC interim clinical considerations	Refer to <a href="#">interim clinical considerations</a> on COVID-19 vaccines from CDC for up-to-date dosing and vaccine schedule recommendations. <sup>6</sup>																				
Route of administration	Intramuscular																				
<b>Interchangeability<sup>6,7</sup></b>	Authorization for using COVID-19 vaccines interchangeably varies by vaccination history, age, and product as shown in the table below (this guidance applies to persons who are <u>not</u> immunocompromised). <i>Exceptions to the recommendations below include situations in which the same vaccine is not available, the previous dose is unknown, the individual would otherwise not complete the vaccination series, and if the individual is unable to complete the vaccination series with the same vaccine due to a contraindication.</i>																				
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<b>Clinical data</b>	Clinical data in humans for 2023-24 omicron XBB.1.5 monovalent vaccine are <u>not</u> available. Data from <i>mice</i> demonstrate equal immunogenicity against XBB.1.5, EG.5.1, and BA.2.86 subvariants. <sup>8</sup>	Clinical data in humans for 2023-24 omicron XBB.1.5 monovalent vaccine are <u>available</u> from a small <b>study</b> , in 50 patients ≥ 18 y, designed to evaluate immunogenicity and safety of an mRNA monovalent (50 mcg omicron XBB.1.5) vaccine and an mRNA bivalent (25 mcg omicron XBB.1.5 / 25 mcg omicron BA.4/BA.5) vaccine. Robust neutralizing antibody titers against XBB.1.5, XBB.1.16, EG.5.1, FL.1.5.1, and BA.2.86	Clinical data in humans for 2023-24 omicron XBB.1.5 monovalent vaccine are <u>not</u> available. Data from <i>macaques</i> demonstrated robust neutralizing antibody responses against XBB subvariants. <sup>11</sup>																		

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		subvariants were demonstrated with the XBB.1.5 vaccine. The safety profile of the XBB.1.5 vaccine was consistent with previously authorized vaccines. <sup>9,10</sup>	
<b>Safety</b>			
Contraindications	Known history of severe allergic reaction (eg, anaphylaxis) to any component of vaccine		
Warnings and precautions	<ul style="list-style-type: none"> <li>• <b>Myocarditis and pericarditis:</b> Postmarketing data demonstrate an increased risk of myocarditis and pericarditis. The observed risk is highest in males 12 to 39 y of age. Cases have occurred most frequently in adolescent and young adult males within 7 d following the second dose of an mRNA vaccine (Moderna or Pfizer-BioNTech); cases have been observed following other doses and in females as well. CDC and ACIP determined that the benefits of COVID-19 vaccination outweigh the rare risk of myocarditis and pericarditis in all populations. Additional information available from <a href="#">CDC</a> and in <a href="#">interim clinical considerations</a>.<sup>6,12</sup></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Myocarditis and pericarditis:</b> Novavax vaccine and post-authorization vaccine safety monitoring outside the US suggest an increased risk of myocarditis and pericarditis following the Novavax COVID-19 vaccine. CDC and ACIP determined that the benefits of COVID-19 vaccination outweigh the rare risk of myocarditis and pericarditis in all populations. Additional information available from <a href="#">CDC</a> and in <a href="#">interim clinical considerations</a>.<sup>6,12</sup></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Management of allergic reactions:</b> Allergic reactions, including anaphylaxis, may occur following vaccination. Ensure appropriate medical treatment is immediately available if needed.</li> <li>• <b>Syncope:</b> Syncope may occur following vaccination, particularly in adolescents; ensure proper precautions are in place to avoid injury if fainting occurs.</li> <li>• <b>Altered immunocompetence:</b> Persons with immunocompromising conditions may have a diminished response to the vaccine.</li> <li>• <b>Limitation of effectiveness:</b> Vaccination may not protect all vaccine recipients.</li> </ul>
Adverse reactions	<p><i>Data from studies evaluating Original, Omicron BA.1, and/or Omicron BA.4/BA.5 strains. Data are <u>not</u> reported for the 2023-24 monovalent XBB.1.5 strain vaccine.</i></p> <ul style="list-style-type: none"> <li>• <b>6 to 23 mo:</b> Most common (incidence ≥ 3%) adverse reactions include irritability, drowsiness, injection site redness, decreased appetite, fatigue, fever, pain at the injection site, and injection site swelling</li> <li>• <b>2 to 4 y:</b> Most common (incidence ≥ 2%) adverse reactions include fatigue, pain at the injection site, injection site redness, diarrhea, injection site swelling, fever,</li> </ul>	<p><i>Data from studies evaluating Original, Omicron BA.1, and/or Omicron BA.4/BA.5 strains. Data are <u>not</u> reported for the 2023-24 monovalent XBB.1.5 strain vaccine.</i></p> <ul style="list-style-type: none"> <li>• <b>6 to 23 mo:</b> Most common (incidence ≥ 5%) adverse reactions include pain at injection site, axillary swelling/tenderness, irritability, drowsiness, loss of appetite, and fever</li> <li>• <b>2 to 3 y:</b> Most common (incidence ≥ 5%) adverse reactions include pain at injection site, axillary swelling/tenderness, erythema, irritability, drowsiness, loss of appetite, and fever</li> </ul>	<p><i>Data from studies evaluating Original, Omicron BA.1, and/or Omicron BA.5 strains. Data are <u>not</u> reported for the 2023-24 monovalent XBB.1.5 strain vaccine.</i></p> <ul style="list-style-type: none"> <li>• <b>≥12 y:</b> Most common (incidence ≥ 5%) adverse reactions include injection site pain/tenderness, headache, fatigue/malaise, muscle pain, nausea/vomiting, joint pain, fever, injection site swelling, and injection site redness.</li> </ul>

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	<p>vomiting, diarrhea, headache, muscle pain, and chills</p> <ul style="list-style-type: none"> <li>• <u>5 to 11 y</u> (incidence ≥ 2%): pain at the injection site, fatigue, headache, muscle pain, joint pain, chills, injection site redness, fever, injection site swelling, vomiting, and diarrhea</li> <li>• <u>≥ 12 y</u> (incidence ≥ 10%): pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, and injection site redness</li> </ul>	<ul style="list-style-type: none"> <li>• <u>3 to 5 y</u>: Most common (incidence ≥ 3%) adverse reactions include pain at injection site, axillary swelling/tenderness, erythema, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, and fever</li> <li>• <u>6 to 11 y</u>: Most common (incidence ≥ 3%) adverse reactions include pain at injection site, axillary swelling/tenderness, erythema, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, and fever</li> <li>• <u>12 to 17 y</u>: Most common (incidence ≥ 13%) adverse reactions include pain at the injection site, fatigue, headache, myalgia, chills, axillary swelling/tenderness, arthralgia, nausea/vomiting, and swelling at the injection site</li> <li>• <u>18 to 64 y</u>: Most common (incidence ≥ 16%) adverse reactions include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, axillary swelling/tenderness, and nausea/vomiting</li> <li>• <u>≥ 65 y</u>: Common (≥ 14%) adverse reactions include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, and axillary swelling/tenderness</li> </ul>	
<b>Administration with other vaccines<sup>6,7</sup></b>	<p>The manufacturer information for the various COVID-19 vaccines note that there is limited information on co-administration with other vaccines. However, per ACIP, it is considered a best practice recommendation to administer all age-appropriate doses of vaccines simultaneously of children, adolescents, and adults, when no specific contraindications exist. Some exceptions, depending on the vaccine, may apply.</p> <p>Immunogenicity and safety of previous COVID-19 vaccine formulations have been observed to be generally similar when vaccines are administered simultaneously with non-COVID-19 vaccines as when administered alone. Studies comparing coadministration vs separate administration of previous COVID-19 formulations and influenza vaccines found similar levels of immunogenicity and similar or slightly higher reactogenicity.</p>		
<b>How supplied</b>			
Product listing	<p><b>Comirnaty (≥ 12 y)</b></p> <ul style="list-style-type: none"> <li>• <u>SDV</u>; dose = 30 mcg XBB.1.5/0.3 mL</li> <li>• <u>PFS</u>; dose = 30 mcg XBB.1.5/0.3 mL</li> </ul>	<p><b>Spikevax (≥ 12 y)</b></p> <ul style="list-style-type: none"> <li>• <u>SDV</u>; dose = 50 mcg XBB.1.5/0.5 mL</li> <li>• <u>MDV</u>; dose = 50 mcg XBB.1.5/0.5 mL</li> </ul>	<p><u>MDV</u>; dose = 5 mcg XBB.1.5/0.5 mL</p>

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	<p><b>EUA product – yellow cap and label with yellow border (6 mo to 4 y)</b></p> <ul style="list-style-type: none"> <li>• <u>MDV</u>; each dose = 3 mcg XBB.1.5/0.3 mL</li> </ul> <p><b>EUA product – blue cap and label with blue border (5 to 11 y)</b></p> <ul style="list-style-type: none"> <li>• <u>SDV</u>; each dose = 10 mcg XBB.1.5/0.3 mL</li> </ul>	<ul style="list-style-type: none"> <li>• <u>PFS</u>; dose = 50 mcg XBB.1.5/0.5 mL</li> </ul> <p><b>EUA product – dark blue cap and label with a green box (6 mo to 11 y)</b></p> <ul style="list-style-type: none"> <li>• <u>SDV</u>; dose = 25 mcg XBB.1.5/0.25 mL</li> </ul>	
Storage (unopened vials and PFS)	<ul style="list-style-type: none"> <li>• Vials and PFS may be shipped frozen on dry ice</li> <li>• Vials and PFS may be transferred to refrigerator to thaw at 2°C to 8°C for up to 10 wks</li> <li>• Alternatively, frozen vials and PFS may be stored in ultra-low temperature freezer (-90°C to -60°C) until product expiration date</li> <li>• Thawed vials and PFS (when in full carton) may be stored at room temperature at 8°C to 25°C for up to 12 h</li> <li>• Individual thawed PFS outside of the carton may be stored at room temperature at 8°C to 25°C for up to 4 h</li> </ul>	<ul style="list-style-type: none"> <li>• Store frozen between -50°C to -15°C</li> <li>• Vials and PFS may be stored under refrigeration at 2°C to 8°C for up to 30 d</li> <li>• Vials and PFS may be stored at room temperature at 8°C to 25°C for up to 24 h; total storage time at room temperature must not exceed 24 h</li> </ul>	<ul style="list-style-type: none"> <li>• Store under refrigeration at 2°C to 8°C</li> <li>• Do <u>not</u> freeze</li> </ul>
Thawing	<ul style="list-style-type: none"> <li>• Do <u>not</u> refreeze vials or PFS after thawing</li> <li>• Frozen vials and PFS may take up to 2 h to thaw under refrigeration</li> <li>• Vials not previously thawed under refrigeration can be thawed at room temperature, up to 25°C, for 30 min</li> <li>• A full carton of PFS may be thawed at room temperature, up to 25°C, for 60 min</li> </ul>	<ul style="list-style-type: none"> <li>• Do <u>not</u> refreeze vials or PFS after thawing</li> <li>• MDV may take up to 2 h to thaw under refrigeration; alternatively, MDV may be thawed at room temperature, up to 25°C, for 45 min</li> <li>• SDV may take up to 45 min to thaw under refrigeration; alternatively, SDV may be thawed at room temperature, up to 25°C, for 15 min</li> <li>• PFS may take up to 1 h to that under refrigeration; alternatively, PFS may be thawed at room temperature, up to 25°C, for 45 min</li> </ul>	NA

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	COVID-19 vaccine, mRNA (Comirnaty) <sup>1,2</sup>	COVID-19 vaccine, mRNA (Spikevax) <sup>3,4</sup>	COVID-19 vaccine, adjuvanted <sup>5</sup>
Handling	<p><b>All formulations:</b></p> <ul style="list-style-type: none"> <li>Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.</li> <li>Do <u>not</u> shake.</li> </ul> <p><b>Comirnaty (≥ 12 y)</b></p> <ul style="list-style-type: none"> <li><u>SDV</u>; do <u>not</u> dilute</li> <li><u>PFS</u>; do <u>not</u> remove from carton to thaw</li> </ul> <p><b>EUA product – yellow cap and label with yellow border (6 mo to 4 y)</b></p> <ul style="list-style-type: none"> <li><u>MDV</u>; dilute with 1.1 mL sterile 0.9% sodium chloride injection USP</li> </ul> <p><b>EUA product – blue cap and label with blue border (5 to 11 y)</b></p> <ul style="list-style-type: none"> <li><u>SDV</u>; do <u>not</u> dilute.</li> </ul>	<p><b>All preparations:</b></p> <ul style="list-style-type: none"> <li>Do <u>not</u> dilute</li> <li>Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light</li> <li>Do <u>not</u> shake</li> </ul>	<ul style="list-style-type: none"> <li>Do <u>not</u> dilute.</li> <li>Protect from light.</li> <li>Do <u>not</u> freeze.</li> <li>Do <u>not</u> shake.</li> </ul>
BUD (opened vials)	<p><b>EUA product – yellow cap and label with yellow border (6 mo to 4 y)</b></p> <ul style="list-style-type: none"> <li><u>MDV</u>; discard after <u>12 h</u> from first puncture</li> </ul>	<p><b>Spikevax MDV (≥ 12 y)</b> – discard <u>12 h</u> after first puncture</p>	<p><b>MDV:</b> after first puncture, hold vial between 2°C to 25°C for up to 12 h. Discard after <u>12 h</u> from first puncture.</p>
WAC <sup>13</sup>	\$120	\$129	\$130
Ordering and distribution	Both Comirnaty and EUA product are available via commercial distribution via direct purchasing and wholesalers.	Both Spikevax and EUA product are available via commercial distribution via direct purchasing and wholesalers.	The XBB.1.5 monovalent Novavax product will be available via commercial distribution. <sup>14</sup>
CPT codes <sup>15</sup>	<ul style="list-style-type: none"> <li>Comirnaty – 30 mcg dose: 91320</li> <li>EUA product (yellow cap) – 3 mcg dose: 91318</li> <li>EUA product (blue cap) – 10 mcg dose: 91319</li> </ul>	<ul style="list-style-type: none"> <li>Spikevax – 50 mcg dose: 91322</li> <li>EUA product – 25 mcg dose: 91321</li> </ul>	EUA product – 5 mcg dose: 91304
CMS payment allowance <sup>15</sup>	<ul style="list-style-type: none"> <li>Comirnaty – 30 mcg dose: \$131.10</li> </ul>	<ul style="list-style-type: none"> <li>Spikevax – 50 mcg dose: \$145.92</li> <li>EUA product – 25 mcg dose: \$145.92</li> </ul>	EUA product – 5 mcg dose: \$148.20

	Generic name (brand name)		
	COVID-19 vaccine, mRNA (Comirnaty) <sup>1,2</sup>	COVID-19 vaccine, mRNA (Spikevax) <sup>3,4</sup>	COVID-19 vaccine, adjuvanted <sup>5</sup>
	<ul style="list-style-type: none"> <li>EUA product (yellow cap) – 3 mcg dose: \$65.36</li> <li>EUA product (blue cap) – 10 mcg dose: \$87.78</li> </ul>		
<b>Coverage<sup>16</sup></b>	<ul style="list-style-type: none"> <li>Insurance plans will cover the COVID-19 vaccines without cost sharing immediately following CDC recommendations.</li> <li>Uninsured children will have access to the COVID-19 vaccine at no cost under the <a href="#">Vaccines for Children Program</a>.</li> <li>Uninsured adults will have access to the COVID-19 vaccine at no cost through the <a href="#">Bridge Access Program</a>.</li> </ul>		

Abbreviations: ACIP = Advisory Committee on Immunization Practices; BLA = Biologics License Application; BUD = beyond-use date; CDC = Centers for Disease Control and Prevention; CMS = Centers for Medicare and Medicaid Services; COVID-19 = coronavirus disease of 2019; EUA = emergency use authorization; FDA = US Food and Drug Administration; MDV = multidose vial; mRNA = messenger RNA; PFS = prefilled syringe; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SDV = single-dose vial; TBD = to be determined; USP = United States Pharmacopeia; WAC = wholesale acquisition cost

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