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FDA Approved Updated (2023-24) COVID-19 Vaccination for Adults

WHAT FDA APPROVED ADULT COVID-19 VACCINES ARE AVAILABLE FOR 2023-24?

There are currently 2* FDA-approved adult COVID-19 vaccines commercially available for the 2023-24 season:

1. **SPIKEVAX** (COVID-19 Vaccine, mRNA; Moderna)
2. **COMIRNATY** (COVID-19 Vaccine, mRNA; Pfizer-BioNTech)

**A 3rd adult COVID-19 immunization – Novavax COVID-19 Vaccine; Adjuvanted – exists but is not FDA-approved (still under Emergency Use Authorization) and is not yet commercially available. This resource will focus on the aforementioned mRNA COVID-19 Vaccines.*

WHY ARE THEY CALLED "MONOVALENT" SHOTS?

These mRNA vaccine formulations are monovalent, meaning they target one strain of the SARS-CoV-2 virus: the Omicron XBB.1.5 subvariant. The FDA voted to target this lineage to better cover the predominantly circulating strains that descend from this variant (>99% of sequenced SARS-CoV-2 specimens in the US as of 9/2/2023) which are forecasted to carry the most infectious risk for the 2023-24 season. The retired bivalent vaccines (covering 2 strains) are no longer authorized/approved/recommended, as the 2 viral strains they covered are no longer in major circulation.

WHY ARE THEY CALLED "UPDATED" SHOTS?

The FDA designates the 2023-24 COVID-19 vaccines as updated shots in anticipation of needing to provide revised formulas annually, similar to the flu shot, which changes each year. Viruses that mutate sufficiently over time require administration of vaccines with updated compositions that reflect those viral changes. This is in contrast to previous COVID-19 vaccines labeled as boosters. A booster shot gives a single "boost" to the immunity conferred from a prior administration of the same vaccine (e.g., shingles, hepatitis, or the original COVID-19 vaccines). As we anticipate regular re-administration, possibly on an annual basis, we are moving away from the term booster, typically reserved for vaccine series.

HOW SAFE/EFFECTIVE ARE THESE UPDATED 2023-24 mRNA COVID-19 VACCINES?

On 9-11-23, the FDA approved these updated mRNA COVID-19 vaccines for persons aged ≥12 years, based on published assessments of the vaccine effectiveness (VE) and safety of their prior bivalent vaccine formulations.

Among adolescents and adults, benefits of bivalent vaccination were assessed using pooled observational VE data for 3 outcomes:

1. Medically attended COVID-19 (ED or UTC visit) – pooled VE: **53%** (95% CI = 50%–56%); low certainty
2. Hospitalization attributed to COVID-19 – pooled VE: **48%** (95% CI = 30%–61%); low certainty
3. Death attributed to COVID-19 – pooled VE: **61%** (95% CI = 41%–74%); very low certainty

Regarding serious adverse event potential, the risk for **myocarditis** or **pericarditis** after receipt of a bivalent vaccine dose is uncertain because myocarditis is a rare outcome, and bivalent vaccination coverage is relatively low, especially in adolescents and young adults. Myocarditis rates after booster doses in adolescent and young adult males are lower than rates after primary series vaccination, but estimates for monovalent and bivalent doses are limited. A longer interval between doses has been associated with lower rates of myocarditis.

In clinical trials of Moderna and Pfizer-BioNTech COVID-19 vaccines, types of post-vaccination reactions were generally similar. The most frequent reported reactions for older children, adolescents, and adults were:

- Local: Pain at the injection site; less commonly, redness and swelling
- Systemic: Fatigue, headache, and myalgia

Overall, symptoms tended to be more frequent and severe following the second dose of vaccine and among adolescents and younger adults compared with older adults. These safety and efficacy statements are abridged for conciseness. Consult the MMWR for more detailed findings.

WHAT ARE THESE VACCINES' INDICATIONS AND RECOMMENDATIONS FOR USE?

INDICATION

Both updated (2023-24) mRNA COVID-19 vaccines carry the same indication: active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

CDC RECOMMENDATION

On September 12, 2023, the Advisory Committee on Immunization Practices (ACIP) recommended vaccination with updated COVID-19 vaccines for all persons aged ≥6 months.

See the CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for current guidance on vaccine selection and timing based on an individual's age, immunocompetence and vaccine history.

The following pages provide the SPIKEVAX and COMIRNATY vaccine product specifications via the CDC's At-A-Glance resources.

VACCINE PRODUCT SPECIFICATIONS
SPIKEVAX (Moderna)

Updated (2023–24 Formula) Moderna COVID-19 Vaccine

At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2023–24 Moderna COVID-19 Vaccine products.

Distributed in:

Ages: 6 months through 11 years
Single-dose vial:
Dark blue cap and green label

Ages: 12 years and older
Single-dose vial:
Dark blue cap and blue label
Manufacturer-filled syringe

Storage and Handling

Find additional guidance on storing vaccine properly at:

- CDC *Vaccine Storage and Handling Toolkit*
- Moderna COVID-19 Vaccine | FDA
- Spikevax | FDA
- Moderna COVID-19 Vaccines | Modernatx.com

Ages	6 months through 11 years	12 years and older	
Supplied in:	Single-dose vial (SDV)	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)
Cap and/or label color:	Dark blue cap and green label	Dark blue cap and blue label	N/A
Storage temperature before puncture	**Between:** ▪ -50°C and -15°C (-58°F and 5°F) until the expiration date ▪ 2°C and 8°C (36°F and 46°F) for up to 30 days ▪ 8°C and 25°C (46°F and 77°F) for a total of 24 hours. Discard vial or syringe and unused vaccine after 24 hours. **NOTE:** The beyond-use date (30 days) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date.		
Thawing frozen vaccine	**Between:** ▪ 2°C and 8°C (36°F and 46°F) for 45 minutes. Let stand at room temperature (between 15°C and 25°C [59°F and 77°F]) for 15 minutes. OR ▪ 15°C and 25°C (59°F and 77°F) for 15 minutes	**Between:** ▪ 2°C and 8°C (36°F and 46°F) for 45 minutes. Let stand at room temperature (between 15°C and 25°C [59°F and 77°F]) for 15 minutes. OR ▪ 15°C and 25°C (59°F and 77°F) for 15 minutes	**Between:** ▪ 15°C and 25°C (59°F and 77°F) for 45 minutes.

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This CDC quick-reference guide also includes guidance for other formulations of the manufacturer's vaccine (e.g., the emergency use authorized pediatric Moderna COVID-19 vaccine). When needed, information specific to the adult formulation (SPIKEVAX) is highlighted with an orange box.

VACCINE PRODUCT SPECIFICATIONS
SPIKEVAX (Moderna)

Updated (2023–2024 Formula) Moderna COVID-19 Vaccine

At-A-Glance

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- Vaccine Administration Resource Library | CDC
- Moderna COVID-19 Vaccines | FDA
- Moderna COVID-19 Vaccine | cvdvaccine.com

Preparation

If the vaccine is frozen, allow to thaw. Before preparing the vaccine, let vaccine stand at room temperature for 15 minutes. Do NOT refreeze thawed vaccine.

- Check the vial label to ensure the expiration date has not passed.
  - Use Moderna expiration date tool at https://modernacovid19global.com/vial-lookup
- Do not shake.
- If using an SDV, gently swirl prior to withdrawing vaccine.
- Refer to package insert or EUA Fact Sheet for detailed instructions.

Administration

- COVID-19 vaccines may be administered at the same clinical visit as other routinely recommended vaccines.
- If using a SDV, withdraw 1 dose. After withdrawing the dose, discard the vial and any residual vaccine. Do NOT save used SDVs.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
6 months through 11 years of age	0.25 mL/25 *ug*	IM injection	22–25 gauge, 1"*	**6 months–2 years of age:** Vastus lateralis muscle in the anterolateral thigh†
				3–11 years of age: Deltoid muscle in the upper arm‡
12 years of age and older	0.5 mL/50 *ug*	IM injection	22–25 gauge, 1–1.5"*	Deltoid muscle in the upper arm‡

* A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the subcutaneous tissue is not bunched for children and adolescents ages 1–18 years and adults ages 19 years and older who weigh less than 130 pounds.

†The deltoid muscle in the upper arm may be used if the muscle mass is adequate in children ages 1–2 years.

‡ The vastus lateralis muscle in the anterolateral thigh may be used as an alternate site.

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This CDC quick-reference guide also includes guidance for other formulations of the manufacturer's vaccine (e.g., the emergency use authorized pediatric Moderna COVID-19 vaccine). When needed, information specific to the adult formulation (SPIKEVAX) is highlighted with an orange box.

VACCINE PRODUCT SPECIFICATIONS
SPIKEVAX (Moderna)

Updated (2023–2024 Formula) Moderna COVID-19 Vaccine

At-A-Glance

Scheduling Doses

The number of recommended 2023–24 COVID-19 vaccine doses varies by age, vaccine, vaccination history, and the presence of moderate or severe immune compromise. Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses, and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine

Precautions

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- 30 minutes for persons with:
  - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
  - A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type
- 15 minutes: All other persons

Documentation

Document each recipient's vaccine administration information:

- **Medical record:** The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
- **Vaccination record for recipient:** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or health care professional
- **Immunization information system (IIS):** Report the vaccination to the appropriate state/local IIS.

Report Adverse Events to the Vaccine Adverse Event Reporting System (VAERS)

- Adverse events that occur in a recipient following administration of any licensed or authorized COVID-19 vaccine should be reported to VAERS, including:
  - 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 myocarditis
  - Cases of pericarditis
  - Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

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This CDC quick-reference guide also includes guidance for other formulations of the manufacturer's vaccine (e.g., the emergency use authorized pediatric Moderna COVID-19 vaccine). When needed, information specific to the adult formulation (SPIKEVAX) is highlighted with an orange box.

VACCINE PRODUCT SPECIFICATIONS
COMIRNATY (Pfizer-BioNTech)

Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine
At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2023–24 Pfizer-BioNTech COVID-19 Vaccine products.

Distributed in:

- **Ages: 6 months through 4 years**
  Multiple-dose vial: yellow cap and yellow label
- **Ages: 5 through 11 years**
  Single dose vial: blue cap and blue label
- **Ages: 12 years and older**
  Single-dose vial: gray cap and gray label
  Manufacturer-filled syringe

Storage and Handling

Find additional guidance on storing vaccine properly at:

- CDC *Vaccine Storage and Handling Toolkit*
- Pfizer-BioNTech COVID-19 Vaccine | FDA
- Comirnaty | FDA
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Ages	6 months through 4 years	5 through 11 years	12 years and older	12 years and older
Supplied in:	3-dose multiple-dose vial (MDV)	Single-dose vial (SDV)	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)
Cap and/or label color:	Yellow cap and yellow label	Blue cap and blue label	Gray cap and gray label	N/A
Storage temperature before puncture	**Between:** ▪ -90°C and -60°C (-130°F and -76°F) until the expiration date ▪ 2°C and 8°C (36°F and 46°F) for up to 10 weeks ▪ 8°C and 25°C (46°F and 77°F) for up to 12 hours prior to the first puncture or use. **Do not store between -25°C and -15°C (-13°F and 5°F).** **NOTE:** The beyond-use date (10 weeks) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date.			
Thawing frozen vaccine	**Between:** ▪ 2°C and 8°C (36°F and 46°F) for up to 2 hours OR ▪ Up to 25°C (77°F) for 30 minutes			**Between:** ▪ 2°C and 8°C (36°F and 46°F) for 2 hours (preferred method) OR ▪ Up to 25°C (77°F) for 60 minutes **Note:** Individual syringes thawed at room temperature that are not used immediately must be used within 4 hours or discarded.

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This CDC quick-reference guide also includes guidance for other formulations of the manufacturer's vaccine (e.g., the emergency use authorized pediatric Pfizer-BioNTech COVID-19 vaccines). When needed, information specific to the adult formulation (COMIRNATY) is highlighted with an orange box.

VACCINE PRODUCT SPECIFICATIONS
COMIRNATY (Pfizer-BioNTech)

Updated (2023-2024 Formula) Pfizer-BioNTech COVID-19 Vaccine

At-A-Glance

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- Vaccine Administration Resource Library | CDC
- Pfizer-BioNTech COVID-19 Vaccines | FDA
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Preparation

- If the vaccine is frozen, thaw before use.
- Check the vial label to ensure the expiration date has not passed.
  - Use Pfizer-BioNTech expiration date tool at lotexpiry.cvdvaccine.com
- Product for ages 6 months through 4 years: mix with diluent.
  - Mix vial with 1.1 mL diluent. If using the MDV for the first time, record the date and time the vial was punctured. **NOTE:** The beyond-use time of 12 hours replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. **Do NOT use vaccine after the expiration date or beyond-use time.**
- Products for ages 5 through 11 years and 12 years and older: **Do NOT dilute.**
- **Do NOT shake.** If using an SDV, gently invert prior to withdrawing vaccine.
- Refer to package insert or EUA Fact Sheet for detailed instructions.

Administration

- COVID-19 vaccines may be administered at the same clinical visit as other routinely recommended vaccines.
- If using a MDV, Do NOT "pool vaccine" from more than 1 vial to obtain a dose. If a full dose cannot be withdrawn, discard the MDV and any remaining vaccine.
- If using a SDV, withdraw 1 dose. After withdrawing the dose, discard the vial and any residual vaccine. Do NOT save used SDVs.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
6 months through 4 years of age	0.3 mL/3 µg	IM injection	22–25 gauge, 1"*	**6 months–2 years of age:** Vastus lateralis muscle in the anterolateral thigh†
				2 through 4 years: Deltoid muscle in the upper arm‡
5 through 11 years of age	0.3 mL/10 µgL	IM injection	22–25 gauge, 1"*	Deltoid muscle in the upper arm‡
12 years of age and older	0.3 mL/30 µg	IM injection	22–25 gauge, 1–1.5"*§	Deltoid muscle in the upper arm‡

* A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the subcutaneous tissue is not bunched for children and adolescents ages 1–18 years and adults ages 19 years and older who weigh less than 130 pounds.

† The deltoid muscle in the upper arm may be used if the muscle mass is adequate for children ages 1–2 years.

‡ The vastus lateralis muscle in the anterolateral thigh may be used as an alternate site.

§ See Vaccine Administration: Needle Gauge and Length chart for more details.

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VACCINE PRODUCT SPECIFICATIONS
COMIRNATY (Pfizer-BioNTech)

Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine

At-A-Glance

Scheduling Doses

The number of recommended 2023–24 COVID-19 vaccine doses varies by age, vaccine, vaccination history, and the presence of moderate or severe immune compromise. Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses, and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine

Precautions

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- 30 minutes for persons with:
  - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
  - A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type
- 15 minutes: All other persons

Documentation

Document each recipient's vaccine administration information:

- **Medical record:** The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
- **Vaccination record for recipient:** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or health care professional
- **Immunization information system (IIS):** Report the vaccination to the appropriate state/local IIS.

Report Adverse Events to the Vaccine Adverse Event Reporting System (VAERS)

- Adverse events that occur in a recipient following administration of any licensed or authorized COVID-19 vaccine should be reported to VAERS, including:
  - 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 myocarditis
  - Cases of pericarditis
  - Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

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