

Joint Interagency Task Force on COVID-19

June 20, 2022

Training for COVID-19 Vaccines: Pfizer BioNTech ages 6 month through 4 years Moderna* ages 6 months through 5 years

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VACCINATE.WV.GOV #CommunityImmunityWV *Note: The ACIP will meet June 23, 2022 to discuss recommendations for Moderna COVID-19 vaccine for ages 6 through 17 years. Information forthcoming.





Two products authorized for our youngest

The FDA authorized, Advisory Committee on Immunization Practices (ACIP) voted, and CDC recommended **Pfizer-BioNtech** COVID-19 Vaccine for **ages 6 months through 4 years** on June 18, 2022. This is a 3 dose primary series.



The FDA authorized, ACIP voted, and CDC recommended **Moderna** COVID-19 Vaccine for Pediatrics for **ages 6 months through 5 years** on June 18, 2022. This is a 2 dose primary series.



The ACIP will meet June 23, 2022 to discuss recommendations for Moderna COVID-19 vaccine for ages 6 through 17 years. Stay tuned for this information.





Pfizer-BioNTech

for ages 6 months through 4 years



Pfizer-BioNTech Formulations & Dosing

Pfizer-BioNTech COVID-19 Vaccine Presentations



Pfizer-BioNTech COVID-19 Vaccine Presentations at https://www.fda.gov/media/159304/download

*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

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** The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

Pfizer-BioNTech Formulations & Storage

Age Indications ^a	12 years and older	5 through 11 years	6 mos through 4 years ^d	
Vial Cap Color and Label with Color Border	GRAY		MAROON	
		Storage Conditions		
ULT Freezer (-90°C to -60°C) ^c	12 months	12 months	12 months	
Freezer (-25°C to -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE	
Refrigerator (2°C to 8°C)	10 weeks	10 weeks	10 weeks	
Room Temperature (8°C to 25°C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	
After First Puncture (2°C to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours	

^a Use the appropriate product based on the age of the recipient. ^b Use the diluent (Sterile 0.9% Sodium Chloride Injection, USP) included in the ancillary supply kit. Do not use any other normal saline or diluent. ^c Regardless of storage condition, vaccines should not be used after 12 months from the date of manufacture printed on the vial and cartons.



Pfizer-BioNTech 6mo through 4yr Preparation & Administration

Pfizer-BioNTech COVID-19 Vaccine, Multiple Dose Vial with Maroon Cap and a Label with a Maroon Border

Age Range	Dilution Information	Doses Per Vial After Dilution	Dose Volume
6 months through 4 years*	Dilute with 2.2 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	10	0.2 mL

* The vial labels may state "Age 2y to < 5y" or "Age 6m to < 5y" and carton labels may state "For age 2 years to < 5 years" or "For age 6 months to < 5 years". Vials with either printed age range can be used for individuals 6 months through 4 years of age.



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Pfizer-BioNTech HealthCare Provider Fact Sheet 6 months through 4 years, maroon cap (must dilute) available at https://www.fda.gov/media/159312/download

Pfizer-BioNTech 6mo through 4yr Storage & Handling



Pfizer BioNTech ages 6 months through 4 years COVID-19 vaccine **cannot** be refrozen.



From the time the vaccine is placed in the refrigerator, it is good for 10 weeks and this date should be written on the vial.



Regardless of storage condition, vaccines should not be used after 12 months from the **date of manufacture** printed on the vial and cartons



Vials should be discarded 12 hours after dilution. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the current EUA supersedes the number of hours printed on vial labels and cartons.



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Pfizer-BioNTech HealthCare Provider Fact Sheet 6 months through 4 years, maroon cap (must dilute) available at https://www.fda.gov/media/159312/download

Pfizer-BioNTech Dosing & Schedule

The Pfizer-BioNTech COVID-19 Vaccine for individuals 6 months through 4 years of age is supplied in multiple dose vials with maroon caps and labels with maroon borders. The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of 3 doses (0.2 mL each) The initial 2 doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose in individuals 6 months through 4 years of age.



Individuals who will turn from 4 years to 5 years of age between any doses in the primary series may receive:

✓ a 2-dose primary series with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 mcg modRNA, supplied in multiple dose vials with orange caps and labels with orange borders)

OR

a 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (each 0.2 mL dose containing 3 mcg modRNA, supplied in multiple dose vials with maroon caps). Each of Doses 2 and 3 may be with:

 Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (supplied in multiple dose vials with maroon caps)



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Pfizer-BioNTech HealthCare Provider Fact Sheet 6 months through 4 years, maroon cap (must dilute) available at https://www.fda.gov/media/159312/download

Pfizer-BioNTech 6mo through 4 years Administration

After dilution:

- Each dose drawn must contain a white to off-white suspension with no particulate
- Each dose must contain 0.2mL of the diluted vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2mL, discard the vial and content
- Do not pool vaccine from multiple vials
- The full 0.2mL dose must come from a single vial





Moderna

for ages 6 months through 5 years



Moderna Formulations & Dosing

Note: The ACIP will meet June 23, 2022 to discuss recommendations for Moderna COVID-19 vaccine for ages 6 through 17 years. Information forthcoming.

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Age Group	6 months through 5 years (Primary Series)	6 years through 11 years (Primary Series) Currently unavailable (Use the vial with dark blue cap and a label with a purple border)	6 years through 11 years (Primary Series) 18 years and older (Booster Dose)	12 years and older (Primary Series) 18 years and older (Booster Dose)
Vial Cap Color	Dark Blue	Dark Blue	Dark Blue	Red
Vial Label Border Color	MAGENTA	TEAL	PURPLE	LIGHT BLUE
Vial Image	Sequences for the second secon	Moderna COVID-19 Vaccine Internet Inter	Moderna Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Proceeding Covid-19 Vaccine Vacci	Moderne (Participation of the second of the
Primary Dose Volume	0.25 mL	0.5 mL	0.5 mL	0.5 mL
Booster Dose Volume	None	None	0.5 mL	0.25 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	www.modernatx.com/ covid19vaccine-eua	www.modernatx.com/ covid19vaccine-eua	www.modernatx.com/ covid19vaccine-eua	www.modernatx.com/ covid19vaccine-eua

MODERNA COVID-19 VACCINE PRESENTATIONS

Moderna COVID-19 Wallchart https://www.fda.gov/media/159306/download



Moderna Dosing and Administration

- The Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a magenta border is administered as a primary series of two doses (0.25 mL each) 1 month apart to individuals 6 months through 5 years of age.
- A third primary series dose (0.25 mL) of the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a magenta border is authorized for administration at least 1 month following the second dose to individuals 6 months through 5 years of age with **certain kinds of immunocompromise**.





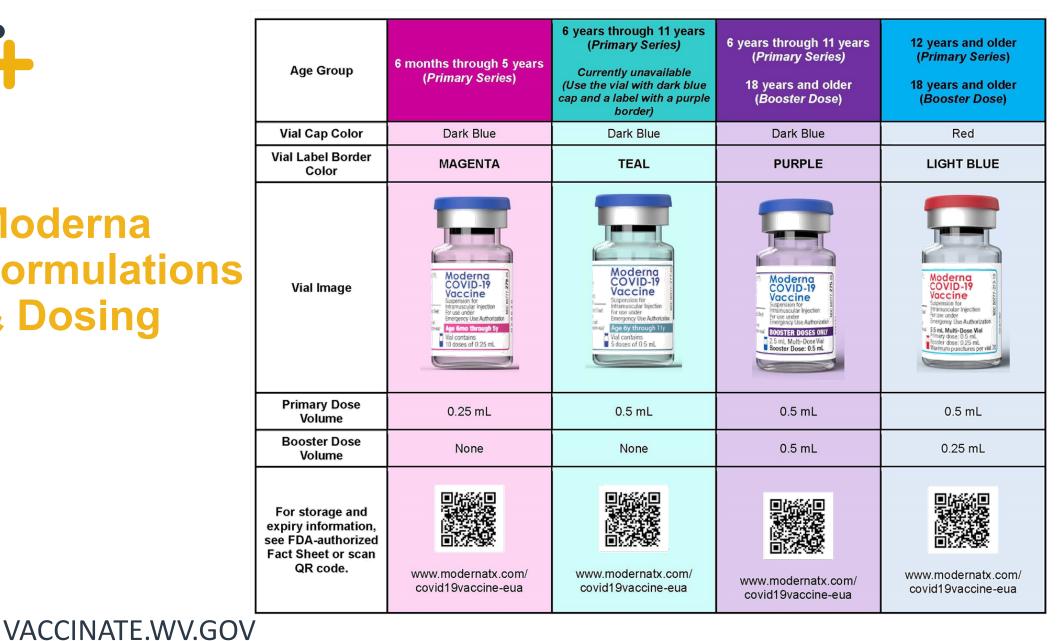
Moderna

for ages 6 years through 11 years ages 12 years through 17 years





Moderna Formulations & Dosing





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Moderna COVID-19 Wallchart https://www.fda.gov/media/159306/download

Moderna Dosing and Administration Ages 6 years through 11 years

- The Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border is administered as a primary series of two doses (0.5 mL each) 4 weeks apart to individuals 6 years through 11 years of age.
- A third primary series dose (0.5 mL) of the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border is authorized for administration at least 4 weeks following the second dose to individuals 6 years through 11 years of age with certain kinds of immunocompromise.



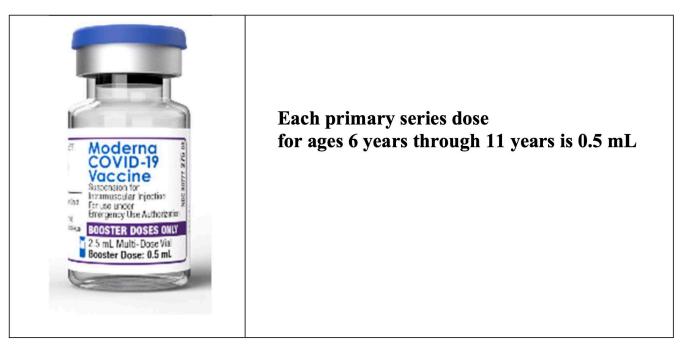
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https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/vaccine-at-a-glance.pdf

"BOOSTER DOSES ONLY" Vial Note:

- The Moderna COVID-19 Vaccine vial labeled "BOOSTER DOSES ONLY" is also authorized to provide primary series doses (0.5mLeach) for individuals 6 through 11 years of age.
- This Moderna COVID-19 Vaccine is supplied as multiple-dose vials with dark blue caps and labels with a purple border.

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*Moderna COVID-19 Vaccine supplied in a vial with a dark blue cap and a label with a **teal border stating "Age 6y through 11y" is currently not available.** Moderna COVID-19 Vaccine supplied in a vial with a dark blue cap and with a purple border stating "BOOSTER DOSES ONLY Booster dose FDA-authorized for use in children ages 6-11 years as a primary seried dose

Moderna Dosing and Administration Ages 12 years through 17 years

- The Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a red cap and a label with a light blue border is administered as a primary series of two doses (0.5 mL each) 4 weeks apart to individuals 12 years through 17 years of age.
- A third primary series dose (0.5 mL) of the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a red cap and a label with a light blue border is authorized for administration at least 4 weeks following the second dose to individuals 12 years through 17 years of age with certain kinds of immunocompromise.



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https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/vaccine-at-a-glance.pdf



COVID-19 Vaccine Considerations

for mRNA vaccines in pediatric populations



Hultiple Vaccine Administration



COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.



If multiple vaccines are administered at a single visit, administer each injection in a different injection site, according to recommendations by age.

- Separate injection sites by 1 inch or more.
- For older children (≥11 years), the deltoid muscle can be used.
- For younger children, if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.



Selection of Appropriate Needle Length

Infants, 1–12 months	22–25-gauge 1 inch (25 mm)	Vastus lateralis muscle of anterolateral thigh
Toddlers, 1–2 years	22–25-gauge 1–1.25 inches (25–32 mm)	Vastus lateralis muscle of anterolateral thigh ³
	22–25-gauge 5/8 ² –1 inch (16–25 mm)	Deltoid muscle of arm
Children, 3–10 years	22–25-gauge 5/8 ² –1 inch (16–25 mm)	Deltoid muscle of arm ³
	22–25-gauge 1–1.25 inches (25–32 mm)	Vastus lateralis muscle of anterolateral thigh

The kits provided with the vaccine will come with 25g 1" needles

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A 5/8"needle may be used in newborns, preterm infants, and patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin. https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

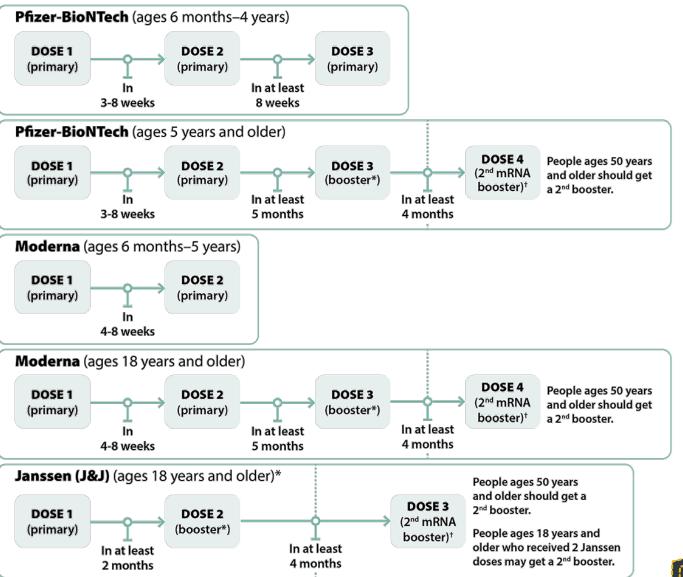


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Summary of COVID-19 Vaccine Schedule for Most People

https://www.cdc.gov/vaccines/covid-19/images/COVID19-vaccinationschedule-most-people.png

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*Age-appropriate mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary and booster vaccination. Janssen COVID-19 Vaccine should only be used in limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-Janssen

[†]2nd booster dose for some groups

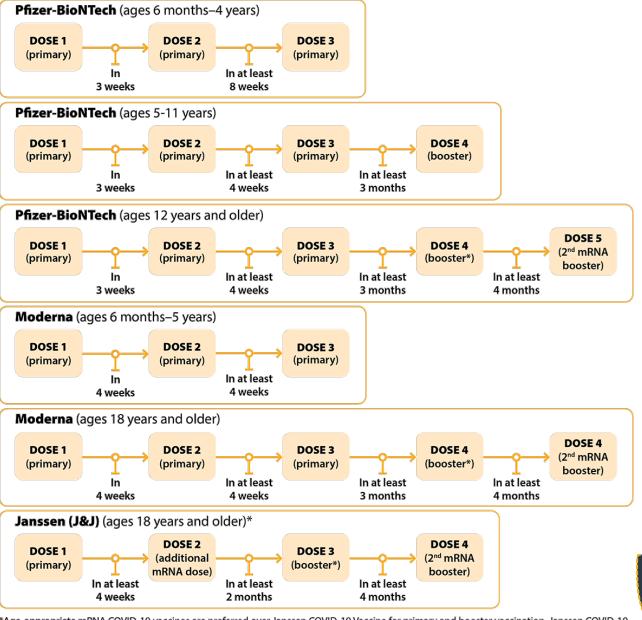


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Summary of COVID-19 Vaccine Schedule for Moderately to Severely Immunocompromised People

https://www.cdc.gov/vaccines/covid-19/images/COVID19-vaccinationschedule-immunocompromised.png

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*Age-appropriate mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary and booster vaccination. Janssen COVID-19 Vaccine should only be used in limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us. html#considerations-Janssen

+ Other Clinical Information



Correct Dosage is based on the child's age the day of the vaccination.



Side Effects:

- Local: pain, swelling, erythema at the injection site
- Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy



Routine antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. Aspirin is NOT recommended in those 18 years and under due to risk of Reye's Syndrome

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Interim Clinical Considerations for COVID-19 Vaccine in Children Ages 5-11. Dr. Woodsworth. ACIP Meeting 11-2-2021 available at <u>https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf</u> EUA for Pfizer BIONTech COVID-19 Vaccine Pediatric (Orange Cap) available at <u>https://www.fda.gov/media/153714/download</u> and https://www.fda.gov/media/153717/download



Administration Errors (Prevention Tips)

- Formulations of COVID-19 Vaccines are NOT interchangeable. e.g., Do NOT dilute adult Pfizer to attempt to make pediatric Pfizer
- mRNA vaccines are not interchangeable for the primary series.
- Double check proper COVID-19 vaccine product type and amount is administered for the person's age and dose within the series.
- Always check cap color and label.



- Ensure correct dose is given for age at time of vaccination (double check age and pediatric vaccination dosing schedule).
- Always keep Wall Charts posted in the vaccine storage/preparation area.

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Follow TED to Avoid COVID-19 Vaccine Errors



TYPE

Are you using the recommended COVID-19 vaccine for this person?

EXPIRATION

☑ Did you check the vial's expiration date?

Is the vaccine within the usable time frame for the storage conditions?

DOSE

- ✓ Is this the correct amount for the person's age, dose number, and vaccine type?
- Was the vaccine prepared correctly for the product type (diluted or not)?

For brand-specific COVID-19 vaccine info, visit the FDA:





If an error occurs: report on **vaers.hhs.gov** and call the WV COVID-19 Hotline 1-800-887-4304



Vaccine Adverse Event Reporting System (VAERS)

- For reporting adverse events or administration errors for vaccines: https://vaers.hhs.gov
 - 1. Must report to VAERS if error adverse event occurs, and
 - 2. Contact WV COVID-19 Hotline **1-800-887-4304**, and further instructions will be provided by Dr. Elizabeth Scharman.

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Follow TED to Avoid COVID-19 Vaccine Errors



TYPE

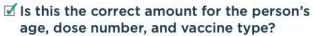
Are you using the recommended COVID-19 vaccine for this person?

EXPIRATION

☑ Did you check the vial's expiration date?

✓ Is the vaccine within the usable time frame for the storage conditions?

DOSE



Was the vaccine prepared correctly for the product type (diluted or not)?

For brand-specific COVID-19 vaccine info, visit the FDA:





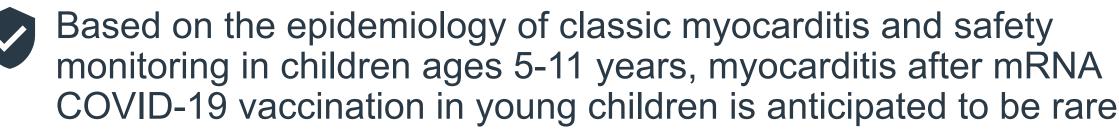
If an error occurs: report on **vaers.hhs.gov and** call the WV COVID-19 Hotline **1-800-887-4304**



Vaccine-associated myocarditis in young children



• No cases occurred during clinical trials (n = 7,804 with at least 7 days of follow-up)



• Dose in younger children is lower than dose used in older children



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Oliver S. Evidence to Recommendation Framework: Moderna COVID-19 vaccine in children ages 6 months – 5 years & Pfizer-BioNTech COVID-19 vaccine in children ages 6 months – 4 years. Presented at ACIP Meeting June 17, 2022 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/03-COVID-Oliver-508.pdf

Myocarditis & pericarditis in children/teens



Rare risk for myocarditis and/or pericarditis following mRNA COVID-19 vaccination. These rare cases of myocarditis or pericarditis have occurred most frequently in adolescent and young adult males within the first week after receiving the second dose of an mRNA COVID-19 vaccine.



May be increased risk of myocarditis and pericarditis in males ages 18–39 years following the second dose of Moderna COVID-19 Vaccine relative to other authorized or approved mRNA COVID-19 vaccines.



The risk of myocarditis/pericarditis from COVID-19 disease is higher than the small risk associated with vaccination



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Oliver S. Evidence to Recommendation Framework: Moderna COVID-19 vaccine in children ages 6 months – 5 years & Pfizer-BioNTech COVID-19 vaccine in children ages 6 months – 4 years. Presented at ACIP Meeting June 17, 2022 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/03-COVID-Oliver-508.pdf

Vaccine-associated myocarditis & dosing intervals



An 8-week interval between the first and second doses of an mRNA COVID-19 vaccine primary series may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years.



A shorter interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.



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Oliver S. Evidence to Recommendation Framework: Moderna COVID-19 vaccine in children ages 6 months – 5 years & Pfizer-BioNTech COVID-19 vaccine in children ages 6 months – 4 years. Presented at ACIP Meeting June 17, 2022 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/03-COVID-Oliver-508.pdf





The Fact Sheets for Healthcare Providers and Recipients/Caregivers for Pfizer BioNTech: https://bit.ly/C19PfizerFactSheets



The Fact Sheets for Healthcare Providers and Recipients/Caregivers for Moderna: https://bit.ly/C19ModernaFactSheets

VACCINATE.WV.GOV #CommunityImmunityWV <u>Pfizer: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine</u>

Moderna: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine</u>



COVID-19 VACCINATION

Due Date Calculator

Available online at vaccinate.wv.gov



COVID-19 Vaccination Due Date Calculator & Medical Info Page



COVID-19 Vaccination Due Date Calculator is an online tool that helps people figure out **when** they may be due for a COVID-19 shot **and the type** they are recommended to get, making it easier to stay up to date.



Use the calculator:

- Visit vaccinate.wv.gov (scroll down)
- Enter birthdate, first type & number of COVID-19 vaccines received, immunocompromise status, and date of most recent COVID-19 shot
- Receive due date for vaccination and recommended type(s) of COVID-19 vaccine
- On **bottom of final page, click "Medical Info" button** for summary of input and additional clinical considerations for healthcare providers (examples next)



"Medical Info" Page for Health Providers (or anybody who wants more in-depth info)

If you need help finding a COVID-19 vaccination location, including vaccination options for someone who is homebound, contact the West Virginia COVID-19 Vaccine Info Line at 1-833-734-0965.

Read COVID-19 vaccination FAQs, including more information on recommended vaccine types here: https://dhhr.wv.gov/COVID-19/Pages/FAQs.aspx

Medical Info Start over



Click this button for a page that provides a summary of entries, clinical considerations & info links

Medical Info (Summary & Clinical Considerations)

COVID-19 Vaccination Due Date Calculator		
To return to the previous page to review prior information, schedule a vaccination appoi reminder to your personal calendar, please click the browser Back button.	ntment, or add a vaccination	
Summary information		
• DOB = August, 22, 1945		
 First Vaccine Type = Pfizer Number of Doses = 2 	LINKS/RESOURCES:	
 Immunocompromised = No Most Recent Shot = April, 25, 2022 	For a calendar view, scroll down here (and scro immunocompromised): https://bit.ly/C19CDCca	Il down even further for the schedule for those who are moderately or severely lview
Date Calculated: Sun, September 25, 2022	For more detailed information about the immun	ization schedule and dosing, go here: https://bit.ly/C19CDCSchedDosing
Recommended Vaccine Type: Any available (mRNA recommended)	For summary clinical considerations, go here: h	https://bit.ly/C19CDCSummaryConsid
See below for vaccination schedule table and links relevant to clinical considerations us type of COVID-19 vaccines.	For the full Interim Clinical Considerations for L here: https://bit.ly/C19cdcClinicalConsideration	lse of COVID-19 Vaccines Currently Approved or Authorized in the United States, go s
	Read COVID-19 vaccination FAQs in WV here:	https://bit.ly/C19VaxFAQ
	For more information about COVID-19 shots in	West Virginia, visit https://vaccinate.wv.gov
	FDA FACT SHEETS:	
	Pfizer (Comirnaty and Pfizer-BioNTech COVID-	19 Vaccine) Fact Sheets: Click Here
	Moderna (Spikevax and Moderna COVID-19 Va	accine) Fact Sheets: Click Here
	J&J (Janssen/Johnson & Johnson COVID-19 V	Accine) Fact Sheets: Click Here Start over

+ Questions?

Krista Capehart, PharmD, MS, BCACP, FAPhA <u>Krista.d.Capehart@wv.gov</u> 304-206-5767





Contact your JIATF liaison or WV COVID-19 Hotline **1-800-887-4304**

VACCINATE.WV.GOV #CommunityImmunityWV *Friendly Reminder:

The ACIP will meet June 23, 2022 to discuss recommendations for Moderna COVID-19 vaccine for ages 6 through 17 years. Information forthcoming.

