July 20, 2022

COVID-19 Today: The Variants, The Vaccines, and The Therapeutics

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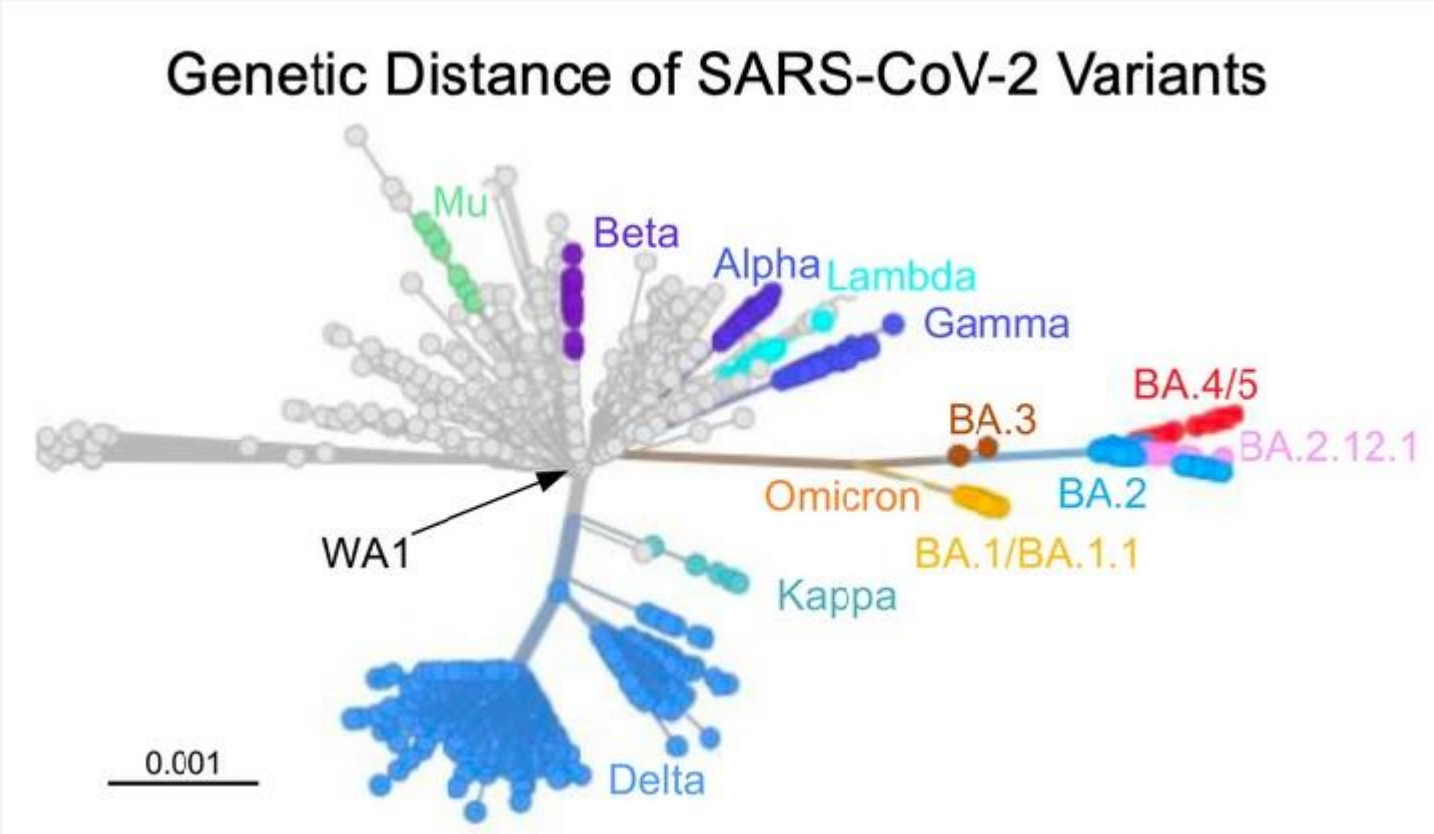
Objectives

- Review variants of concern and circulating variants.
- Discuss the current variants
- Describe current COVID-19 vaccines and recommendations
- Review COVID-19 outpatient therapeutic recommendations.

Variants

- Original COVID-19 SARS-CoV-2 Variants



https://erictopol.substack.com/p/the-ba5-story

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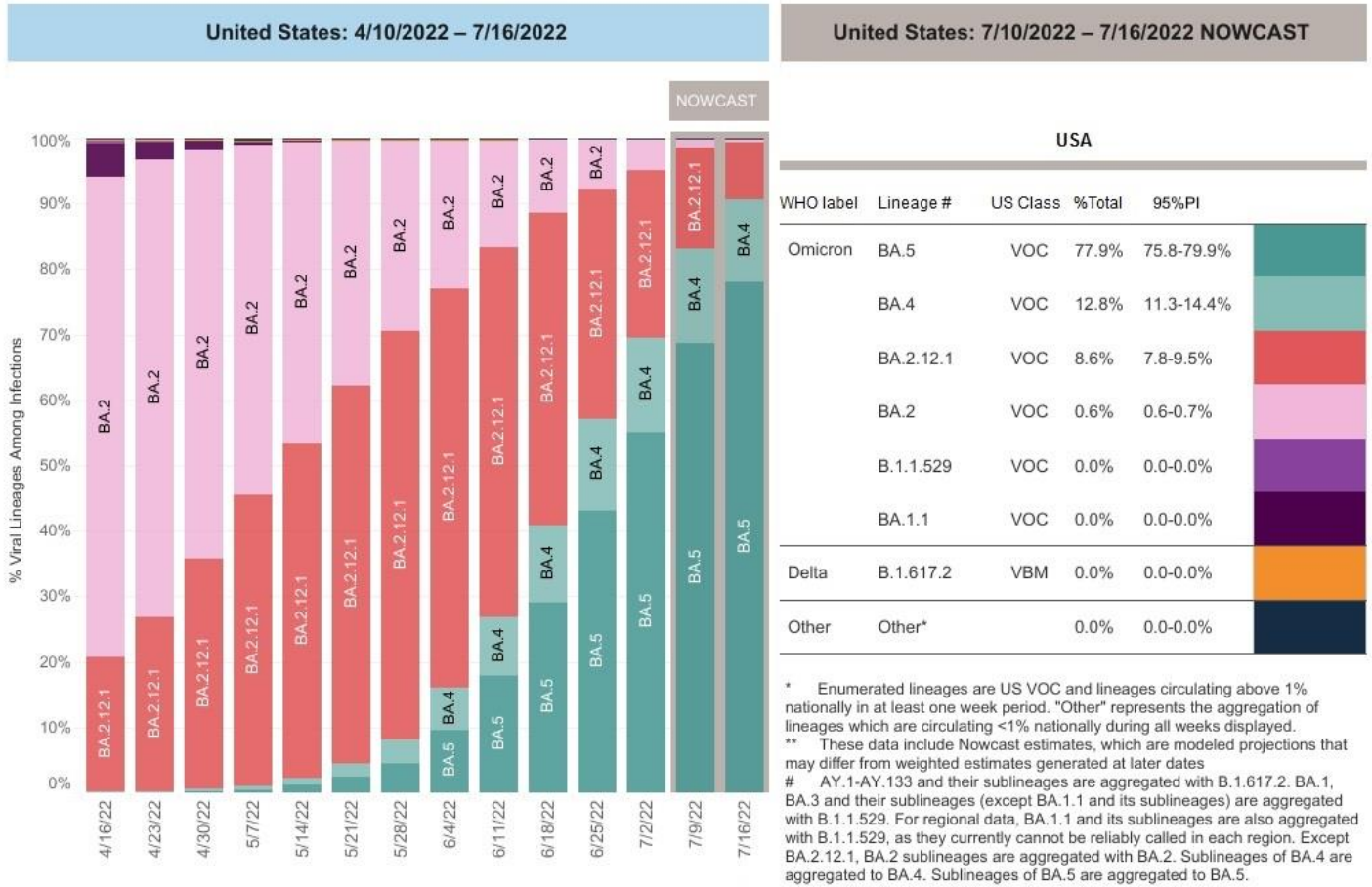
Variants by week



United States: 7/10/2022 – 7/16/2022 NOWCAST

USA

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.5	VOC	77.9%	75.8-79.9%
	BA.4	VOC	12.8%	11.3-14.4%
	BA.2.12.1	VOC	8.6%	7.8-9.5%
	BA.2	VOC	0.6%	0.6-0.7%
	B.1.1.529	VOC	0.0%	0.0-0.0%
	BA.1.1	VOC	0.0%	0.0-0.0%
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.0%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# AY.1-AY.133 and their sublineages are aggregated with B.1.617.2. BA.1, BA.3 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. For regional data, BA.1.1 and its sublineages are also aggregated with B.1.1.529, as they currently cannot be reliably called in each region. Except BA.2.12.1, BA.2 sublineages are aggregated with BA.2. Sublineages of BA.4 are aggregated to BA.4. Sublineages of BA.5 are aggregated to BA.5.

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https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Symptoms of BA5

- Less sensitive to neutralizing antibodies
- Runny nose, sore throat, headache, persistent cough and fatigue
- Lower airways
- Cross protection is not very good

Three 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 met June 23, 2022 and recommended Moderna COVID-19 vaccine for ages 6 through 17 years.
- ACIP met July 19, 2022 and recommended Novavax COVID 19 for ages 18 and over

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Pfizer-BioNTech

for ages 6 months through 4 years

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Pfizer-BioNTech Formulations & Dosing

Pfizer-BioNTech COVID-19 Vaccine Presentations

Age Group	6 months through 4 years	5 through 11 years	12 years and older	12 years and older
Vial Cap Color and Label Border Color	MAROON 	ORANGE 	PURPLE** 	GRAY** 
Is Dilution Needed?	Dilute Before Use	Dilute Before Use	Dilute Before Use	Do Not Dilute
Amount of Diluent* Needed per Vial	2.2 mL	1.3 mL	1.8 mL	NO DILUTION
Dose Volume	0.2 mL	0.2 mL	0.3 mL	0.3 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	www.cvdvaccine-us.com	www.cvdvaccine-us.com	www.cvdvaccine-us.com	www.cvdvaccine-us.com

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

*** 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.*

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

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 	ORANGE 	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.

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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.

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

Moderna

for ages 6 months through 5 years

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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**.

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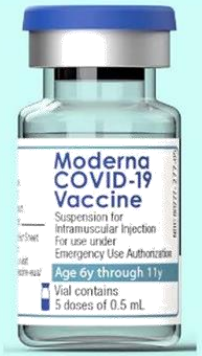
Moderna COVID-19 Fact Sheet 6 mo through 5 years (magenta border) https://www.fda.gov/media/159307/download

Moderna Formulations & Dosing

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				
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

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

Moderna

for ages 6 years through 11 years

ages 12 years through 17 years

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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.

Each primary series dose for ages 6 years through 11 years is 0.5 mL

*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 [illegible] with a purple border stating “BOOSTER DOSES ONLY Booster dose [illegible]mL is FDA-authorized for use in children ages 6-11 years as a primary series dose

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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

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Multiple 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.

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https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.htm

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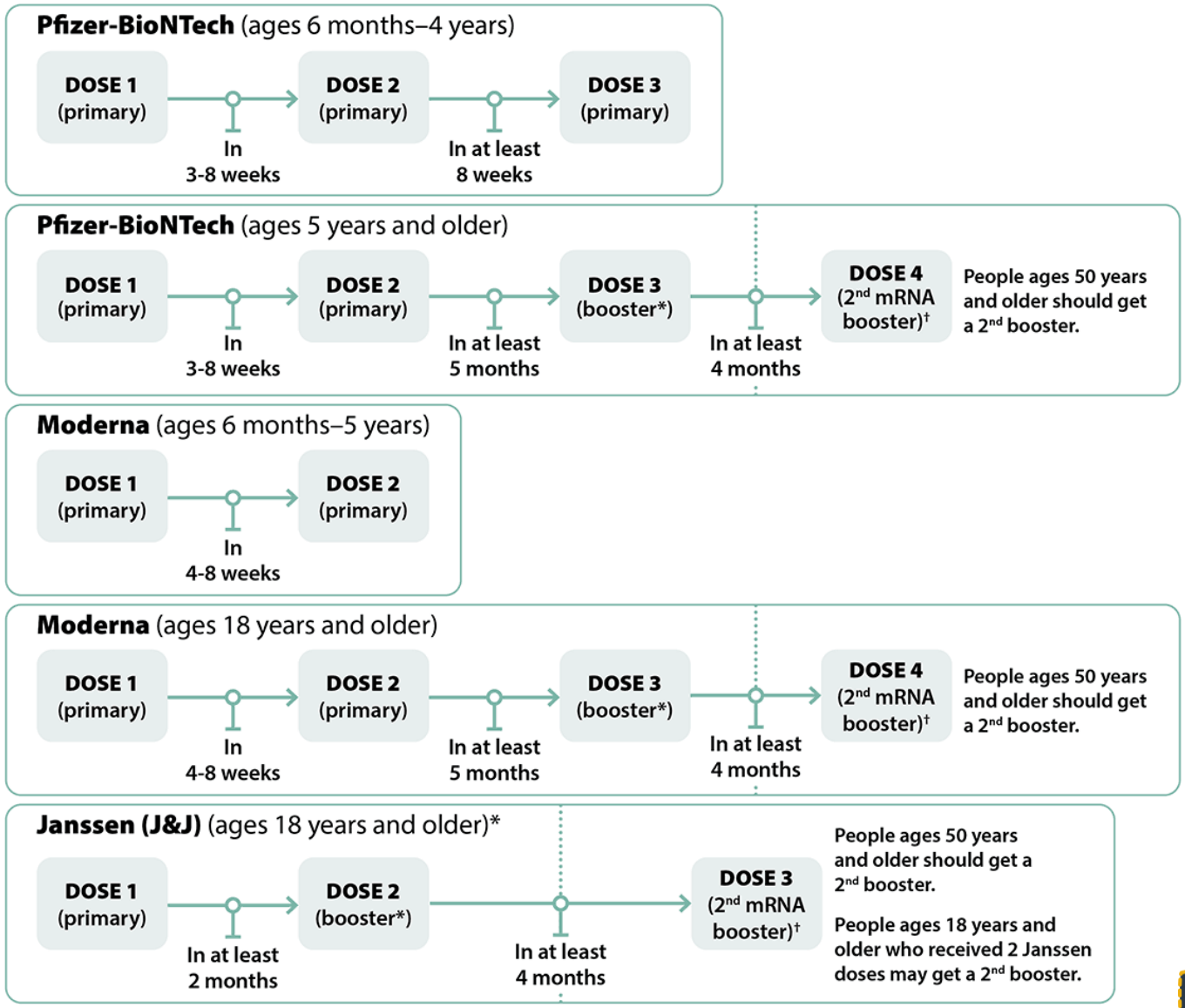
A 5/8"needle may be used in newborns, preterm infants, and patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.
https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-lengt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

Summary of COVID-19 Vaccine Schedule for Most People



*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

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

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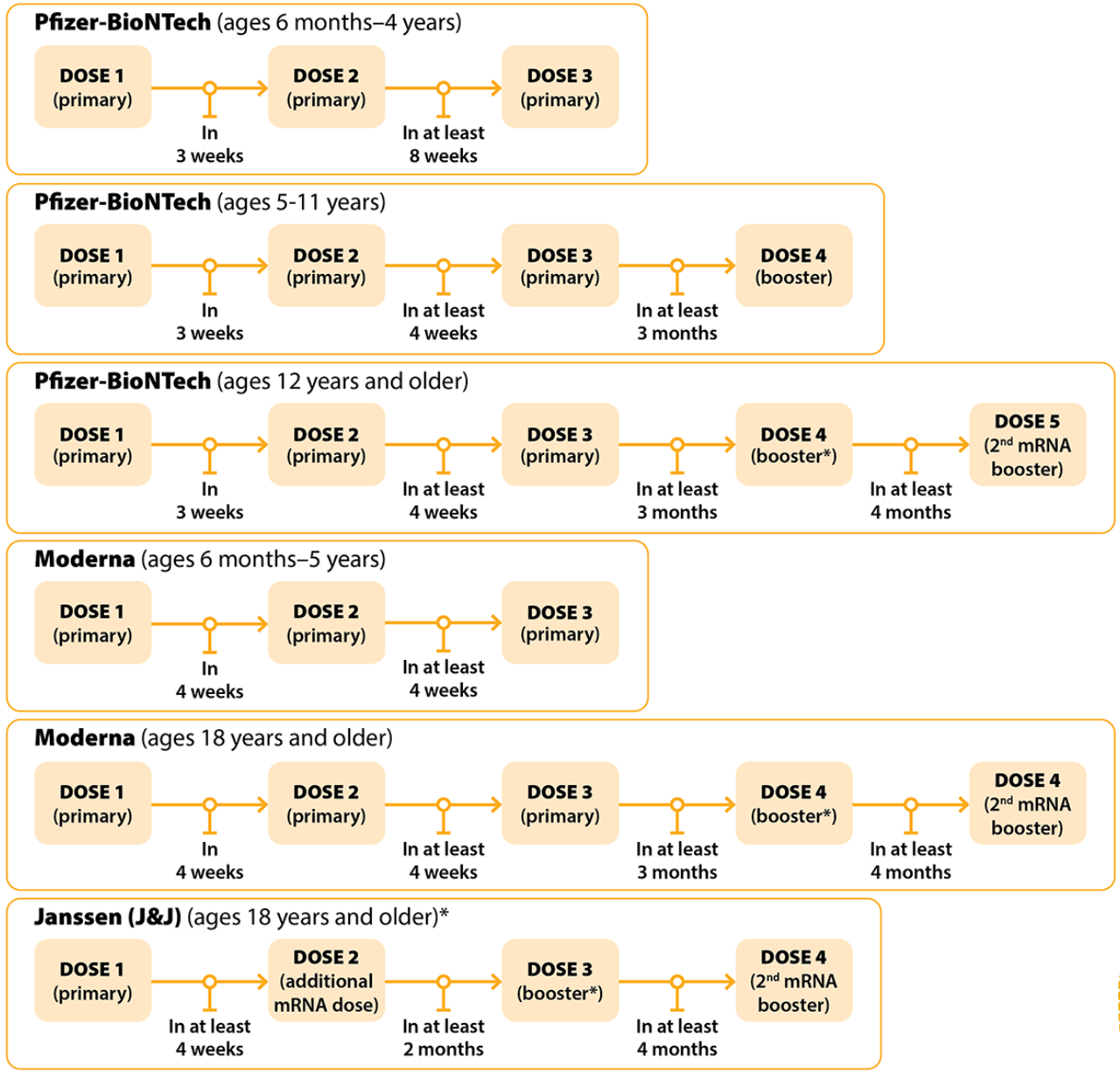
Summary of COVID-19 Vaccine Schedule for Moderately to Severely Immunocompromised People



*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

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

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Other Clinical Information

- Correct Dosage is based on the child's age the day of the vaccination.
- COVID-19 primary vaccination would be recommended for everyone ages 6 months years and older, **regardless of underlying medical conditions**.
- 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 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf
EUA for Pfizer BIONTech COVID-19 Vaccine Pediatric (Orange Cap) available at https://www.fda.gov/media/153714/download 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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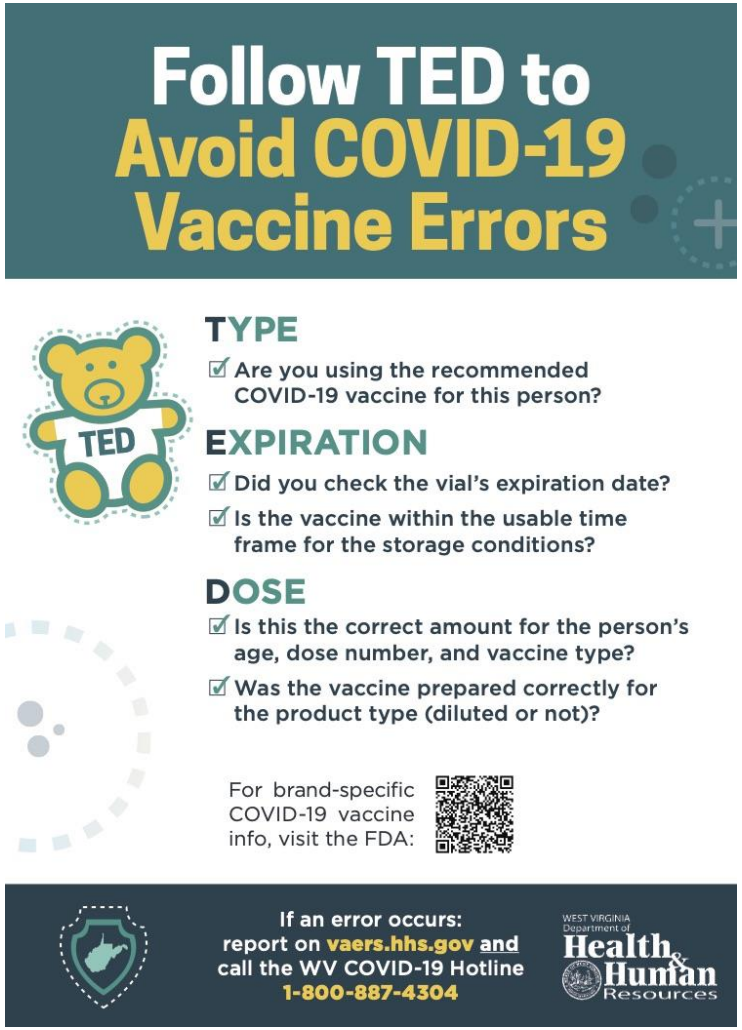

Vaccine Adverse Event Reporting System (VAERS)

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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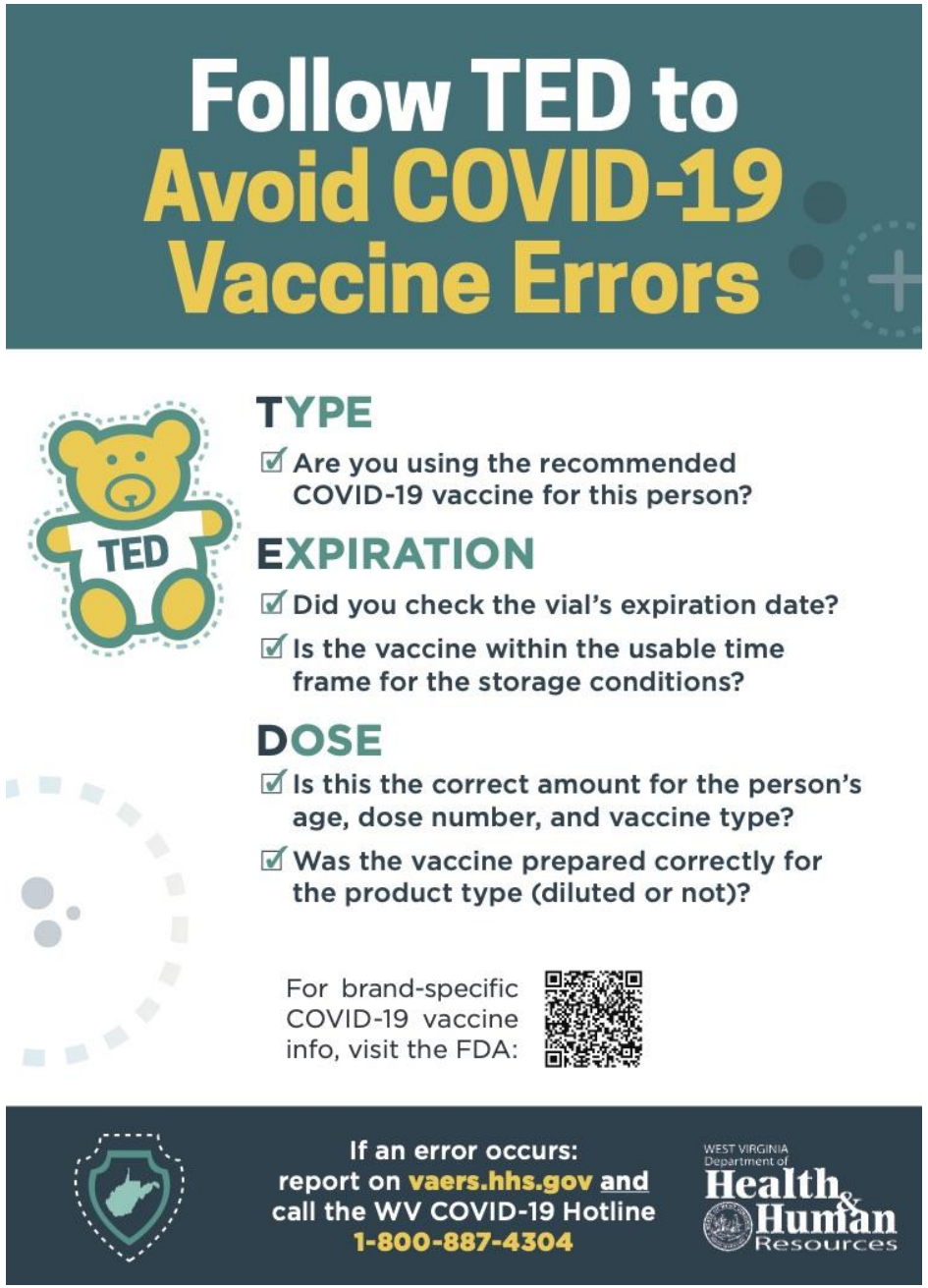

Vaccine-associated myocarditis in young children

- Risk of myocarditis after mRNA COVID-19 vaccination, if any, in young children is unknown
  - No cases occurred during clinical trials (*n* = 7,804 with at least 7 days of follow-up)
- Based on the epidemiology of classic myocarditis and safety monitoring in children ages 5-11 years, myocarditis after mRNA COVID-19 vaccination in young children is anticipated to be rare
  - Dose in younger children is lower than dose used in older children

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

EUA Fact Sheets

- 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

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Pfizer: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

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

NOVAVAX ®

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Novavax COVID-19 Vaccine

- COVID-19 Vaccine, Adjuvanted is a suspension for intramuscular injection
- Authorized for emergency use to provide a two-dose primary series to individuals 18 years of age and older
- The primary series of the Novavax COVID-19 Vaccine, Adjuvanted is two doses (0.5 mL each) given 3 weeks apart

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Novavax COVID-19 Vaccine - Storage

- Store the unpunctured multi-dose vial in a refrigerator between 2° to 8°C (36° to 46°F)
- After the first needle puncture, hold the vial between 2° to 25°C (36° to 77°F) for up to 6 hours. Discard the vial 6 hours after the first puncture
- Each multi-dose vial contains 10 doses of 0.5 mL each
- After the first needle puncture, hold the vial between 2° to 25°C (36° to 77°F) for up to 6 hours
- Side effects: pain, tenderness at site, swelling, fever, headache, fatigue, muscle pain, joint pain, nausea/vomiting

https://www.fda.gov/media/159897/download

COVID-19 VACCINATION

Due Date Calculator

Available online at

vaccinate.wv.gov

WEST VIRGINIA Department of Health & Human Resources

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)

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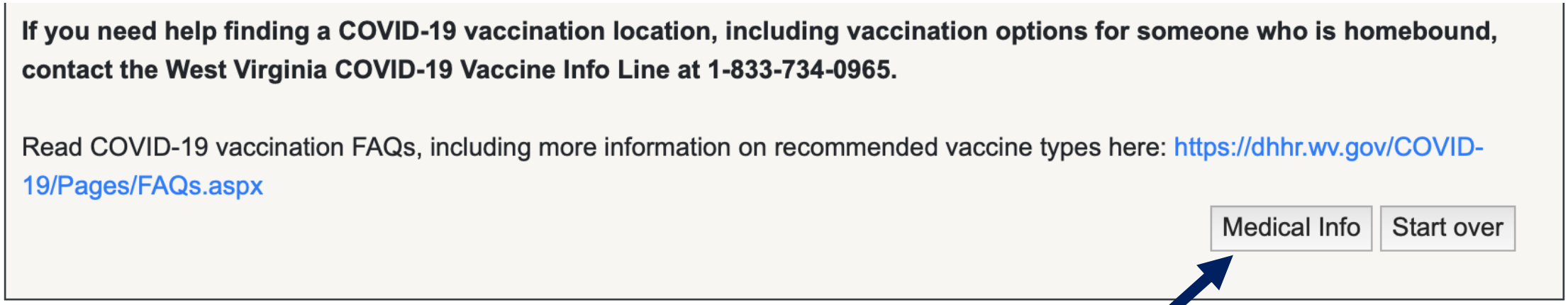
“Medical Info” Page for Health Providers (or anybody who wants more in-depth info)



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

COVID-19 Therapeutics

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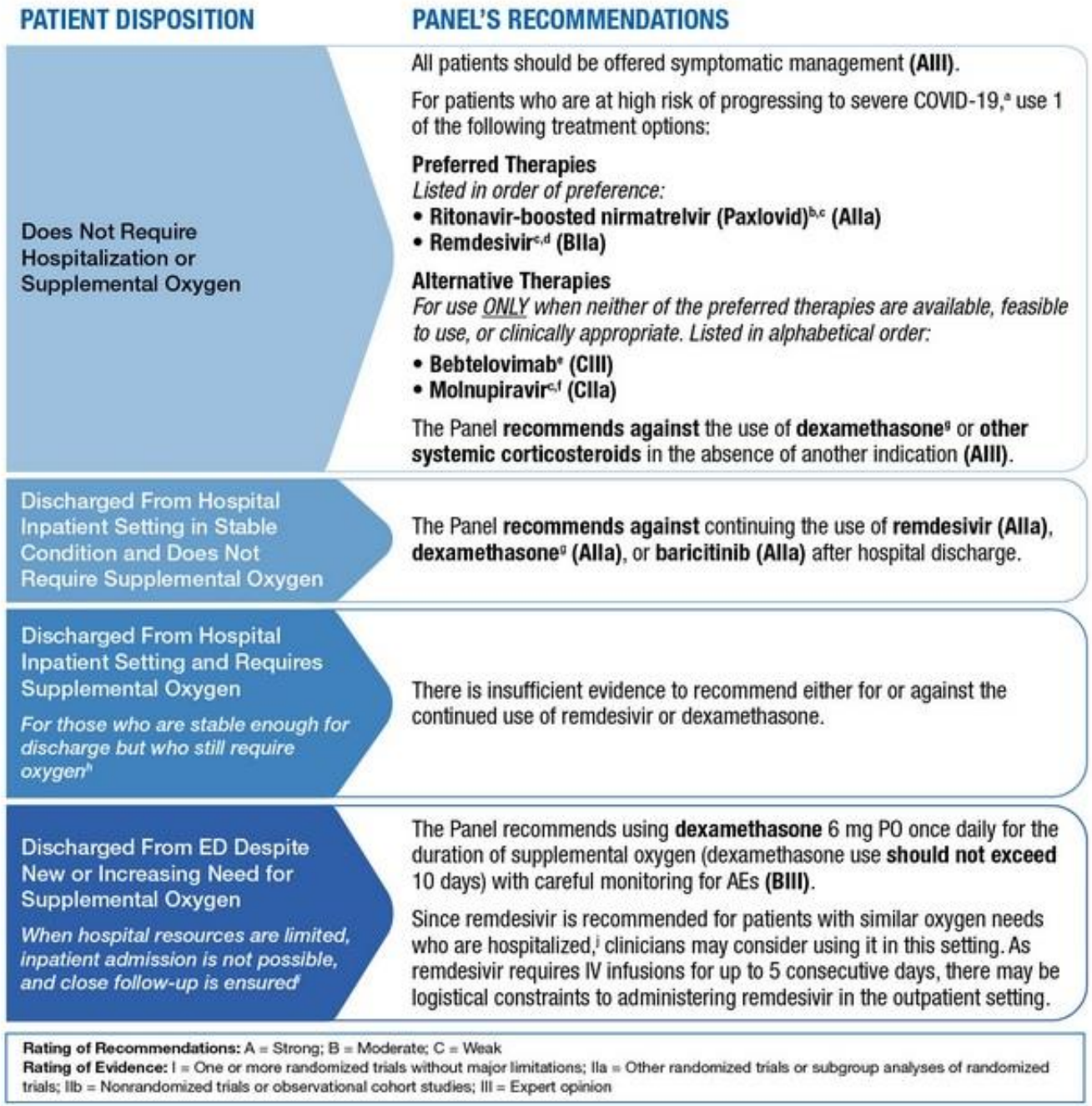
What are our outpatient treatment options?

- Paxlovid ®
- Remdesivir
- Bebtelovimab
- Molnupiravir

NIH COVID-19 Treatment Guidelines

Figure 1. Therapeutic Management of Nonhospitalized Adults With COVID-19



https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/clinical-management-summary/?utm_source=site&utm_medium=home&utm_campaign=highlights

Paxlovid and Paxlovid Renal

- Nirmatrelvir tablets co-packaged with ritonavir tablets
- Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days
- Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days
- PAXLOVID is not recommended in patients with severe renal impairment (eGFR <30 mL/min)
- PAXLOVID is not recommend in patients with severe hepatic impairment (Child-Pugh Class C)

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

- Positive SARS-CoV-2 test (Confirmation of a positive home rapid SARS-CoV-2 test result with additional direct SARS-CoV-2 viral testing is not required.)
- Age ≥ 18 years OR > 12 years of age and weighing at least 40 kg
- Has one or more risk factors for progression to severe COVID-191 (Healthcare providers should consider the benefit-risk for an individual patient.)
- Symptoms consistent with mild to moderate COVID-19
- Symptom onset within 5 days (Prescriber is encouraged to include a note to the pharmacist in the prescription stating: Please fill prescription by [insert date]. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.)
- Not requiring hospitalization due to severe or critical COVID-19 at treatment initiation
- No known or suspected severe renal impairment (eGFR < 30 mL/min)
- No history of clinically significant hypersensitivity reactions [e.g., toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome] to the active ingredients (nirmatrelvir, ritonavir) or other components of the product

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Paxlovid Concomitant Medication issues

- HMG-CoA reductase inhibitors (statins)
- Hormonal contraceptives containing ethinyl estradiol
- Medications for HIV-1 Treatment
- Antiarrhythmic, anticonvulsants, antipsychotics, PDE5 inhibitor etc
- ADDITIONAL RESOURCES:
- PAXLOVID - Fact Sheet for Healthcare Providers: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
- Prescribing Information (Label/Package Insert) for Individual Drugs (Drugs@FDA): https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
- University of Liverpool COVID-19 Drug Interactions: https://www.covid19-druginteractions.org/checker
- NIH COVID-19 Treatment Guidelines: https://www.covid19treatmentg

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Remdesivir - outpatient

- 200 mg IV on Day 1, followed by 100 mg IV once daily on Days 2 and 3
- Must be started within 7 days of symptoms
- Each infusion should be administered over 30–120 minutes. Patients should be observed for ≥1 hour after infusion as clinically appropriate.
- An eGFR <30 mL/min at screening or <90 days before screening was considered an exclusion criterion in the outpatient RDV study PINETREE, but only if a participant's weight was <48 kg.

Bebtelovimab – monoclonal antibody

- 175 mg as a single IV injection, administered over ≥30 seconds. Patients should be observed for ≥1 hour after injection.
- Started within 7 days of symptoms
- Active in vitro against all circulating Omicron subvariants, but there are no clinical efficacy data from placebo-controlled trials that evaluated the use of bebtelovimab in patients who are at high risk of progressing to severe COVID-19. Therefore, bebtelovimab should be used only when the preferred treatment options are not available, feasible to use, or clinically appropriate.

Molnupiravir (LAGEVRIO)

- Oral antiviral
  - with positive results of direct SARS-CoV-2 viral testing, and
  - who are at high risk for progression to severe COVID-19, including hospitalization or death, and
  - for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate

  - For those 18 yr and older
  - For no longer than 5 consecutive days
  - Not for pre-exposure or post-exposure prophylaxis

Molnupiravir (LAGEVRIO)

- Dosage in adult patients is 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food
- Not recommended for use during pregnancy
- Authorized to be prescribed to a pregnant individual only after the healthcare provider has determined that the benefits would outweigh the risks for that individual patient
- Females of childbearing potential should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of LAGEVRIO
- Males of reproductive potential who are sexually activ e with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.

Evusheld ®

- (tixagevimab co-packaged with cilgavimab) for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or**
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Evusheld ®

- EVUSHELD is not authorized for use in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.
- Contact COVID-19 Hotline at **1-800-887-4304** and we can arrange to get for your patient.

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Questions?

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