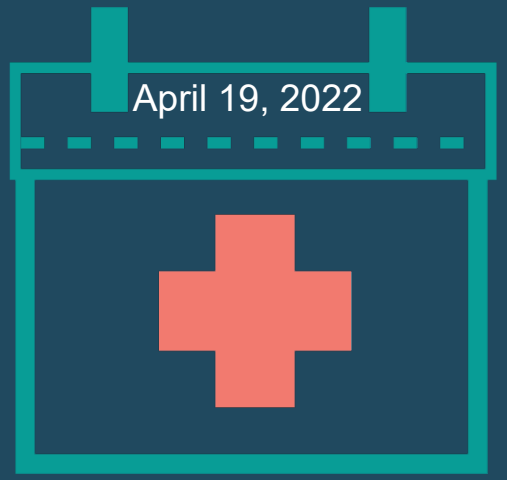
West Virginia Immunization Network



Update: COVID-19 Vaccination in West Virginia

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Speakers have no financial disclosures

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Learning Objectives

- Describe the differences and similarities of each COVID-19 vaccine
- State the indications and contraindications for each vaccine
- Answer common patient questions about the vaccines' safety and effectiveness

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About COVID-19 Vaccines

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Types of COVID-19 Vaccines Authorized in US

- **mRNA: l**ipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2
- **Viral Vector:** a recombinant, replication-incompetent adenovirus type 26 (Ad26) vector encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2

Source: Different COVID-19 vaccines. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html

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3 Vaccines Approved/Authorized by the FDA

Vaccine manufacturer	Age indication	Vaccine vial cap color	Dilution required	Primary series		Booster doses	
				Dose	Injection volume	Dose	Injection volume
Pfizer-BioNTech	5–11 years	Orange*	Yes	10 µg	0.2 mL	NA	NA
Pfizer-BioNTech	12 years and older	Purple*	Yes	30 µg	0.3 mL	30 µg	0.3 mL
Pfizer-BioNTech	12 years and older	Gray*	No	30 µg	0.3 mL	30 µg	0.3 mL
Moderna	18 years and older	Red†	No	100 µg	0.5 mL	50 µg	0.25 mL
Moderna	18 years and older	Blue†	No	NA	NA	50 µg	0.5 mL
Janssen	18 years and older	Blue	No	5×10^{10} viral particles	0.5 mL	5×10^{10} viral particles	0.5 mL

* The Pfizer-BioNTech COVID-19 Vaccine supplied in a vial with an orange cap is authorized for use only in children ages 5-11 years. It is NOT interchangeable with Pfizer-BioNTech COVID-19 Vaccine for people ages 12 years and older (supplied in vials with a purple cap or a gray cap).
†Either Moderna COVID-19 Vaccine supplied in a vial with a red cap (0.25 mL injection volume) or Moderna COVID-19 Vaccine supplied in a vial with a blue cap (0.5 mL injection volume) can be used to administer a 50 µg booster dose.

Common Possible Vaccine Side Effects

- **Pfizer BioNTech:** Possible side effects: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling
- **Moderna:** Possible side effects: pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, erythema at the injection site, and rash
- **Janssen (Johnson & Johnson):** Possible side effects: pain, redness, swelling at injection site, tiredness, headache, fever, muscle pain, chills, nausea

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines

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Vaccine dosing terminology

Primary series: the initial dose(s) of vaccine that teach the body to recognize and fight the virus

- For most people, a 2-dose series of an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) or a single dose of Janssen COVID-19 Vaccine.
- For people who are moderately or severely immunocompromised, a 3-dose series of an mRNA COVID-19 vaccine or a single dose of Janssen COVID-19 Vaccine.

Additional dose: A subsequent dose of vaccine administered to people who were less likely to mount a protective immune response after initial vaccination.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines

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Vaccine dosing terminology

Booster dose: A subsequent dose of vaccine administered to enhance or restore protection which might have waned over time after primary series vaccination.

- **Homologous booster dose:** The same vaccine product used for the booster dose was administered for the primary series.
- **Heterologous booster dose (mix-and-match booster):** The vaccine product used for the booster dose differs from the product administered for the primary series.

Up-to-date: A person has received all recommended doses in their primary vaccine series, and a booster dose, when eligible. Receipt of a second booster dose is not necessary to be considered up to date at this time.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines

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COVID-19 Schedule for Patients – NOT immunocompromised

Primary series vaccine manufacturer	Age group	Number of doses in primary series	Number of booster doses	Interval between 1st and 2nd primary doses	Interval between primary series and booster dose
Pfizer-BioNTech	5–11 years	2	NA	3 weeks	NA
Pfizer-BioNTech	12 years and older	2	1†	3-8 weeks‡	At least 5 months†
Moderna	18 years and older	2	1†	4-8 weeks‡	At least 5 months†
Janssen	18 years and older	1	1†	NA	At least 2 months†

†All people ages 12 years and older should receive 1 booster dose of a COVID-19 vaccine. Some adults may receive a second booster dose:

- Adults ages 18-49 years: Those who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive an mRNA COVID-19 booster dose at least 4 months after the Janssen booster dose.
- Adults ages 50 years and older: A second mRNA booster dose could benefit people ages 50 years and older, as they are at increased risk for severe COVID-19. People ages 50 years and older may choose to receive a second booster dose, if it has been at least 4 months after the first booster

‡An **8-week** interval may be optimal for some people ages 12 years and older, 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

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COVID-19 Schedule for Patients – Immunocompromised

Vaccine	0 month	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month
Pfizer-BioNTech (ages 5–11 years)	**1st dose**	**2nd dose** (3 weeks after 1st dose)	**3rd dose** (at least 4 weeks after 2nd dose)							
Pfizer-BioNTech (ages 12 years and older)	**1st dose**	**2nd dose** (3 weeks after 1st dose)	**3rd dose** (at least 4 weeks after 2nd dose)			**Booster dose*** (at least 3 months after 3rd dose)			See footnote§	
Moderna (ages 18 years and older)	**1st dose**	**2nd dose** (4 weeks after 1st dose)	**3rd dose** (at least 4 weeks after 2nd dose)			**Booster dose*** (at least 3 months after 3rd dose)				See footnote§
Janssen (ages 18 years and older)	**1st dose**	**2nd** (additional) dose† using an mRNA COVID-19 vaccine (at least 4 weeks after 1st dose)		**Booster dose*** (at least 2 months after additional dose)				See footnote§		

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#recommendations

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COVID-19 Schedule for Patients – Immunocompromised (cont)

*An mRNA COVID-19 vaccine is preferred over the Janssen COVID-19 Vaccine for booster vaccination of people ages 18 years and older. For people ages 12–17 years, only Pfizer-BioNTech can be used. A booster dose is not authorized for people ages 5–11 years.

†Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used. See Appendix D for more information on vaccinating people who are moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine for the primary series.

‡People ages 12 years and older may choose to receive a second booster dose using an mRNA COVID-19 vaccine if it has been at least 4 months after the first booster dose. For people ages 12–17 years, only Pfizer-BioNTech can be used.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines

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Contraindications and Precautions

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Contraindications

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine	Contraindication	Do not vaccinate with the same type of COVID-19 vaccine (i.e., mRNA or Janssen COVID-19 Vaccine). See Appendix E for actions and additional information.
History of a known diagnosed allergy to a component of the COVID-19 vaccine	Contraindication	
For **the Janssen COVID-19 Vaccine**, TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors, e.g., AstraZeneca)	Contraindication	Do not vaccinate with Janssen COVID-19 Vaccine.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines

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Not Recommended

Medical condition or history	Guidance	Recommended action(s)
For **the Janssen COVID-19 Vaccine**, history of an episode of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.
For the **Janssen COVID-19 Vaccine**, GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines

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Children with history of multisystem inflammatory syndrome in children (MIS-C)

- COVID-19 vaccination is recommended for children with history of MIS-C in those who meet all of the following criteria:
- Clinical recovery has been achieved, including return to normal cardiac function;
- It has been ≥90 days since their diagnosis of MIS-C;

Interim Clinical Considerations COVID-19 Vaccines Available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us

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Children with history of multisystem inflammatory syndrome in children (MIS-C)

- COVID-19 vaccination is recommended for children with history of MIS-C in those who meet all of the following criteria:
- They are in an area of high or substantial community transmission of SARS-CoV-2 or otherwise have an increased risk for SARS-CoV-2 exposure and transmission; and
- Onset of MIS-C occurred before any COVID-19 vaccination

Interim Clinical Considerations COVID-19 Vaccines Available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us

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Vaccine Safety & Efficacy

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What do we know about COVID vaccine safety?

Local and systemic reactions
- Mild to moderate in severity
- Early on after receiving the vaccine

- Serious adverse effects that occur during Phase 3 trials are thoroughly investigated
- Historically, long lasting adverse effects from vaccines have been rare

- COVID vaccine safety is monitored closely
  - **Vaccine Adverse Events Reporting System (VAERS**)- provides data on the safety profile of new vaccines when they are introduced into the population
  - **Vaccine safety assessment for essential workers (V-SAFE)-** a smartphone based surveillance program which conducts health checks on vaccine recipients via text messages and email

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Robust vaccine safety monitoring systems exist

- **Existing** systems and data sources are used to monitor safety of vaccines post-authorization and post-licensure, such as:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - Clinical Immunization Safety Assessment (CISA)
  - Biologics Effectiveness and Safety System (BEST)

- **New** systems have been developed to monitor COVID-19
- vaccine safety, such as **v-safe**:
  - Active surveillance that uses text messaging to initiate web-based survey monitoring.
  - Will provide telephone follow up to anyone who reports medically significant adverse events.

Are the COVID-19 vaccines safe?

- **Yes.** COVID-19 vaccines were evaluated in tens of thousands of volunteers in clinical trials. The trials met the same rigorous standards set for all vaccines by the Food and Drug Administration.
- COVID-19 vaccines have been safely administered to billions of people in the U.S. and around the world.
- COVID-19 vaccines have had the most robust safety monitoring in history.

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What do we know about COVID vaccine efficacy?

- The COVID-19 vaccines currently authorized for use were found to be highly effective in preventing COVID-19 in clinical trials.
- All approved/authorized COVID-19 vaccines have high efficacy in protecting against severe COVID-19 disease as well as COVID-19 related hospitalizations and death.
- They all have been reviewed rigorously by the scientific experts and have met the FDA efficacy standards for emergency use authorization and/or approval.

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Are the COVID-19 Vaccines Effective?

- **Yes.** COVID-19 vaccines are highly effective in preventing severe COVID-19 disease, hospitalizations, and death.
- The majority of people with severe illness who are hospitalized or pass away from COVID-19 complications in West Virginia are **un**vaccinated.
- Keeping up to date with vaccination, including booster shots when due, is the best protection against existing variants and keeping new variants from forming (variants are new strains that happen when a virus is able to spread and mutate).

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West Virginia COVID-19 Vaccination Due Date Calculator

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COVID-19 VACCINATION

Due Date Calculator

Available online at

vaccinate.wv.gov

WEST VIRGINIA Department of Health & Human Resources

Find out when you're due for a COVID-19 shot in three steps:

Step 1: Scroll down to the **COVID-19 Vaccination Due Date Calculator** at vaccinate.wv.gov.

Step 2: After reading the welcome and disclaimer, enter your birthdate, the type and number of COVID-19 shots you've received (if any), whether you are immunocompromised, and the date of your most recent COVID-19 shot (if any).

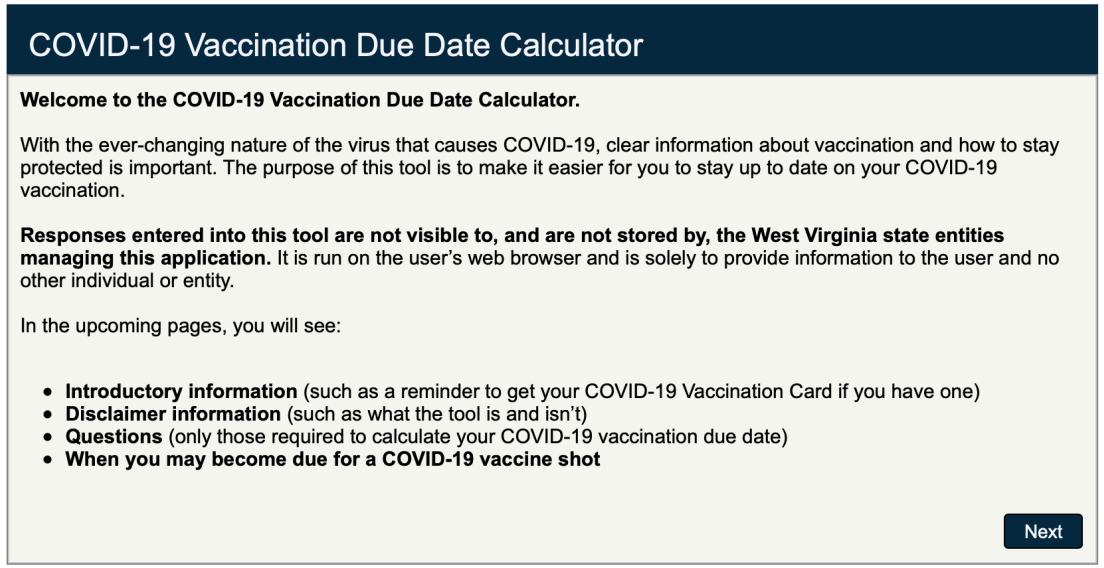
Step 3: Find out the date you may become due for a COVID-19 shot.

vaccinate.wv.gov

WEST VIRGINIA Department of Health & Human Resources

Step 1: Visit Vaccinate.WV.gov

Scroll down to the CVDD Calculator



Step 2: View Welcome/Disclaimer & Make Selections

COVID-19 Vaccination Due Date Calculator

This calculator is a tool that can be used to determine when you may be due for a COVID-19 vaccine. To do so, please fill in the following information for yourself (or, if you are the authorized guardian/caregiver using this tool for someone else, fill it in that person's information).

If you have had any previous COVID-19 shots, please have your COVID-19 Vaccination Card handy.

The tool's questions will ask about:

- birthdate,
- type and number of COVID-19 shots received (if any),
- whether you are considered moderately to severely immunocompromised, and
- the date of the most recent COVID-19 shot

This will let the tool calculate for you if/when you may be due for a COVID-19 vaccine additional information about what type of vaccines are recommended based on variou end of the tool.

This is meant as an individual education tool and not to replace licensed medical deci **change, so please check back periodically.**

More information about the purpose and limitations of this tool is next.

CVDD Calculator Disclaimer

This tool is a product of the WV Governor's Joint Interagency Task Force for COVID-19 and the WV Department of Health and Human Resources' Bureau for Public Health.

This tool is based on U.S. COVID-19 vaccination guidelines and was last updated Tue, Mar 15, 2022.

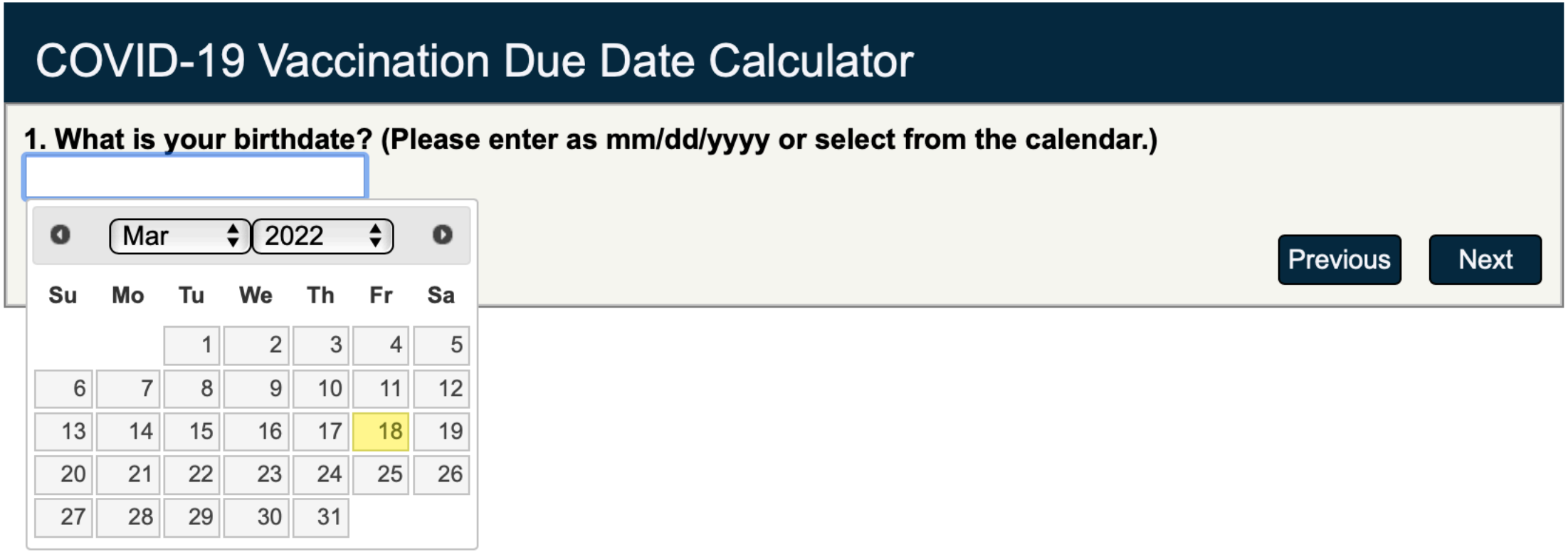
The information contained in this product is not intended to be, nor should it be used as, a substitute for the exercise of professional judgement by a licensed healthcare provider.

This tool does not account for all possible medical situations. The West Virginia state partners who manage this tool have strived to use best efforts to accurately convey immunization recommendations for COVID-19 vaccines, but cannot guarantee whether it is outdated, incomplete, or accurate in all cases.

This tool is to be used as a method **for individuals to simplify and customize complex medical information** in a general way to determine when the user may be due for another shot to stay up to date on COVID-19 vaccination, and it does not constitute, or substitute for, licensed medical practice.

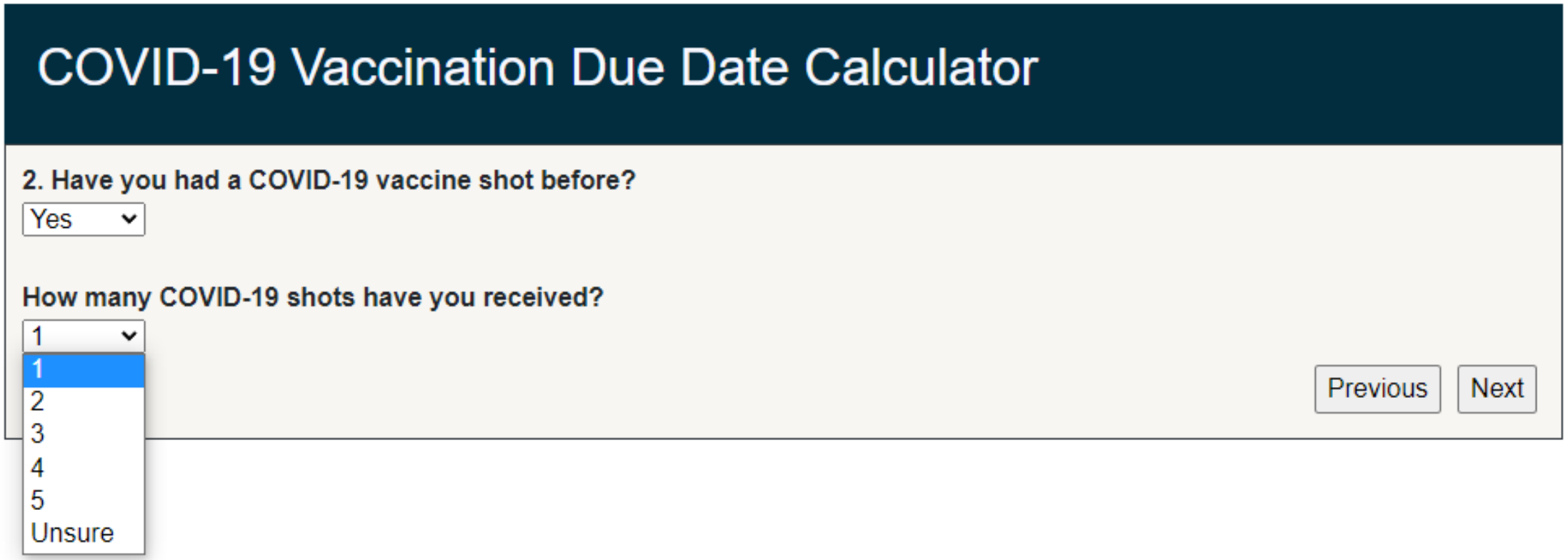
Previous Next

Step 2: View Welcome/Disclaimer & Make Selections



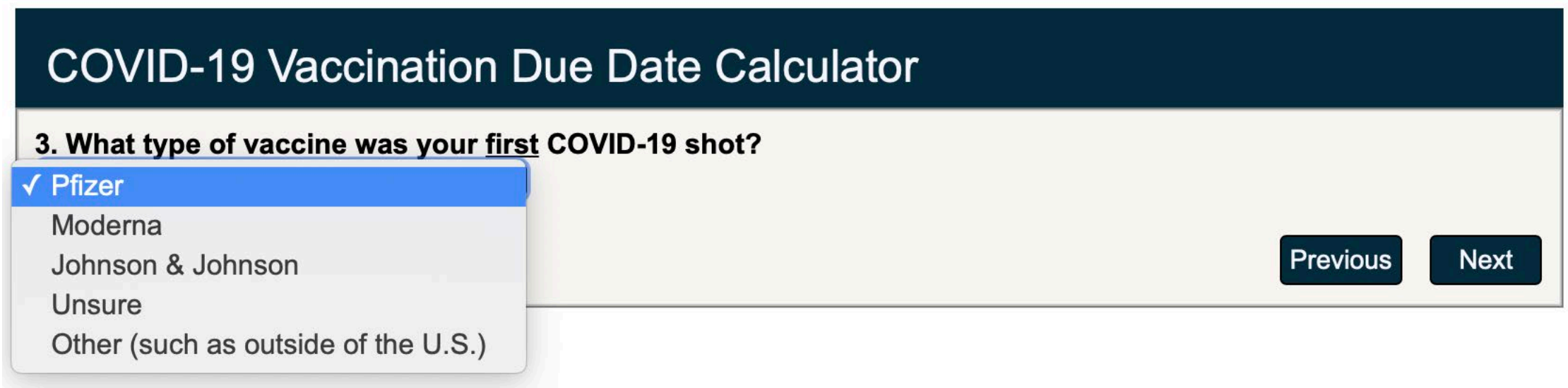
Birthdate

Step 2: View Welcome/Disclaimer & Make Selections



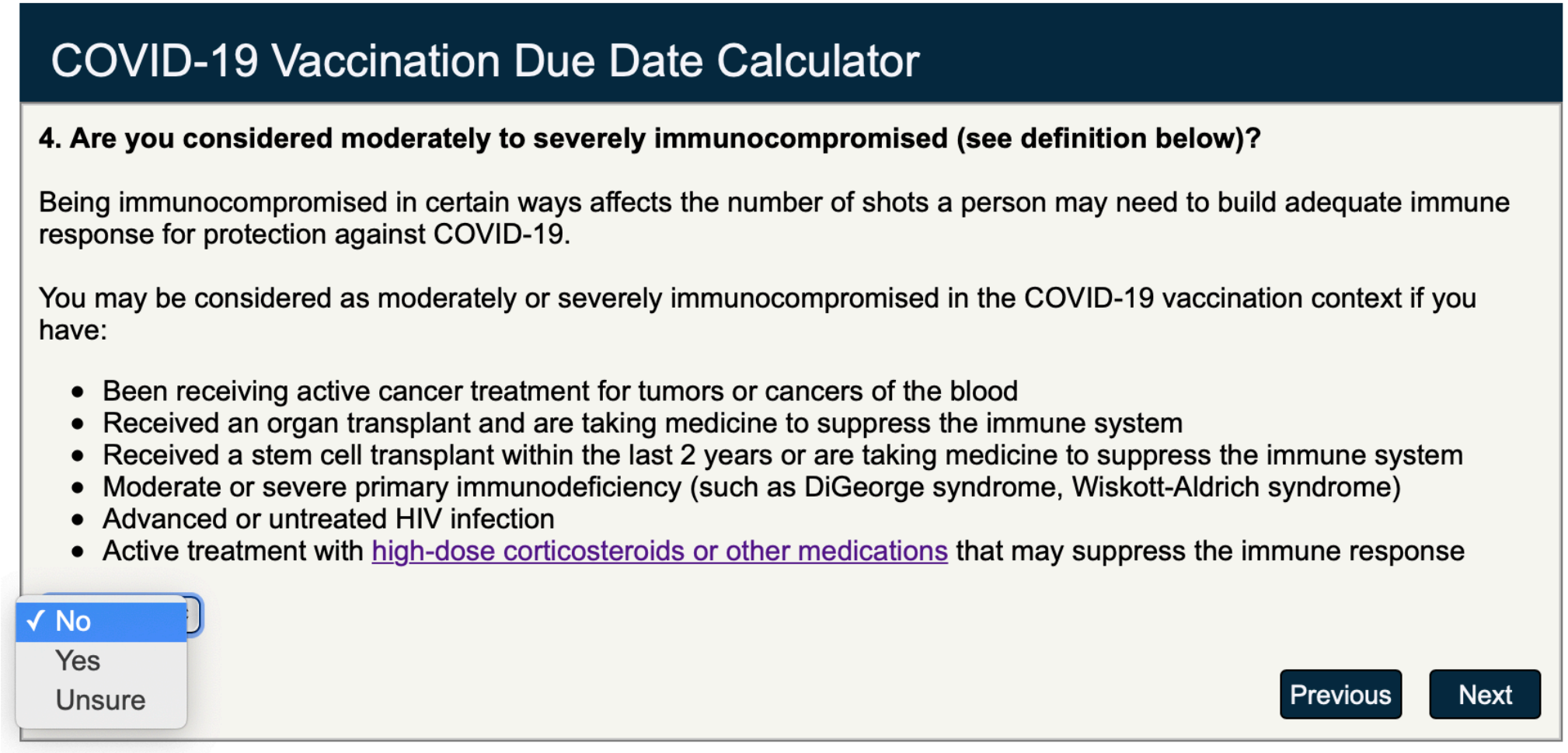
Previous COVID-19 Shots (if any)

Step 2: View Welcome/Disclaimer & Make Selections



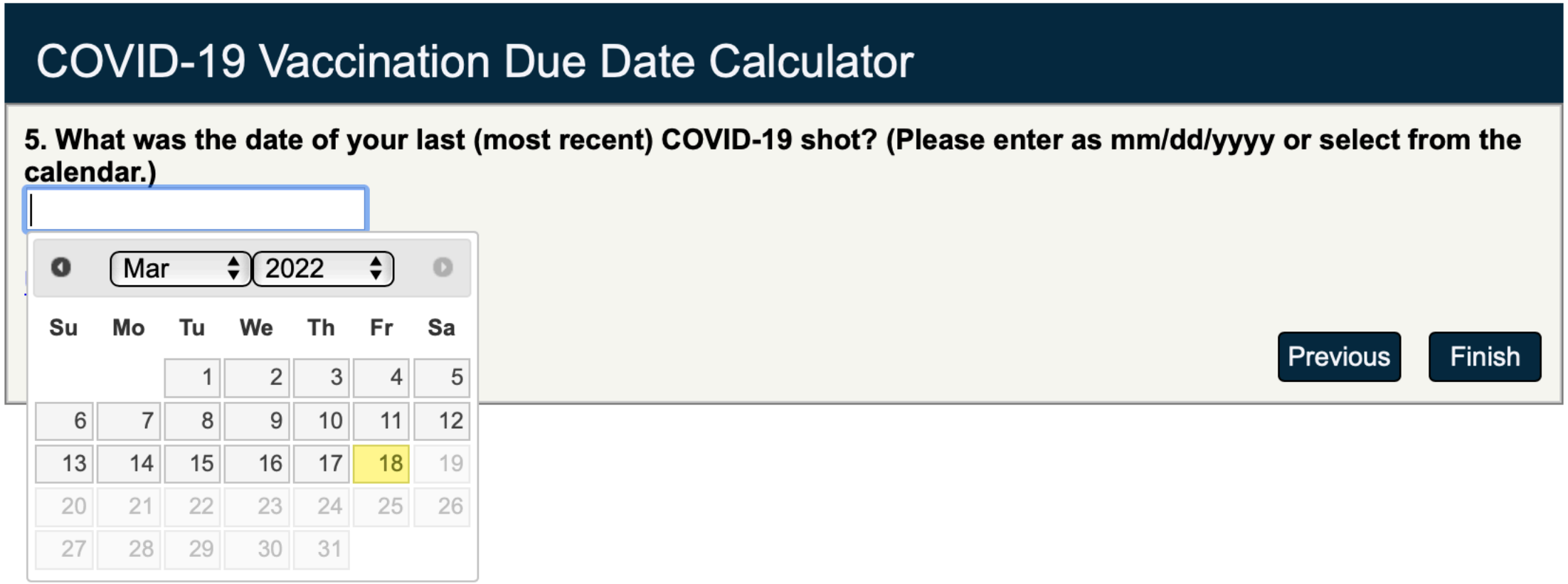
FIRST COVID-19 Vaccine Type

Step 2: View Welcome/Disclaimer & Make Selections



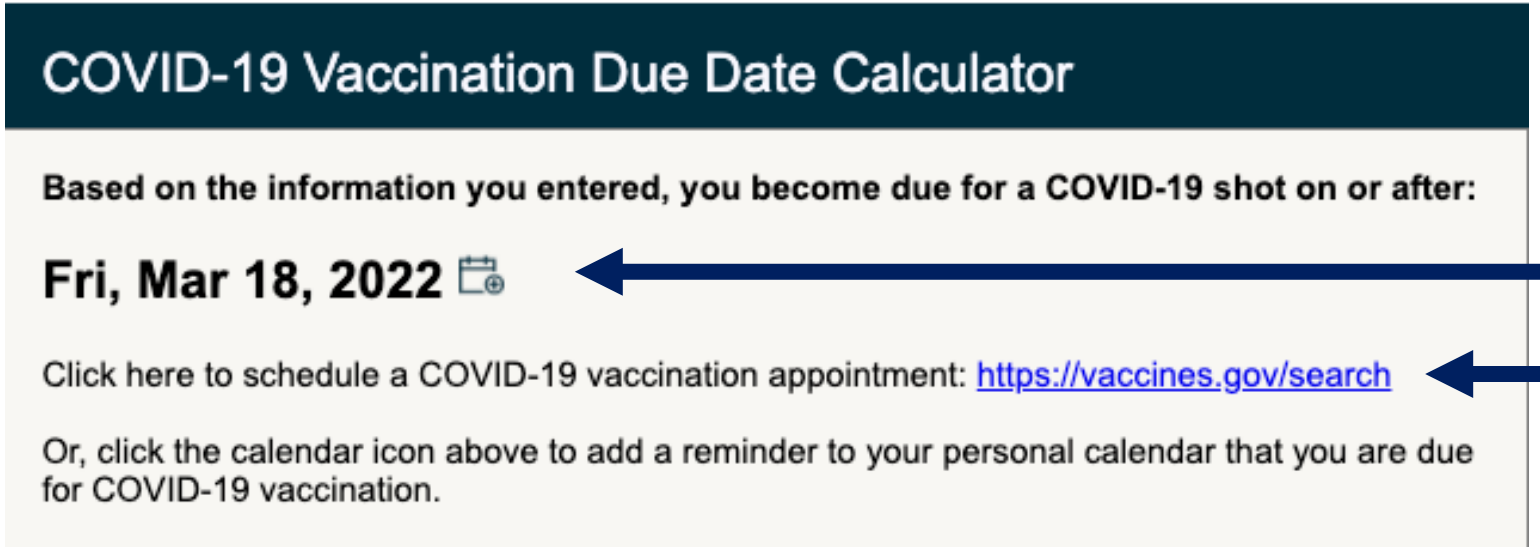
Immunocompromised

Step 2: View Welcome/Disclaimer & Make Selections



Most Recent COVID-19 Shot

Step 3: Get Your Due Date & Stay Up to Date



Personal Calendar Reminder

Schedule Vaccination

Find Out When You Become Due for a Shot

Stay up to date with your **COVID-19 vaccination!**

Find out when you're due for a shot with the

COVID-19 Vaccination Due Date Calculator.

Available online at

vaccinate.wv.gov

WEST VIRGINIA Department of Health & Human Resources

Resources

- Vaccinate.wv.gov
  - FAQs
- Social Presskit
- Coming soon: Provider Toolkit with Resources
- West Virginia COVID-19 Vaccine Info Line
  - 1-833-734-0965
- CDC – Resource: How to talk to your patients about COVID-19 vaccination
- HHS – “We Can Do This” Frequently Asked Questions about COVID-19

COVID-19 VACCINATION

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begins with me.

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