



MASSACHUSETTS COVID-19 VACCINE PROGRAM

BULLETIN

What Massachusetts COVID-19 Vaccine Providers Need to Know Week of 4/25/2023

Information related to the use of COVID-19 vaccines changes frequently. Please be sure to refer to the CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#) as your primary source for the most up-to-date information.

LATEST NUMBERS

- As of 4/25/2023 **5,942,979** people in Massachusetts have completed primary series of monovalent vaccine. However, only 2,024,432 Massachusetts residents have received the recommended bivalent booster dose.

LATEST NEWS

Updates to the CDC Clinical Considerations were made April 22nd.

(At the time of this Bulletin's release, updates had not yet been made to ['Information about the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised'](#) or the [FAQs](#).)

- As of April 18, 2023, the monovalent Moderna and Pfizer COVID-19 vaccines are no longer authorized for use in the U.S.
- At the time of initial vaccination, depending on vaccine product, children ages 6 months–4 years are recommended to receive 2 or 3 bivalent mRNA vaccine doses; children aged 5 years are recommended to receive 1 or 2 bivalent mRNA vaccine doses
- People ages 6 years and older who are unvaccinated or previously received only monovalent vaccine doses are recommended to receive 1 bivalent mRNA vaccine dose
- People ages 65 years and older may receive 1 additional bivalent mRNA vaccine dose

COVID-19 Public Health Emergency Ending on May 11th

The Department of Health and Human Services has announced that the Federal Public Health Emergency for COVID-19 is planned to end on May 11, 2023. Please note that the Public Health Emergency ending will not have any immediate impacts on your site's ability to continue to order COVID-19 vaccines. COVID-19 vaccines will still be available to order via the MIIS system for all enrolled sites with a signed MCVP Agreement. The associated EUA's for the COVID-19 vaccine formulations will still be active and hold true, even after the official Public Health Emergency ends.

QUESTION OF THE WEEK

Q: Am I correct in understanding that for all kids 6 years and older, who are NOT immunocompromised, they need only ONE bivalent dose? There is no more "primary series and boosters"?

A: Correct – everyone 6 years and older should have ONE bivalent mRNA dose. They are considered up to date if/when they have the one bivalent mRNA dose. Regardless of vaccination history – whether they have had zero past monovalent vaccines, or 5 past monovalent vaccines, they should get ONE bivalent dose. If they have already had one bivalent dose, they are all set/up to date and do not need to take any action unless they are 65 years or older or immunocompromised.

WHO TO VACCINATE

COVID-19 vaccination is recommended for everyone ages 6 months and older in the United States for the prevention of COVID-19. There is currently no FDA-authorized COVID-19 vaccine for children younger than age 6 months. CDC recommends that people stay [up to date](#) with COVID-19 vaccination.

VACCINE ADMINISTRATION RECOMMENDATIONS

- 6+ years old: 1 bivalent mRNA dose. Regardless of vaccine history.
- 6 months through <6 years old:
 - Moderna: at least 2 doses, including at least 1 bivalent dose.
 - Pfizer:
 - 5 years: 1 bivalent dose.
 - 6 months through < 5 years old: at least 3 doses, including at least 1 bivalent dose.

In addition, people *may* now choose to receive an additional optional spring dose if:

- 65 years of age and older and got a first bivalent (updated) COVID-19 vaccine booster 4 or more months ago.
- Moderately or severely immunocompromised and received a bivalent (updated) COVID-19 vaccine booster 2 or more months ago.

Novavax COVID-19 Vaccine

People ages 12 years and older who previously received 1 or 2 monovalent Novavax COVID-19 primary series dose(s) are recommended to receive 1 bivalent mRNA vaccine dose. The monovalent Novavax COVID-19 Vaccine remains authorized for use as a 2-dose primary series and as a booster dose in certain limited situations.

Janssen COVID-19 Vaccine

The monovalent Janssen COVID-19 Vaccine is authorized for use in certain limited situations due to safety considerations ([Appendix A](#)). As a reminder, the Janssen vaccine is expiring in early May and will not be available after that.

Vaccine dosage and administration

In general, CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination in accordance with the recommended intervals for that age group ([1](#)). However, for COVID-19 vaccination there is an FDA-authorized exception for children who receive the Pfizer-BioNTech COVID-19 Vaccine and transition from age 4 to 5 years during the 3-dose vaccination series (see [Transitioning from a younger to older age group](#)).

COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised

The COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised is summarized in [Table 1](#), which should be consulted for age-specific information.

The schedule is organized by age and COVID-19 vaccination history. It provides the number of bivalent mRNA vaccine doses an individual needs based on COVID-19 vaccine doses previously received, including the number of prior doses, whether the doses were monovalent or bivalent, and the vaccine manufacturer (Moderna, Novavax, or Pfizer-BioNTech).

Most people ages 6 years and older who are not moderately or severely immunocompromised and have received 1 dose of a bivalent mRNA vaccine do not need any further vaccine doses at this time. People ages 65 years and older who received 1 dose of a bivalent vaccine have the option to receive 1 additional dose at least 4 months after the first bivalent dose.

Considerations for people ages 65 years and older to receive an additional bivalent mRNA dose

People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose if it has been at least 4 months after their first bivalent mRNA dose. The option to receive 1 additional bivalent mRNA dose may be informed by the clinical judgement of a healthcare provider, a person's risk for severe COVID-19 due to the presence of underlying medical conditions and age, and personal preference and circumstances.

COVID-19 vaccination guidance for people who are moderately or severely immunocompromised

Per CDC's webpage at the time of this Bulletin's release, "Information about the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised will be available soon."

Interchangeability of COVID-19 vaccines

The COVID vaccination schedules within the CDC Clinical Considerations should be consulted for age-specific information.

Children ages 6 months–5 years who are unvaccinated and are recommended to receive more than 1 bivalent mRNA vaccine dose for initial vaccination should receive all doses from the same manufacturer.

For people who are **not** moderately or severely immunocompromised and previously initiated vaccination with a monovalent mRNA vaccine:

- People ages 6 months–4 years who previously received 1 or more doses of a monovalent mRNA vaccine are authorized to receive only bivalent mRNA vaccine dose(s) from the same vaccine manufacturer.
- People aged 5 years who previously received 1 or more doses of:
 - Monovalent Moderna COVID-19 Vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer COVID-19 vaccine.
 - Monovalent Pfizer COVID-19 are authorized to receive only bivalent Pfizer-BioNTech COVID-19 Vaccine.
- People ages 6 years and older who previously received 1 or more doses of a monovalent mRNA vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.

In the following exceptional situations, a different COVID-19 vaccine may be administered (at a minimum interval of 28 days between the first and second doses) when FDA authorization requires that a vaccine from the same manufacturer be used. A Vaccine Adverse Event Reporting System (VAERS) report is not required for these exceptional situations:

- Same vaccine not available
- Previous dose unknown
- Person would otherwise not complete the vaccination series
- Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

VACCINE MANAGEMENT

Expired Monovalent COVID-19 vaccines - Storage and handling for expired and wasted doses

Monovalent COVID-19 vaccine is no longer available for ordering in the MIIS. Expiration dates for monovalent vaccines have been updated in the MIIS to April 18, 2023. All monovalent doses are now expired. Please process a storage and handling issue in the MIIS to report the wasted doses. Discard all expired or wasted doses in medical waste.

COVID-19 Vaccine Reconciliation and Inventory Cleanup

By signing the Massachusetts COVID-19 Vaccination Program (MCVP) provider agreement, providers agreed to comply with all data reporting requirements. These requirements include reporting administered doses as well as processing storage and handling issues for all expired and wasted vaccines in the MIIS.

Consistently check the expiration and Beyond Use Dates (BUD) to ensure expired and/or nonviable doses are not administered to patients. A storage and handling issue should be entered into MIIS to account for all expired and wasted doses. Please discard any expired or wasted COVID-19 doses in medical waste at your facility, as these do not need to be returned.

During the month of April, the MDPH Vaccine Management Unit will be working with sites to reconcile inventory in the MIIS. To ensure that your MIIS inventory counts align appropriately with your physical counts, your site must take the following actions:

- Ensure that all COVID-19 vaccine doses administered are reported to the MIIS as required by law. Your site must account for all administered doses by your facility.
- Review your [Inventory Decrementing Tool](#) to ensure that all reported doses have decremented out of your MIIS inventory appropriately.
- Submit [storage and handling](#) issues in MIIS for any wasted, spoiled (including lots that have reached their Beyond Use Date) or expired doses of COVID vaccines that are still appearing in your MIIS inventory.
- As part of the reporting requirements all wasted, spoiled, and expired doses must be accounted for in the MIIS system. As is noted in our [updated guidance](#) regarding allowable wastage for COVID-19 vaccines, there are no penalties for sites wasting doses. Sites should take every opportunity to vaccinate a potential patient, even if it results in the remaining doses in the open multi-dose vial being wasted.

To ensure that all administered, transferred and wasted doses are reported accurately into MIIS, please conduct a full review of your MIIS COVID-19 vaccine inventory by April 30, 2023. On May 1, 2023, the Vaccine Management Unit will be auto-clearing out any COVID-19 vaccine lots listed as expired in your MIIS inventory on or before April 1, 2023.

In addition to reviewing your MIIS COVID inventory, please keep a close eye on the expiration dates on the ancillary supplies your site received with your COVID vaccine shipments. Please note that all ancillary kit materials have expiration dates, and they may not align to the same date. Any expired ancillary supplies should be disposed of by your site and never used for vaccine administration. If you have any questions, please reach out to the Vaccine Management Unit at 617-983-6828 or dph-vaccine-management@mass.gov.

Pfizer 12+ bivalent single dose vials now available for ordering by Primary Care Provider (PCP) Sites

The Pfizer bivalent vaccine formulation for 12+ is now available in single dose vials. Due to limited quantities of this formulation, it is currently being made available only to PCP sites (pediatricians, family practices, internal medicine offices, community health centers). To add this vaccine formulation/packaging click on the "[add a vaccine](#)" button in the lower left-hand corner of the ordering screen. **SDVs will not include ancillary kits.**

Expiry Date vs Beyond Use Date (BUD)

The **expiration date** is set by the manufacturer and is the date by which the vaccine should be used. The expiration date assumes that the vaccine has been stored and handled according to the manufacturer's guidance. Expiration dates cannot change based on how vaccine is being stored or when a vial is punctured. However, on occasion, the expiration date may be updated by the manufacturer as additional stability data become available.

Beyond Use Date (BUD) is the date of when the vaccine can no longer be used due to a change in storage temperature, reconstitution, puncturing the vial, etc. It is recommended to place a label with the BUD and the initials of the person making the calculation whenever a vaccine vial or box is moved to a different temperature storage unit, reconstituted, or had a vial punctured resulting in a change in the BUD.

You can find BUD guidance and labels for [Moderna](#), [Novavax](#), [Janssen](#), and [Pfizer](#) from the CDC's U.S. COVID-19 Vaccine Product Information webpage.

COVID Vaccines Available for ordering in the MIIS

All providers enrolled Massachusetts COVID-19 Vaccine Program (MCVP) are able to place routine orders for all of the following COVID-19 vaccine formulations through the Massachusetts Immunization Information System (MIIS).

Brand	NDC	NDC Description	Minimum ordering size
-	59267-0304-02	COVID-19 (Pfizer);BIVALENT;MDV6; 10-pack	180
-	59267-1404-02	COVID-19(Pfizer);BIVALENT;SDV;10pk	50
-	59267-0565-02	COVID-19 (Pfizer);BIVALENT;(PED 5-11) MDV10;10pk	100
-	59267-0609-02	COVID-19 (Pfizer);BIVALENT;(PED 6m-4y) MDV10; 10-pack	100
-	80777-0282-99	COVID-19 (Moderna);BIVALENT;MDV5; 10-pack	100
-	80777-0283-99	COVID-19 (Moderna); BIVALENT;(PED 6m-5y) MDV2;10-pack	20
-	80631-0102-10	COVID-19 (Novavax); MDV5; 10-pack	50

Initial shipments of the Pfizer-BioNTech vaccine for children aged 6m–4 years may state “2y to <5y” or “6m to <5y” on the vial or carton labels. Please note that vials or cartons with labels that state “2y to <5y” can be used for children aged 6m through 4 years.

Pfizer-BioNTech vaccine vial labels and cartons may also state that a vial should be discarded 6 hours after the first dilution however as stated in the EUA Fact Sheet the timeframe for use post-dilution is actually 12 hours just like orange and gray cap Pfizer vaccine formulations.

RESOURCES & LEARNING OPPORTUNITIES

Commercialization of COVID-19 products

HHS recently published a [question-and-answer document](#) with frequently asked questions on the commercialization of COVID-19 medical countermeasures.

Moderna’s COVID-19 Vaccine Training

Moderna is having live 10-minute presentations, followed by Q&A, available at <https://app.livestorm.co/moderna-na-medical/regional-medical-affairs-office-hours-simplified-dosing-schedules-for-moderna-covid-19-vaccine-bivalent>

Pfizer’s COVID-19 Vaccine Training

Pfizer has live medical update sessions
<https://www.pfizermedicalinformation.com/en-us/medical-updates>

EUA Fact Sheets

Once a new EUA Fact Sheet is issued, it must be used. Previous ones no longer contain accurate information.

Moderna EUAs can be found on the FDA website [here](#)

Pfizer EUAs can be found on the FDA website [here](#)

Novavax EUAs can be found on the FDA website [here](#)

Janssen EUAs can be found on the FDA website [here](#)

Standing Orders

Watch for updated standing orders: <https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>

MDPH RESOURCES

Immunization Division Main Number

For questions about immunization recommendations, disease reporting, etc.

Phone: 617-983-6800 (24/7 MDPH Epi line)

Fax: 617-983-6840

Website: <https://www.mass.gov/topics/immunization>

MIIS Help Desk

Phone: 617-983-4335

Fax: 857-323-8321

Email questions to: miishelpdesk@mass.gov

Website: <https://www.mass.gov/massachusetts-immunization-information-system-miis>

MDPH Vaccine Unit

Phone: 617-983-6828

Email questions to: dph-vaccine-management@mass.gov

Website: <https://www.mass.gov/service-details/vaccine-management>

Color Help

Email questions to: colorhelp@mass.gov

Website: <https://www.mass.gov/info-details/vaccine-clinic-management-platform>

COVID-19 Email Box

Email questions to: COVID-19-Vaccine-Plan-MA@mass.gov