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| **BULLETIN****What Massachusetts COVID-19 Vaccine Providers Need to Know****Week of 5/9/2023** |

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| *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*](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html) *as your primary source for the most up-to-date information.***LATEST NUMBERS*** As of 5/9/2023 **5,949,142** people in Massachusetts have completed primary series of monovalent vaccine. However, only 2,051,258 Massachusetts residents have received the recommended bivalent booster dose.

**LATEST NEWS****Updates to the CDC Clinical Considerations were made May 1st .** *(At the time of this Bulletin’s release, updates had not yet been made to the* [*FAQ*](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html)*s or the Standing Orders)*On May 1, 2023, the clinical guidance for [**people who are moderately or severely immunocompromised**](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised) was revised as follows:* At the time of initial vaccination, people ages 6 months and older are recommended to receive 3 bivalent mRNA doses
* People ages 6 months and older who previously received only monovalent doses are recommended to receive 1 or 2 bivalent mRNA vaccine doses, depending on age and vaccine product
* People who previously received a bivalent mRNA vaccine dose(s) have the option to receive 1 or more additional bivalent mRNA doses

**CDC COCA Call, “Updated Recommendations for COVID-19 Vaccine Use”, May 11, 2023, 2:00–3:00 p.m.** During this COCA Call, presenters will discuss updated COVID-19 vaccine recommendations by age group and for those with immunocompromise. They will also highlight optional COVID-19 vaccine doses for specific populations. More info and webinar link can be found [here](https://emergency.cdc.gov/coca/calls/2023/callinfo_051123.asp).At the conclusion of the session, the participant will be able to accomplish the following:1. Describe current recommended vaccine doses for people ages 6 years and older.
2. Cite where to find in-depth tables for COVID-19 vaccines indicated for children ages 6 months through 5 years.
3. Discuss the difference in recommendations for use of COVID-19 vaccines between those with and without immunocompromise.
4. Name two populations who can receive an optional additional dose of the updated COVID-19 vaccines.

**COVID-19 Public Health Emergency Ending on May 11th** The Federal Public Health Emergency for COVID-19 is ending 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:** I’m confused about when to use Moderna’s vaccine formulation with the dark pink cap/label and yellow box.**A:** The Moderna formulation with the ‘dark pink cap/label and yellow box’ is used ONLY in a very small subpopulation of children. **Moderna’s ‘dark pink cap/label and yellow box’ formulation is only used for children 6m-5y that have already received 2 or 3 doses of monovalent Moderna.** For most individuals, it is Moderna’s ‘dark blue cap/label and gray border’ formulation that should be used. The ‘dark blue cap/label and gray border’ can be used to vaccinate people 6 months and older. [Table 1](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-01) and [Table 2](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02) of the CDC’s Clinical Considerations contains detail on when to use each.**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](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html) with COVID-19 vaccination.See Appendices B ([People who received COVID-19 vaccine outside the United States](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-b)) and C ([People who received COVID-19 vaccine as part of a clinical trial](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-c)) for recommendations for these populations.**VACCINE ADMINISTRATION RECOMMENDATIONS**As of April 18, 2023, the **monovalent** Moderna and Pfizer COVID-19 vaccines are no longer authorized for use in the U.S.CDC recommends that people ages 6 months and older receive at least 1 bivalent mRNA COVID-19 vaccine.An overview of COVID-19 vaccination is summarized below; detailed schedules can be found in [Table 1](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-01) for people who are not moderately or severely immunocompromised, and in [Table 2](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02) for people who are moderately or severely immunocompromised.**Bivalent mRNA vaccines**The number of bivalent doses varies by age, vaccine, previous COVID-19 vaccines received, and the presence of moderate or severe immune compromise.For people who **are not moderately or severely immunocompromised**:* 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
* 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 have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first bivalent dose

For people who **are moderately or severely immunocompromised**:* At the time of initial vaccination, people ages 6 months and older are recommended to receive 3 bivalent mRNA doses
* People ages 6 months and older who previously received only monovalent doses are recommended to receive 1 or 2 bivalent mRNA vaccine doses, depending on age and vaccine product
* People who previously received a bivalent mRNA vaccine dose(s) have the option to receive 1 or more additional bivalent mRNA doses at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose.

**Novavax COVID-19 Vaccine**People ages 12 years an 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.**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. However, for COVID-19 vaccination there are exceptions for children who receive the Pfizer COVID-19 Vaccine and transition from age 4 to 5 years during the 3-dose vaccination series and children who transition from age 5 years to 6 years during the Moderna COVID-19 vaccination series (see [Transitioning from a younger to older age group](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#transitioning-younger-older)).* FDA [EUA](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines) requires that children who receive the Pfizer COVID-19 Vaccine and transition from age 4 years to 5 years during the 3-dose vaccination series must complete the series they start (i.e., receive the 0.2 mL/3 ug dosage supplied in vials with a maroon cap and label with a maroon border for all 3 doses).
* Additionally, children who transition from age 5 years to 6 years during the Moderna vaccination series should receive 2 doses of Moderna COVID-19 Vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border).

**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](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-01) , 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 medial conditions and age, and personal preference and circumstances.**COVID-19 vaccination guidance for people who ARE moderately or severely immunocompromised**To assist healthcare providers, the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised ([Table 2](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02)) provides detailed age-specific guidance. However, the EUAs for [Moderna](https://www.fda.gov/media/167208/download) and [Pfizer-BioNTech](https://www.fda.gov/media/167211/download) COVID-19 vaccines allow healthcare providers flexibility for use of vaccine products, number of doses, dosage, and intervals between doses; alternative schedules within the parameters of the EUAs may be appropriate based on individual circumstances and clinical judgement.People who are moderately or severely immunocompromised have the option to receive 1 additional dose of a bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose. Further additional bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose. Specific information on which vaccine formulation to use is included within [Table 2](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02) and its footnotes.People who are or who become moderately or severely immunocompromised should follow the COVID-19 vaccination schedule according to their age and immune status at the time of eligibility for that dose; see [Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-timing-COVID-19-vaccination-immunosuppressive-therapies) for vaccination of people who will shortly become moderately or severely immunocompromised (e.g., prior to organ transplant) and [Considerations for COVID-19 revaccination](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-COVID-19-revaccination). |
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| **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. However, as detailed below, FDA authorization allows for administration of a mixed product series for initial vaccination in some age groups.Authorization to use COVID-19 vaccines interchangeably from different manufacturers varies by vaccination history, age, and product as follows:* People ages **6 months–4 years** who are unvaccinated or 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 age **5 years** who are unvaccinated or previously received 1 or more doses of monovalent Moderna COVID-19 Vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.
* People age **5 years** who are unvaccinated or previously received 1 or more doses of monovalent Pfizer-BioNTech COVID-19 are authorized to receive only bivalent Pfizer-BioNTech COVID-19 Vaccine.
* People ages **6 years and older** who are unvaccinated or previously received 1 or more doses of any monovalent COVID-19 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

Recommended actions for vaccine administration errors are found in [Appendix D Vaccine Administration Errors and Deviations](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-d) and in the ‘Interchangeability of COVID-19 vaccines’ section of the Clinical Considerations.

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| **VACCINE MANAGEMENT** **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](https://resources.miisresourcecenter.com/trainingcenter/New%20Order_2018_Mini%20Guide.pdf)” 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 chance in the BUD.   You can find BUD guidance and labels for [Moderna,](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-handling-label.pdf) [Novavax](https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/downloads/novavax-bud-tracking-labels.pdf), and [Pfizer](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-handling-label.pdf) 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).

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| 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 |

There are 2 presentations of Moderna COVID-19 Vaccine, Bivalent. Even though vials and cartons of both presentations are labeled “BOOSTER DOSES ONLY,” doses from these vials are authorized ford for ALL doses for individuals 6 months of age and older.**RESOURCES & LEARNING OPPORTUNITIES** **Commercialization of COVID-19 products**HHS recently published a [question-and-answer document](https://urldefense.com/v3/__https%3A/immunizationmanagers.us16.list-manage.com/track/click?u=13b4fdc9ac0078e4c57522c2b&id=c4349edb49&e=4f158a4069__;!!CUhgQOZqV7M!mOJ1HacJneXLSjQ5ZfhT0d9FRTQ70-wNRhMBaNIFv3Zzh-ju5wb8TNlskW5-iCHlfrsxXy2c4hkRTipWdV-sypc0DJ6wA9E$) with frequently asked questions on the commercialization of COVID-19 medical countermeasures.**Moderna’s medical updates**Moderna is having live 10-minute presentations, followed by Q&A. Sign up at <https://app.livestorm.co/moderna-na-medical/regional-medical-affairs-office-hours-simplified-dosing-schedules-for-moderna-covid-19-vaccine-bivalent> Moderna resources are expected to be posted [here](https://eua.modernatx.com/).**Pfizer’s medical updates**Pfizer has live medical update sessions. Sign up at <https://www.pfizermedicalinformation.com/en-us/medical-updates> [Pfizer’s Vaccine Formulation/Presentation Guide](https://www.cvdvaccine-us.com/images/pdf/PP-CVV-USA-2534_Formulation-Presentation%20Guide%20April%202023%20Update.pdf)is a document from Pfizer-BioNTech withinformation about the formulations and presentations of the vaccines.**EUA Fact Sheets**Once a new EUA Fact Sheet is issued, it must be used. Previous ones no longer contain accurate information.* Moderna EUAscan be found on the FDA website[here](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines)
* Pfizer EUAs can be found on the FDA website [here](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines)
* Novavax EUAscan be found on the FDA website[here](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted)

**Standing Orders** Watch for updated standing orders: <https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html> **Other Helpful Resources*** [AAP Pediatric COVID-19 Vaccine Dosing Quick Reference Guide](https://downloads.aap.org/AAP/PDF/COVID%20Vaccine%20Dosing_Quick%20Reference.pdf)
* [CDC’s Stay Up to Date with COVID-19 Vaccines](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html)

**MDPH RESOURCES****2023 MDPH Immunization Updates**The Immunization Updates are a series of immunization-related webinars for healthcare providers, presented by the Immunization Division every spring. Registration is open – click on the links below to reserve your spot.2023 Schedule:* Immunization Schedule Updates Wednesday, May 17 – [Click here to register](https://cvent.me/ZLwNl1)
* Vaccine Confidence - with guest speaker [Karen Ernst](https://www.voicesforvaccines.org/person/karen-ernst-ma/) from Voices for VaccinesWednesday, May 24 - [Click here to register](https://cvent.me/XrrAga)
* Massachusetts Immunization Information System (MIIS)Wednesday, May 31 - [Click here to register](https://cvent.me/odd8Ey)
* VFC Compliance and Vaccine Storage & Handling - Earn your VFC Certificate!Wednesday, June 7 - [Click here to register](https://cvent.me/zyyg9l)
* Epidemiology of Vaccine-Preventable Diseases in Mass.Wednesday, June 14 - [Click here to register](https://cvent.me/lLLeB2)

**Immunization Division Main Number**For questions about immunization recommendations, disease reporting, etc.Phone: 617-983-6800 (24/7 MDPH Epi line)Fax: 617-983-6840Website: <https://www.mass.gov/topics/immunization> **MIIS Help Desk**Phone: 617-983-4335Fax: 857-323-8321 Email questions to: miishelpdesk@mass.gov Website: <https://www.mass.gov/massachusetts-immunization-information-system-miis>**MDPH Vaccine Unit**Phone: 617-983-6828Email questions to: dph-vaccine-management@mass.gov Website: <https://www.mass.gov/service-details/vaccine-management> **Color Help**Email questions to: colorhelp@mass.govWebsite: <https://www.mass.gov/info-details/vaccine-clinic-management-platform>**COVID-19 Email Box**Email questions to: COVID-19-Vaccine-Plan-MA@mass.gov  |

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