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| **BULLETIN****What Massachusetts COVID-19 Vaccine Providers Need to Know****Week of 8/8/2023** |

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| *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.** [COVID-19 Vaccination Recommendations Infographic](https://www.cdc.gov/vaccines/covid-19/downloads/COVID19-vaccination-recommendations-most-people.pdf) (Updated 5/16/2023)
* [COVID-19 Vaccination Recommendations Infographic (Immunocompromised)](https://www.cdc.gov/vaccines/covid-19/downloads/COVID19-vaccination-recommendations-immunocompromised.pdf) (Updated 5/16/2023)
* [Bivalent Moderna COVID-19 Vaccine: When to use the pink versus blue-capped vial](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/Moderna-Vaccine-Vial-Infographic-508.pdf) (Updated 6/12/2023)
* [Interim COVID-19 Immunization Schedule](https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf) (Updated 5/31/2023)
* [FAQs for the Interim Clinical Considerations](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html) (Updated 6/14/2023)
* [COVID-19 Vaccine Product Information](https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html) (Updated 5/16/2023)

**LATEST NUMBERS*** As of 8/8/2023 **5,960,620** people in Massachusetts have completed a primary series. However, only **2,107,907** Massachusetts residents have received the recommended bivalent booster dose.

**LATEST NEWS****COVID-19 ordering availability**COVID-19 vaccine ordering is no longer available in the MIIS at the current time. The latest information from the CDC is signaling that commercialization is likely to occur in mid to late September. Providers serving individuals <19 years of age will continue to receive free state-supplied vaccine once commercialization occurs. We will inform providers once ordering for your <19 population is available again in the MIIS. Providers serving adult populations must start planning for private purchase of COVID-19 vaccines for when commercialization takes effect. Public providers (LBOHs, CHCs) who serve uninsured adult populations will receive additional information about accessing free COVID-19 vaccines through the federal Bridge program once additional information becomes available. If your site requires additional doses of COVID-19 vaccine prior to commercialization, please reach out to provider sites in your area or network that may be able to supply your site with the requested doses. If your site needs assistance with identifying available doses in your area , please contact the Vaccine Management Unit at 617-983-6828 or dph-vaccine-management@mass.gov. Please ensure that anytime your site is transferring vaccines to another location, you are following all guidance detailed in the [Vaccine Transport SOP](https://www.mass.gov/doc/vaccine-transport-sop-2023/download).**Shelf-life extension for some Moderna under 6 years of age vaccine**The FDA has approved Moderna’s request for a 3-month shelf-life extension for all **Moderna under 6 years** of age COVID-19 vaccines in the lots identified in the table below. Moderna has update their web-based [Vial Expiration Checker](https://urldefense.com/v3/__https%3A/modernacovid19global.com/vial-lookup?*vialLookUpTool__;Iw!!CUhgQOZqV7M!iN5Em5P0i931ipNJ0wyNKBD9sbfWcW2lNXHHnWeBx5YQTgMCHhCWKHhVFaZ8QwcfofeGOqNtYZdzkqJGvcHfYP_73Q$) tool to reflect the extension for the four lots listed below.  Only the lot numbers below are included in this SLE approval.

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| **Lot Number** | **Expiry Date Prior to SLE** | **Extended SLE Date** |
| ***201L22A*** | Sept. 6, 2023 | Dec. 6, 2023 |
| ***214K22A***  | Aug. 29, 2023 | Nov. 29, 2023 |
| ***215K22A***  | Aug. 19, 2023 | Nov. 19, 2023 |
| ***216K22A*** | Aug. 22, 2023 | Nov. 22, 2023 |

 Remember to check all COVID-19 Vaccine expiration dates using the manufacturers’ online expiry checking tools: * [Moderna Vial Expiration Checker](https://urldefense.com/v3/__https%3A/modernacovid19global.com/vial-lookup__;!!CUhgQOZqV7M!iN5Em5P0i931ipNJ0wyNKBD9sbfWcW2lNXHHnWeBx5YQTgMCHhCWKHhVFaZ8QwcfofeGOqNtYZdzkqJGvcF-weOJkA$)
* [Pfizer-BioNTech COVID-19 Vaccine Expiry Checker](https://urldefense.com/v3/__https%3A/lotexpiry.cvdvaccine.com/__;!!CUhgQOZqV7M!iN5Em5P0i931ipNJ0wyNKBD9sbfWcW2lNXHHnWeBx5YQTgMCHhCWKHhVFaZ8QwcfofeGOqNtYZdzkqJGvcH4qM_U0A$)
* [Novavax Expiry Date Checker](https://urldefense.com/v3/__https%3A/us.novavaxcovidvaccine.com/hcp__;!!CUhgQOZqV7M!iN5Em5P0i931ipNJ0wyNKBD9sbfWcW2lNXHHnWeBx5YQTgMCHhCWKHhVFaZ8QwcfofeGOqNtYZdzkqJGvcE0_w-HOQ$)

**Changes expected this fall**Plans continue for the transition to routine commercial use of COVID-19 vaccines. In June 2023, the FDA’s VRBPAC voted to update the vaccine composition, and FDA subsequently advised manufacturers to update their vaccines to a monovalent XBB.1.5 composition. These vaccines are currently being manufactured. They are not yet available or licensed/authorized.Once these updated vaccines do become licensed or authorized by FDA, ACIP will review evidence and update its recommendations for all age groups. Current estimates are that this will happen in mid-September to early October.These vaccines will be the first COVID-19 vaccines to be available directly from the manufacturers as part of the commercial market, rather than through the United States Government. These vaccines will be available commercially at no out-of-pocket cost for adults with insurance (including Medicaid and Medicare). These vaccines will also be available at no out-of-pocket cost for all individuals under 19 years of age (regardless of insurance status) in Massachusetts through the Commonwealth’s universal pediatric vaccine program. The US Department of Health and Human Services is designing a special 1-year bridge program to create affordable access to the new COVID-19 vaccines for the 25 million uninsured adults residing in the US. More details of the bridge program will be forthcoming. **Current transitional phase**Currently, the COVID-19 Vaccination Program is in a unique, transitional position. Although we anticipate that commercialization, or the transition of vaccines to more traditional pathways for procurement, distribution, and payment, for adult providers will occur in the fall, at this time the COVID-19 Vaccine Program remains unchanged. The expiration of the federal PHE for COVID-19 on May 11, 2023, did NOT affect the requirements of the [COVID-19 Vaccination Provider Agreement](https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html). In May, the Department of Health and Human Services (HHS) released the [Fact Sheet: End of the COVID-19 Public Health Emergency | HHS.gov](https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html) which stated * “at the end of the COVID-19 PHE on May 11, Americans will continue to be able to access COVID-19 vaccines at no cost, just as they have during the COVID-19 PHE, due to the requirements of the CDC COVID-19 Vaccination Program Provider Agreement.”

During this transitional phase, it is important to understand the need to adhere to the COVID-19 Vaccination Provider Agreement, particularly as it pertains to patient access. CDC and MDPH want to ensure that providers in the COVID-19 Vaccination Program are not denying requests or turning away patients from obtaining COVID-19 vaccine. The COVID-19 Vaccination Provider Agreement requires that healthcare providers abide by the terms of the agreement, which states that **COVID-19 vaccines are provided at 100% no cost to the vaccine recipient**. The [COVID-19 Vaccination Provider Agreement](https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html) requires that all organizations and providers participating in the Program:* **must** administer COVID-19 Vaccine at no out-of-pocket cost to the recipient
* may **not** deny anyone vaccination based on the vaccine recipient’s coverage status or network status
* may **not** charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided
* may **not** require additional medical services to receive COVID-19 vaccination
* **may** seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient, such as:
	+ vaccine recipient’s private insurance company
	+ Medicare or Medicaid reimbursement
* may **not** seek any reimbursement, including through balance billing, from the vaccine recipient

**CURRENT COVID-19 VACCINES**The following COVID-19 vaccines, categorized into three vaccine types, are currently authorized under an [EUA](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines) by FDA and available for use in the United States:* **mRNA vaccines**
	+ Moderna COVID-19 Vaccine, Bivalent
	+ Pfizer-BioNTech COVID-19 Vaccine, Bivalent
* **Protein subunit vaccine**
	+ Novavax COVID-19 Vaccine, Adjuvanted

The monovalent formulations of the two mRNA COVID-19 vaccines (COMIRNATY/Moderna COVID-19 Vaccine and SPIKEVAX/Pfizer-BioNTech COVID-19 Vaccine) should no longer be used for COVID-19 vaccination.All currently available mRNA COVID-19 vaccines in the United States are formulated as a bivalent vaccine based on the original (ancestral) strain of SARS-CoV-2 and the Omicron BA.4 and BA.5 (BA.4/BA.5) variants of SARS-CoV-2.Novavax COVID-19 Vaccine is formulated as a monovalent vaccine based on the original (ancestral strain) of SARS-CoV-2. Janssen COVID-19 Vaccine is no longer available in the United States.None of the currently FDA-authorized COVID-19 vaccines are live-virus vaccines.COVID-19 vaccine-specific [FDA fact sheets](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines) and [U.S. COVID-19 Vaccine Product Information](https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html) can be consulted for a full list of ingredients and information on the conditions of use, storage and handling, preparation, and administration procedures.**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 A ([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-a)) and B ([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-b)) for recommendations for these populations.**VACCINE ADMINISTRATION RECOMMENDATIONS**CDC recommends that people ages 6 months and older receive at least 1 bivalent mRNA COVID-19 vaccine.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.**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-BioNTech 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)).**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.  If Moderna is used, administer 0.5 mL/50 ug (dark blue cap and label with a gray border); if Pfizer-BioNTech is used, administer 0.3 mL/30 ug (gray cap and label with a gray border). |
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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.CDC recommends children ages 6 months–5 years who are unvaccinated and recommended to receive more than 1 bivalent mRNA vaccine dose for initial vaccination 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.

A [Vaccine Adverse Event Reporting System](https://vaers.hhs.gov/index.html) (VAERS) report is required following administration of a vaccine in an unauthorized manner.In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered when FDA authorization requires that a vaccine from the same manufacturer be used. A 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

See [Appendix C](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-c) for recommended actions following interchangeability-related COVID-19 vaccine administration errors or deviations.

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| **REPORTING OF VACCINE ADVERSE EVENTS**Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by FDA and the provider agreement for the CDC COVID-19 Vaccination Program to report the following that occur after any COVID-19 vaccination:* Vaccine administration errors whether or not associated with an adverse event
* [Serious adverse events](https://vaers.hhs.gov/faq.html), irrespective of attribution to vaccination
* Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
* Cases of myocarditis
* Cases of pericarditis
* Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at [https://vaers.hhs.gov](https://vaers.hhs.gov/) or by calling 1-800-822-7967.**VACCINE MANAGEMENT** **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.**Helpful Graphics****RESOURCES & LEARNING OPPORTUNITIES** **Commercialization of COVID-19 products**[HHS Commercialization Transition Guide](https://urldefense.com/v3/__https%3A/www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html%2Ahhs-commercialization-transition-guide__;Iw!!CUhgQOZqV7M!mewpi5dqWnO16v2Rl46u0LCWuHAAzRALtKzaVBVhk5pMc_-no56yvQr0bd0Uf2zmhOiTnR7kXQxT_DoJXX5jxLiJPg$) (pdf available [here](https://www.cdc.gov/vaccines/covid-19/downloads/HHS-Commercialization-Transition-Guide-508.pdf))HHS recently published a [question-and-answer document](https://urldefense.com/v3/__https%3A/immunizationmanagers.us16.list-manage.com/track/click?u=13b4fdc9ac0078e4c57522c2b&id=c4349edb49&e=4f158a4069__;!!CUhgQOZqV7M!mOJ1HacJneXLSjQ5ZfhT0d9FRTQ70-wNRhMBaNIFv3Zzh-ju5wb8TNlskW5-iCHlfrsxXy2c4hkRTipWdV-sypc0DJ6wA9E$) with frequently asked questions on the commercialization of COVID-19 medical countermeasures.**Moderna’s medical updates**Moderna resources are posted [here](https://eua.modernatx.com/).**Pfizer’s medical updates**Pfizer has recordings of recent live medical update sessions available for viewing 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** Standing orders can be found under the ‘Administration’ tab of each vaccine at: <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)
* CDC’s [COVID-19 Vaccination Clinical & Professional Resources](https://www.cdc.gov/vaccines/covid-19/index.html)
* Immunize.org: [Checklist of Current Versions of U.S. COVID-19 Vaccination Guidance and Clinic Support Tools](https://www.immunize.org/catg.d/p3130.pdf) (PDF)
* Immunize.org: [Vaccines: COVID-19](https://www.immunize.org/covid-19/) main page
* Immunize.org: [Ask the Experts: COVID-19](https://www.immunize.org/askexperts/experts_cov.asp) web page
* [COVID-19 Vaccine Education and Equity Project - CVEEP](https://covidvaccineproject.org/)

**MDPH RESOURCES****Immunization Division Main Number**For questions about immunization recommendations, disease reporting, etc.Phone: 617-983-6800 (24/7 MDPH Epi line)Fax: 617-983-6840Website: <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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