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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 7/6/2023 **5,956,122** people in Massachusetts have completed a primary series. However, only **2,090,998** Massachusetts residents have received the recommended bivalent booster dose.   **LATEST NEWS**  **Summary of the June 2023 ACIP session on COVID-19 vaccines** ACIP met June 21 – 23. As part of the meeting, they reviewed current COVID-19 vaccine epidemiology and vaccine effectiveness. While vaccine effectiveness against hospitalization clearly wanes over about 6 months, protection against severe disease and death persists longer in people of all ages, including pregnant people. Vaccination during pregnancy reduced the likelihood of hospitalization of infants younger than age 6 months. Despite the clear benefit to recipients of all ages, uptake of the recommended bivalent vaccine remains low, with 43% of people age 65 and older having received a dose, but fewer than 5% of children under age 12 years having received one.   Plans are underway for the transition to routine commercial use of COVID-19 vaccines. A new monovalent COVID-19 vaccine containing a current variant XBB.1.5 has been recommended by FDA for fall 2023. This vaccine will be available commercially at no out-of-pocket cost for adults with insurance (including Medicaid and Medicare), as well as all individuals under 19 years of age (regardless of insurance status) in Massachusetts thru the Commonwealth’s pediatric vaccine program. A special 1-year bridge program is being designed to create affordable access to the new COVID-19 vaccines for 25 million uninsured adults. More details of the program are forthcoming. Once updated vaccines are licensed or authorized by FDA, ACIP will review evidence to inform its recommendations.      **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](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html)   + Moderna COVID-19 Vaccine, Bivalent   + Pfizer-BioNTech COVID-19 Vaccine, Bivalent * [Protein subunit vaccine](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/proteinsubunit.html)   + 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.  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 age 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 have the option to receive 1 additional bivalent mRNA vaccine 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 vaccine doses   **Novavax COVID-19 Vaccine**  People ages 12 years an older who previously received 1 or 2 monovalent Novavax 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-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)).  **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); see also [COVID-19 Vaccination Recommendations Infographic](https://www.cdc.gov/vaccines/covid-19/downloads/COVID19-vaccination-recommendations-most-people.pdf).  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.  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).  **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; see also [COVID-19 Vaccination Recommendations Infographic (Immunocompromised)](https://www.cdc.gov/vaccines/covid-19/downloads/COVID19-vaccination-recommendations-immunocompromised.pdf). 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 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). | | |  | | --- | |  | | |  | | |  | | --- | |  | | | |  | | --- | |  | | |  | | |  | | --- | |  | | |  | |  | | CDC’s [Clinical Considerations](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html) contain a description of moderate and severe immunocompromising conditions. It also affirms that people can self-attest to their moderately or severely immunocompromised status and receive COVID-19 vaccine doses wherever vaccines are offered. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.  **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   The COVID vaccination schedules for [People who are **not** moderately or severely immunocompromised](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-01) and [People who are moderately or severely immunocompromised](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02) should be consulted for age-specific information; 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.   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **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**  **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).   |  |  |  |  | | --- | --- | --- | --- | | 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:/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: 617-983-6840  Website: <https://www.mass.gov/topics/immunization>  **MIIS Help Desk**  Phone: 617-983-4335  Fax: 857-323-8321  Email questions to: [miishelpdesk@mass.gov](mailto: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](mailto:dph-vaccine-management@mass.gov)  Website: <https://www.mass.gov/service-details/vaccine-management>  **Color Help**  Email questions to: [colorhelp@mass.gov](mailto: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](mailto:COVID-19-Vaccine-Plan-MA@mass.gov) | | | | | |