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As of 9/11/2023 bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States. Therefore, administration of bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines must stop immediately.  On 9/11/2023, the [FDA approved and authorized](https://www.fda.gov/news-events/press-announcements/fda-takes-action-updated-mrna-covid-19-vaccines-better-protect-against-currently-circulating) updated Moderna and Pfizer COVID-19 vaccines formulated to more closely target currently circulating variants and to provide better protection against serious consequences of COVID-19, including hospitalization and death. These vaccines have been updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5.  On 9/12/2023, [ACIP recommended](https://www.cdc.gov/vaccines/acip/meetings/slides-2023-09-12.html) 2023–2024 (monovalent, XBB containing) COVID-19 vaccines as authorized under Emergency Use Authorization (EUA) or approved by Biologics License Application (BLA) in persons ≥6 months of age. A short time later, [CDC Director](https://www.cdc.gov/media/releases/2023/p0912-COVID-19-Vaccine.html) Mandy Cohen signed off on the recommendation.  Please watch all resources (ie., CDC, Immunize.org, AAP), for updated materials and clinical guidance.  **2023 – 2024 (monovalent, XBB containing) mRNA COVID-19 vaccine recommendations:**   * Everyone ages 5 years and older is recommended to receive 1 dose of a 2023–2024 mRNA COVID-19 vaccine * Children ages 6 months–4 years should complete a multi-dose initial series (2 doses of Moderna or 3 doses of Pfizer-BioNTech mRNA COVID-19 vaccine) with at least one dose of the 2023–2024 COVID-19 vaccine * People who are moderately or severely immunocompromised should complete a 3- dose initial series with at least one dose of the 2023–2024 COVID-19 vaccine and may receive 1 or more additional 2023–2024 COVID-19 vaccine doses * Bivalent mRNA COVID-19 vaccines are no longer recommended in the United States | | |  | | --- | |  | | |  | | |  | | --- | |  | | | |  | | --- | |  | | |  | | |  | | --- | |  | | |  | |  | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **VACCINE MANAGEMENT**  **New COVID-19 Formulation Now Available for Ordering**  The new Omicron variant XBB.1.5 formulations are now available for ordering for VFC and BAP enrolled providers (see below regarding enrollment information) through the MIIS. To order COVID-19 vaccines, please navigate to the “Orders” page in the MIIS to create a submit your request for additional doses.   |  |  |  |  | | --- | --- | --- | --- | | **Vaccine** | **Age Group** | **Package** | **NDC** | | Moderna Spikevax COVID-19 Vaccine | 12+ years | 10 pack- SDV | 80777-0102-95 | | *Moderna COVID-19 Vaccine\** | *6 months-11 years* | *10 pack- SDV* | *80777-0287-92* | | Pfizer Comirnaty COVID-19 Vaccine | 12+ years | 10 pack- SDV | 00069-2362-10 | | Pfizer COVID-19 Vaccine | 5 years-11 years | 10 pack- SDV | 59267-4331-02 | | Pfizer COVID-19 Vaccine | 6 months-4 years | 10 pack- 3-dose MDV | 59267-4315-02 |   *\*Moderna 6 months – 11 years vaccine is currently not available for ordering from CDC. It is available in the MIIS to be added to your COVID order. Any orders for Moderna 6m-11y will be placed on hold until the vaccine becomes available for shipment (anticipated to be early next week).*  An updated Novavax vaccine is not yet available. Authorizations or approvals for 2023 – 2024 Novavax COVID-19 vaccine will be determined by FDA (anticipated soon) with CDC recommendations to follow shortly thereafter.  **Bivalent Moderna and Pfizer-BioNTech COVID-19**  Bivalent COVID-19 vaccines are expired in the MIIS. Please process a storage and handling to remove vaccines from MIIS inventory. Expired COVID-19 vaccine can be discarded in medical waste.  Report all administered doses and enter a storage and handling issue in the MIIS by September 21st. On September 22nd, all expired COVID vaccines will be clear from your MIIS inventory.  **Massachusetts COVID-19 Program (MCVP) Agreements**  **Now that COVID-19 vaccines have been commercialized, the Massachusetts COVID-19 Program (MCVP) Agreements will be ending, resulting in all signed MCVP Agreements being considered null and void.** If your site is already enrolled in the Vaccines for Children (VFC) Program (currently order and receive state-supplied pediatric vaccines), you will not need to complete any additional steps in order to receive pediatric COVID-19 vaccines. Current VFC enrolled sites will start seeing COVID-19 vaccines as one of the vaccine ordering options once the formulations become available for routine ordering.  If your site is not currently enrolled in the VFC Program and would like to continue to receive COVID-19 vaccine for patients aged 18 years or younger, your site will need to enroll in the VFC Program and follow all programmatic guidelines detailed in the [Guidelines for Compliance with Federal Vaccine Administration Requirements](https://urldefense.com/v3/__https:/r20.rs6.net/tn.jsp?f=00153ymtBVygY0h8QaAVpweBcRluSyOHKH6AHqlxXYhGx13wWg_MtU8bYl-H3ckKgJeRMGO_E-hjFiOpPBf--8k9ouvV73vcZ9yjOvinhjvm64JFTJ8XjX_bD2vVSGz1IQpLDfSwKmxhoX4WyOA-7t6iwt4Lvoj0103uTCGDcHhsnwqc81nb_d47Jw2YUTMHznunzaoH8bVALepMw9mmt2HNfYAp7CpBQ7VmBVRx2Av43nMeHA2eXq3tx8WpxET1KdzYezOCqOJ3rc=&c=7d-ZL03g999a70jnyUq6ClfwxWqHd7xfnJcEy73NZi7PnHU1XZilLA==&ch=KfM2GqDJ06VQswKRpMTvo4FdVRJ7vFaDrtJtXgtZ3Brk32kXEDsGrg==__;!!CPANwP4y!Xn8-MJzNlygmlOCOKwbJ37ZgCNTpwV7xSlCvLwaczVhi1wKy6wBQxkP93Ycx_cKGAhFzS2qbzyvtJdhB2Yre2OGlVPaVKAc$). If your site has questions on how to enroll in the VFC Program, please contact the Vaccine Management Unit at 617-983-6828 or [dph-vaccine-management@mass.gov](mailto:dph-vaccine-management@mass.gov).  Additionally, there is a subset of public provider sites (local health departments, community health centers, Indian health services, county jails, state-sponsored mobile vendors) that are eligible to receive COVID-19 vaccines to administer to uninsured and underinsured adults, as part of the federal COVID-19 Vaccine Bridge Access Program (BAP). Providers that are eligible to take part in the BAP have received additional instructions by the Vaccine Management Unit.  **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.  **RESOURCES & LEARNING OPPORTUNITIES**  **Moderna’s medical updates**  MSL Briefings: Understanding the Updated Moderna COVID-19 Vaccine (2023-2024 Formulation)  Multiple dates and times. Sign up [here](https://app.livestorm.co/moderna-na-medical/msl-briefings-understanding-the-updated-moderna-covid-19-vaccine-2023-2024-formulation).  **Pfizer’s medical updates**  Healthcare provider page [here](https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine) and sign up for medical updates on the 2023-2024 vaccine [here](https://www.pfizermedicalinformation.com/en-us/document/a0r68000000YRxVAAW).  **EUA Fact Sheets**  Once a new 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](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 EUAs can 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:   * under the ‘Administration’ tab of each vaccine at: <https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html> * on Immunize.org at: <https://www.immunize.org/standing-orders/>   **Vaccine Expiration Date and Beyond Use Date or Time Video Series**  The Public Health Foundation (PHF), in partnership with the CDC, launched a three-part instructional video series, [Vaccine Expiration Date and Beyond Use Date or Time (BUD)](https://urldefense.com/v3/__https:/r20.rs6.net/tn.jsp?f=0017x4gGQJa-_MkvlxPZBxOXqoiHZ-V5mPdUhH5yLTchdqSFXdsSYBzPFwHAZE0eEPsH47ddnfwqWu4tfYflDGlGMNBY2hZstR--ZIwE_rlEo05s8WAleNzclXSZ_jW5dIY_t2V8ir0uYeU3cD7HUJrOg8o8CwOQh1Ju-QRimcFWzGGxe_VoUH7SrLeSpu3cbf58oyEeGByueZ3HwoSJfWtvrZKvPL0ohIcYe3rj5fGoC98dr18rWGMsPxPKtYgGmoDzd0qw1POk1oj-mH4hujTCsHvCyv37t03SzSGJdVXGm41lJi2ptT5QZwL48mhnwqz6PgxX6eabBw=&c=vZ7SLskQF0MTT-DuqBMXdXgWuWYtHyk1TFN5eRhQe3eFfiv01_3aNA==&ch=9NrjzacuBdaZKY1gmASr99its7XaQFL6ZiTg9KsgukdhAKbW0xhmVQ==__;!!CUhgQOZqV7M!koEcqu8_AXgR2Y5VbofhTBp5hmqWzBFR0Fvgnj7YeGxKEsU-SpSeZRAYhb2Z88gVZwzzSQIawiq0y6PgUyrr2x2rtMHbp2c$).    **Resources** (watch for updates!)   * CDC’s [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html) * CDC’s [COVID-19 Vaccination Clinical & Professional Resources](https://www.cdc.gov/vaccines/covid-19/index.html) * CDC’s [Coronavirus Disease 2019 (COVID-19) | CDC](https://www.cdc.gov/coronavirus/2019-nCoV/index.html) * CDC’s  [Stay Up to Date with COVID-19 Vaccines](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html) * Immunize.org: [Vaccines: COVID-19](https://www.immunize.org/covid-19/) main page * [AAP Pediatric COVID-19 Vaccine Dosing Quick Reference Guide](https://downloads.aap.org/AAP/PDF/COVID%20Vaccine%20Dosing_Quick%20Reference.pdf)   **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> | | | | | |