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| **BULLETIN****What Massachusetts COVID-19 Vaccine Providers Need to Know****Special Notice – 09/11/2023** |

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| **Bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States****Administration** **of bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines must stop immediately**Today, September 11, 2023, the U.S. Food and Drug Administration (FDA) took action to approve and authorize for emergency use updated 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. The FDA action today relates to updated mRNA vaccines for 2023-2024 manufactured by Moderna and Pfizer-BioNTech. These vaccines have been updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5.**The bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States. Administration of bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines must stop immediately.** We acknowledge that this will create a brief time period where no COVID-19 vaccines are currently authorized for use. We encourage you to create recall lists of any patients that are actively seeking vaccinations in the coming days, and to call them in once the new formulation becomes available.**ACIP is meeting tomorrow, September 12, 2023**. We expect significantly more detail and clinical guidance following that meeting. We are also expecting additional ordering instructions for the new formulation of vaccine from CDC in the coming days. We will follow up with a more detailed Provider Bulletin with additional information as soon as we can. **What You Need to Know*** **Pending recommendation by ACIP and approval by the CDC**, today’s FDA approval/authorization includes:
* **Individuals 5 years of age and older regardless of previous vaccination** are eligible to receive a single dose of an updated mRNA COVID-19 vaccine at least 2 months since the last dose of any COVID-19 vaccine.
* **Individuals 6 months through 4 years of age who have previously been vaccinated** against COVID-19 are eligible to receive one or two doses of an updated mRNA COVID-19 vaccine (timing and number of doses to administer depends on the previous COVID-19 vaccine received).
* **Unvaccinated individuals 6 months through 4 years of age** are eligible to receive three doses of the updated authorized Pfizer-BioNTech COVID-19 Vaccine or two doses of the updated authorized Moderna COVID-19 Vaccine.
* The FDA is confident in the safety and effectiveness of these updated vaccines and the agency’s benefit-risk assessment demonstrates that the benefits of these vaccines for individuals 6 months of age and older outweigh their risks.
* Individuals who receive an updated mRNA COVID-19 vaccine may experience similar side effects as those reported by individuals who previously received mRNA COVID-19 vaccines as described in the respective prescribing information or fact sheets.
* The updated vaccines are expected to provide good protection against COVID-19 from the currently circulating variants. Barring the emergence of a markedly more virulent variant, the FDA anticipates that the composition of COVID-19 vaccines may need to be updated annually, as is done for the seasonal influenza vaccine.
* The U.S. Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices will meet tomorrow (Sept. 12), to discuss clinical recommendations on who should receive an updated vaccine, as well as further considerations for specific populations such as immunocompromised and older individuals.
* Manufacturers have publicly announced that the updated vaccines would be ready this fall, and the FDA anticipates that the updated vaccines will be available in the very near future.

**Vaccine Management****Upon the commercialization of COVID-19 vaccines in the coming days, 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 post commercialization. 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%3A/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. 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. Providers that are eligible to take part in the COVID-19 Vaccine Bridge Access Program have received additional instructions by the Vaccine Management Unit. |
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