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Provider sites should prepare to switch to the BLA-labeled product (COMIRNATY), which is interchangeable with the EUA-labeled product and available to order at any time. The EUA-labeled product will no longer be available for ordering in the MIIS after 5 PM on January 27.  **Pfizer 12+ bivalent single dose vials now available for ordering by Primary Care Provider (PCP) Sites**  The Pfizer-BioNTech 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.  See below for additional information about the SDV presentation of the Pfizer (12+) Bivalent COVID-19 Vaccine:   * The order quantity is 50 doses.   + All single-dose vials, plan to use every single dose. * Product dimensions: 1.47in x 1.535in x 3.504in   + Storage space required equals that of a 300-dose MDV order * **SDVs will not include ancillary kits**. SDVs do not require the use of low-dead-volume syringes. * This product is new packaging, not a new vaccine. Storage and handling requirements remain the same as the Pfizer bivalent multi-dose vial. (Store at ultra-low temperature until expiry, may refrigerate up to 10 weeks within the expiry period).   **Novavax COVID-19 vaccine No Longer Available to Order After January 2023**   * Novavax product will remain available to order via MIIS for the reminder of January 2023, but will no longer be orderable after the end of January. Please note that all other COVID-19 vaccine formulations will remain available to order once Novavax ordering is turned off.   **FDA Advisory Committee Meeting to Discuss Future Vaccination Regimens Addressing COVID-19**  On Jan. 26, 2023, the U.S. Food and Drug Administration will hold [a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC)](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-hold-advisory-committee-meeting-discuss-future-vaccination-regimens) to consider whether and how the composition for primary doses of the currently available COVID-19 vaccines should be modified and how and whether the composition and schedule for booster doses should be adjusted moving forward. Along with the independent experts of the advisory committee, representatives from the U.S. Centers for Disease Control and Prevention and the National Institutes of Health will also participate in the meeting.  The meeting can be viewed [here](https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-january-26-2023-meeting-announcement).  As part of routine surveillance, [[CDC detected a preliminary signal for stroke in people ages 65 and older](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/bivalent-boosters.html) who received the Pfizer-BioNTech COVID-19 bivalent mRNA vaccine](https://urldefense.com/v3/__https:/www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/bivalent-boosters.html__;!!CUhgQOZqV7M!mOxzyuGZRLX7CYadA8iHAIFe5aa1AwKE3RErPKL8gzbMgNCXLU8XmU25gtCAh_ZesUaUKpFb1h_t-S-YsYHUhnABnpmE$). As a response to the signal, CDC and FDA examined several large databases including, Medicare’s database of 5 million doses, VA’s database of millions of veterans, in addition to Israel and European countries’ databases.  The totality of the data currently suggests that it is very unlikely that the signal in VSD represents a true clinical risk. We continue to believe that the updated bivalent vaccines are safe and effective and provide the best protection against COVID-19, and we continue to encourage Americans of all ages to get their updated COVID-19 shot right away.  **QUESTION OF THE WEEK**  **Q: Does the 4-day grace period apply to COVID-19 vaccine?**  **A:** **Yes.** People should not be routinely scheduled to receive a dose earlier than recommended. Schedulers should offer appointments beginning on the date of the recommended interval or later. However, CDC guidance does allow for doses to be given up to 4 days before the recommended interval (known as the 4-day grace period) in order to avoid missed vaccination opportunities when a recipient unexpectedly arrives early and might not return on schedule.  This applies to primary series and booster doses of vaccine.  If a dose is administered earlier than the grace period, see [Appendix D](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-d) for guidance on corrective actions. It is considered a vaccine administration error; you are required to report COVID-19 vaccine administration errors to the [Vaccine Adverse Event Reporting System (VAERS)](https://vaers.hhs.gov/).  Doses administered at any time after the recommended interval are valid.  **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-approved or FDA-authorized COVID-19 vaccine for children younger than age 6 months.  People can stay [up to date](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html) with COVID-19 vaccination by completing a primary series and receiving the most recent booster dose recommended for them by CDC (see [Table 2](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html?ACSTrackingID=USCDC_2120-DM91977&ACSTrackingLabel=Updated%20Guidance%3A%20Interim%20Clinical%20Considerations%20for%20Use%20of%20COVID-19%20Vaccines&deliveryName=USCDC_2120-DM91977#table-02) and [Table 3](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html?ACSTrackingID=USCDC_2120-DM91977&ACSTrackingLabel=Updated%20Guidance%3A%20Interim%20Clinical%20Considerations%20for%20Use%20of%20COVID-19%20Vaccines&deliveryName=USCDC_2120-DM91977#table-03)).  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.  **Primary series vaccination**  For primary series vaccination, **three monovalent COVID-19 vaccines** (listed in alphabetical order by manufacturer), are recommended: Moderna, Novavax, and Pfizer-BioNTech.  People ages 6 months and older are recommended to complete a primary series.  Monovalent vaccines should be used for the primary series, with one EXCEPTION: Children ages 6 months through 4 years who received 2 doses of a monovalent Pfizer vaccine should receive a bivalent Pfizer vaccine as their third primary series dose.  Vaccine products made by the same manufacturer should be used for all doses of the primary series (see [Interchangeability of COVID-19 vaccine products](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability)).  **Booster vaccination**  Monovalent mRNA vaccines are not authorized as a booster dose.  People ages 6 months and older are recommended to receive 1 bivalent mRNA booster dose after completion of any FDA-approved or FDA-authorized primary series or previously received monovalent booster dose(s) with one EXCEPTION: children 6 months through 4 years who receive a3-dose Pfizer primary series are not authorized to receive a booster doseat this time regardless of which Pfizer vaccine (i.e., a monovalent or bivalent) was administered for the third primary series dose.  A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in**limited situations**in people ages 18 years and older who completed any FDA-approved or FDA-authorized monovalent primary series, have not received any previous booster dose(s), and are unable (i.e., contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.  **Bivalent booster product varies by age**   * Ages **6 months–4 years** and completed the **Moderna primary series**: 1 **bivalent Moderna booster** dose. * Ages **6 months–4 years** and completed **Pfizer primary series**: **No booster** dose is recommended at this time. * Age **5 years** and completed **Moderna primary series**: **1 bivalent mRNA booster dose (Moderna or Pfizer)**. * Age **5 years** and completed **Pfizer primary series**: **1 bivalent Pfizer booster** dose. (Regardless of whether the third primary series dose was a monovalent or bivalent Pfizer vaccine) * Ages **6 years and older** and **any primary series**: **1 bivalent mRNA booster dose (Moderna or Pfizer)**.   **Moderna bivalent COVID-19 vaccine for children 6 months through 5 years of age**   * Dark pink capped vial with yellow-bordered label * Supplied in a **2-dose vial. These are NOT single-dose vials.** * **This could cause confusion for vaccine administrators as no other vaccine is supplied in a 2-dose vial.** * The dosage/injection volume for each booster dose is 0.2 mL.     **VACCINE ADMINISTRATION RECOMMENDATIONS**  **Four COVID-19 vaccines are currently approved under a BLA or authorized under an EUA by the FDA:**  The following COVID-19 vaccines, categorized into three [vaccine types](https://www.cdc.gov/vaccines/hcp/conversations/understanding-vacc-work.html), are currently approved under a BLA or authorized under an EUA by the FDA:   * [mRNA vaccines](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html)   + Moderna COVID-19 Vaccine/SPIKEVAX and Moderna COVID-19 Vaccine, Bivalent   + Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY and 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 * [Adenovirus vector vaccine](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html)   + Janssen (Johnson & Johnson) COVID-19 Vaccine   COVID-19 vaccine products are formulated as follows:   * Monovalent vaccine: The vaccine product is based on the original (ancestral) strain of SARS-CoV-2 * Bivalent vaccine: The vaccine product is 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   None of the currently FDA-approved or FDA-authorized COVID-19 vaccines are live-virus vaccines.  Janssen COVID-19 Vaccine is authorized for adults ages 18 years and older in [certain limited situations](https://www.fda.gov/media/146304/download) due to safety considerations (see [Appendix A](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a)).  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.  **COVID-19 vaccine formulations currently approved or authorized in the United States**  The table below can be found [here](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf). | | |  | | --- | |  | | |  | | |  | | --- | |  | | | |  | | --- | | **COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised**  For primary series vaccination, Moderna, Novavax, and Pfizer COVID-19 vaccines are recommended; only monovalent vaccines are approved or authorized for primary series doses. The same vaccine product should be used for all doses of the primary series (see [Interchangeability of COVID-19 vaccine products](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability)). The graphic below is available [here](https://www.cdc.gov/vaccines/covid-19/images/COVID19-vaccination-schedule-most-people.png) | | | |  | | --- | |  | | | |  | | --- | | **Considerations for intervals for mRNA COVID-19 vaccine primary series**  **An 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months-64 years, especially for males ages 12–39 years.** COVID-19 vaccines are FDA-approved or FDA-authorized for a 3-week (Pfizer vaccine) or 4-week (Moderna vaccine) interval between the first and second dose. A 3- or 4-week interval continues to be the recommended interval for people who are moderately or severely immunocompromised, adults ages 65 years and older, and in situations when the fullest possible protection needs to be achieved sooner (e.g., increased concern about [COVID-19 community levels](https://urldefense.com/v3/__https:/www.cdc.gov/coronavirus/2019-ncov/science/community-levels.html__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLnC1H_DIA$) or an individual’s higher risk for severe disease).  mRNA COVID-19 vaccines are safe and effective at the FDA-approved or FDA-authorized intervals, but a longer interval may be considered for some populations. While absolute risk remains small, the risk for myocarditis is higher for males ages 12-39 years, and this risk might be reduced by extending the interval between the first and second dose. [Some studies](https://urldefense.com/v3/__https:/www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/11-COVID-Moulia-508.pdf__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLm2YAf_jw$) in adolescents (ages 12-17 years) and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. Extending the interval beyond 8 weeks has not been shown to provide additional benefit. **In summary, an 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months-64 years, especially for males ages 12–39 years.**  **Transitioning from a younger to older age group**  In general, CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination. If a person moves from a younger age group to an older age group during the primary series or between the primary series and the booster dose, they should receive the vaccine product and dosage for the older age group for all subsequent doses with the following EXCEPTION: [FDA EUA](https://www.fda.gov/media/159312/download) requires that **children who receive the Pfizer Vaccine and transition from age 4 years to 5 years during the primary series must complete the series they start.**  FDA authorization allows for [dosing options](https://www.cdc.gov/vaccines/covid-19/downloads/child-age-transition-508.pdf) for certain other situations when a child ages from a younger to older age group for Moderna and Pfizer COVID-19 vaccines.        **COVID-19 vaccination schedule for people who ARE moderately or severely immunocompromised**  People with immunocompromising conditions or people who take immunosuppressive medications or therapies are [at increased risk for severe COVID-19](https://urldefense.com/v3/__https:/www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLkIiPeCZA$). Because the immune response following COVID-19 vaccination may differ in people who are moderately or severely immunocompromised at the time of vaccination, specific guidance for this population is provided.  For primary series vaccination, Moderna, Novavax, and Pfizer COVID-19 vaccines are recommended; only monovalent vaccines are approved or authorized for primary series doses. The same vaccine product should be used for all doses of the primary series (see [Interchangeability of COVID-19 vaccine products](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability)).  For booster vaccination, Moderna and Pfizer are recommended. Recommendations vary based on age and primary series product.  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. For example, people who become moderately or severely immunocompromised after completing a 2-dose mRNA primary series do not need additional primary doses; however, they should follow the schedule for people who are moderately or severely immunocompromised for the booster dose. The graphic below is available [here](https://www.cdc.gov/vaccines/covid-19/images/COVID19-vaccination-schedule-immunocompromised.png). | | | |  | | --- | |  | | |  | |  | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **VACCINE MANAGEMENT**  **Vaccine Inventory Management Reminder**  Proper vaccine inventory management is critical to ensure expired or vaccines past the Beyond Use Date (BUD) are not administered to patients. Vaccine inventory should be checked daily. During the daily check (1) review and compare your physical inventory to your MIIS inventory, (2) process storage and handling issues in the MIIS for all wasted or expired doses. Vaccine orders may be canceled or reduced due to MIIS inventory showing high inventory or expired vaccines. If you do have expired or wasted vaccines, be sure to process a vaccine storage and handling problem in the MIIS.  **Watch for Expired Vaccine**  We continue to encourage you to properly manage and report your inventory:   * Practice first in/first out inventory management. * Store older vaccines to the front of the refrigerator or freezer unit. * Continually monitor vaccines to help reduce administration errors. * Verify expiry dates using the manufacturers’ online checkers:   + **Pfizer:** [https://lotexpiry.cvdvaccine.com](https://urldefense.com/v3/__https:/lotexpiry.cvdvaccine.com__;!!CUhgQOZqV7M!g1Yw5s9rP2l4dkC-7CD1gxNax-9_NEnMVlrrMsI7fKtol4z38iBzCVOWymrfdx2hFKkXG21JexZO0BFcRHYFXWo$)   + **Moderna:** [https://modernacovid19global.com/vial-lookup](https://urldefense.com/v3/__https:/modernacovid19global.com/vial-lookup__;!!CUhgQOZqV7M!g1Yw5s9rP2l4dkC-7CD1gxNax-9_NEnMVlrrMsI7fKtol4z38iBzCVOWymrfdx2hFKkXG21JexZO0BFc0u-dkYA$)   + **Novavax:** [https://us.novavaxcovidvaccine.com/hcp](https://urldefense.com/v3/__https:/us.novavaxcovidvaccine.com/hcp__;!!CUhgQOZqV7M!g1Yw5s9rP2l4dkC-7CD1gxNax-9_NEnMVlrrMsI7fKtol4z38iBzCVOWymrfdx2hFKkXG21JexZO0BFcSHj6TOA$)   + **Johnson and Johnson/Janssen:** [https://vaxcheck.jnj/](https://urldefense.com/v3/__https:/vaxcheck.jnj/__;!!CUhgQOZqV7M!g1Yw5s9rP2l4dkC-7CD1gxNax-9_NEnMVlrrMsI7fKtol4z38iBzCVOWymrfdx2hFKkXG21JexZO0BFcjMhtgo4$) * Ensure your inventory is up to date by report administered doses and process storage and handling for expired or wasted vaccine. * Dispose of any expired or wasted vaccine.   **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), [Janssen](https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-storage-handling-label.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.  **Pfizer and Moderna Expiration Date Extensions and Beyond Use Dates**  **Pfizer**  Recently the FDA extended the expiration date for Pfizer COVID-19 vaccine (monovalent and bivalent) from 12 to 18 months from manufacturer date. **NOTE: This expiration date extension applies to both vaccine vials currently stored at ultra-cold temperatures and at refrigerated temperatures – even if these vials were moved to refrigerated temperatures prior to the extension.**    For example, if a vaccine (original expiration date = 12/20/2022) was removed from ultra-cold storage and placed in a refrigerator on 12/4/2022.  Pfizer COVID-19 vaccine stored in a refrigerator must be used within 10 weeks (beyond-use date [BUD]).  Based on the date the vaccine was placed in the refrigerator, the vaccine’s BUD is 2/12/2023.  Without the expiration date extension, this vaccine could only be used up to the expiration date (12/20/2022)–not the full 10 weeks**. HOWEVER, with this extension, the expiration date is now AFTER the BUD. The vaccine can be used for the full 10 weeks.**  **Moderna**  Recently the FDA extended the expiration date for select lots of Moderna COVID-19 vaccine (monovalent). This extension includes some lots of Moderna COVID-19 Vaccine (ages 12+ and 6-11). **NOTE: This expiration date extension applies to both vaccine vials currently stored at both frozen temperatures and refrigerated temperatures – even if these vials were moved to refrigerated temperatures prior to the extension.**    For example, if a vaccine (original expiration date = 12/20/2022) was removed from frozen storage and placed in a refrigerator on 12/4/2022.  Moderna COVID-19 Vaccine stored in a refrigerator must be used within 30 days (beyond-use date [BUD]). Based on the date the vaccine was place in the refrigerator, the vaccine’s BUD is 1/03/2023.  Without the expiration date extension, this vaccine could only be used up to the expiration date (12/20/2022)–not the full 30 days**.  HOWEVER, with this extension, the expiration date is now AFTER the BUD. The vaccine can be used for the full 30 days.**  **Moderna Bivalent Ancillary supply kits – Adult or Pediatric**  Pediatric provider sites ordering the Moderna bivalent COVID-19 vaccine booster will be sent two pediatric ancillary kits per minimum dose order by default to accommodate double the number of doses provided in each vial. Family practices and other provider types will be sent one adult ancillary kit per minimum dose order.   * If you would like ancillary supply kits different than what is described above, please specify pediatric or adult kits requested in the notes section of your vaccine order.   **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 | | - | 59267-0078-04 | COVID-19 (Pfizer);(PED 6m-4y) MDV10;10-pk | 100 | | - | 59267-1055-04 | COVID-19 (Pfizer);(PED 5-11) MDV10;10-pk | 100 | | - | 59267-1025-04 | COVID-19 (Pfizer); TRIS; MDV6; 10-pack | 180 | | - | 59267-1404-02 | COV-19(Pfizer);BIVALENT;SDV;10pk | 50 | | COMIRNATY | 00069-2025-10 | COVID-19; MDV6; 10-pack | 180 | | - | 59267-0565-02 | COVID-19 (Pfizer);BIVALENT;(PED 5-11) MDV10;10pk | 100 | | - | 59267-0304-02 | COVID-19 (Pfizer);BIVALENT;MDV6; 10-pack | 180 | | - | 80777-0279-99 | COVID-19 (Moderna)(PED 6m-5y)MDV10;10-pack | 100 | | - | 80777-0273-99 | COVID-19 (Moderna); MDV10; 10-pack | 100 | | - | 80777-0275-99 | COVID-19 (Moderna); MDV5; 10-pack | 100 | | - | 80777-0282-99 | COVID-19 (Moderna);BIVALENT;MDV5; 10-pack | 100 | | - | 59676-0580-15 | COVID-19 (Janssen); MDV5; 10-pack | 100 | | - | 80631-0100-10 | COVID-19 (Novavax); MDV10; 10-pack | 100 |  * Initial shipments of the Pfizer-BioNTech vaccine for children aged 6m–4 years may state “2y to <5y” or “6m to <5y” on the vial or carton labels. Please note that vials or cartons with labels that state “2y to <5y” can be used for children aged 6m through 4 years. * Pfizer-BioNTech vaccine vial labels and cartons may also state that a vial should be discarded 6 hours after the first dilution however as stated in the EUA Fact Sheet the timeframe for use post-dilution is actually 12 hours just like orange and gray cap Pfizer vaccine formulations.   **Characteristics of Bivalent COVID-19 Vaccines for Children Aged 6 Months Through 4 or 5 Years**  [Pfizer-BioNTech COVID-19 Vaccines](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/storage.html)  Characteristics of Pfizer-BioNTech bivalent COVID-19 vaccine for children aged 6 months through 4 years:   * Ultra-cold freezer storage (-90°C to -60°C) until expiry * NO FREEZER STORAGE (-25°C to -15°C) * Refrigerate (2°C to 8°C) up to 10 weeks without puncturing * Requires 2.2 mL diluent per vial * Packaged in 10-dose vials in cartons of 10 vials each (100 doses total) * Dose 3mcg/0.2mL * Minimum order quantity of 100 doses * Maroon cap identical to the monovalent Pfizer-BioNTech product for this age group * New label identifying the product as a bivalent vaccine (i.e., Original and Omicron BA.4/BA.5) * **Once punctured, each vial must be used within 12 hours**   [Moderna COVID-19 Vaccines](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/storage.html)  Characteristics of Moderna bivalent COVID-19 vaccine for children aged 6 months through 5 years:   * NO ULTRA-COLD FREEZER STORAGE (-90°C to -60°C) * Freezer storage (-50°C to -15°C) until expiry * Refrigerate (2°C to 8°C) up to 30 days without puncturing * Does not require diluent * Packaged in **2-dose vials** in cartons of 10 vials each (20 doses total)   *(CAUTION: no other COVID vaccine is supplied in a 2-dose vial)*   * Dose 10mcg/0.2mL * Minimum order quantity of 100 doses * Vial with dark pink cap and yellow border on the label * **Once punctured, each vial must be used within 8 hours**  |  | | --- | | **RESOURCES & LEARNING OPPORTUNITIES**  **Moderna’s COVID-19 Vaccine Medical Updates and Interactive Office Hours**  Moderna is hosting two types of events, which cover the same topics, with several day and time options to accommodate schedules. You're welcome to attend multiple events but please register for each date separately.   * 25-minute presentation followed by live Q&A – link [here](https://urldefense.com/v3/__https:/i.modernatx.com/OTQ5LUJERy0yNzQAAAGImGfIBI9XDZA7E3eibLACrUV_KuFiYebuuK4e0ZnALn1a025Eg4uSkxFymiOn2aUkUFKtmg4=__;!!CUhgQOZqV7M!iO6-kpWuH27pb8RoOeNta5Bw4x3dIeF5M9UZ_YydwANs7zUHB5fX62YoO-lzdxjPMDNsAKLSTknXnCZ3J2WhhH0eY6kL$) * 5-minute presentations with emphasis on live Q&A – link [here](https://urldefense.com/v3/__https:/i.modernatx.com/OTQ5LUJERy0yNzQAAAGImGfIBM24l3DZy7nIZGc_JTUtR28J-oSGOBq5ym5bvj9RBajh4o2rOPFaDv97LGev9MlS-Og=__;!!CUhgQOZqV7M!iO6-kpWuH27pb8RoOeNta5Bw4x3dIeF5M9UZ_YydwANs7zUHB5fX62YoO-lzdxjPMDNsAKLSTknXnCZ3J2WhhODE0pcm$)   **Pfizer COVID-19 Vaccine Medical Updates**  Pfizer Vaccines US Medical Affairs continues to host frequent *Medical Updates & Immunization Site Training for All Providers.* To access the training sessions, please visit: [https://www.pfizermedicalinformation.com/en-us/medical-updates](https://urldefense.com/v3/__https:/www.pfizermedicalinformation.com/en-us/medical-updates__;!!CUhgQOZqV7M!wnopdixLkKhCVeMjUiwcd-KVQVUN9jXipkisyDlTme9oe3pB9EYR1yJo7AhKgBWejq3FUBI%24)  **EUA Fact Sheets**  Once a new EUA Fact Sheet is issued, it must be used. Previous ones no longer contain accurate information.   * 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) * 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) * 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) * Janssen EUAscan be found on the FDA website[here](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine)   **“At a Glance” Summaries**  The CDC “At a Glance” Summaries include Storage and Handling basics, Preparation and Administration Basics, and a Schedule graphic.   * Pfizer <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/vaccine-at-a-glance.pdf> * Moderna <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/vaccine-at-a-glance.pdf> * Novavax [https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/downloads/novavax-prep-admin-summary.pdf](https://urldefense.com/v3/__https:/www.cdc.gov/vaccines/covid-19/info-by-product/novavax/downloads/novavax-prep-admin-summary.pdf__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLmS8GIhaA$)     **Standing Orders**   * Novavax <https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/downloads/novavax-standing-orders.pdf> * CDC’s Moderna COVID-19 Vaccine info (including the standing orders below) <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html> * Moderna 6 months through 5 years of age <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/infant_standing-orders.pdf> * Moderna 6 through 11 years of age <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/6-11-standing-orders.pdf> * Moderna 12 years of age and older <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/12-17-standing-orders.pdf> * CDC’s Pfizer COVID-19 Vaccine info (including the standing orders below) <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html> * Pfizer 6 months through 4 years of age <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/infant-standing-orders.pdf> * Pfizer 5 through 11 years of age <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/Pfizer_PED_StandingOrders.pdf> * Pfizer, Monovalent and Bivalent: 12 years of age and older <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/gray-cap-Pfizer-BioNTech-standing-orders.pdf>   **Helpful Reference Materials**   * [Interim COVID-19 Immunization Schedule](https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf) * [Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf) * [AAP’s Pediatric COVID-19 Vaccine Dosing Quick Reference Guide](https://urldefense.com/v3/__https:/downloads.aap.org/AAP/PDF/COVID*20Vaccine*20Dosing_Quick*20Reference.pdf__;JSUl!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLkQx_euEA$) * [Moderna COVID-19 Vaccine for Children who Transition from a Younger to Older Age Group](https://www.cdc.gov/vaccines/covid-19/downloads/child-age-transition-508.pdf) * [Pfizer-BioNTech for Children who Transition from a Younger to Older Age Group](https://urldefense.com/v3/__https:/www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Child-Age-Transition-508.pdf__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLm3fhfIdw$) * [Vaccine administration errors and deviations (Appendix D)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-d) * [FAQs for the Interim Clinical Considerations](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html) * [COVID-19 vaccination and SARS-CoV-2 infection](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection) * [People who received COVID-19 vaccine outside the United States (Appendix B)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-b) * [People who received COVID-19 vaccine as part of a clinical trial (Appendix C)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-c)  * [Triage of people with a history of allergies or allergic reactions (Appendix E)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html" \l "appendix-e) * [Resources to Promote COVID-19 Vaccines for Children & Teens](https://www.cdc.gov/vaccines/covid-19/planning/children/resources-promote.html) (includes social media graphics, posters, videos, external partner resources) * [Stay Up to Date with COVID-19 Vaccines Including Boosters](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html) (the COVID19 booster tool can be found here also)   **Information for parents and caregivers:**   * [[Stay Up to Date with COVID-19 Vaccines Including Boosters|](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html) CDC](https://urldefense.com/v3/__https:/www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html?CDC_AA_refVal=https*3A*2F*2Fwww.cdc.gov*2Fcoronavirus*2F2019-ncov*2Fvaccines*2Frecommendations*2Fadolescents.html__;JSUlJSUlJSU!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLkfB9jY2A$) * [Frequently Asked Questions about COVID-19 Vaccination in Children | CDC](https://urldefense.com/v3/__https:/www.cdc.gov/coronavirus/2019-ncov/vaccines/faq-children.html__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLl-eqIMAQ$) * [6 Things to Know about COVID-19 Vaccination for Children | CDC](https://urldefense.com/v3/__https:/www.cdc.gov/vaccines/covid-19/planning/children/6-things-to-know.html?CDC_AA_refVal=https*3A*2F*2Fwww.cdc.gov*2Fvaccines*2Fcovid-19*2Fplanning*2Fchildren*2F10-things-to-know.html__;JSUlJSUlJSU!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLn4H4jdWg$) * [V-safe After Vaccination Health Checker | CDC](https://urldefense.com/v3/__https:/www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLnDCjkUdQ$) * [COVID-19 Vaccine: Frequently Asked Questions | American Academy of Pediatrics](https://urldefense.com/v3/__https:/www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/about-the-covid-19-vaccine-frequently-asked-questions/__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLn2BtygXA$) |   **COVID-19 Vaccine Training Modules**  CDC’s four training modules (General Overview, Pfizer, Moderna, Janssen) can be found [here](https://urldefense.com/v3/__https:/www2.cdc.gov/vaccines/ed/covid19/__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLmgOEuTAw$).  **COVID-19 Vaccine Webinar Series**  CDC is offering a series of brief (15-20 minute) webinars addressing topics around COVID-19 vaccination. These interactive, web-based training modules offer a real-world perspective on different issues around COVID-19 vaccines. Topics range from routine clinical and vaccine safety information to guidance for on-site clinic vaccination activities and having conversations with vaccine recipients. Each webinar includes self-test practice questions and lists additional resources related to the topic discussed. The landing page for all mini webinars is here: <https://www.cdc.gov/vaccines/covid-19/training-education/webinars.html>  **CDC interactive tool for the public to assess if they are eligible for a booster dose of COVID-19 vaccine**  CDC has an interactive tool to help users identify whether they (or someone else) need to receive a booster dose of COVID-19 vaccine. The “Find Out When You Can Get Your Booster” tool asks a series of simple questions about age, immunocompromise, number and type of previous doses of COVID-19 vaccines, and how long ago they received the most recent vaccination. From these answers, the tool reports whether a booster dose may be beneficial and presents considerations for when to receive it. Find the tool [here](https://urldefense.com/v3/__https:/www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html*when-you-can-get-booster__;Iw!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLkqIhXZbA$).  **Morbidity and Mortality Weekly Report**, better known as MMWR, is CDC’s primary publication for disseminating the science it produces. The staff at MMWR have launched a [landing page](https://urldefense.com/v3/__https:/www.cdc.gov/mmwr/covid19_vaccine_safety.html__;!!CUhgQOZqV7M!nRUoQQ3O0sXDsoGrcKqMZNaYlntqzHaLjaVFFHDNRBSX8TjPyGoFcmPD-tBZlBdXf0iARx3zc_y54hIzVRIvIryBSLmguNExOQ$) to help people find the latest information on COVID-19 vaccine effectiveness and safety.  **Recent CDC MMWRs**  January 6, 2023   * [Racial and Ethnic Differences in COVID-19 Vaccination Coverage Among Children and Adolescents Aged 5–17 Years and Parental Intent to Vaccinate Their Children — National Immunization Survey–Child COVID Module, United States, December 2020–September 2022](https://www.cdc.gov/mmwr/volumes/72/wr/mm7201a1.htm?s_cid=mm7201a1_w)   January 13, 2023   * [Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Children Aged 5–11 Years — United States, October 12–January 1, 2023](https://www.cdc.gov/mmwr/volumes/72/wr/mm7202a5.htm?s_cid=mm7202a5_w)   **MDPH RESOURCES**  **Massachusetts Resources**   * [COVID-19 Vaccine main page](https://www.mass.gov/covid-19-vaccine) * COVID-19 vaccinations for [children ages 6 months to 4 years old](https://www.mass.gov/info-details/covid-19-vaccinations-for-children-ages-6-months-to-4-years-old) * COVID-19 vaccinations for [children ages 5-17](https://www.mass.gov/info-details/covid-19-vaccinations-for-children-and-youth-ages-5-17" \t "_blank) * Search for a COVID-19 vaccine at [vaxfinder.mass.gov](https://vaxfinder.mass.gov/) * COVID-19 [booster frequently asked questions](https://www.mass.gov/info-details/covid-19-booster-frequently-asked-questions) * COVID-19 Vaccine Resource Line/2-1-1 is available for individuals who are unable to use Vaxfinder, or have difficulty accessing the internet. Available in English and Spanish and has translators available in approximately 100 additional languages. * COVID-19 Vaccine Training and Education Resources for Providers: <https://www.mass.gov/info-details/covid-19-vaccine-training-and-education-resources-for-providers> * [Multilingual COVID-19 Materials](https://www.mass.gov/resource/multilingual-covid-19-materials). Resources related to Coronavirus Disease 2019 (COVID-19) in multiple languages. Includes videos and printables on topics like vaccine safety, pregnancy and the vaccine, and FAQs.   **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) | | | | | |