

# Maine Immunization Program

## COVID-19 Commercialization Weekly Update 9/29/2023



Commercialization is the transition of COVID-19 medical countermeasures—vaccines, treatments, and test kits—previously purchased by the U.S. Government (USG) to established pathways of procurement, distribution, and payment by both public and private payers. This guide summarizes the [HHS Commercialization Transition Guide](#), [HHS Bridge Access Program Fact Sheet](#), and Maine Immunization Program guidance as the USG prepares to stop distributing COVID-19 vaccines and vaccines transition to the commercial market. Updated topics highlighted below, are all subject to change. Sections include:

- Fall Transition Timeline
- Sunsetting of the Federal COVID-19 Vaccination Program
- Commercialization of COVID-19 Vaccines
- Anticipated Vaccination Schedule for the Fall

Topic	Guidance	Effective Date
Section 1	Fall Transition Timeline	
<p><b>Updated 9/29/2023</b></p>	<p><b>VFC COVID-19 vaccine distribution</b></p> <ul style="list-style-type: none"> <li>• Routine COVID-19 ordering is now open through ImmPact for enrolled Vaccines for Children (VFC) provider.</li> <li>• COVID-19 and routine vaccine orders should be placed separately.</li> <li>• Possibility for delays in vaccine shipments.</li> <li>• Vaccine orders will be shipped when vaccine is available at the depot. We will continue to fill orders as more vaccine becomes available.</li> </ul> <p><b>Bridge Access Program (BAP) Updates</b></p> <ul style="list-style-type: none"> <li>• BAP providers may not charge an administration fee to patients receiving BAP COVID-19 vaccine if they are receiving reimbursement for administration through Maine’s BAP.</li> <li>• Providers receiving BAP vaccine may not transfer vaccine to another facility that is NOT an enrolled BAP provider.</li> <li>• <a href="#">BAP FAQs</a></li> <li>• Check <a href="https://www.vaccines.gov">vaccines.gov</a> for list of participating provider sites</li> </ul> <p><b>Updated Reference Materials</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Updated Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States</a></li> <li>• <a href="#">Interim 2023-2024 COVID-19 Immunization Schedule for Persons 6 Months of Age and Older</a></li> <li>• <a href="#">COVID-19 Vaccination Recommendations Infographic</a></li> <li>• <a href="#">COVID-19 Vaccination Recommendations Infographic (Immunocompromised)</a></li> <li>• <a href="#">COVID-19 Vaccine Product Information</a></li> </ul>	

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<p><b>Updated 9/15/2023</b></p>	<ul style="list-style-type: none"> <li>• <b>Early this week, FDA and ACIP authorized the newly updated COVID-19 vaccine.</b> <ul style="list-style-type: none"> <li>• Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula): individuals ages 6 months and older</li> <li>• Moderna COVID-19 Vaccine (2023-2024 Formula): individuals ages 6 months and older</li> <li>• Note that FDA has not yet authorized or approved an updated Novavax vaccine for 2023-2024. As a result, the existing Novavax vaccine may still be administered at this time if it is determined that the individual should not wait for a 2023-2024 Novavax COVID-19 vaccine.</li> </ul> </li> <li>• <b>Bivalent mRNA COVID-19 Vaccines Are No Longer Authorized</b> <ul style="list-style-type: none"> <li>• Remove all bivalent mRNA COVID-19 vaccines from storage units immediately, even if they are not expired.</li> <li>• MIP staff have deleted all bivalent mRNA COVID-19 vaccine listings from the available vaccine inventory from your site in ImmPact.</li> </ul> </li> </ul> <table border="1" data-bbox="470 800 1444 1029"> <thead> <tr> <th>Manufacturer</th> <th>Presentation</th> <th>Unit of Sale NDC</th> </tr> </thead> <tbody> <tr> <td>ModernaTX Inc.</td> <td>12y+; SDV; 10pk</td> <td>80777-0102-95</td> </tr> <tr> <td>Pfizer Inc.</td> <td>12y+; SDV; 10pk</td> <td>00069-2362-10</td> </tr> <tr> <td>Pfizer Inc.</td> <td>Peds 5y-11y; SDV; 10pk</td> <td>59267-4331-02</td> </tr> <tr> <td>Pfizer Inc.</td> <td>Peds 6m-4y; MDV3; 10pk</td> <td>59267-4315-02</td> </tr> </tbody> </table>	Manufacturer	Presentation	Unit of Sale NDC	ModernaTX Inc.	12y+; SDV; 10pk	80777-0102-95	Pfizer Inc.	12y+; SDV; 10pk	00069-2362-10	Pfizer Inc.	Peds 5y-11y; SDV; 10pk	59267-4331-02	Pfizer Inc.	Peds 6m-4y; MDV3; 10pk	59267-4315-02	
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- **Novavax vaccine is still under review by the FDA**
  - Providers can continue to administer this vaccine at this time if it is determined that the individual should not wait for a 2023-2024 Novavax COVID-19 vaccine.
- **Pre-ordering is ongoing**
  - Preorders for the presentations below will continue to be filled over the next couple weeks as vaccine becomes available for distribution. Once pre-orders are filled and additional allocations are received, we will open for routine ordering.

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- Preorders for Moderna’s pediatric presentation for children 6m-11y will also be filled.
- Updated recommended schedules and clinical considerations are expected to be available in the coming days.
- **Bridge Access Program**
  - Enrollment into the Bridge Access Program has begun for select provider sites
  - Due to the limited quantities of COVID-19 vaccination available through Maine’s Bridge Access Program and the overwhelming response from our providers, at this time we are only able to accommodate enrollments from **FQHCs, IHS, and Public Health Departments.**
  - We will be reassessing the available doses at the beginning of the new year and will reach out if we are able to enroll your site at that time. The Bridge Access Program is a temporary program and will only continue through December 31, 2024.
  - For more information on commercialization and the Bridge Access Program please see the [COMMERCIALIZATION OF COVID-19 VACCINE FAQs](#) document.

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Updated 8/25/23	<p data-bbox="369 418 653 451"><b>Week of July 31, 2023</b></p> <ul data-bbox="751 402 1774 516" style="list-style-type: none"> <li>CDC set vaccine thresholds to -0- in anticipation of decreased vaccine demand.</li> <li>Providers were encouraged to place necessary orders to maintain their COVID-19 inventory while current vaccines are still authorized.</li> </ul> <p data-bbox="390 597 663 630"><b>August 3 – mid Sept.</b></p> <ul data-bbox="751 548 1774 646" style="list-style-type: none"> <li></li> </ul> <p data-bbox="331 813 663 846"><b>TBD (expected mid Sept.)</b></p> <p data-bbox="793 678 1732 922">         FDA decisions and amendments to Emergency Use Authorization (EUAs)/Biologics License Applications (BLAs). Approve new products, and de-authorize current products.          Concurrently, USG will discontinue distribution of current COVID-19 vaccine composition          ACIP discussion on COVID-19 and CDC recommendation          Maine Immunization Program works on VFC enrollment of COVID-19 providers       </p> <p data-bbox="342 995 674 1027"><b>TBD (expected mid Sept.)</b></p> <ul data-bbox="751 963 1774 1027" style="list-style-type: none"> <li>Fall vaccine availability for administration begins for VFC and Bridge Access Program</li> <li>Providers will dispose of any remaining supply of de-authorized COVID-19 vaccines</li> </ul>	

Topic	Guidance	Effective Date
Section 2	Sunsetting of the Federal COVID-19 Vaccination Program	TBD
Ordering	<p style="text-align: center;"><b>Post Sunset of the Federal COVID-19 Vaccination Program</b></p> <p>Plan to transition to traditional pathways for ordering and distribution of COVID-19 vaccines.</p> <p><b>Vaccine:</b> Providers should begin planning to incorporate COVID-19 vaccine into their ordering with standard vaccine supply procurement processes for the practice or organization.</p> <p><b>Ancillary Kits:</b> Kits are not provided as part of routine vaccine ordering. Therefore, any COVID-19 vaccine ordered privately or through publicly funded COVID-19 vaccine programs (Vaccines for Children Program and Bridge Access Program) will NOT ship with ancillary kits. Providers should look at ancillary supplies and consider needs post-commercialization to ensure they have adequate supply of ancillary supplies budgeted and planned to purchase.</p>	
Billing	<p>Providers should continue planning to transition COVID-19 vaccine billing to traditional pathways for payment of COVID-19 vaccine administration. Planning includes making sure billing practices and systems are updated.</p> <p>COVID-19 vaccine will be provided to VFC enrolled providers at no cost, along with all other pediatric routine vaccinations. VFC providers may not bill for the cost of the vaccine. It is allowable to bill a reasonable administration fee, provided that no patient is denied state supplied vaccine for inability to pay. If the patient is VFC eligible you may not bill for more than \$21.58 for the administration fee.</p>	
Program Requirements	<p>Any COVID-19 Vaccination Program Provider who plans to continue administering COVID-19 vaccinations MUST complete the Maine Immunization Program Provider Agreement. To inquire about enrollment, providers should contact the Maine Immunization Program at: <a href="mailto:ImmunizeME.DHHS@maine.gov">ImmunizeME.DHHS@maine.gov</a>.</p> <p>VFC enrolled providers will be required to offer all routine ACIP recommended vaccines, in addition to the COVID-19 vaccine.</p> <p>Until commercialization occurs and the USG announces the end of the COVID-19 Vaccination Program, COVID-19 Vaccination Program providers must continue to comply with all program requirements outlined in the <a href="#">Provider Agreement</a> to ensure patients seeking vaccination during this transition period can receive vaccine without barriers, to the greatest extent possible, with vaccine provided by the federal government. What does this mean for Providers?</p> <ul style="list-style-type: none"> <li>• Providers should adhere to the <a href="#">COVID-19 Vaccination Provider Agreement</a>, particularly as it pertains to patient access.</li> <li>• Providers should continue to offer COVID-19 vaccines during this transitional time.</li> <li>• Providers maintain a COVID-19 vaccine supply.</li> <li>• Patients should <b>NOT</b> be denied based on insurance coverage status or provider network status.</li> <li>• Patients should <b>NOT</b> be charged for an office visit or any other fee if the only service provided is COVID-19 vaccination.</li> </ul>	

Topic	Guidance	Effective Date
	<b>Reporting Doses Administered:</b> Continue to document vaccine administration into ImmPact within 24 hours of administration and report doses administered as soon as practicable and no later than 72 hours.	
	<b>Reporting &amp; Disposal of Nonviable Vaccine:</b> Continue to report all nonviable doses in ImmPact; dispose of all vaccines following practice protocols. Providers should maintain their inventories of EUA and/or BLA vaccines until vaccine exceeds its shelf life or the FDA announces a change to EUAs and/or BLAs, whichever occurs first.	
	<b>Vaccine Replacement Procedure:</b> When commercialization occurs, any preventable wastage of COVID-19 vaccine over the allowable 5% threshold, will be subject to the <a href="#">Vaccine Replacement Procedure</a> .	Fall 2023
<b>Section 3</b>	<b>Commercialization of COVID-19 Vaccines</b>	
<b>COVID-19 Agreements</b>	CDC's <a href="#">COVID-19 Provider Agreement</a> and all related reporting requirements will no longer be valid.	Fall 2023
	<b>Reporting Doses Administered:</b> Providers are required to report doses administered as required in Maine Immunization Program's Provider Agreement. All MIP-supplied doses must be entered into the client record within five days of administration.	
<b>Access and Eligibility</b>	<b>Pediatric Populations:</b> Vaccines will be made available through the Vaccines for Children (VFC) Program for all children from birth through 18 years of age.	Fall 2023
	<b>Adult Populations:</b> Because a national Vaccines for Adults (VFA) Program, modeled after the childhood VFC Program, has not been enacted into law as a permanent solution, <b>limited</b> supply of COVID-19 vaccine will be made available through the HHS Bridge Access Program (BAP)—only to public health departments, FQHCs, and Indian Health Service providers—serving uninsured adults (19 years and older) to prevent loss of access. Vaccines for privately insured adults will be purchased following established mechanisms for non-COVID-19 vaccines.	Fall 2023— December 2024

	<p>Select provider sites will have access to COVID-19 vaccines for adults 19+ without insurance (uninsured individuals) coverage once COVID-19 vaccines become commercially available.</p> <p>This will bring to a closure the previously enacted federal pandemic COVID-19 vaccine program. Moving forward, the Bridge Access Program doses provided through publicly funded COVID-19 programs will only be for eligible adults (uninsured individuals). Adult populations with insurance coverage will no longer be eligible to receive monovalent COVID-19 vaccines authorized this fall. It is important that clinics assess patient populations served to ensure adequate vaccine supply is available and patients continue to access COVID-19 vaccines. Screening and documentation must occur with each vaccine administration.</p>	Fall 2023
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	<p>The <a href="#">HHS Bridge Access Program for COVID-19 Vaccines and Treatments</a> will create a unique public-private partnership that will help maintain access to COVID-19 care for uninsured/under-insured adults. The program has two major components:</p> <ul style="list-style-type: none"> <li>• <u>Public Health Component</u>: Distribution of vaccines to FQHCs, IHS, Public Health Departments, and HRSA-supported health centers using Section 317 funding; HRSA will also provide support directly to its networks of health centers to support delivery of both vaccines and treatments.</li> <li>• <u>Pharmacy Component</u>: This will be a new, CDC-funded partnership with select pharmacy chains that will enable pharmacies to continue offering free COVID-19 vaccinations and treatments to uninsured and under-insured adults through their network or retail locations as has been done during the COVID-19 Public Health Emergency.</li> </ul>	



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<p>Products &amp; Formulations</p>	<table border="1"> <thead> <tr> <th data-bbox="359 453 693 545">Manufacturer</th> <th data-bbox="693 453 999 545">Age Indication</th> <th data-bbox="999 453 1373 545">CDC Description</th> <th data-bbox="1373 453 1734 545">Storage</th> </tr> </thead> <tbody> <tr> <td data-bbox="359 545 693 734"><b>Moderna</b></td> <td data-bbox="693 545 999 734">           Two presentations:           <ul style="list-style-type: none"> <li>• 6M – 11Y</li> <li>• 12Y+</li> </ul> </td> <td data-bbox="999 545 1373 734">           Single dose vials            10-pk.         </td> <td data-bbox="1373 545 1734 734">           - Shipped as frozen products             - Storage and handling will be the same as previous Moderna presentations         </td> </tr> <tr> <td data-bbox="359 734 693 889"><b>Novavax</b></td> <td data-bbox="693 734 999 889"> <ul style="list-style-type: none"> <li>• 12Y+</li> </ul> </td> <td data-bbox="999 734 1373 889">           5-dose            Multi-dose vials            2-pk.         </td> <td data-bbox="1373 734 1734 889">           - Shipped as refrigerated product            - Storage and handling will be the same as original Novavax         </td> </tr> <tr> <td data-bbox="359 889 693 1172" rowspan="3"><b>Pfizer</b></td> <td data-bbox="693 889 999 987">           Three presentations:           <ul style="list-style-type: none"> <li>• 6M – 4Y (requires diluent)</li> </ul> </td> <td data-bbox="999 889 1373 987">           3-dose vials, yellow cap            3 x 0.3mL doses            (after 1.1mL saline dilution)         </td> <td data-bbox="1373 889 1734 1172" rowspan="3">           - Ships at ultra-low temperatures but expect a shift for commercial Comirnaty: wholesalers may ship it at 2° to 8° C for both vials and prefilled syringes            - Storage and handling will be the same as bivalent Pfizer         </td> </tr> <tr> <td data-bbox="693 987 999 1052"> <ul style="list-style-type: none"> <li>• 5-11Y (no diluent)</li> </ul> </td> <td data-bbox="999 987 1373 1052">           single-dose vials, blue cap            0.3 mL dose         </td> </tr> <tr> <td data-bbox="693 1052 999 1172"> <ul style="list-style-type: none"> <li>• 12Y+ (no diluent)</li> </ul> </td> <td data-bbox="999 1052 1373 1172">           single-dose vials, gray cap            0.3 mL dose         </td> </tr> </tbody> </table>	Manufacturer	Age Indication	CDC Description	Storage	<b>Moderna</b>	Two presentations: <ul style="list-style-type: none"> <li>• 6M – 11Y</li> <li>• 12Y+</li> </ul>	Single dose vials 10-pk.	- Shipped as frozen products  - Storage and handling will be the same as previous Moderna presentations	<b>Novavax</b>	<ul style="list-style-type: none"> <li>• 12Y+</li> </ul>	5-dose Multi-dose vials 2-pk.	- Shipped as refrigerated product - Storage and handling will be the same as original Novavax	<b>Pfizer</b>	Three presentations: <ul style="list-style-type: none"> <li>• 6M – 4Y (requires diluent)</li> </ul>	3-dose vials, yellow cap 3 x 0.3mL doses (after 1.1mL saline dilution)	- Ships at ultra-low temperatures but expect a shift for commercial Comirnaty: wholesalers may ship it at 2° to 8° C for both vials and prefilled syringes - Storage and handling will be the same as bivalent Pfizer	<ul style="list-style-type: none"> <li>• 5-11Y (no diluent)</li> </ul>	single-dose vials, blue cap 0.3 mL dose	<ul style="list-style-type: none"> <li>• 12Y+ (no diluent)</li> </ul>	single-dose vials, gray cap 0.3 mL dose	
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Section 4	<b>Anticipated Vaccination Schedule for the Fall</b>	
	Detail on the current recommended vaccine schedules for each age group can be found on the <a href="#">CDC website</a> . An updated recommendation for all age groups is expected in mid to late September after anticipated FDA regulatory authorizations or approvals of an updated COVID-19 vaccine composition. We anticipate that providers will be able to order and receive updated COVID-19 vaccines shortly thereafter.	Mid to late September

### Resources:

- [Commercialization Transition Guide](#) (HHS)
- [Fact Sheet: Bridge Access Program for COVID-19 Vaccines and Treatments](#) (HHS)
- [COVID-19 Commercialization](#) (HHS)
- [Bridge Access Program](#) (CDC)

Please contact the Maine Immunization Program at (207) 287-3746 or email [ImmunizeME.DHHS@maine.gov](mailto:ImmunizeME.DHHS@maine.gov) with any questions.

**Post Sunset of the Federal COVID-19 Vaccination Program: Vaccine ordering will follow more traditional pathways for purchasing vaccines**

