Immunization Program Provider Update
August 23, 2022

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Agenda – 08/23/2022

- COVID-19 vaccine updates and reminders
  - Fall Bivalent Boosters
  - Vaccine for under 5
  - Moderna 6 through 11 years
  - Novavax
- Vermont Vaccine Program Updates
  - Full VCVP/VAVP team
  - 2022/2023 Flu season
  - MenQuadfi replaces Menactra
  - Polio Vaccine
- hMPXV (human monkeypox virus)
  - JYNNEOS vaccine availability

Contact Information

- Ordering, vaccine storage and handling, vaccine-specific information:
  AHS.VDHImmunizationProgram@vermont.gov
- Immunization registry and reporting questions:
  IMR@vermont.gov
- COVID-19 Vaccine Distribution Team:
  AHS.VDHcovidVaxDistribution@vermont.gov
- Program updates available on the Vaccine Information for Health Care Professionals Page:
  www.healthvermont.gov/disease-control/immunization-providers#vvpupdate

Slides and recording will be posted by end of the day at www.healthvermont.gov/COVID19-vaccine-healthpros#resources
Pfizer-BioNTech and Moderna Bivalent Boosters

Timeline

- **June 30, 2022**: the FDA advised manufacturers to add the BA.4/5 component.
- **September 1, 2022**: approximate date the EUA for new formulations is expected.
- **Following EUA**: ACIP will meet to offer clinical guidance and recommendations.

As with past rollouts, bivalent boosters will be prepositioned in states prior to approval. Administration can begin only after CDC’s official recommendation, expected around labor day.
Pfizer-BioNTech and Moderna Bivalent Boosters

Assumptions for upcoming recommendation

- Single booster dose given to those who previously completed a primary series
- New formulation will not be authorized for use as a primary series. Practices should continue to maintain a small stock of primary series COVID-19 vaccine.
- Pfizer authorized for 12 years and older, Moderna for 18 years and older. Younger pediatric groups to follow later in the fall
- Recommendation will not vary by primary series or type of prior booster doses received
- Timing following previous doses will be determined during approval process.
Assumptions for upcoming presentation

- Official details from the manufacture will be available following EUA
- New products with new NDC number and presentation
  - [IIS COVID-19 Vaccine Related Code | CDC](https://www.cdc.gov/vaccines/)
- Same storage and handling parameters as original products

### Pfizer
- Ultra Cold storage through expiration
- NO FREEZER STORAGE
- Refrigerator (2°C to 8°C) up to 10 weeks
- Once punctured dispose after 12 hours
- 6 dose vials, min. direct order of 300 doses
- NDC: 59267-0304-02
- CVX: 300

### Moderna
- NO ULTRA COLD STORAGE
- Freezer (-50°C to -15°C) through expiration
- Refrigerator (2°C to 8°C) up to 30 days
- Once punctured dispose after 12 hours
- 5 dose vials, min. direct order of 100 doses
- NDC: 80777-0282-99
- CVX: 229
Modern COVID-19 Vaccine Products

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL; – SHARED FOR JURISDICTIONAL PLANNING PURPOSES ONLY

<table>
<thead>
<tr>
<th></th>
<th>Current Presentations</th>
<th>Future Presentations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Indication</strong></td>
<td>Primary Series (≥12 years of age)</td>
<td>Primary Series (6-11 years of age)</td>
</tr>
<tr>
<td><strong>Vial Label &amp; Cap Color</strong></td>
<td>Blue border label &amp; red cap</td>
<td>Purple border label &amp; dark blue cap</td>
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<tr>
<td><strong>Dose Volume/Dose</strong></td>
<td>0.5 mL/100mcg</td>
<td>0.5 mL/50mcg</td>
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<tr>
<td><strong>Doses per Vial</strong></td>
<td>maximum of 11 doses (range: 10-11 doses)</td>
<td>5 doses</td>
</tr>
</tbody>
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**Storage & Handling**

<table>
<thead>
<tr>
<th></th>
<th>Freezer</th>
<th>Refrigerator</th>
<th>Thawed Shelf Life</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Freezer</strong></td>
<td>-50°C to -15°C (-58°F to 5°F)*</td>
<td>12 months*</td>
<td>12 months*</td>
</tr>
<tr>
<td><strong>Refrigerator</strong></td>
<td>2°C to 8°C (36°F to 46°F)*</td>
<td>30 days</td>
<td>30 days</td>
</tr>
<tr>
<td><strong>Room Temperature</strong></td>
<td>8°C to 25°C (46°F to 77°F)</td>
<td>24 hours</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>After First Puncture</strong></td>
<td>2°C to 25°C (36°F to 77°F)</td>
<td>Discard after 12 hrs</td>
<td>Discard after 12 hrs</td>
</tr>
</tbody>
</table>

When available, find Pfizer info here:

- [https://webfiles.pfizer.com/formulation-guide](https://webfiles.pfizer.com/formulation-guide)
- Pfizer-BioNTech COVID-19 Vaccine At A Glance
Pfizer-BioNTech and Moderna Bivalent Boosters

Vermont planning

• Bivalent COVID-19 vaccine will be made available to pharmacies. Participating Vermont pharmacies unknown at this time.
• Vermont will leverage robust state sponsored walk-in clinic structure (EMS, VDH) for initial roll-out of boosters. Vaccine | Vermont Department of Health (healthvermont.gov)
• It is a priority to make flu vaccine for those under 65 years available with COVID boosters at all walk-in clinics
• Timing and guidance for PCP ordering in September will be communicated in the coming weeks.
COVID-19 for under 5 years
COVID-19 vaccine for children under 5

As of 08/21/2022
- Primary Care administered 3,291 (62%)  
- EMS administered 1,428 (27%)  
- Hospitals 301 (6%)  
- District Offices administering to WIC have administered 139 (3%)  
- Pharmacies have administered 13 doses
Proportion of US Children Ages 6 Months - 4 Years Who Received the Initial Dose of the COVID-19 Vaccine, by State of Residence

Moderna 6 through 11 years
Very low demand: Most children in this age range have been vaccinated with Pfizer

High potential for errors: Labeling and packaging state “booster dose only”

A small amount available at the vaccine depot. If you have a need for this vaccine as a primary series, or a 5-year-old ages into this product mid-series, contact AHS.VDHImmunizationProgram@vermont.gov to request this product.
Pediatric COVID-19 vaccine resources

- Summary Document for Interim Clinical Considerations
- Interim COVID-19 Immunization Schedule
- At-A-Glance COVID-19 Vaccination Schedule
- Moderna for Children who Transition from a Younger to Older Age Group
- Pfizer-BioNTech for Children who Transition from a Younger to Older Age Group
- Moderna COVID-19 Vaccine At A Glance
- Pfizer-BioNTech COVID-19 Vaccine At A Glance
Novavax COVID vaccine

Details

• Adjuvanted protein sub-unit vaccine
• Two-dose primary series, given 3 weeks apart to individuals 12 and older.
  • [CDC Recommends Novavax COVID-19 Vaccine for Adolescents 08.22.2022](https://www.cdc.gov/ncidod/dvbd/mrsa/novavax/index.htm) | CDC Online Newsroom
• 10 doses/vial, Beyond Use Time of 6 hours after the first puncture
• Refrigerated storage through expiration date ([look-up tool available](https://www.cdc.gov/vaccines/hcp/payment/look-up.html))

Ordering

• Stock is limited. If you would like to order Novavax vaccine, please reach out to [AHS.VDHImmunizationProgram@vermont.gov](mailto:AHS.VDHImmunizationProgram@vermont.gov) for your initial order.
• If you have specific patients in mind, order vials for second doses at the same time as the first
Novavax COVID vaccine

Novavax resources and additional information

- Interim Clinical Considerations for Novavax COVID-19 Vaccine | ACIP July 19, 2022
- Novavax COVID-19 Vaccine: Storage and Handling Summary | CDC
- Novavax COVID-19 Vaccine: Vaccine Preparation and Administration Summary | CDC
- Fact Sheet for Health Care Providers
- Fact Sheet for Recipients

Novavax Vaccine Available to Order | Immunization 07/28/2022 e-mail communication
Additional COVID Information
COVID-19 expiring vaccine

- Expiration Dates are starting to come up for certain COVID-19 vaccines
- The dates in VIMS are accurate.
- Expiration dates may also be checked online from all manufacturers
  - Pfizer - https://lotexpiry.cvdvaccine.com/
  - Janssen - https://vaxcheck.jnj/
  - Novavax - https://us.novavaxcovidvaccine.com/hcp
- Expiration dates are not Beyond Use Dates, which are dependent on when a vaccine is removed from permanent storage into refrigerated temperatures.
  - 10 weeks after removal from Ultra cold for Pfizer
  - 30 days after removal from a standard freezer for Moderna
  - Janssen and Novavax permanent storage is in the refrigerator and so BUD does not apply
  - See the Beyond Use Date Guidance for more information.
Vaccination cards

1. Vaccination cards will continue to come as a part of the ancillary supplies.

2. Limited entries available on vaccination cards

3. When full, start a new card and staple them together.

4. Store cards securely/dispose of unused cards to prevent fraud.
Full time VCVP/VAVP Team

Four new VCVP/VAVP Regional Specialists are hired and in training.

- Nick Tatakos (He/Him): Morrisville, Barre, White River Junction, Springfield
- Tamera Mizioch (She/Her): St. Albans, Newport, St. Johnsbury
- Meghan Critchlow (She/Her): Burlington, Brattleboro
- Tanya Getz (She/Her): Middlebury, Rutland, Bennington

VCVP/VAVP Regional Specialist Map
Flu 2022-2023
Practices will be able to place initial flu vaccine orders in VIMS starting August 29, 2022

- Initial orders: reconcile full inventory
- Subsequent orders: flu-only reconciliation
- Base order quantity on immediate need and storage. Plan to order 3-4 weeks as storage allows.
- It is a priority of the state to have flu vaccine available to those under 65 years old wherever COVID-19 vaccine is available, including all state sponsored (EMS and VDH run) walk-in clinics. With this increased access, patients may get their flu vaccine at a walk-in clinic rather than their primary care office. We suggest ordering vaccines thoughtfully with that in mind.
State-supplied flu may be given to any patient under the age of 65.

- CDC has made a preferential recommendation for high-dose and adjuvanted flu vaccines for people aged 65 and older.
- The Immunization Program encourages practices to purchase these vaccines privately or refer older patients to the pharmacy.
- State-run walk-in clinics will not have high-dose flu vaccine available. Please ensure you can serve this population with the appropriate vaccine through private purchase or referral to a pharmacy.
Flu / COVID Clinic Grant Funding

Grant money will be available to assist with clinics again this year.

• These funds may be available for a broader usage than in the past.
• The application process will remain essentially the same, with more information to be communicated soon.
• Check the AAPVT website for future details: Welcome to the American Academy of Pediatrics Vermont Chapter | AAPVT
2022/2023 Flu Season Resources

- Flu Vaccine FAQ 2022/2023 | VDH
- 2022/2023 Flu Season Update-emailed 08.19.2022 | Immunization Program
- Immunization & Health Care Professionals | VDH
- Welcome to the American Academy of Pediatrics Vermont Chapter | AAPVT
- Clinical Guidance for COVID-19 Vaccination - Coadministration | CDC

For 65 and Older

- CDC Director Adopts Preference for Specific Flu Vaccines for Seniors | CDC Online Newsroom | CDC
- Flu & People 65 Years and Older | CDC
- Fluzone High-Dose Seasonal Influenza Vaccine | CDC
MenQuadfi Replaces Menactra
Transition from Menactra to MenQuadfi

- MenQuadfi replaced Menactra in practice catalogs August 1.

- This change does not impact practices that previously selected Menveo for Oct 2021 – Sept 2022 through the vaccine choice process.

- Use the existing inventory of Menactra at your practice before ordering MenQuadfi.

- Practices in need of MenACYW vaccine for patients younger than age 2 can make a special request of Menveo by e-mailing AHS.VDHImmunizationProgram@vermont.gov, or leaving a comment in VIMS.
MenACYW resources

Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020 | MMWR

"ACIP recommends routine vaccination with a quadrivalent meningococcal conjugate vaccine (MenACWY) for adolescents aged 11 or 12 years, with a booster dose at age 16 years. ACIP also recommends routine vaccination with MenACWY for persons aged ≥ 2 months at increased risk for meningococcal disease."

- MenQuadfi to replace Menactra – emailed 07.25.2022 | Immunization Program
- Vaccine Availability August 2022 (healthvermont.gov)
- See the MenACWY Vaccine Recommendation by Age and Risk Factor for guidance on when a request for Menceo is appropriate.
Polio vaccine
Polio Case in NY

- A case of Polio was detected in an unvaccinated adult in NY state
- Wastewater testing has revealed that there may be other cases in that community

“In July 2022, CDC was notified of a case of polio in an unvaccinated individual from Rockland County, New York, caused by vaccine-derived poliovirus type 2. CDC is consulting with the New York State Department of Health on their investigation. This does not change CDC recommendations for polio vaccination. CDC urges everyone who is not fully vaccinated to complete the polio vaccination series as soon as possible.” - https://www.cdc.gov/polio/what-is-polio/hcp.html

- Polio Vaccination: What Everyone Should Know | CDC
Polio Vaccine Recommendations - Children

Polio vaccination in children

- Any Vermont Children’s Vaccine Program (VCVP) enrolled provider receives the polio vaccine (IPV) for use in children at no cost through a CDC contract.
  - 10 dose MDV good through expiration after puncture
- CDC recommends that children get four doses of polio vaccine. They should get one dose at each of the following ages: 2 months old, 4 months old, 6 through 18 months old, and 4 through 6 years old. Up-to-date polio vaccination is required for child care and school attendance.
- For pediatric catch-up scheduling see the [IPV Catch-up Guidance for Children 4 months through 17 years of age](#).

Practices that see patients under 18 years old will see polio rates highlighted in the upcoming quarterly report, sent from the IMR by mail. For assistance in using the Immunization Registry (IMR) for patient recall, see the [Not-Up-To-Date Guidance](#).
Polio vaccination in adults

Most adults were vaccinated for polio as children, and IPV is not a routine adult vaccine. The CDC vaccine purchase contract does not include IPV for adults, state-supplied IPV may not be used for adults 19+.

However, adults SHOULD receive a polio vaccine if they are:
- unvaccinated
- incompletely vaccinated
- completely vaccinated but at higher risk for contact with poliovirus

Adults who are unvaccinated or without any documentation of previous polio vaccination should be given three doses of IPV at recommended intervals. Titers should not be drawn to assess immunity.

You may receive requests from adults searching for the polio vaccination for any of the above reasons. Currently, the only option is to purchase the vaccine privately or refer these patients to an administering pharmacy, or travel clinic if appropriate. If and when the CDC contract changes to allow for IPV administration in adults, the Immunization Program will update the Vaccine Availability Sheet and communicate by e-mail.
Polio Vaccine for Displaced Ukrainians

Small amount of CDC funding available to purchase polio vaccine for adult use for displaced Ukrainians

If your office is seeing these patients, please let our program know
Polio Resources

- Polio Vaccination Reminders – 08.18.2022 e-mail | Immunization Program
- Polio Vaccination: What Everyone Should Know | CDC
- Pinkbook: Poliomyelitis | CDC
- Polio Vaccination: For Healthcare Providers | CDC
- Catch-up Guidance for Children 4 months through 17 years of age-Inactivated Polio Vaccine (IPV) | CDC
- Vermont Vaccine Availability August 2022 | VDH
- Not Up To Date Report | VDH
hMPXV and JYNNEOS vaccine
hMPXV (human monkeypox virus) in Vermont

Two cases in Vermont so far [2022 U.S. Map & Case Count | Monkeypox | Poxvirus | CDC](#)

Clinicians who suspect hMPXV should call the Infectious Disease Program at (802) 863-7240, Option 2 to speak with an epidemiologist 24/7.

They will help determine whether testing is indicated. If so, they will guide you through the process of specimen collection and sending specimens to the Vermont Department of Health Laboratory (VDHL). Testing is also available through the commercial labs Labcorp, Aegis and Quest. Turn-around time and cost may vary by lab.
JYNNEOS: Vermont Vaccine Eligibility

Current Eligibility:

- **NEW** Gay, bisexual, and other men or trans people who have sex with men, who had or expect to have more than one (1) sexual partner.
- People who have had recent exposures to individuals with confirmed human monkeypox virus (hMPXV) infections.
- People who have had recent exposures to individuals with possible hMPXV infections.
- Certain health care and laboratory personnel whose jobs regularly put them at high risk of exposure to the virus, such as performing testing or caring for multiple people infected with hMPXV.

Human Monkeypox Virus (hMPXV) | Vermont Department of Health
Interim Clinical Considerations for Use Vaccines during the 2022 U.S. Monkeypox Outbreak | CDC
JYNNEOS: Vermont Vaccine Availability

Still a very limited supply of JYNNEOS vaccine in Vermont

- The following providers have a limited supply of vaccine, by appointment for current patients only: Planned Parenthood (all locations), CHCB (some locations), Comprehensive Care Clinics (some locations)

- The Health Department is working to add more opportunities for those eligible to be vaccinated. The District Offices will function as a referral location in the coming weeks.

- Looking for weekend coverage
JYNNEOS Vaccine Reporting

Inventory Reporting
• JYNNEOS vaccine is not in VIMS
• If you maintain a stock of JYNNEOS, or receive a small amount for a single patient or set of patients, Reconciliation will be asked via E-mail weekly

IMR Reporting
“Vaccinia, Smallpox Monkeypox Vaccine,...”
Name may change to be easier to locate in IMR
JYNNEOS Vaccine: Resources

VDH Resources
• 2022 hMPXV Outbreak Partner Toolkit | VDH
• hMPXV (human monkeypox virus) website | VDH
• More to come...

CDC Resources
JYNNEOS Vaccine | CDC: This CDC website contains the Interim Guidance for the use of JYNNEOS vaccine including information on intervals, safety, coadministration and reporting of adverse events. CDC is updating this document regularly so check it out periodically to stay up to date with the latest guidance from CDC.

JYNNEOS Vaccine Resources | CDC: includes storage and handling, standing orders, translations and administration resources. Resources added regularly.
Questions
Summary: JYNNEOS Smallpox and Monkeypox Vaccine Storage and Handling Summary

- Will be delivered from the Depot at refrigerated temperatures (2°C to 8°C)
- Beyond Use Date of 8 weeks starts after thawing. BUD will be clearly marked on the Depot Delivery.

JYNNEOS Subcutaneous Vaccine Administration Summary: STANDARD REGIMEN

JYNNEOS Intradermal Vaccine Administration Summary: ALTERNATIVE DOSING
JYNNEOS vaccine is licensed as a series of two doses administered 28 days (4 weeks) apart.

CDC is recommending that JYNNEOS vaccine be administered intradermally (alternative regimen). The subcutaneous route of administration should only be given to those who are under 18 years of age or those over 18 years of age who have a history of keloids.

- **JYNNEOS Subcutaneous Vaccine Administration Summary: STANDARD REGIMEN**
- **Subcutaneous (SC or Subcut) Injection: Administration – YouTube**

- **JYNNEOS Intradermal Vaccine Administration Summary: ALTERNATIVE DOSING**
- **How to administer a JYNNEOS vaccine intradermally - YouTube**

- **JYNNEOS Vaccine Information Statement** provided for subcutaneous administration (standard regimen) **JYNNEOS EUA FactSheet for Recipients Caregivers** for intradermal administration (alternative regimen) and administration to those younger that 18.