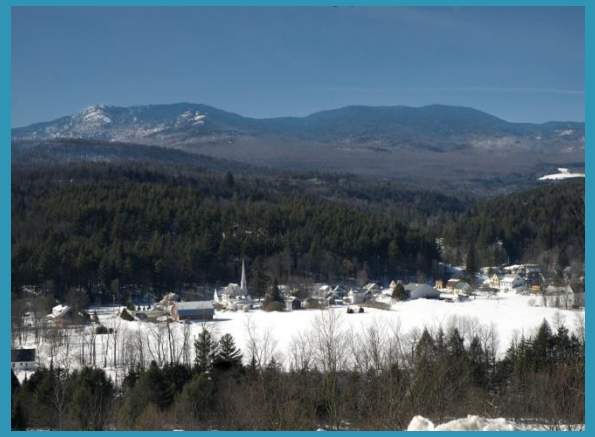


Provider Update Call
September 28, 2023

Merideth Plumpton, RN – *Immunization Program Manager*
Katie Mahuron, RN – *Adult Coordinator*

VERMONT
DEPARTMENT OF HEALTH

RSV

New RSV Products

Target Population	RSV product(s)
Birth to 8 months of age entering/during 1st RSV season	Nirsevimab (Beyfortus)
8 months –19 months at increased risk of severe RSV disease entering 2nd RSV season	Nirsevimab (Beyfortus)
Pregnant individuals 32 – 36 gestational weeks of pregnancy	Abrysvo (Pfizer)
Adults 60 years and older	Abrysvo (Pfizer) Arexvy (GSK)

RSV – Burden of Disease in Children

- Each year among infants and children under 5 years:
  - Approximately 520,000 ED visits
  - 50,000-80,000 RSV-associated hospitalizations
  - 100-300 RSV-associated deaths
- An estimated 79% of infants and children aged <2 years hospitalized with RSV have no underlying medical conditions.

Babies are 16x more likely to be hospitalized with RSV than with the flu.

RSV is the leading cause of hospitalization in babies under age 1.

Beyfortus (Nirsevimab)

- Approved for use in
  - neonates and infants born during or entering their first RSV season
  - children 8-19 months who remain vulnerable to severe RSV disease through their second RSV season
- One dose of Beyfortus, administered as a single intramuscular injection prior to or during RSV season, may provide protection during the RSV season.

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses.

- CDC Recommends a Powerful New Tool to Protect Infants from the Leading Cause of Hospitalization | CDC Online Newsroom | CDC
- Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

Beyfortus (Nirsevimab)

- Available in a 50 mg/0.5mL and 100 mg/mL pre-filled syringe
  - 2nd RSV season: single 200 mg dose administered as 2 IM injections
- Administer shortly before start of RSV season (October – March)
- Store refrigerated 2° C to 8° C (36° F to 46° F)
- Coadministration with other immunizations following general best practices for immunization
- Most common side effects include rash, and pain, swelling or hardness at injection site

Recommended Dose of BEYFORTUS in Infants Aged <8 months Born During or Entering Their 1st RSV Season	
Body Weight at Time of Dosing	**Recommended Dosage**
Less than 5 kg	50 mg by IM injection
5 kg and greater	100 mg by IM injection

Recommended Dose of BEYFORTUS in Children 8-19 Months at Increased Risk of Severe RSV Disease Entering Their 2nd RSV Season	
Recommended Dosage	200 mg by IM injection

Efficacy of Beyfortus (Nirsevimab)

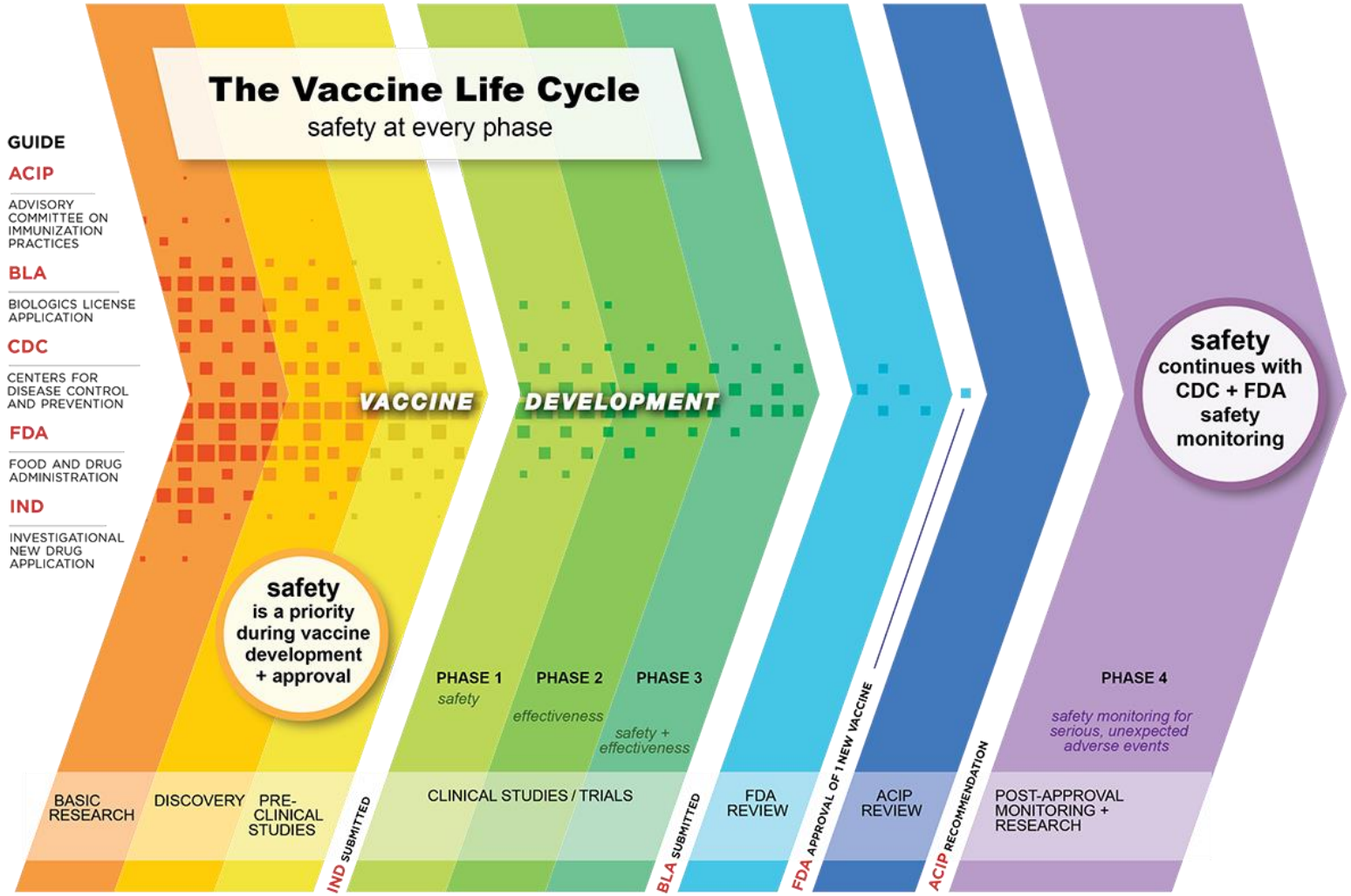
- Medically attended RSV LRTI: 79% efficacy estimate (95% CI: 68.5% - 86.1%)
- RSV LRTI with hospitalization: 80.6% efficacy estimate (95% CI: 62.3% - 90.1%)
- RSV LRTI with ICU admission: 90.0% efficacy estimate (95% CI: 16.4%-98.8%)

Who is recommended to receive Nirsevimab during their 2nd RSV season?

Infants and children aged 8-19 months with increased risk for severe disease who are recommended to receive Nirsevimab when entering their second RSV season:

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season.
- Children with severe immunocompromise
- Children with cystic fibrosis who have either 1) manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or 2) weight-for-length <10th percentile
- American Indian or Alaska Native children

Vaccine Approval Process

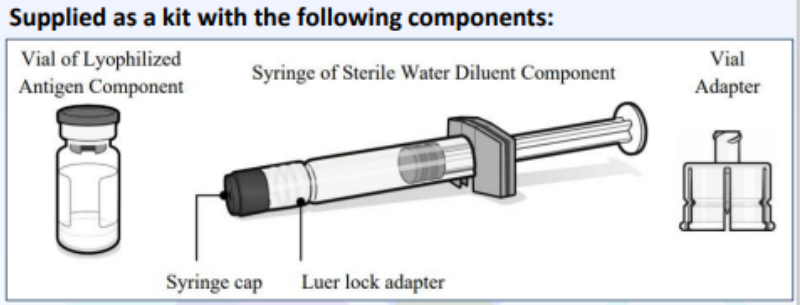


- CDC Director reviews ACIP recommendation and makes an official recommendation
  - Recommendation becomes official CDC public health guidance for safe use of the vaccine in the United States.
- Published in CDC's MMWR
  - Offers additional clinical guidance
- CDC makes vaccine available on CDC contracts for VDH Immunization Program to purchase and distribute

RSV Vaccine for Pregnant Individuals (Abrysvo)

ACIP recommendation: Abrysvo – a Respiratory Syncytial Virus (RSV) vaccine is recommended for pregnant people during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants.

- Overall clinical implementation similar to other vaccines
  - Stored at 2° to 8° C
  - Administered as a single dose through intramuscular route
- Additional steps required for dilution, including reconstitution of the lyophilized antigen component with the sterile water diluent component



Preparing Abrysvo Video

Vaccine Efficacy & Safety

Abrysvo reduced risk of severe LRTD:

- In one clinical study risk of severe LRTD was reduced by:
  - 81.8% within 90 days of birth
  - 69.4% within 180 days after birth
- In a subgroup of pregnant individuals who were 32 – 36 weeks gestational age, Abrysvo reduced risk of LRTD by 34.7% and by 91.1% within 90 days after birth.

Safety:

- Pre-eclampsia (1.8% Abrysvo; 1.4% placebo)
- Low birth weight and jaundice in infants occurred at a higher rate in the pregnant Abrysvo recipients compared to pregnant placebo recipients.
- Numerical imbalance in preterm births in Abrysvo recipients (5.7%) occurred compared to those who received placebo (4.7%).

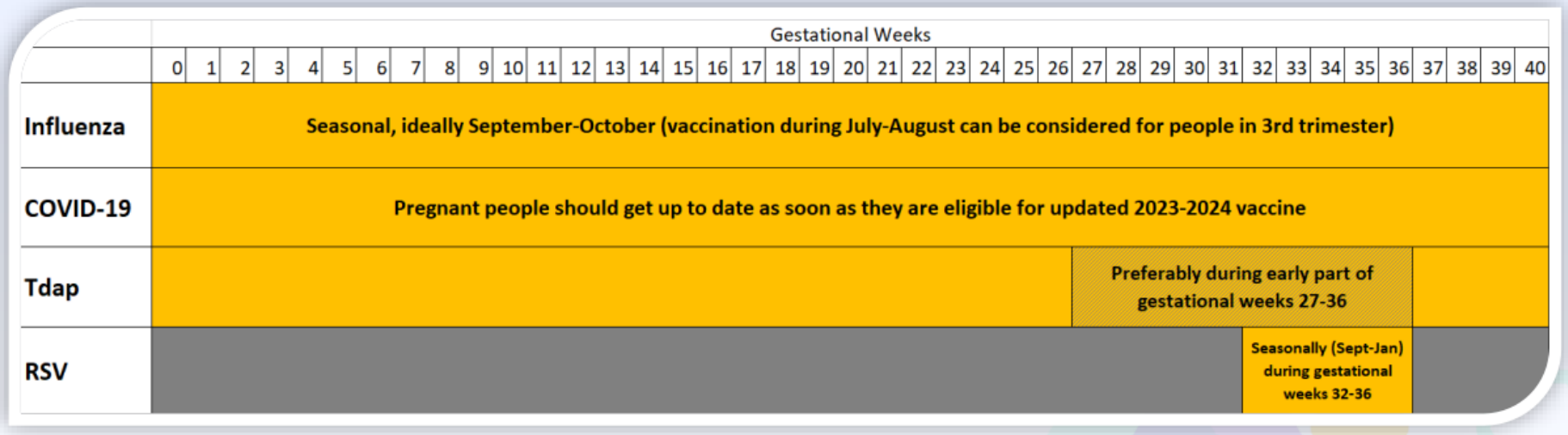
Source: FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants | FDA

Role of OBGYN in Maternal RSV Vaccine

- Decisions for whether to administer maternal RSV vaccine or infant Nirsevimab will need to be made during pregnancy
- Studies continue to demonstrate healthcare providers as pregnant people's most trusted source of information on vaccines, and provider recommendation is a strong predictor of vaccination1
- However, one survey showed that 2/3 of obstetricians did not feel providing information about routine childhood immunizations was part of their role

Barriers of Maternal RSV Vaccine

Increasing Complexity of Maternal Immunization Schedule



- Increasingly complex maternal immunization schedule, with different timing of vaccines based on season and/or gestational age (with seasonal timing varying in some locations)
- Limited window for RSV vaccine administration
- Unclear willingness of pregnant people to accept multiple vaccines in pregnancy

Role of Pediatrician in RSV Vaccine

- Recommendations for Nirsevimab that are contingent upon knowledge of maternal vaccination status could be challenging if the pediatric provider does not receive the maternal record
- Verbal report of vaccines received during pregnancy may not be reliable
- Pediatric providers may need to make decisions on Nirsevimab administration with incomplete information on maternal vaccination status

RSV Communication Challenges

Communications Challenges

- Terminology: Vaccine (maternal product) vs. Immunization (infant product)
- Conveying potential risks and benefits of each approach, and helping the pregnant person make an informed decision
  - Including potential but undetermined risk of preterm birth with maternal immunization
- Discussing financial implications to patient in setting of uncertainties about coverage during the first year of implementation

RSV Protection for Infants

	Nirsevimab (Beyfortus)	Abrysvo (Pfizer)
Who receives product?	Infants (birth to 8 months) for 1st RSV season; high-risk 8-19 months for 2nd RSV season	Pregnant people during 32 through 36 weeks gestation
What type of product?	Monoclonal antibody (passive immunization)	Vaccine
What time of year administered?	October – March	September – January
What is the plan for availability?	Covered through VFC; administered in birthing hospitals and provider offices	Will be available through VFA; reaching out to OB/GYN offices

Relative risks and benefits of maternal vaccination and nirsevimab

Both products are safe and effective in preventing RSV lower respiratory infection in infants

Maternal RSV vaccine	Nirsevimab
Benefits • Provides protection immediately after birth • May be more resistant to virus mutation • Avoids injection of infant **Risks** • Protection reduced if fewer antibodies produced or are transferred from mother to baby (e.g., mother immunocompromised or infant born soon after vaccine) • Potential risk of preterm birth	**Benefits** • Studies of antibody levels suggest that protection might wane more slowly • Can provide antibodies directly if infant receives less antibodies from mother • No risk of adverse pregnancy outcomes **Risks** • Potentially limited availability during 2023-2024 RSV season

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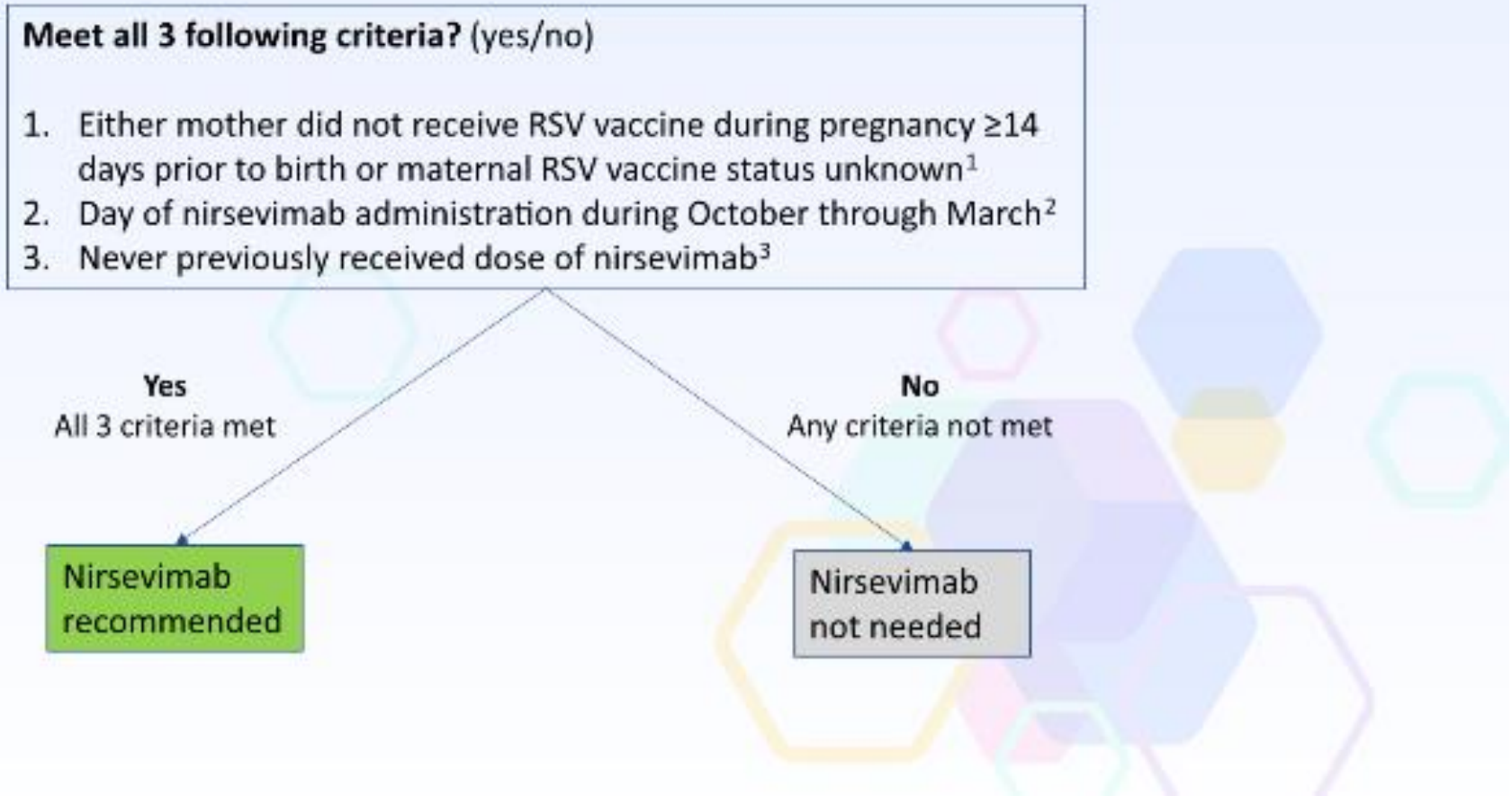
Nirsevimab administration algorithm for children aged <8 months on the day of administration



RSV Vaccines for Older Adults

ACIP Recommendation: Adults 60 years of age and older may receive a single dose of RSV vaccine, using shared clinical decision-making.

Vaccine information:

- *Arexvy (GSK):* Single dose, IM, must be reconstituted, 0.5 mL
- *Abrysvo (Pfizer):* Single dose, IM, must be reconstituted (prefilled syringe w/ diluent & vial adapter), 0.5 mL

RSV Vaccines for Older Adults

Arexy (GSK)

- Administer 0.5 mL intramuscularly
- Contains same adjuvant that is in RZV (Shingrix)
- Must be reconstituted prior to administration
- Stored in refrigerator
- Most common local adverse reaction: injection pain site (60.9%)
- Most common systemic adverse reactions: fatigue (33.5%), myalgia (28.9%), headache (27.2%) and arthralgia (18.1%)

Abrysvo (Pfizer)

- Administer 0.5 mL intramuscularly
- No adjuvant
- Must be reconstituted prior to administration; has a vial adapter mechanism
- Stored in refrigerator
- Most common local adverse reaction: injection site pain (10.5%)
- Most common systemic adverse reactions: fatigue (15.5%), headache (12.8%), muscle pain (10.1%)

Medical Conditions & RSV Hospitalizations

Underlying medical conditions among adults ≥18 years hospitalized with lab-confirmed RSV: RSV-NET 2014–2018

Major underlying condition categories (n=4,970)	N=4,970	%
Cardiovascular disease	2833	57.0
Chronic lung disease	2486	50.0
Diabetes mellitus	1692	34.0
Renal disease	1378	27.7
Immunocompromised condition	1126	22.7
Neurologic disorder	1041	21.0
Chronic metabolic disease (except diabetes)	934	18.8
Liver disease	332	6.7
Blood disorders/ hemoglobinopathy	132	2.7
Other disease or condition	429	8.7

94% of hospitalized adults have underlying medical conditions:

- **46%: 1–2 conditions**
- **48%: ≥3 conditions**

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https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-23/RSV-Adults-04-Melgar-508.pdf

Melgar, M. (2023). *Respiratory Syncytial Virus (RSV) Vaccines for Adults: General Information and Clinical Guidance* [PowerPoint slides].

RSV Product Ordering

Nirsivimab (infants)

- Will be available to order in sometime in October.
- May have limited availability to start

Arexvy (60+) and Abrysvo (pregnant people, 60+)

- Available in pharmacies now
- No CDC contract yet
- Will send ordering instructions when available through the Immunization Program

RSV Vaccine Webinar

The Fall 2023 “Current Issues in Vaccines” recording, slides and Q&A document are now available. Dr. Offit discussed, **“RSV Vaccines Across the Lifespan.”** The Q&A session also included discussion of the latest COVID-19 vaccine recommendations, as does the Q&A document.

Check out the materials or listen to the presentation.

Free continuing education credits are available for viewers of the archived event.

Product Information

Beyfortus - Beyfortus™ (nirsevimab-alip) for the prevention of RSV in infants and eligible children

Abrsyvo - ABRYSVO (Respiratory Syncytial Virus Vaccine) | Pfizer Medical Information - US

Arexvy - Administration | AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) (arexvyhcp.com)

COVID-19

Updated ACIP Recommendations: 2023-24 Formulation

Recommendations for 2023-2024 formulations of mRNA vaccines:

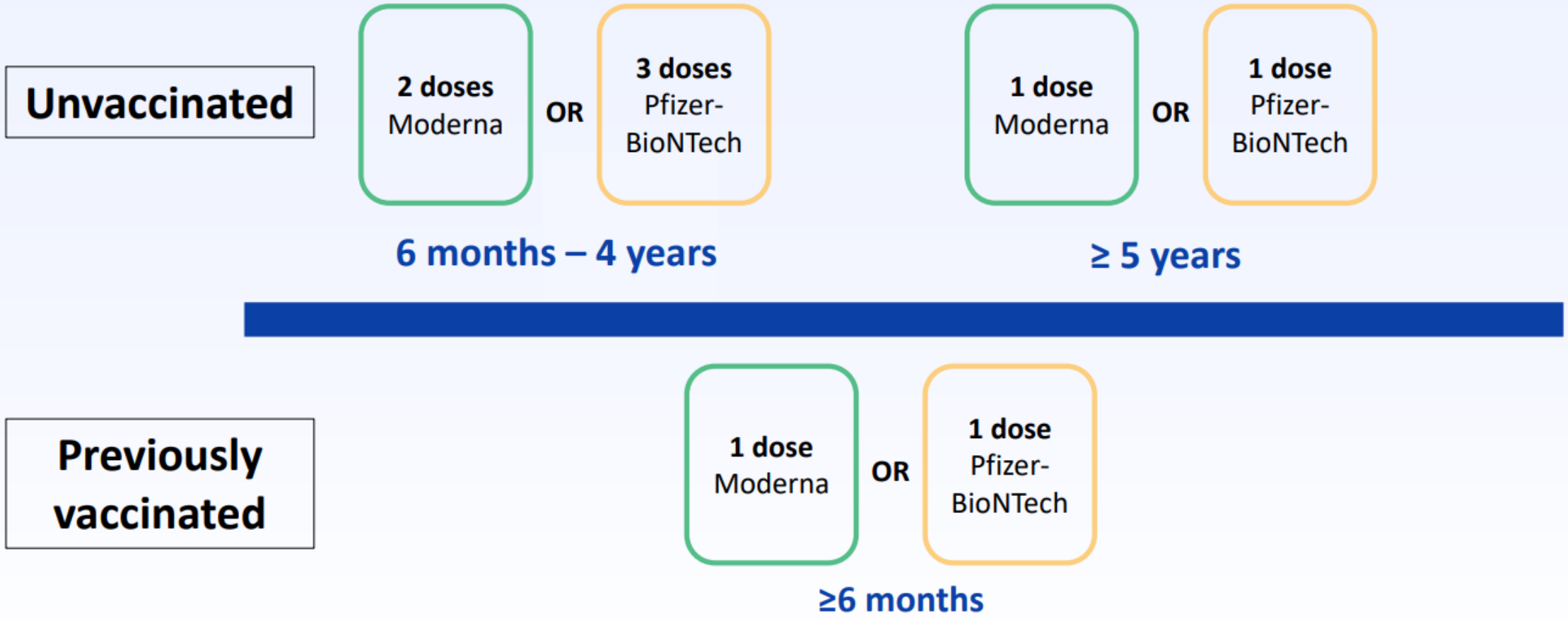
- Everyone age 5 years and older recommended to receive 1 dose of updated mRNA COVID-19 vaccine at least 2 months since last dose of any COVID-19 vaccine.
- Children ages 6 months – 4 years:
  - Initial vaccination: should receive 2 doses of updated Moderna or 3 doses of updated Pfizer-BioNTech
  - Received previous mRNA doses: need 1 or 2 doses updated Moderna or updated Pfizer-BioNTech, depending on number of prior doses
- Individuals who are moderately or severely immunocompromised:
  - Initial vaccination: receive 3-dose series of updated Moderna or updated Pfizer-BioNTech COVID-19 vaccine
  - Received previous mRNA doses: need 1 or 2 doses of updated Moderna or updated Pfizer-BioNTech depending number of prior doses
  - May receive 1 or more additional updated (2023-2024 Formula) mRNA COVID-19 vaccine doses

"ACIP recommends 2023–2024 (monovalent, XBB containing) COVID-19 vaccines as authorized under EUA or approved by BLA in persons ≥6 months of age."

Key changes from bivalent mRNA recommendations

2022 – 2023 bivalent recommendations	2023 – 2024 vaccine recommendations	Rationale
Everyone ages **6 years** and older recommended for a single bivalent dose	Everyone ages **5 years** and older recommended for a single 2023 – 2024 dose	Eliminates complex recommendations for 5-year-olds
Two Moderna dosages authorized for 6 months – 5 years, depending on vaccination history and immune status	All Moderna doses in ages 6 months – 11 years are now 25 µcg	Reduces the number of COVID-19 vaccine products in use
Optional 2nd bivalent dose for those ages 65 years and older	No additional dose recommendation **at this time**	Will monitor epidemiology and vaccine effectiveness to determine if additional doses are needed

2023 – 2024 COVID-19 vaccine recommendations for mRNA COVID-19 vaccines



Note: Those ages 6 months – 4 years who have previously received a single dose of Pfizer-BioNTech would need 2 additional doses. Additional doses are recommended for persons with immunocompromising conditions.

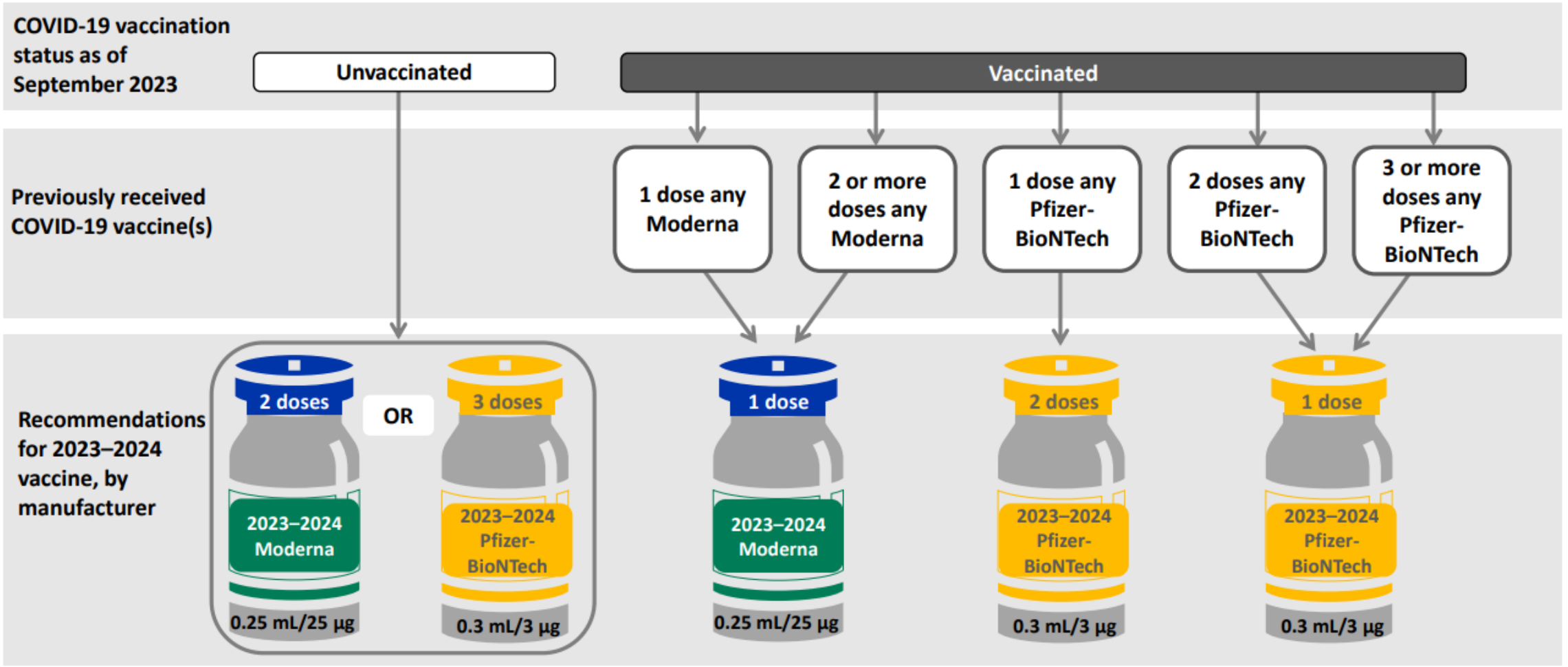
Recommendations for children aged 6 months – 4 years without immunocompromise

Doses recommended:

- Initial series of 2 Moderna vaccine doses OR 3 Pfizer-BioNTech vaccine doses
- **At least 1 dose of 2023–2024 COVID-19 vaccine**

- All doses should be homologous (i.e., from the same manufacturer)
- All Moderna doses in ages 6 months – 11 years are now 25 µcg

Recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 6 months–4 years*



*For information about administration intervals and people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

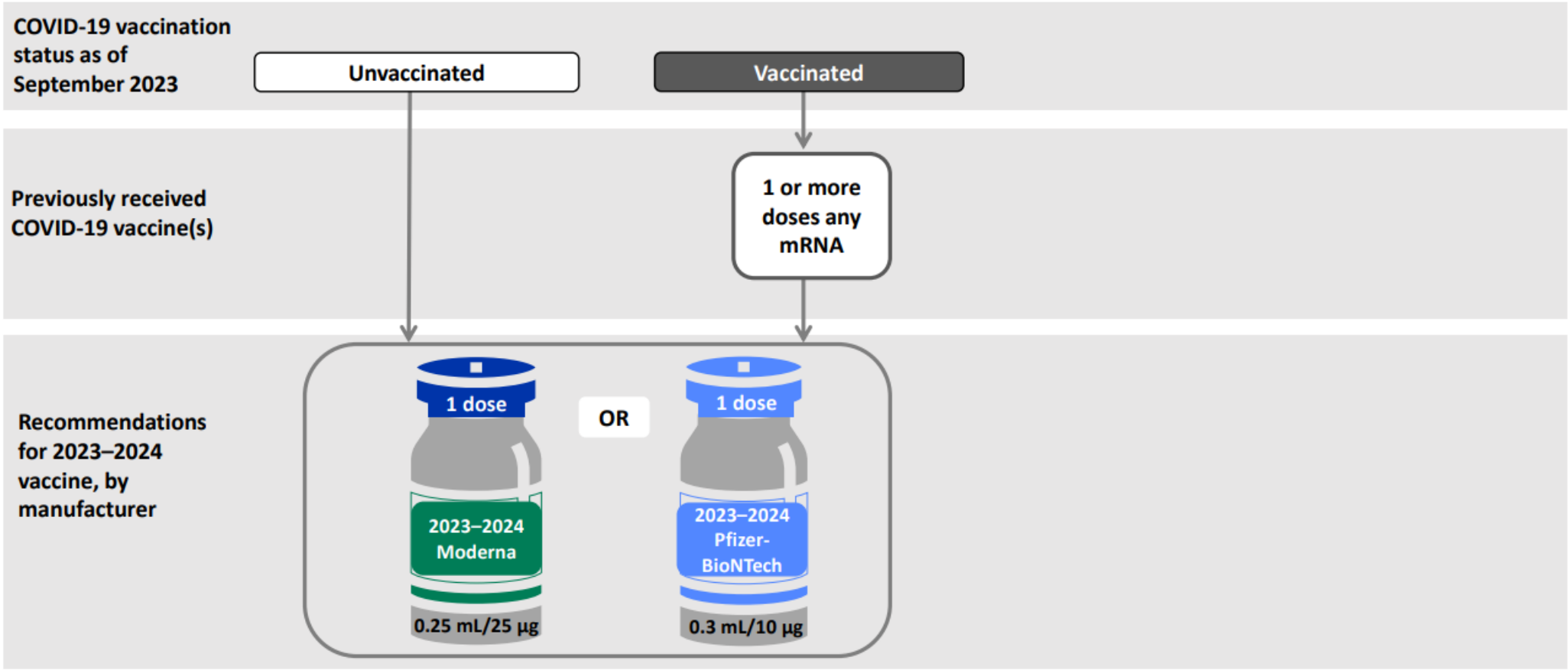
Recommendations for people aged 5 years and older without immunocompromise

Doses recommended:

- **1 dose of 2023–2024 COVID-19 vaccine**, regardless of prior vaccination history

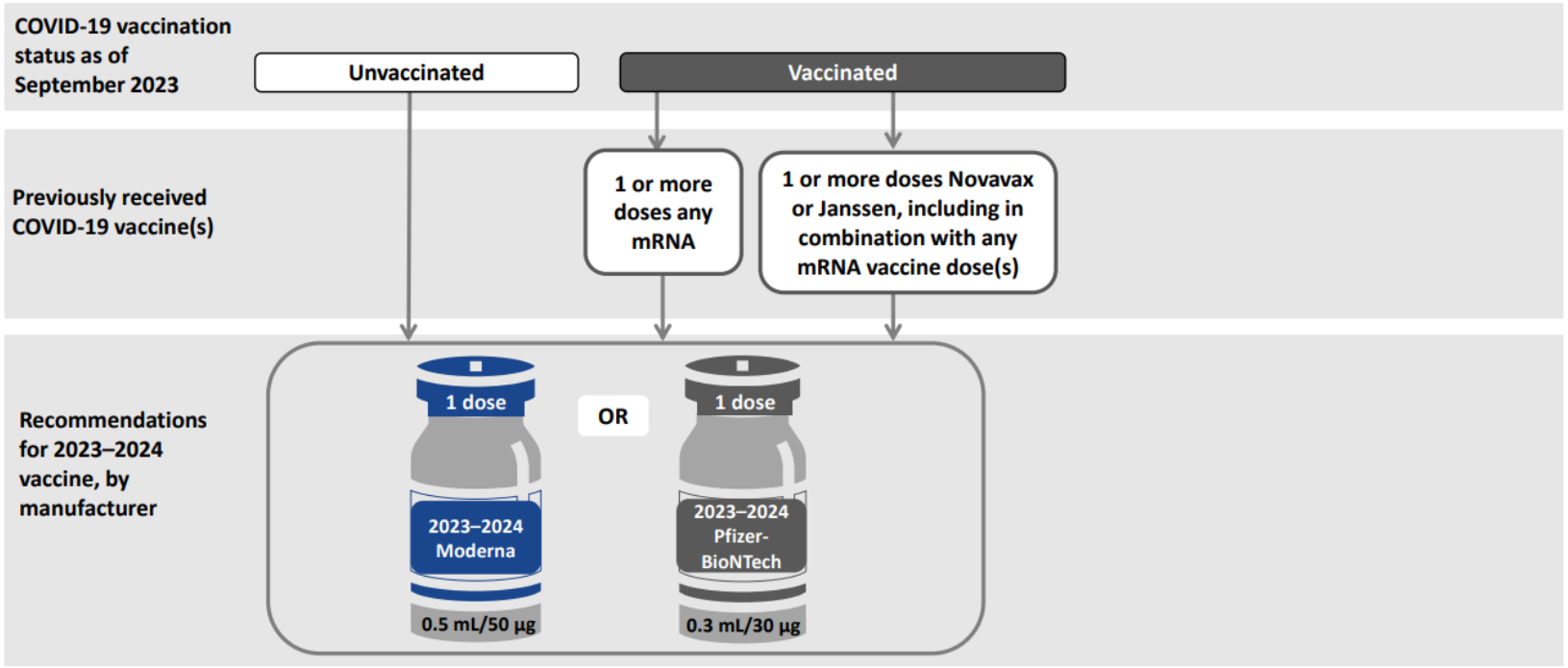
- New harmonized age cutoff for recommendations for young children for Moderna and Pfizer-BioNTech COVID-19 vaccines
- Resulting in simplified recommendations for 5-year-olds
- All Moderna doses in ages 6 months – 11 years are now 25 µcg
- 2023–2024 COVID-19 vaccine dose is recommended at least 2 months after receipt of the last COVID-19 vaccine dose

Recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 5–11 years*



*For information about administration intervals and people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

Recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged ≥12 years*



*For information about administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

Recommendations for people aged ≥6 months who are moderately or severely immunocompromised

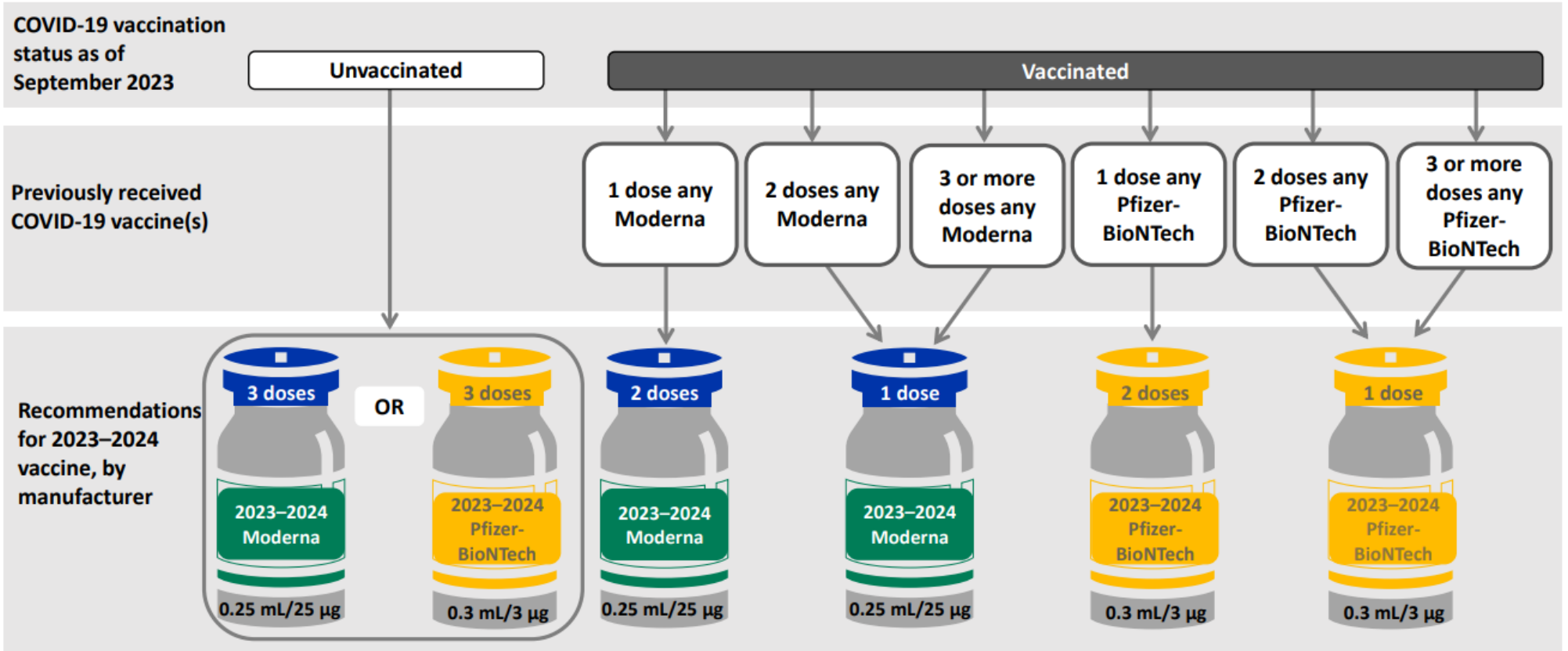
Doses recommended:

- Initial COVID-19 vaccine series*
- **At least 1 2023–2024 COVID-19 vaccine dose**
- May receive 1 or more additional 2023-2024 mRNA COVID-19 vaccine doses**

*Series of 3 homologous mRNA COVID-19 vaccine doses at time of initial vaccination. This could also include a history of receipt of 1 or more doses of Novavax or Janssen, including in combination with mRNA vaccine dose(s).

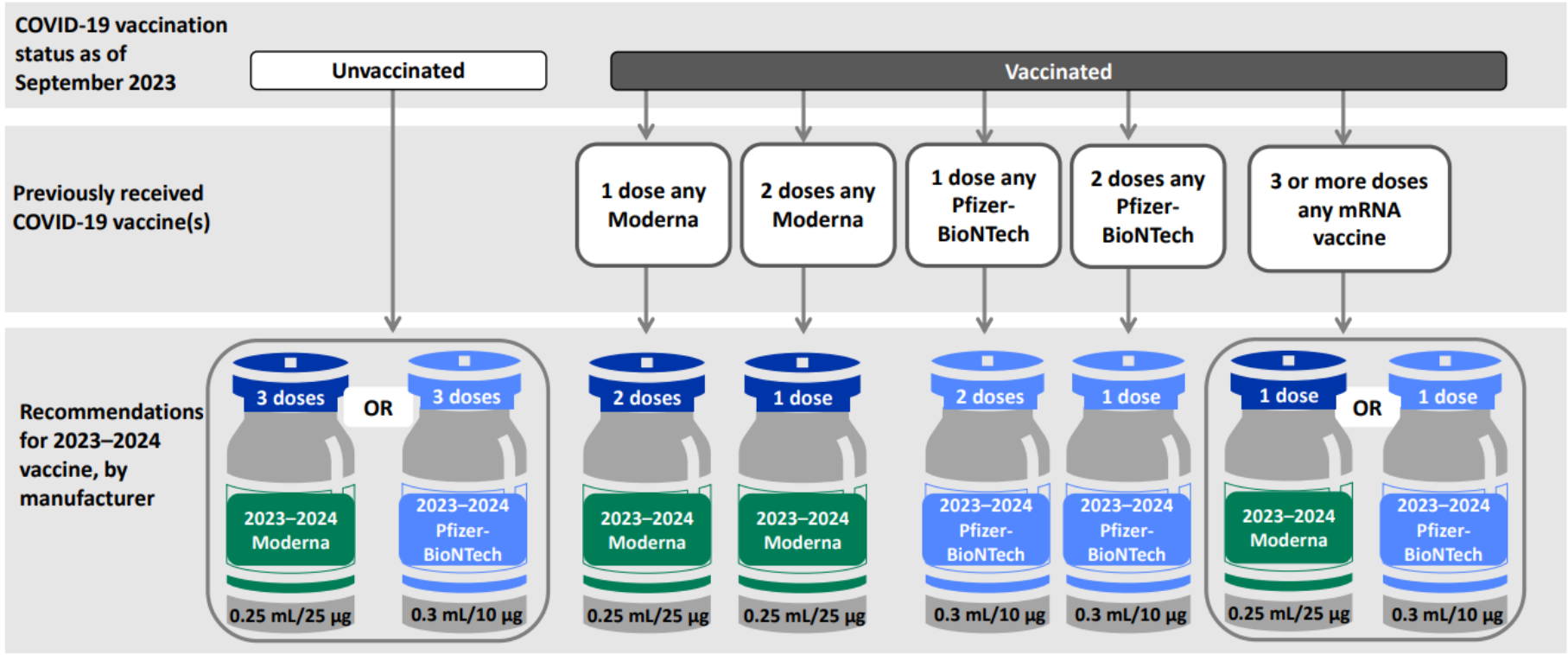
**Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Further additional doses should be administered at least 2 months after the last 2023-2024 COVID-19 vaccine dose.

Recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 6 months–4 years*



*For information about administration intervals, people who transition from age 4 years to age 5 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

Recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 5–11 years*



*For information about administration intervals, people who transition from age 4 years to age 5 years or age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

COVID-19 Vaccine Products

Age 12 years and older *(vaccines have full FDA licensure)*

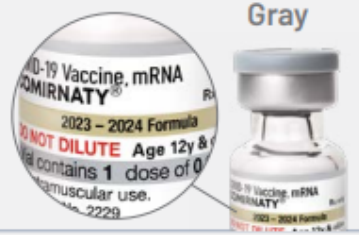
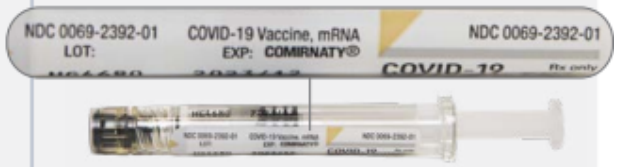
Product	Presentation	Identifying Colors		mL and mcg/dose	Dilution required?
		Vial Cap	Label		
Comirnaty (Pfizer-BioNTech)	Single-dose vial	Gray	Gray	0.3 mL/30 mcg	no
	Prefilled syringe	n/a	Gray		
Spikevax (Moderna)	Single-dose vial	Dark blue	Blue	0.5 mL/50 mcg	no
	Prefilled syringe	n/a	Blue		

Novavax (protein subunit vaccine) – Original formulation still available for 12+; anticipate updated 2023-24 monovalent formulation

COVID-19 Vaccine Products

Age 6 months through 11 years *(vaccines available under EUA)*

Product	Presentation	Identifying Colors		mL and mcg/dose	Dilution required?
		Vial Cap	Label		
Pfizer-BioNTech *6 mos through 4 y*	3-dose vial	Yellow	Yellow	0.3 mL/3 mcg after dilution	yes
5 through 11 y	Single-dose vial	Blue	Blue	0.3 mL/10 mcg	no
Moderna *6mo through 11 y*	Single-dose vial	Dark blue	Green	0.25 mL/25 mcg	no

Name	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula DO NOT DILUTE	COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula PREFILLED SYRINGE
Age Group	**12 years and older**	**12 years and older**
Cap Color & Label *Cap colors and labels with matching borders*	Gray 	
Dose	**30 mcg**	**30 mcg**
Dose Volume	0.3 mL	0.3 mL
Dilution	**DO NOT DILUTE**	**N/A**
Doses per Vial/Syringe	**Single Dose Vial[a]**	**Single Dose Prefilled Syringe[b]**
Storage Conditions		
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	18 months[c]	9 months[c]
Freezer [-25 °C to -15 °C (-13 °F to 5 °F)]	**DO NOT STORE**	**DO NOT STORE**
Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]	Up to 10 weeks	Up to 10 weeks
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	A total of 12 hours	Refer to product labeling[d]
After Puncture [2 °C to 25 °C (35 °F to 77 °F)]	N/A	N/A

	Pfizer-BioNTech COVID-19 Vaccine (2023–2024 Formula) DILUTE BEFORE USE	Pfizer-BioNTech COVID-19 Vaccine (2023–2024 Formula) DO NOT DILUTE
Age Group	6 months through 4 years[a]	5 through 11 years[a]
Cap Color & Label *Cap colors and labels with matching borders*	Yellow 	Blue 
Dose	**3 mcg**	**10 mcg**
Dose Volume	0.3 mL	0.3 mL
Dilution	1.1 mL[b]	**DO NOT DILUTE**
Doses per Vial	**Multiple Dose Vial[c,d]:** 3 doses per vial (after dilution)	**Single Dose Vial[c]:** 1 dose per vial
Storage Conditions		
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	12 months[e]	12 months[e]
Freezer [-25 °C to -15 °C (-13 °F to 5 °F)]	**DO NOT STORE**	**DO NOT STORE**
Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]	10 weeks	10 weeks
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	12 hours prior to first puncture[f,g]	12 hours prior to use[f]
After First Puncture [2 °C to 25 °C (35 °F to 77 °F)]	Discard 12 hours after dilution.[e]	N/A

	Moderna		
	Pediatric 6 months–11 years	**Spikevax 12+ years**	**Spikevax 12+ years**
	 Green label 2023-24 Product	 Blue label 2023-24 Product	 2023-24 Product
Packaging	Dark Blue Cap	Dark Blue Cap	Syringe
Doses Per Vial	1 dose	1 dose	1 dose
Carton Size	10 doses	10 doses	10 doses
NDC-Unit of Use (vial)	80777-0287-07	80777-0102-04	80777-0102-01
CVX Code	311	312	312
CPT Code	91321	91322	91322
Program Availability	VFC	VFC, BAP	TBD
Min. Standard Order*	10 doses	10 doses	TBD
Administration			
Diluent (supplied)	Do not dilute		
Dose Volume & Dose	0.25 mL 25 mcg	0.5 mL 50mcg	0.5 mL 50mcg
Refrigerator Thaw Time (Do not refreeze)	45 minutes for single dose vial or 1 hour for syringe at 2°C to 8°C (36°F to 46°F). Let stand at room temp for 15 min before administering.		
Room Temp Thaw Time (Do not refreeze)	15 minutes for single dose vial or 45 minutes for syringe at 15° to 25°C (59° to 77°F)		
Total Time at Room Temp	Store up to 24 hours at 8°C to 25°C (46°F to 77°F)		

Interchangeability of COVID-19 vaccines

- Children ages 6 months – 4 years should receive all doses from the same manufacturer
- People ages 5 years and older who are moderately or severely immunocompromised should receive a 3-dose initial vaccination series using vaccines from same manufacturer.
- In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered:
  - **Same vaccine not available**
  - Previous dose unknown
  - Person would otherwise not complete the vaccination series
  - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

Other ACIP Recommendation Updates

- Guidance regarding myocarditis or pericarditis
- Guidance regarding multisystem inflammatory syndrome (MIS) in children (MIS-C) and in adults (MIS-A)
- Reorganization and consolidation of sections on contraindications and precautions including allergic reactions to COVID-19 vaccines

Myocarditis or Pericarditis

- ACIP and CDC determined benefits of COVID-19 vaccination outweigh the rare risk of myocarditis and pericarditis in all populations recommended for vaccination
- Extending the interval to 8 weeks between first and second doses for some people might reduce the rare risk of vaccine-associated myocarditis and pericarditis
- People, especially males 12-39 years, should be made aware of the rare risk of myocarditis and pericarditis following receipt of these vaccines and the benefit of COVID-19 vaccination
  - Counsel on the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination, particularly in the week after vaccination.

Myocarditis or Pericarditis after COVID-19 vaccine

- Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to subsequent dose of any COVID-19, and subsequent doses should generally be avoided.
- Experts advise that these people should:
  - Generally not receive a subsequent dose of any COVID-19 vaccine
  - If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until at least after their episode of myocarditis or pericarditis has resolved

EUA and VIS Statements

What should we do if recommendations for a vaccine change but there is a delay in updating the appropriate VIS?

Production of a VIS can be held up for a variety of reasons. Never withhold a vaccine because there is not a current VIS for it. The provider can provide the patient with the manufacturer's package insert or other print materials.

Comirnaty and Spikevax are fully licensed vaccines. No VIS available yet. Use:

Comirnaty pages 35-37

Spikevax

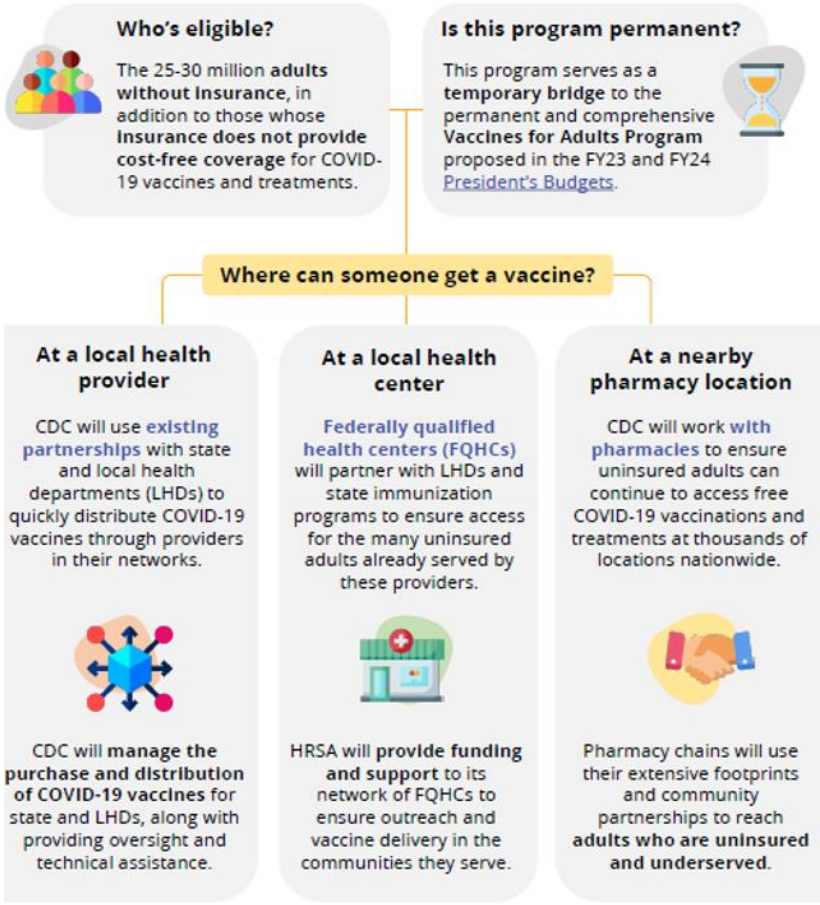
EUA fact sheets for Pfizer and Moderna pediatric products:

Pfizer

Moderna

COVID Bridge Access Program

Provides no-cost COVID-19 vaccines to adults without health insurance and adults whose insurance does not cover all COVID-19 vaccine costs. COVID-19 vaccines through this program will be available until December 31, 2024.



COVID Bridge Access Program

Healthcare providers play important roles in COVID-19 vaccination, particularly among adults without health insurance.

- Use program resources to share information on no-cost COVID-19 vaccines through the Bridge Access Program.
- Use promotional materials to let patients how they can find COVID-19 vaccines at no cost to them through the Bridge Access Program.

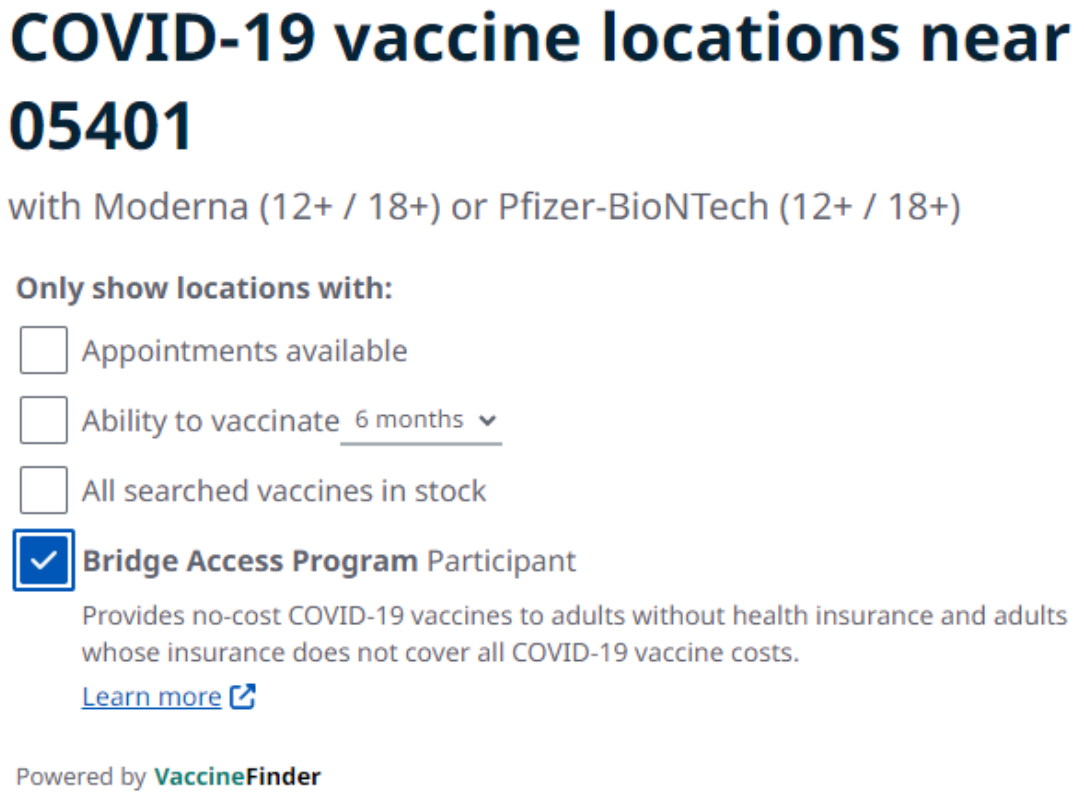
COVID Bridge Access Program in Vermont

[COVID-19 Vaccine | Vermont Department of Health (healthvermont.gov)]

To locate COVID vaccine near you please go to [Vaccines.gov]

In Vermont, the following locations are participating in the Bridge Access Program:

- CVS and Walgreens
- FQHC's, RHC, Free Clinics
- Health Department District Offices



2023-2024 COVID Ordering

2023-2024 Pfizer and Moderna products available

No new Novavax yet

Limited allocations

Adult ordering open

- Limit order to 20 doses
- Ages 19-64
- Can not use state supply for 65+
- Choose one brand
- May need to substitute

Pediatric ordering open for limited offices

- Extremely limited doses
- 3 Pfizer products
  - 6mo-4, 5-11, 12+
- 2 Moderna products
  - 6mo-11, 12+
- Choose one brand

COVID Vaccines Still Have a Beyond Use Date

The Public Health Foundation (PHF) partnered with the Centers for Disease Control and Prevention (CDC) to create three instructional videos to help clinicians differentiate between “expiration dates” and “beyond use date or time (BUD)” information when it comes to vaccines:

1. What is a vaccine expiration date? (3:48)
2. What is a vaccine beyond use date or time (BUD)? (3:55)
3. The difference between a vaccine expiration date and a beyond use date or time (BUD). (6:16)

Learn more or check out the three videos today!

FAQs

- Do we need to carry both Pfizer and Moderna?
  - With our limited initial supply we are asking practices to choose one brand

- How is Pfizer MDV formulation for 6 months to 4 years diluted?
  - Add 1.1 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.
  - Before removing the needle from the vial, equalize vial pressure by withdrawing air into the empty diluent syringe.
  - Record the date and time of dilution on the vial label.
  - Store at 2ºC to 25°C (35°F to 77°F) and discard after 12 hours.
  - After dilution, multiple-dose vials contain 3 doses of 0.3 mL each.
  - If the amount of vaccine in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

Flu

2023-24 Influenza Season Vaccine Recommendations

Annual influenza vaccination recommended for everyone age 6 months and older.

- For people age 6 months through 64 years, CDC recommends any available age-appropriate vaccine product.

All available influenza vaccines are quadrivalent (two influenza A and two influenza B strains)

CDC still has a preferential recommendation for 65+

Influenza Vaccine Composition

	US '22-'23	US '23-'24	AU '23
A	Victoria/2750/2019 (H1N1)pdm09-like virus	Victoria/4897/2022 (H1N1) pdm09-like virus	Sydney/5/2021 (H1N1) pdm09-like virus
A	Darwin/9/2021 (egg-based) Darwin/6/2021 (cell-based) (H3N2)-like virus	Same	Same
B	Austria/1359417/2021 (Victoria lineage)	Same	Same
B	Phuket/3073/2013 (Yamagata lineage)	Same	Same

Fiscus, Michelle, MD. (2023) *AIM Annual Influenza Update Webinar* [PowerPoint slides].

Influenza Vaccine Products for the 2023–2024 Influenza Season

Manufacturer	Trade Name (vaccine abbreviation)[1]	How Supplied	Mercury Content (mcg Hg/0.5mL)	Age Range	CVX Code	Vaccine Product Billing Code[2] CPT
AstraZeneca	FluMist (LAIV4)	0.2 mL (single-use nasal spray)	0	2 through 49 years	149	90672
GSK	Fluarix (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older[3]	150	90686
	FluLaval (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older[3]	150	90686
Sanofi	Flublok (RIV4)	0.5 mL (single-dose syringe)	0	18 years & older	185	90682
	Fluzone (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older[3]	150	90686
		0.5 mL (single-dose vial)	0	6 months & older[3]	150	90686
		5.0 mL multi-dose vial (0.25 mL dose)	25	6 through 35 months[3]	158	90687
		5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older	158	90688
	Fluzone High-Dose (IIV4-HD)	0.7 mL (single-dose syringe)	0	65 years & older	197	90662
Seqirus	Afluria (IIV4)	5.0 mL multi-dose vial (0.25 mL dose)	24.5	6 through 35 months[3]	158	90687
		5.0 mL multi-dose vial (0.5 mL dose)	24.5	3 years & older	158	90688
		0.5 mL (single-dose syringe)	0	3 years & older[3]	150	90686
	Fluad (aIIV4)	0.5 mL (single-dose syringe)	0	65 years & older	205	90694
	Flucelvax (ccIIV4)	0.5 mL (single-dose syringe)	0	6 months & older[3]	171	90674
		5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older[3]	186	90756

NOTES

1. IIV4 = egg-based quadrivalent inactivated influenza vaccine (injectable); where necessary to refer to cell culture-based vaccine, the prefix "cc" is used (e.g., ccIIV4); RIV4 = quadrivalent recombinant hemagglutinin influenza vaccine (injectable); aIIV4 = adjuvanted quadrivalent inactivated influenza vaccine.
2. An administration code should always be reported in addition to the vaccine product code. Note: Third party payers may have specific policies and guidelines that might require providing additional information on their claim forms.
3. Dosing for infants and children age 6 through 35 months:
   - Afluria 0.25 mL
   - Fluarix 0.5 mL
   - Flucelvax 0.5 mL
   - FluLaval 0.5 mL
   - Fluzone 0.25 mL or 0.5 mL
4. Afluria is approved by the Food and Drug Administration for intramuscular administration with the PharmaJet Stratis Needle-Free Injection System for persons age 18 through 64 years.

Influenza Vaccine Products for the 2023-2024 Influenza Season (immunize.org)

Preferential Recommendation for 65 Years and Older

ACIP recommends adults aged ≥65 years ***preferentially*** receive any one of the 3 higher dose or adjuvanted influenza vaccines:

- Fluzone High-Dose Quadrivalent vaccine (HD-IIV4)
- Flublok Quadrivalent recombinant flu vaccine (RIV4)
- Fluad Quadrivalent adjuvanted flu vaccine (aIIV4)

MMWR – Update on recommendation for those with egg allergies

Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.

"Egg allergy alone necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available."

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023–24 Influenza Season | MMWR (cdc.gov)

PCV20

PCV20

ACIP has approved recommendations for the use of pneumococcal 20-valent conjugate (PCV) vaccine in children ages 18 years or younger.

As of September 25, 2023 the MMWR has not yet been published.

As of October 2nd, PCV20 will replace PCV15 in VFC enrolled catalogs. Please plan to use your stock of PCV15 before you order PCV20.

General Vaccine Recommendations

Coadministration

Routine administration of all age-appropriate doses of vaccines simultaneously, also known as coadministration, is recommended for children, adolescents, and adults if there are no contraindications at the time of the healthcare visit.

Nirsevimab: simultaneous administration of COVID-19 vaccine and nirsevimab (a long-acting monoclonal antibody for certain infants and young children for prevention of RSV) is recommended.

General Best Practice Guidelines for Immunization

See RSV HAN for additional context on coadministration for RSV vaccines.

QUESTIONS?

Resources

RSV Vaccine Resources

- Health Advisory: RSV Vaccine Approved for Adults Aged 60 Years and Older (healthvermont.gov)
- Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)
- RSV Vaccine Information Statement | CDC
- For Healthcare Professionals: RSV (Respiratory Syncytial Virus) | CDC
- RSV vaccine recommendations & ACIP meeting recap w/ Dr. Fryhofer | AMA Update Video | AMA (ama-assn.org)
- ACIP RSV Vaccine in Pregnancy Implementation Considerations Presentation | CDC

RSV Monoclonal Antibody Resources

- Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

Resources

COVID Vaccine Resources

- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- EZIZ COVID-19 Vaccine Product Guide
- CDC COCA PowerPoint Presentation 9_19_2023(cdc.gov)
- Pfizer formulation-guide (pfizer.com)

Influenza Vaccine Resources

- Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023–24 Influenza Season | MMWR (cdc.gov)
- Influenza Vaccine Products for the 2023-2024 Influenza Season (immunize.org)

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