Respiratory Season 2024 – 2025 Vaccine Recommendations for Pediatrics and Adolescents

Maine Immunization Program
Virtual Training

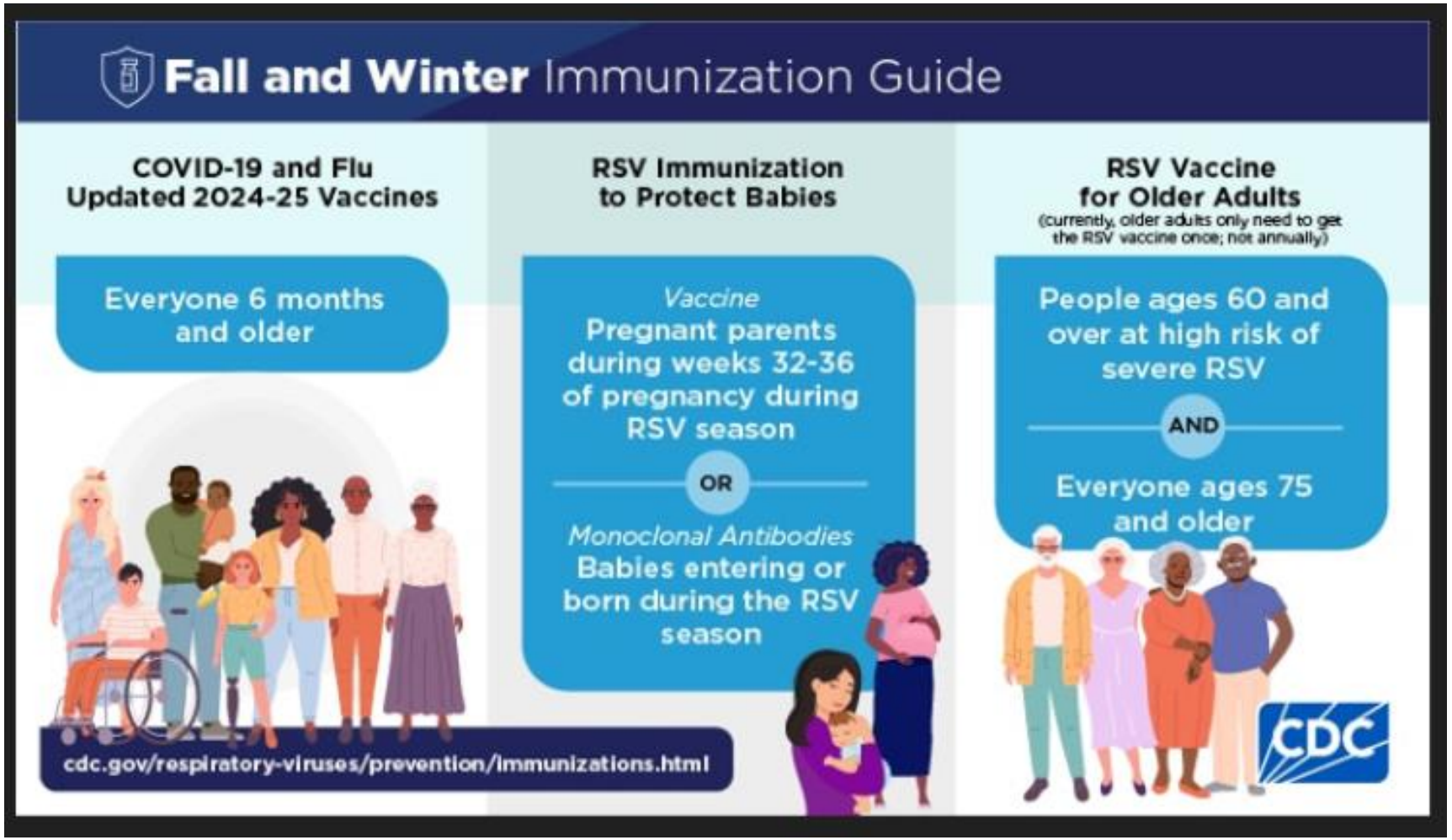
November 21, 2024

Objectives

2024 - 2025 Respiratory Season (COVID-19, FLU, RSV)

- COVID-19 Vaccine Presentations and Recommendations for 2024 - 2025
  - Moderna/SPIKEVAX
  - Pfizer/COMIRNATY
  - Novavax
- Influenza Vaccine Recommendations for Pediatric and Adolescent Age Groups
- Respiratory Syncytial Virus (RSV) Season 2024 - 2025 Timeline
  - Beyfortus (nirsevimab) recommendations for infants and young children
- Respiratory Vaccine Coadministration
- Storage and Beyond-Use Date Tracking Labels for Respiratory Vaccines
- Resources

Respiratory Season 2024 – 2025
COVID-19 – FLU - RSV



COVID -19 Vaccine Presentations 2024 – 2025

Pediatric and Adolescent Age Groups

Trade Name/ NDC#	MIP ordering recommendations for specific patient population	Presentations
Moderna/80777-0291-80	6m - 11 years	Prefilled syringe
Moderna/80777-0110-93*	12 years and older	
Novavax /80631-0107-10*	12 years and older	Prefilled syringe
Pfizer/59267-4426-02	6m – 4 years	Multi-dose vial
Pfizer/59267-4438-02	5 – 11 years	Single dose vial
Pfizer/00069-2432-10*	12 years and older	Prefilled syringe

Moderna/SPIKEVAX COVID-19 Vaccine Summary 2024 - 2025

Presentations and Indications

- Moderna COVID-19 Vaccine 2024-2025 Formula is indicated for people 6 months through 11 years of age
- Moderna SPIKEVAX® is indicated for people 12 years and older

Storage Requirements

The following requirements apply to both Moderna COVID-19 Vaccine 2024-2025 Formula and SPIKEVAX®:

- Store frozen between -50ºC to -15ºC (-58ºF to 5ºF)
- After thawing, products may be stored refrigerated between 2ºC to 8ºC (36ºF to 46ºF) for up to **60 days** or up to the expiration date printed on the carton, whichever comes first
- After thawing, products may be stored between 8ºC to 25ºC (46ºF to 77ºF) for up to 12 hours
- Do not refreeze once thawed

Moderna and Spikevax COVID-19 Vaccine Shelf Life 2024 - 2025

Shelf Life

Shelf Life	Moderna COVID-19 Vaccine 2024-2025 Formula 6 months through 11 years	SPIKEVAX® 12 and older
Frozen vaccine	10 months	10 months
Refrigerated vaccine	Up to 60 days or until the expiration date printed on the carton, whichever comes first	Up to 60 days or until the expiration date printed on the carton, whichever comes first
Room temperature vaccine (8°C to 25°C)	Up to 12 hours	Up to 12 hours

Pfizer COVID-19 Vaccine Summary 2024 - 2025

Presentations and Indications

- **COMIRNATY** (30 mcg/0.3mL glass pre-filled syringe presentation) is indicated for individuals 12 years of age and older.
- **Pfizer-BioNTech COVID-19 Vaccine** is indicated for individuals 5 through 11 years of age (via a 10mcg / 0.3mL single-dose vial presentation) and for individuals 6 months through 4 years of age (via a 3mcg / 0.3mL multi-dose vial (3 doses per vial) presentation).

Storage Requirements:

- **Multi-dose and single-dose vials**
  - The multi-dose and single-dose vials must be stored frozen at ultra-cold temperatures (between -90ºC and -60ºC). Once the vials are thawed, the multi-dose and single-dose vials must be stored refrigerated (between 2ºC and 8ºC).
- **Glass single-dose pre-filled syringes**
  - The glass single-dose pre-filled syringes for ages 12 and older must be stored refrigerated (between 2ºC and 8ºC); **DO NOT FREEZE**. The total time out of refrigeration (at temperatures between 8°C and 25°C) must not exceed 12 hours.

Diluent Type and Volume

- 1.1 mL of sterile 0.9% Sodium Chloride Injection, USP.
- Reconstitution is required only for the Pfizer-BioNTech COVID-19 Vaccine for individuals 6 months through 4 years of age in multi-dose vials.

Pfizer COVID-19 Vaccine Shelf Life 2024 - 2025

Shelf Life

Shelf Life	6 months through 4 years	5 years through 11 years	12 and older
Unopened, frozen vaccine	Once received, frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C until the expiration date printed on the vials and cartons. Do not store vials at -25°C to -15°C. Once vials are thawed, they should not be refrozen.		DO NOT FREEZE.
Unopened, refrigerated vaccine	Once received, frozen vials may be immediately transferred to the refrigerator [2°C to 8°C], thawed and stored for up to 10 weeks, not to exceed the expiration date printed on the vial and cartons. If vials and cartons are received at 2°C to 8°C, they should be stored at 2°C to 8°C. Check that the carton has been updated to reflect the 10-week refrigerated expiry date, not to exceed the expiration date printed on the vial and cartons.		The vaccine may be stored at 2°C to 8°C until the expiration date printed on the carton and syringe labels (not to exceed 8 months). DO NOT FREEZE.
Opened, refrigerated vaccine	If not previously thawed at 2°C to 8°C, allow multi-dose vials or single dose vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes. Multi-dose or single dose vials may be stored at room temperature [8°C to 25°C] for a total of 12 hours prior to the first puncture. After dilution, multiple dose vials should be held between 2°C to 25°C. Multi-dose vials should be discarded 12 hours after dilution.		After removing the tip cap and attaching an appropriate needle, the glass prefilled syringe should be used immediately. If it cannot be used immediately, it must be used within 4 hours. DO NOT FREEZE.
Opened, room temperature vaccine	If not previously thawed at 2°C to 8°C, allow multi-dose vials or single dose vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes. Multi-dose or single dose vials may be stored at room temperature [8°C to 25°C] for a total of 12 hours prior to the first puncture. After dilution, multiple dose vials should be held between 2°C to 25°C. Multi-dose vials should be discarded 12 hours after dilution.		After removing the tip cap and attaching an appropriate needle, the glass prefilled syringe should be used immediately. If it cannot be used immediately, it must be used within 4 hours. DO NOT FREEZE.

Novavax COVID-19 Vaccine Summary 2024 - 2025

Presentations and Indications

- Novavax COVID-19 Vaccine, Adjuvanted is indicated for individuals 12 years of age and older.
- Novavax's product will be presented in prefilled syringes, and there is one dosage strength (0.5mL) for all authorized uses.

Storage Requirements

- Must be stored refrigerated (between 2ºC and 8ºC).

Diluent Type and Volume

- Ready to use. No dilution, mixing, thawing, or reconstitution required.

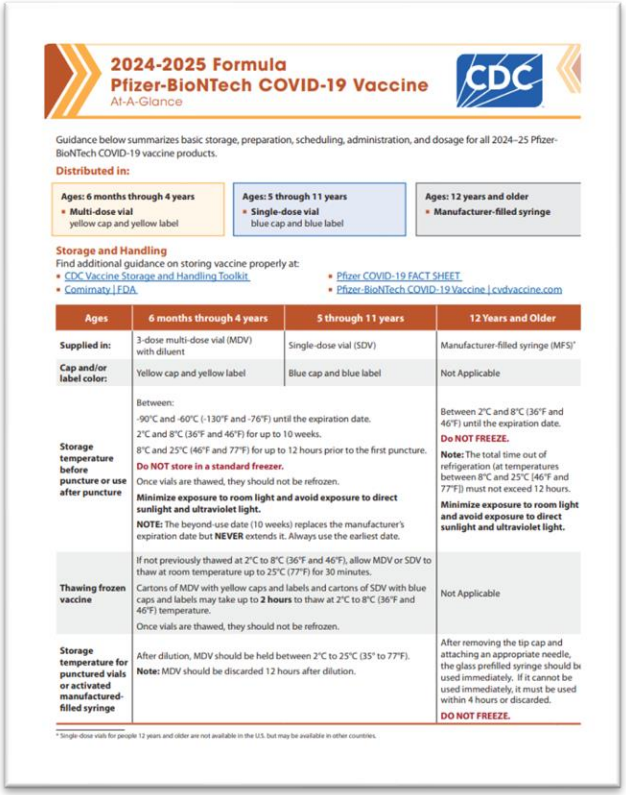
Novavax COVID-19 Vaccine Shelf Life 2024 - 2025

Shelf Life

Shelf Life	Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula)
Unopened, frozen vaccine	N/A; Novavax's product is never frozen. DO NOT FREEZE.
Unopened, refrigerated vaccine	3 months
Opened, refrigerated vaccine	Prefilled syringe must be immediately used or discarded once opened. Discard each syringe after single use.
Opened, room temperature vaccine	Prefilled syringe must be immediately used or discarded once opened. Discard each syringe after single use.

2024 – 2025 COVID-19 Vaccine At-A-Glance

Pfizer



2024-2025 Formula
Pfizer-BioNTech COVID-19 Vaccine
At-A-Glance

CDC

Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2024–25 Pfizer-BioNTech COVID-19 vaccine products.

Distributed in:

Ages: 6 months through 4 years	Ages: 5 through 11 years	Ages: 12 years and older
▪ Multi-dose vial yellow cap and yellow label	▪ Single-dose vial blue cap and blue label	▪ Manufacturer-filled syringe

Storage and Handling

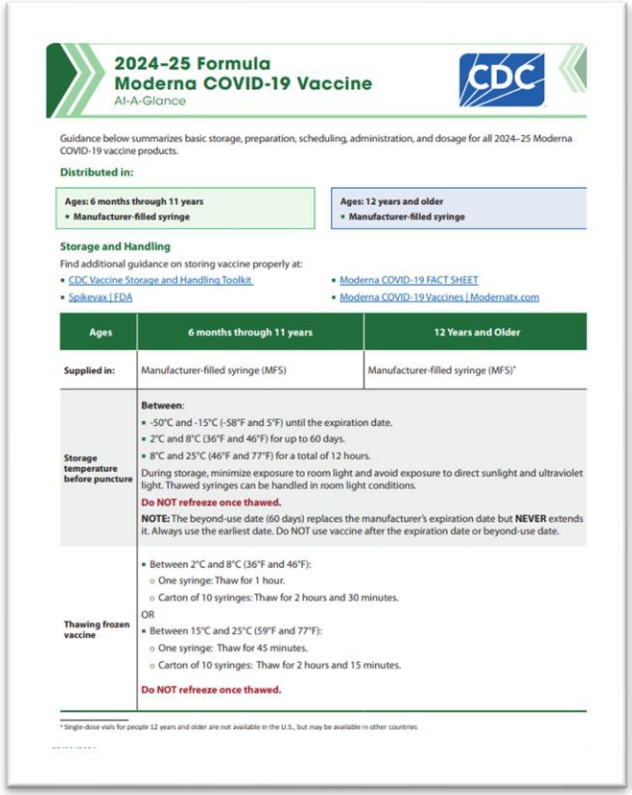
Find additional guidance on storing vaccine properly at:

- CDC Vaccine Storage and Handling Toolkit
- Comirnaty | FDA
- Pfizer COVID-19 FACT SHEET
- Pfizer-BioNTech COVID-19 Vaccine | cvdvaccine.com

Ages	6 months through 4 years	5 through 11 years	12 Years and Older
Supplied in:	3-dose multi-dose vial (MDV) with diluent	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)*
Cap and/or label color:	Yellow cap and yellow label	Blue cap and blue label	Not Applicable
Storage temperature before puncture or use after puncture	Between: -90°C and -60°C (-130°F and -76°F) until the expiration date. 2°C and 8°C (36°F and 46°F) for up to 10 weeks. 8°C and 25°C (46°F and 77°F) for up to 12 hours prior to the first puncture. **Do NOT store in a standard freezer.** Once vials are thawed, they should not be refrozen. **Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.** **NOTE:** The beyond-use date (10 weeks) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date.		Between 2°C and 8°C (36°F and 46°F) until the expiration date. **Do NOT FREEZE.** **Note:** The total time out of refrigeration (at temperatures between 8°C and 25°C [46°F and 77°F]) must not exceed 12 hours. **Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.**
Thawing frozen vaccine	If not previously thawed at 2°C to 8°C (36°F and 46°F), allow MDV or SDV to thaw at room temperature up to 25°C (77°F) for 30 minutes. Cartons of MDV with yellow caps and labels and cartons of SDV with blue caps and labels may take up to **2 hours** to thaw at 2°C to 8°C (36°F and 46°F) temperature. Once vials are thawed, they should not be refrozen.		Not Applicable
Storage temperature for punctured vials or activated manufactured-filled syringe	After dilution, MDV should be held between 2°C to 25°C (35° to 77°F). **Note:** MDV should be discarded 12 hours after dilution.		After removing the tip cap and attaching an appropriate needle, the glass prefilled syringe should be used immediately. If it cannot be used immediately, it must be used within 4 hours or discarded. **DO NOT FREEZE.**

* Single-dose vials for people 12 years and older are not available in the U.S. but may be available in other countries.

Moderna



2024-25 Formula
Moderna COVID-19 Vaccine
At-A-Glance

CDC

Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2024–25 Moderna COVID-19 vaccine products.

Distributed in:

Ages: 6 months through 11 years	Ages: 12 years and older
▪ Manufacturer-filled syringe	▪ Manufacturer-filled syringe

Storage and Handling

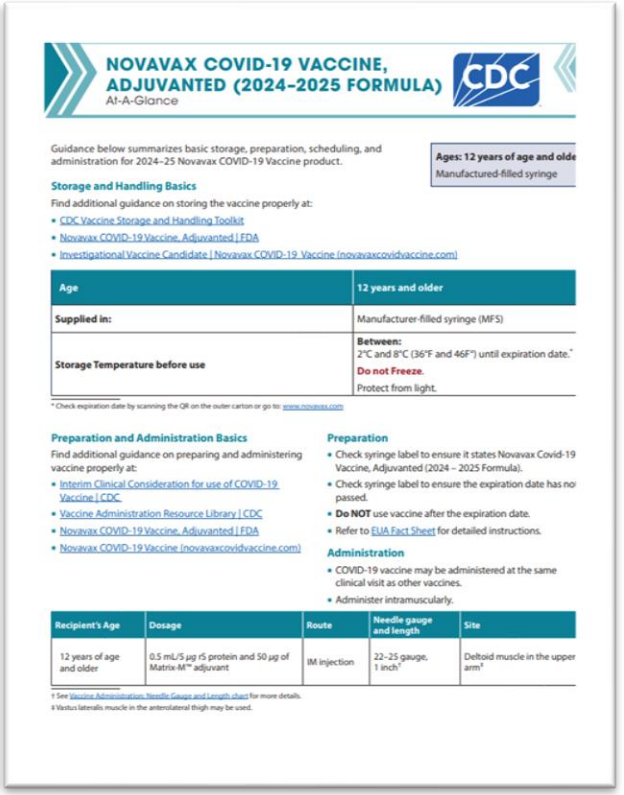
Find additional guidance on storing vaccine properly at:

- CDC Vaccine Storage and Handling Toolkit
- Spikevax | FDA
- Moderna COVID-19 FACT SHEET
- Moderna COVID-19 Vaccines | Modernatx.com

Ages	6 months through 11 years	12 Years and Older
Supplied in:	Manufacturer-filled syringe (MFS)	Manufacturer-filled syringe (MFS)*
Storage temperature before puncture	**Between:** ▪ -50°C and -15°C (-58°F and 5°F) until the expiration date. ▪ 2°C and 8°C (36°F and 46°F) for up to 60 days. ▪ 8°C and 25°C (46°F and 77°F) for a total of 12 hours. During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. Thawed syringes can be handled in room light conditions. **Do NOT refreeze once thawed.** **NOTE:** The beyond-use date (60 days) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date.	
Thawing frozen vaccine	▪ Between 2°C and 8°C (36°F and 46°F): ○ One syringe: Thaw for 1 hour. ○ Carton of 10 syringes: Thaw for 2 hours and 30 minutes. OR ▪ Between 15°C and 25°C (59°F and 77°F): ○ One syringe: Thaw for 45 minutes. ○ Carton of 10 syringes: Thaw for 2 hours and 15 minutes. **Do NOT refreeze once thawed.**	

* Single-dose vials for people 12 years and older are not available in the U.S., but may be available in other countries

Novavax



NOVAVAX COVID-19 VACCINE, ADJUVANTED (2024-2025 FORMULA)
At-A-Glance

CDC

Guidance below summarizes basic storage, preparation, scheduling, and administration for 2024–25 Novavax COVID-19 Vaccine product.

Ages: 12 years of age and olde
Manufactured-filled syringe

Storage and Handling Basics

Find additional guidance on storing the vaccine properly at:

- CDC Vaccine Storage and Handling Toolkit
- Novavax COVID-19 Vaccine, Adjuvanted | FDA
- Investigational Vaccine Candidate | Novavax COVID-19 Vaccine (novavaxcovidvaccine.com)

Age	12 years and older
Supplied in:	Manufacturer-filled syringe (MFS)
Storage Temperature before use	**Between:** 2°C and 8°C (36°F and 46°F) until expiration date.* **Do not Freeze.** Protect from light.

* Check expiration date by scanning the QR on the outer carton or go to: www.novavax.com

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Consideration for use of COVID-19 Vaccine | CDC
- Vaccine Administration Resource Library | CDC
- Novavax COVID-19 Vaccine, Adjuvanted | FDA
- Novavax COVID-19 Vaccine (novavaxcovidvaccine.com)

Preparation

- Check syringe label to ensure it states Novavax Covid-19 Vaccine, Adjuvanted (2024 – 2025 Formula).
- Check syringe label to ensure the expiration date has not passed.
- **Do NOT** use vaccine after the expiration date.
- Refer to EUA Fact Sheet for detailed instructions.

Administration

- COVID-19 vaccine may be administered at the same clinical visit as other vaccines.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
12 years of age and older	0.5 mL/5 µg rS protein and 50 µg of Matrix-M™ adjuvant	IM injection	22–25 gauge, 1 inch†	Deltoid muscle in the upper arm‡

† See Vaccine Administration, Needle Gauge and Length chart for more details.
‡ Vastus lateralis muscle in the anterolateral thigh may be used.

[U.S. COVID-19 Vaccine Product Information | CDC]

Updated Interim Clinical Considerations for Use of Covid-19 Vaccine

The Center for Disease Control and Prevention (CDC) has updated the Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States with guidance for use of the 2024–2025 COVID-19 vaccines.

Summary of recent changes (last updated October 31, 2024):

- People ages 6 months and older **who are moderately or severely immunocompromised** are recommended to receive:
  - Unvaccinated: A multidose initial series with an age-appropriate COVID-19 vaccine and 1 dose 6 months (minimum interval 2 months) after completion of the initial series; may receive additional doses under shared clinical decision making
  - Previously completed the multidose initial series: 2 age-appropriate doses of 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) apart; may receive additional doses under shared clinical decision making

Pediatric and Adolescent Influenza Recommendations 2024 - 2025

The CDC recommends that every person aged 6months and older get the flu vaccine by the end of October. It does take up to two weeks after vaccination to be protected from the flu.

All flu vaccine for the 2024-2025 season are Trivalent vs. the previous quadrivalent formulation. This change is due to one of last years strains no longer circulating.

When should vaccination start?

- If only 1 dose is needed for the season, vaccination should ideally be done during September or October. Though it is recommended vaccination continue throughout the season if influenza is circulating.

- Children 6 months through 8 years who require 2 doses should receive the first dose as soon as vaccine is available.

Available Influenza Vaccines 2024 - 2025

Trade Name/NDC#	MIP Ordering Recommendations for Specific Patient Population	Presentations
FluMist/66019-0311-10	Children 2- 18 years	0.2mL single dose sprayer, 10 pack
FluLaval/19515-0810-52	Children 6 months – 18 years	0.50mL prefilled syringe, 10 pack
Fluzone/49281-0641-15	Children 6 months – 18 years	0.50mL prefilled syringe, 10 pack
Flucelvax/70461-0654-03 *Recommended for those with egg allergy	Children 6 months – 18 years	0.50mL prefilled syringe, 10 pack
Fluarix/58160-0884-52	Children 6 months – 18 years	0.50mL prefilled syringe, 10 pack

All presentations of these flu vaccines must be refrigerated between 36°F and 46°F

FluLaval, Flucelvax and Flu-Mist need to be protected from light

FluMist – Protection Without The Injection

Flu protection without the injection!

- FluMist helps prevent flu in people aged 2-49. It's a nasal spray flu vaccine that starts working in the nose.

- FluMist continues to trigger your immune system to help build antibodies against influenza in 3 ways :

FluMist Dosing:

- 1 spray in each nostril = a single dose
- People 9 years of age and older need 1 dose of FluMist each year
- Children 2 through 8 years old may need 2 doses of FluMist depending on their history of previous influenza vaccination.

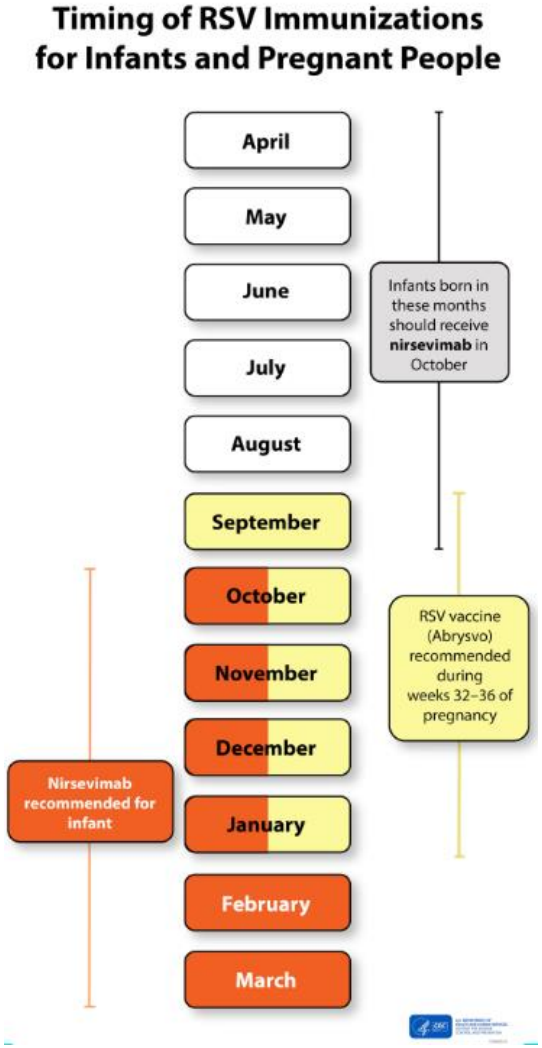
Respiratory Syncytial Virus (RSV) Season 2024 - 2025

Timing of Respiratory Syncytial Virus (RSV) immunization is very important in protecting infants and young children from getting very sick with RSV during the respiratory season.

Nirsevimab is a seasonal immunization that should be administered during the RSV season, October through the end of March.

- Infants born during the seasonal administration window (October 1 through March 31) should get nirsevimab within one week after birth, ideally during birth hospitalization.
    - Throughout March, any eligible infant or young child who has not yet received a recommended dose should receive nirsevimab at the earliest opportunity.

- For infants born *outside* of the seasonal administration window (April through September) and for young children who are at increased risk for severe RSV disease and entering their second RSV season, the optimal timing for nirsevimab administration is shortly before the RSV season begins (October or November).



Nirsevimab for Infants and Young Children 2024 - 2025

RSV Antibody Beyfortus (Nirsevimab):

Beyfortus (nirsevimab) is an injectable monoclonal antibody that provides immediate protection against RSV disease in infants and young children and last up to 5 months.

Nirsevimab is recommended for all babies younger than 8 months of age born to mothers who did not receive a maternal RSV vaccine (Pfizer's Abrysvo) during pregnancy.

Nirsevimab is also recommended for a small group of young children 8 through 19 months of age who are at increased risk for severe RSV. This nirsevimab dose should be given shortly before the child's second RSV season.

This group includes:

- Children who were born prematurely and have chronic lung disease
- Children with severe immunocompromise
- Children with severe cystic fibrosis
- American Indian and Alaska Native children

- Children ages 8 months and older who are not at increased risk of severe RSV disease should not receive nirsevimab.
- The CDC does not currently recommend nirsevimab for anyone aged 20 months or older.

RSV in Infants and Young Children

Nirsevimab Product Summary 2024 - 2025

Dosage and Administration

The recommended dosage of nirsevimab in neonates and infants born during or entering their first RSV season is based on body weight and is administered as one single intramuscular (IM) injection.

Age less than 8 months:

- 50 mg for infants weighing <5 kg [<11 lb]
- 100 mg for infants weighing ≥5 kg [≥11 lb]

Age 8 through 19 months:

- 200 mg, administered as two 100 mg injections

Recommended Dosage of Beyfortus in Neonates and Infants Born During or Entering Their First RSV Season[5]	
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

50 mg by IM injection

100 mg by IM injection

Nirsevimab Shelf Life

Shelf Life

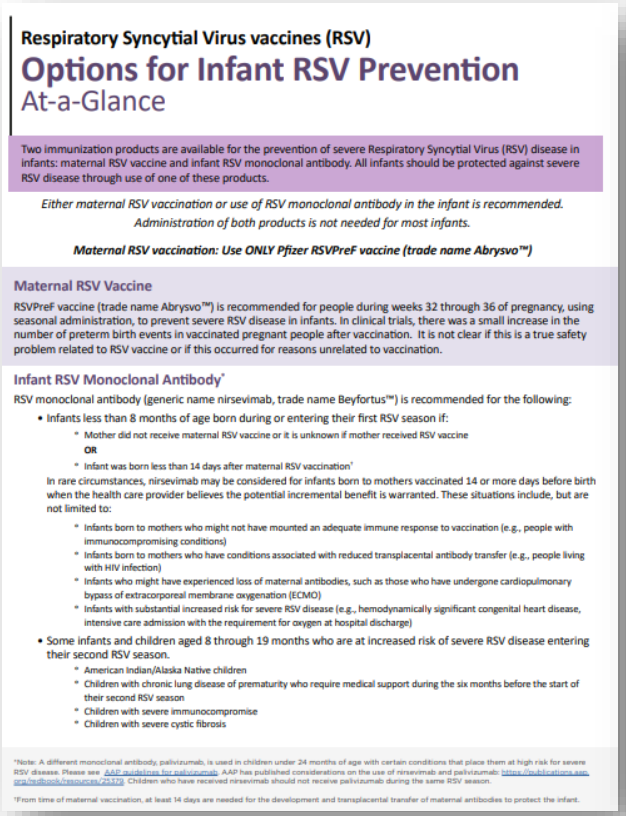
Shelf Life	Beyfortus
Refrigerated product	Current shelf life is 24 months from the time the syringes are filled during manufacturing.
Room temperature product	Shelf life is 8 hours at room temperature.

Storage Requirements

Must be stored refrigerated (between 2ºC and 8ºC)

**Any remaining nirsevimab products from the 2024-2025 season should continue to be stored at appropriate temperature and used first at the start of the 2025-2026 RSV season

Infant RSV Prevention At-a-Glance



Respiratory Syncytial Virus vaccines (RSV)

Options for Infant RSV Prevention At-a-Glance

Two immunization products are available for the prevention of severe Respiratory Syncytial Virus (RSV) disease in infants: maternal RSV vaccine and infant RSV monoclonal antibody. All infants should be protected against severe RSV disease through use of one of these products.

Either maternal RSV vaccination or use of RSV monoclonal antibody in the infant is recommended. Administration of both products is not needed for most infants.

Maternal RSV vaccination: Use ONLY Pfizer RSVPreF vaccine (trade name Abrysvo™)

Maternal RSV Vaccine

RSVPreF vaccine (trade name Abrysvo™) is recommended for people during weeks 32 through 36 of pregnancy, using seasonal administration, to prevent severe RSV disease in infants. In clinical trials, there was a small increase in the number of preterm birth events in vaccinated pregnant people after vaccination. It is not clear if this is a true safety problem related to RSV vaccine or if this occurred for reasons unrelated to vaccination.

Infant RSV Monoclonal Antibody*

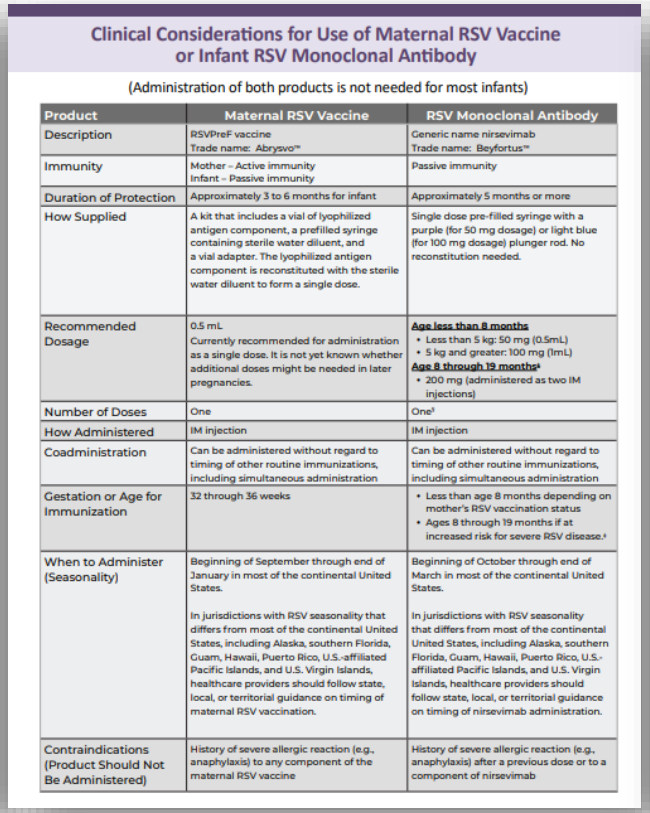
RSV monoclonal antibody (generic name nirsevimab, trade name Beyfortus™) is recommended for the following:

- Infants less than 8 months of age born during or entering their first RSV season if:
  - Mother did not receive maternal RSV vaccine or it is unknown if mother received RSV vaccine
  - **OR**
  - Infant was born less than 14 days after maternal RSV vaccination†

  In rare circumstances, nirsevimab may be considered for infants born to mothers vaccinated 14 or more days before birth when the health care provider believes the potential incremental benefit is warranted. These situations include, but are not limited to:
  - Infants born to mothers who might not have mounted an adequate immune response to vaccination (e.g., people with immunocompromising conditions)
  - Infants born to mothers who have conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)
  - Infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass of extracorporeal membrane oxygenation (ECMO)
  - Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with the requirement for oxygen at hospital discharge)
- Some infants and children aged 8 through 19 months who are at increased risk of severe RSV disease entering their second RSV season.
  - American Indian/Alaska Native children
  - Children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season
  - Children with severe immunocompromise
  - Children with severe cystic fibrosis

*Note: A different monoclonal antibody, palivizumab, is used in children under 24 months of age with certain conditions that place them at high risk for severe RSV disease. Please see AAP guidelines for palivizumab. AAP has published considerations on the use of nirsevimab and palivizumab: https://publications.aap.org/redbook/resources/20329. Children who have received nirsevimab should not receive palivizumab during the same RSV season.

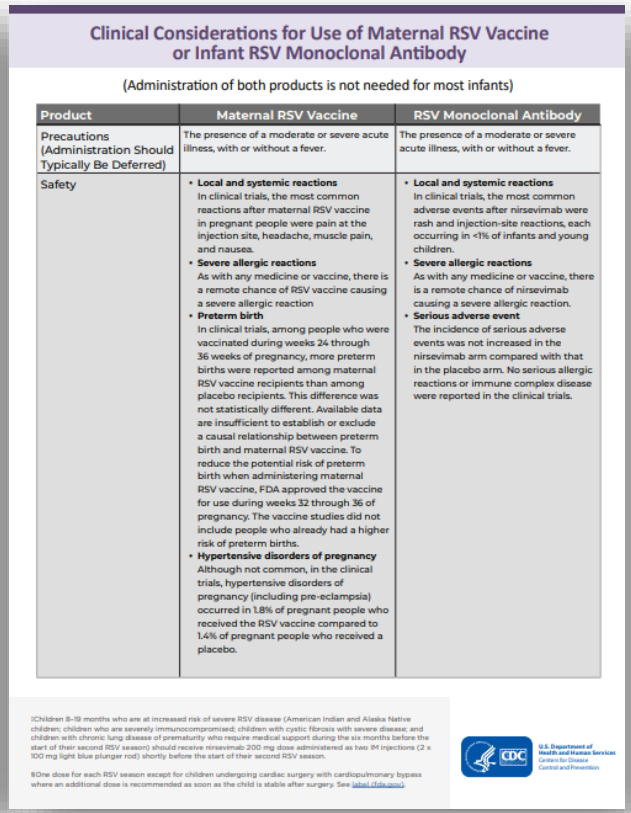
†From time of maternal vaccination, at least 14 days are needed for the development and transplacental transfer of maternal antibodies to protect the infant.



Clinical Considerations for Use of Maternal RSV Vaccine or Infant RSV Monoclonal Antibody

(Administration of both products is not needed for most infants)

Product	Maternal RSV Vaccine	RSV Monoclonal Antibody
Description	RSVPreF vaccine Trade name: Abrysvo™	Generic name nirsevimab Trade name: Beyfortus™
Immunity	Mother – Active immunity Infant – Passive immunity	Passive immunity
Duration of Protection	Approximately 3 to 6 months for infant	Approximately 5 months or more
How Supplied	A kit that includes a vial of lyophilized antigen component, a prefilled syringe containing sterile water diluent, and a vial adapter. The lyophilized antigen component is reconstituted with the sterile water diluent to form a single dose.	Single dose pre-filled syringe with a purple (for 50 mg dosage) or light blue (for 100 mg dosage) plunger rod. No reconstitution needed.
Recommended Dosage	0.5 mL Currently recommended for administration as a single dose. It is not yet known whether additional doses might be needed in later pregnancies.	**Age less than 8 months** • Less than 5 kg: 50 mg (0.5mL) • 5 kg and greater: 100 mg (1mL) **Age 8 through 19 months‡** • 200 mg (administered as two IM injections)
Number of Doses	One	One§
How Administered	IM injection	IM injection
Coadministration	Can be administered without regard to timing of other routine immunizations, including simultaneous administration	Can be administered without regard to timing of other routine immunizations, including simultaneous administration
Gestation or Age for Immunization	32 through 36 weeks	• Less than age 8 months depending on mother's RSV vaccination status • Ages 8 through 19 months if at increased risk for severe RSV disease.‡
When to Administer (Seasonality)	Beginning of September through end of January in most of the continental United States. In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should follow state, local, or territorial guidance on timing of maternal RSV vaccination.	Beginning of October through end of March in most of the continental United States. In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should follow state, local, or territorial guidance on timing of nirsevimab administration.
Contraindications (Product Should Not Be Administered)	History of severe allergic reaction (e.g., anaphylaxis) to any component of the maternal RSV vaccine	History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of nirsevimab



Clinical Considerations for Use of Maternal RSV Vaccine or Infant RSV Monoclonal Antibody

(Administration of both products is not needed for most infants)

Product	Maternal RSV Vaccine	RSV Monoclonal Antibody
Precautions (Administration Should Typically Be Deferred)	The presence of a moderate or severe acute illness, with or without a fever.	The presence of a moderate or severe acute illness, with or without a fever.
Safety	• **Local and systemic reactions** In clinical trials, the most common reactions after maternal RSV vaccine in pregnant people were pain at the injection site, headache, muscle pain, and nausea. • **Severe allergic reactions** As with any medicine or vaccine, there is a remote chance of RSV vaccine causing a severe allergic reaction • **Preterm birth** In clinical trials, among people who were vaccinated during weeks 24 through 36 weeks of pregnancy, more preterm births were reported among maternal RSV vaccine recipients than among placebo recipients. This difference was not statistically different. Available data are insufficient to establish or exclude a causal relationship between preterm birth and maternal RSV vaccine. To reduce the potential risk of preterm birth when administering maternal RSV vaccine, FDA approved the vaccine for use during weeks 32 through 36 of pregnancy. The vaccine studies did not include people who already had a higher risk of preterm births. • **Hypertensive disorders of pregnancy** Although not common, in the clinical trials, hypertensive disorders of pregnancy (including pre-eclampsia) occurred in 1.8% of pregnant people who received the RSV vaccine compared to 1.4% of pregnant people who received a placebo.	• **Local and systemic reactions** In clinical trials, the most common adverse events after nirsevimab were rash and injection-site reactions, each occurring in <1% of infants and young children. • **Severe allergic reactions** As with any medicine or vaccine, there is a remote chance of nirsevimab causing a severe allergic reaction. • **Serious adverse event** The incidence of serious adverse events was not increased in the nirsevimab arm compared with that in the placebo arm. No serious allergic reactions or immune complex disease were reported in the clinical trials.

‡Children 8–19 months who are at increased risk of severe RSV disease (American Indian and Alaska Native children; children who are severely immunocompromised; children with cystic fibrosis with severe disease; and children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season) should receive nirsevimab 200 mg dose administered as two IM injections (2 x 100 mg light blue plunger rod) shortly before the start of their second RSV season.

§One dose for each RSV season except for children undergoing cardiac surgery with cardiopulmonary bypass where an additional dose is recommended as soon as the child is stable after surgery. See label (fda.gov).

CDC U.S. Department of Health and Human Services Centers for Disease Control and Prevention

[Infant RSV Prevention At-A-Glance | CDC]

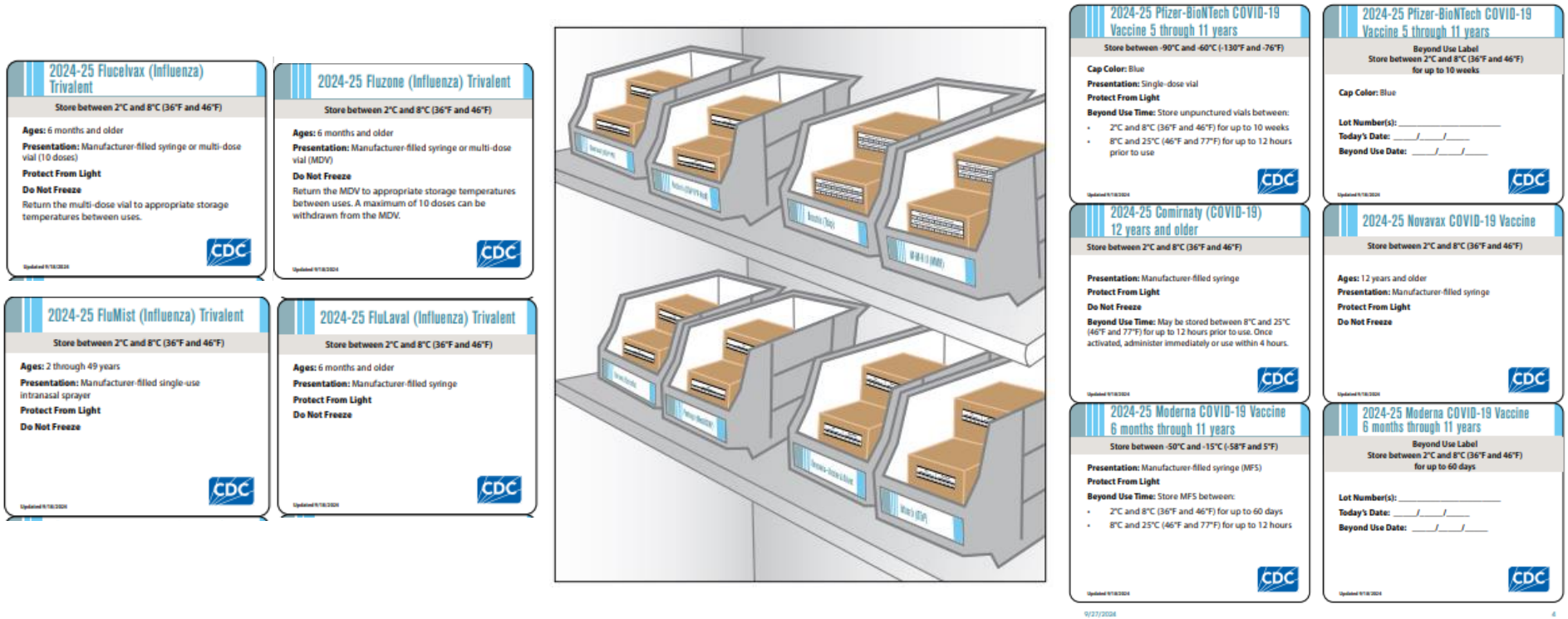
Respiratory Vaccine Coadministration

Getting COVID-19, flu, and RSV vaccines at the same time.
Flu, COVID-19, and RSV vaccines may be given at the same visit. For eligible patients, this means that if you're only able to make one trip to get your fall and winter vaccines, you can get all of those vaccines at the same visit. Talk with your health care provider about this option. If you prefer to receive each vaccine at a separate visit, there is no minimum waiting period between vaccines. It is important to make sure you are up to date and protected for this season. Talk with a healthcare provider or pharmacist if you have questions about these vaccines.

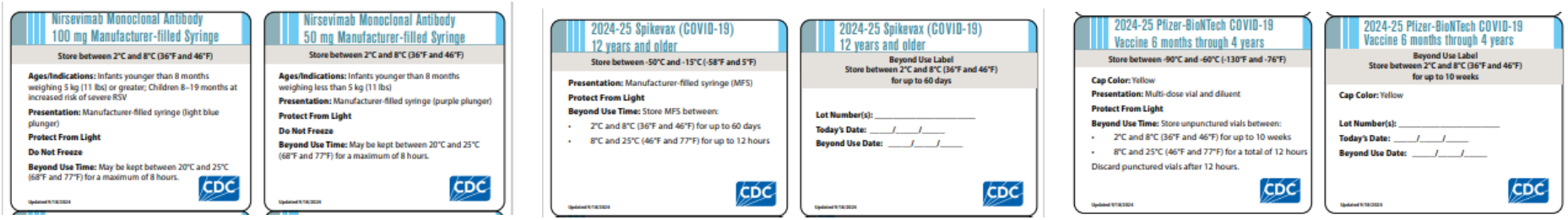
Nirsevimab and routine childhood vaccines **can be administered** during the same visit. No interval between nirsevimab and live vaccines (such as measles, mumps, and rubella [MMR] and varicella) is necessary.

Getting more than one vaccine at the same visit.
Vaccines given with a needle at the same visit should be given at separate places on the body (at least one inch apart). Adults and older children can get them in the same arm at least an inch apart, or they can get them in different arms. Young children can get them in the same thigh at least an inch apart, or they can get them in different thighs.

Vaccine Labels
Storage and Beyond-Use Date Tracking Labels



[Vaccine Labels: Storage and Beyond-Use Date Tracking]



Resources

COVID-19 Vaccine:

- CDC Recommends Updated COVID-19 Vaccine for Fall/Winter Virus Season | CDC Online Newsroom | CDC
- 2024–2025 COVID-19 Vaccine Immunization Schedule for People 6 Months of Age and Older
- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- Pfizer COVID-19 Vaccine Summary | Vaccines & Immunizations | CDC
- Moderna COVID-19 Vaccine Summary | Vaccines & Immunizations | CDC
- Immunization and Vaccine Product Summaries | Vaccines & Immunizations | CDC

Influenza Vaccine:

- Who Needs a Flu Vaccine | CDC
- Preventing Seasonal Flu | Influenza (Flu) | CDC
- Seasonal Flu Vaccine Basics | Influenza (Flu) | CDC
- Influenza: Questions and Answers

RSV - Nirsevimab:

- RSV Immunization Guidance for Infants and Young Children | RSV | CDC
- Nirsevimab Frequently Asked Questions
- Immunizations to Protect Infants | RSV | CDC

Immunization Resources:

- Immunization | Maine CDC | DHHS
- Vaccine Labels: Storage and Beyond-Use Date Tracking

Questions?

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