National Center for Immunization & Respiratory Diseases

Respiratory Syncytial Virus (RSV) Immunization Recommendations

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National Center for Immunization and Respiratory Diseases

May 9, 2024

CDC recommendations for maternal RSV vaccination and nirsevimab

Maternal RSV Vaccine and Nirsevimab Recommendations

- Two products are available to protect infants from RSV lower respiratory tract infection.
- To protect **eligible** infants in their **first season**, **either maternal vaccination** (Abrysvo, Pfizer) **or use of nirsevimab** (Beyfortus, Sanofi / AstraZeneca) in the infant is recommended to prevent RSV lower respiratory tract infection, but administration of both products is not needed for most infants.
- To protect **eligible** infants in their **second season**, **nirsevimab** is recommended regardless of maternal RSV vaccination.

Fleming-Dutra KE, Jones JM, Roper LE, et al: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf
https://www.fda.gov/media/168889/download

Maternal Vaccination Recommendations

Maternal Vaccine Recommendations

- Maternal vaccine is recommended for pregnant people during **32 through 36 weeks gestation**, with seasonal administration.
  - During **September through January** in most of the continental United States
  - In jurisdictions with seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climates), providers should follow **state, local, or territorial guidance** on timing of administration

- Maternal Pfizer vaccine can be **simultaneously administered** with other indicated vaccinations.

Fleming-Dutra KE, Jones JM, Roper LE, et al: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Maternal Vaccine Recommendations

- Pfizer maternal RSV vaccine is recommended as a one-time dose at this time.
- Currently, no data are available on either the efficacy of the first lifetime dose to protect infants born after subsequent pregnancies or the safety of additional doses given in subsequent pregnancies.
- Additional data are needed to determine whether additional seasonal doses in subsequent pregnancies would be indicated, and ACIP might update recommendations in the future, as data become available.

Fleming-Dutra KE, Jones JM, Roper LE, et al: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Contraindications and Precautions

- Precaution
  - Moderate or severe illness
- Contraindication
  - History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a product component

Fleming-Dutra KE, Jones JM, Roper LE, et al: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Maternal RSV Vaccine, Abrysvo (Pfizer)

- Recombinant prefusion F protein (preF) vaccine
- Single dose
- 0.5mL
- Requires reconstitution
- Intramuscular injection
- Abrysvo (Pfizer) is the ONLY RSV vaccine approved for pregnant people
  - Approved for use in people ages 60 years and older AND pregnant people
- Arexvy (GSK) is NOT approved for pregnant people
  - Approved for use ONLY in people ages 60 years and older

https://www.fda.gov/media/168889/download

Pfizer/Abrysvo: Storage and Handling

BEFORE Reconstitution

VS

AFTER Reconstitution

Store **refrigerated** between 2°C and 8°C (36°F and 46°F)

Do **NOT freeze**

Store at **room temperature** [15°C to 30°C (59°F to 86°F)]

Do **NOT refrigerate**

Do **NOT freeze**

Use within **4 hours**

https://www.fda.gov/media/168889/download

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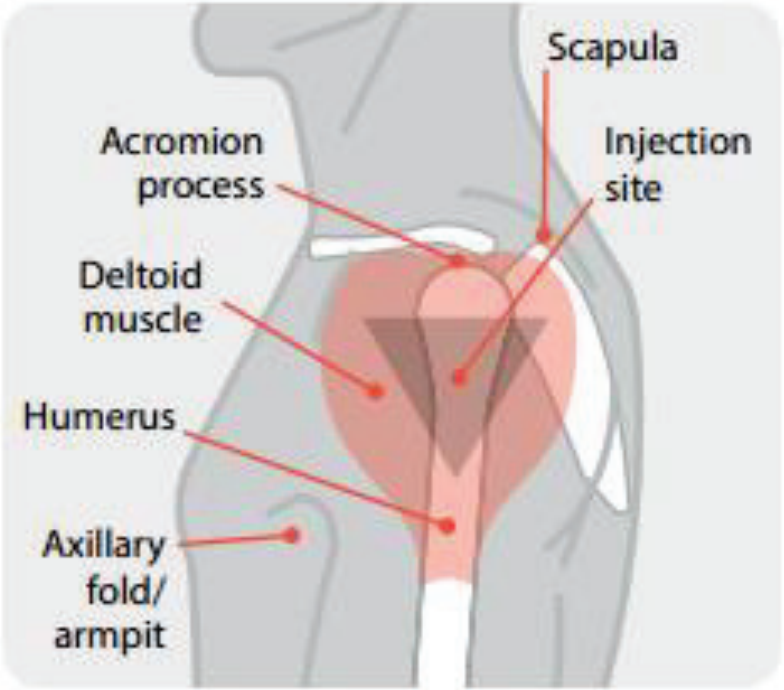
		Do **NOT freeze**
		Use within **4 hours**

https://www.fda.gov/media/168889/download

Administration

- Route: Intramuscular injection
- Site: Deltoid muscle in the upper arm
  - Alternate: Vastus lateralis muscle of anterolateral thigh



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Nirsevimab Recommendations

Nirsevimab Recommendations

- Infants **younger than age 8 months** born during or entering their **first RSV season** are recommended to receive 1 dose, if:
  - The mother did not receive RSV vaccine during pregnancy.
  - The mother's RSV vaccination status is unknown.
  - The infant was born within 14 days of maternal RSV vaccination.
- Children **ages 8–19 months** who are at **increased risk** of severe RSV disease and entering their **second RSV season** are recommended to receive 1 dose.
- Age ranges represent the infant's or child's age **at the time of immunization**.

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Nirsevimab Timing

Infants at birth

First RSV Season

- Immunize if **born October–March***
- Immunize **within 1 week** of birth
  - Administration can occur during the birth hospitalization or in the outpatient setting.
- Immunize infants with prolonged birth hospitalizations due to **prematurity** or other causes **shortly before or promptly after discharge**

*Because the timing of the onset, peak, and decline of RSV activity might vary geographically, providers can adjust administration schedules based on local epidemiology. Refer to local guidance, when applicable.

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Nirsevimab Timing

All other infants younger than age 8 months

First RSV Season

- Ideally immunize shortly before the start of RSV season
- Administer if:
  - Age of infant is **younger than 8 months** at the **time of immunization**
  - Day of immunization is during **October through March***
  - Infant has **not yet received a dose** of nirsevimab

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Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Nirsevimab Timing

At-risk children ages 8–19 months

Second RSV Season

- Ideally immunize **early**; shortly before the start of RSV season
- Administer if:
  - Age is **8–19 months** at the time of immunization
  - Day of immunization is during **October through March***
  - Infant has **not received 2 total doses** of nirsevimab
  - Infant has **not received 1 dose this season**

*Because the timing of the onset, peak, and decline of RSV activity might vary geographically, providers can adjust administration schedules based on local epidemiology. Refer to local guidance, when applicable.

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Children Ages 8–19 Months at Increased Risk

Children with chronic lung disease of prematurity who required medical support 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 manifestations of severe lung disease or weight-for-length <10th percentile

American Indian and Alaska Native children

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Nirsevimab Timing:

<u>Fall/October</u>:
Administer RSV immunization starting in October

Continue to offer nirsevimab through <u>March</u> to eligible infants and children.

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Nirsevimab Timing

<u>Local guidance</u>:

Administration schedules can be adjusted based on local epidemiology.

Nirsevimab **can be given outside of October through March**, when appropriate.

Follow local guidance, when provided.

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Nirsevimab Timing

<u>Local guidance</u>:

Areas with seasonality that differs from most of the continental United States may include, but are not limited to:

Florida, Hawaii, Guam, Puerto Rico, U.S. Virgin Islands, U.S.-affiliated Pacific Islands, and Alaska.

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Coadministration

Nirsevimab can
be administered with other recommended immunizations

Storage and Handling of Nirsevimab

- Store **refrigerated** between 2°C and 8°C (36°F and 46°F).
- Use within **8 hours** of removing from refrigerator.
  - May store at room temperature [between 20°C and 25°C (68°F and 77°F)] for a maximum of 8 hours.
- Do **NOT freeze**.
- Do **NOT shake**.
- Protect from **light**.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

Preparation

- Supplied as a:
  - **0.5 mL (50 mg)** prefilled syringe with **purple plunger rod**
  - **1 mL (100 mg)** prefilled syringe with **light blue plunger rod**
- Do **NOT** use if liquid is cloudy, discolored, or contains large particles.
- Do **NOT** use if prefilled syringe has been dropped, damaged, or security seal on carton has been broken.
- Follow the preparation instructions indicated in the package insert.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

Dosage

RSV Season	Body Weight the Day of Immunization	Number of Injections	Recommended Total Dosage
First	Less than 5 kg	One 50 mg prefilled syringe	0.5 mL (50 mg)
First	5 kg and greater	One 100 mg prefilled syringe	1 mL (100 mg)
Second	N/A	Two 100 mg prefilled syringes	2 mL (200 mg total)

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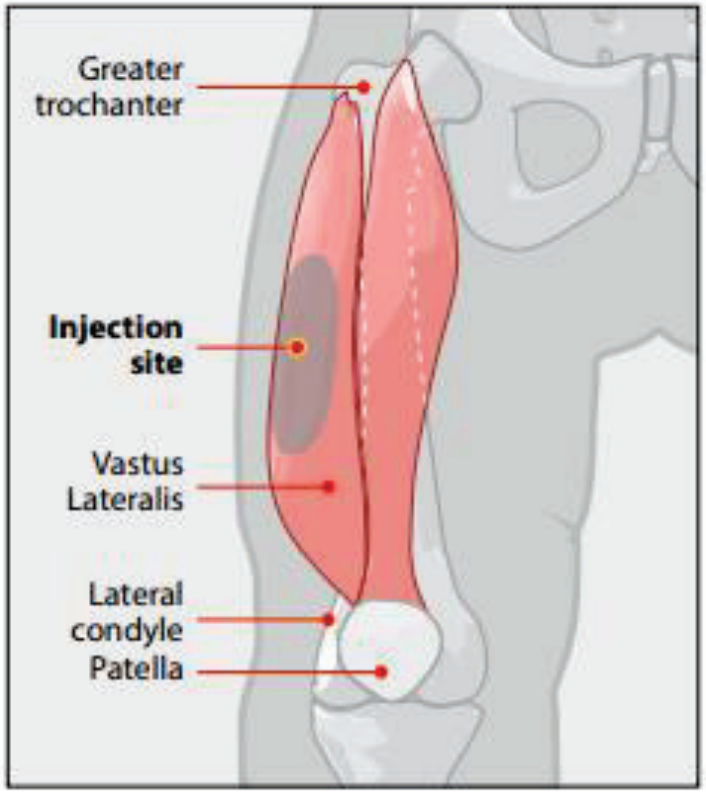
Administration

- Route: **Intramuscular** injection
- Site: Vastus lateralis muscle of **anterolateral thigh**



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Considerations for Maternal Vaccine or Nirsevimab

Maternal RSV Vaccine and Nirsevimab Recommendations

- Either maternal vaccination or use of nirsevimab in the infant is recommended to prevent RSV lower respiratory tract infection, but administration of both products is not needed for most infants.
- Healthcare providers of pregnant people should provide information on both products and consider patient preferences when determining whether to vaccinate the pregnant patient or to not vaccinate and rely on administration of nirsevimab to the infant after birth.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Relative Risks and Benefits of Maternal Vaccination and Nirsevimab

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

Maternal Vaccine
Advantages • Provides protection immediately after birth • May be more resistant to virus mutation • Avoids injection of infant
Disadvantages • Protection reduced if fewer antibodies produced or are transferred from mother to baby (e.g., mother immunocompromised or infant born soon after vaccination) • Potential risk of preterm birth and hypertensive disorders of pregnancy

Nirsevimab
Advantages • 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
Disadvantages • Injection for infant

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Adult RSV vaccination recommendations

In June 2023, ACIP and CDC recommended the first two RSV vaccines for older adults.

- RSVPreF3 (**Arexvy, GSK**) is a 1-dose adjuvanted ($AS01_E$) recombinant prefusion F protein (preF) vaccine.

- RSVpreF (**Abrysvo, Pfizer**) is a 1-dose recombinant preF vaccine.*

*The same vaccine formulation is FDA-approved and CDC-recommended for vaccination of pregnant persons for RSV prevention in infants.
https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

RSV Vaccination Recommendations

- ACIP and CDC recommend that adults ages 60 years and older may receive a **single dose** of RSV vaccine using **shared clinical decision making**.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

Shared clinical decision-making

- There is no **default decision** to vaccinate.
- Recommendations are **individually based** and informed by a decision process between the **health care provider and patient**.


Best available evidence


Patients' risk for disease, characteristics, values, preferences


Clinical discretion


Characteristics of the vaccine

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

Chronic Underlying Medical Conditions Associated with Increased Risk of Severe RSV Disease

- Lung disease
- Cardiovascular disease
- Moderate or severe immune compromise
- Diabetes Mellitus
- Neurologic or neuromuscular conditions
- Kidney disorders
- Liver disorders
- Hematologic disorders
- Other conditions that might increase the risk for severe disease

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

Other Factors Associated with Increased Risk of Severe RSV Disease

- Residence in a nursing home or other long-term care facility (LTCF)
- Frailty
- Advanced age

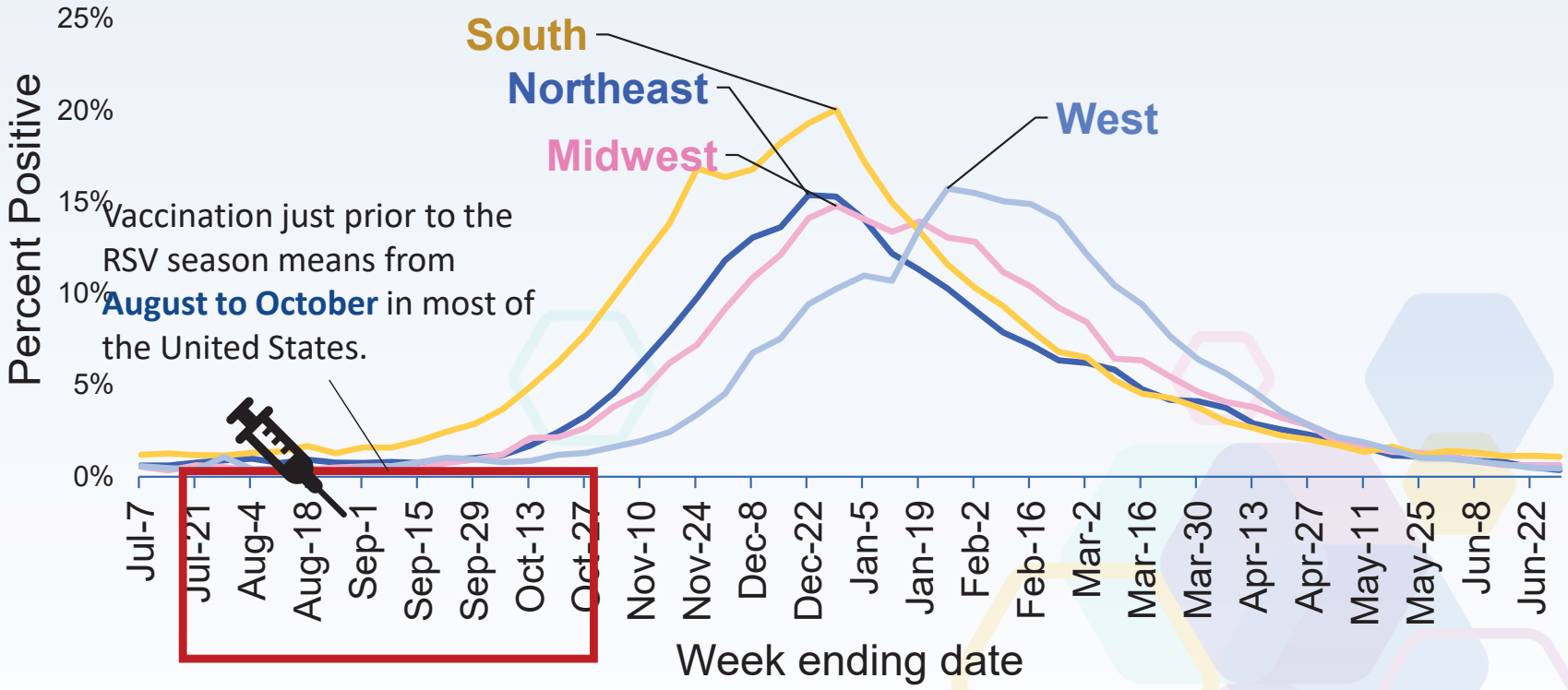
https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

CDC now recommends that providers and patients consider timing of RSV vaccination as part of shared clinical decision-making discussions.

In most of the United States, RSV vaccination will have the most benefit if given in late summer or early fall.

- For adults ages 60 years and older who remain unvaccinated and who decide with their healthcare provider to get RSV vaccination, the **best time for vaccination is just before the start of the next RSV season** to maximize the benefits of the vaccine.
- **NOT** a transition to a formal seasonal recommendation for RSV vaccination.
  - Older adults **may continue to receive RSV vaccination year-round,** using shared clinical decision-making.
  - Intent is to allow providers and patients maximum flexibility. Patients with infrequent healthcare contact may benefit from every opportunity to vaccinate.
- **NOT** a recommendation for annual re-vaccination.
  - RSV vaccine for adults 60 and older is currently still recommended as a **one-time** vaccine.

Mean weekly RSV percent positivity of PCR results by census region, NREVSS*, 2015–2019



*Data from Florida, Hawaii, and Alaska are excluded.
All results presented from nucleic acid amplification tests which represent >90% of the diagnostic tests reported to NREVSS.
NREVSS is an abbreviation for the National Respiratory and Enteric Virus Surveillance System.
For more information on NREVSS, please visit www.cdc.gov/surveillance/nrevss.
RSV: Respiratory Syncytial Virus. Types A and B are reported but not shown separately in this report.
Results are crude, and therefore may differ from smoothed results reported online.

Additional policy issues Adult RSV Work Group plans to address in June 2024

1. Potential FDA approval of Moderna mRNA-1345 vaccine for use in adults aged ≥60 years
2. Potential FDA approval of GSK RSV vaccine for use in adults aged 50–59 years "at increased risk for RSV disease" (*regulatory decision expected June 2024*)
3. Consideration of whether shared clinical decision-making remains the preferred policy option.

Closing Slide / Disclaimer

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.