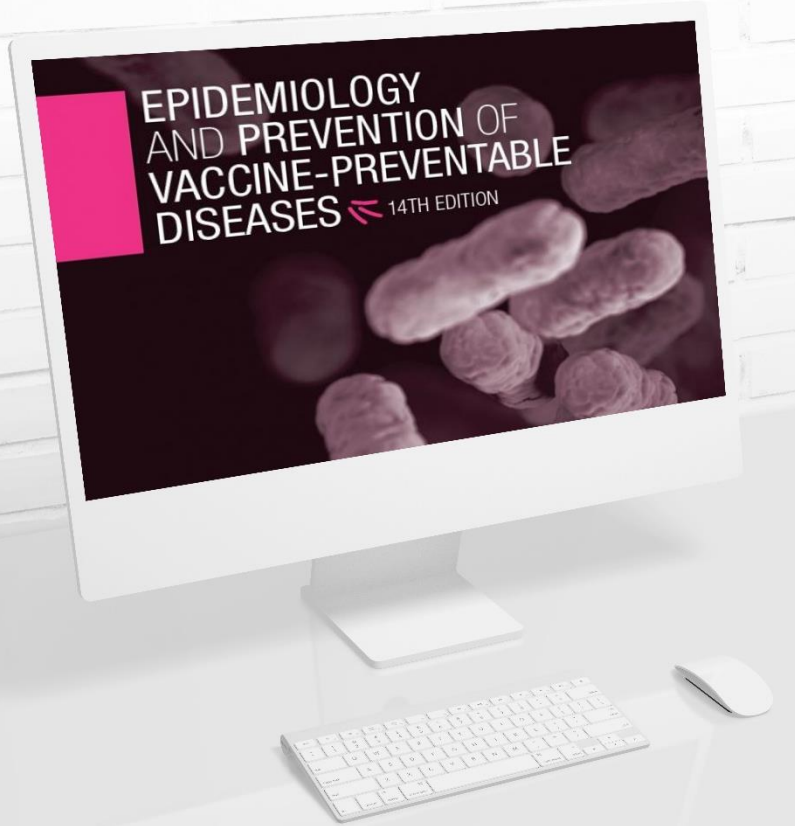
National Center for Immunization and Respiratory Diseases

Respiratory Syncytial Virus (RSV) Immunization Products



Pink Book Web-on-Demand Series

Learning Objectives

- Describe the fundamental principles of the immune response.
- Describe immunization best practices.
- Describe an emerging immunization issue.
- For each vaccine-preventable disease, identify those for whom routine immunization is recommended.
- For each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

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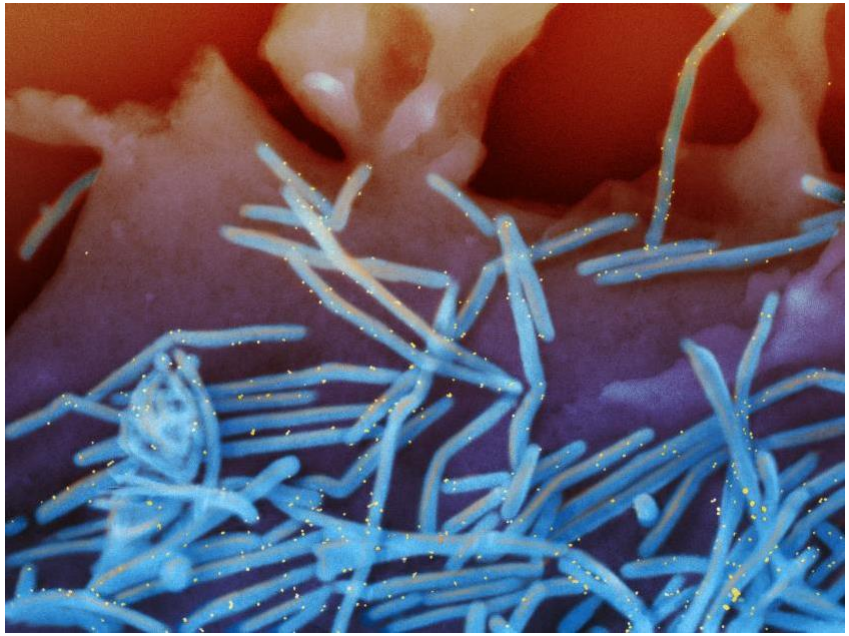
Disclosure Statements

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

1

RSV Disease

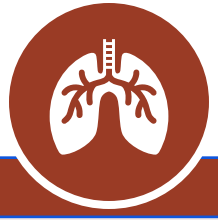
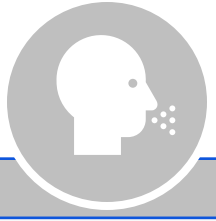
Respiratory Syncytial Virus (RSV)



- Name derived from syncytia that form when infected cells fuse
- RNA pneumovirus
- Two major subtypes:
  - A
  - B

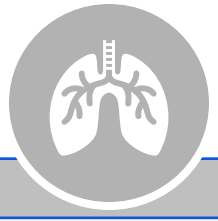
Diseases & Conditions | NIAID: National Institute of Allergy and Infectious Diseases (nih.gov)

Respiratory Syncytial Virus (RSV)

			
Common respiratory virus	Spreads through respiratory droplets, direct contact, fomites	Most infected people are contagious for 3 to 8 days, starting 1 to 2 days before symptom onset	Seasonal epidemics, typically fall to spring

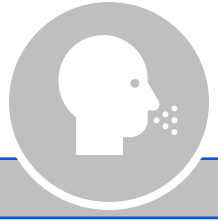
About RSV | RSV | CDC

RSV Transmission



Common respiratory virus

Spreads through respiratory droplets, direct contact, fomites

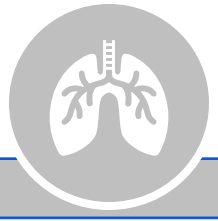


Most infected people are contagious for 3 to 8 days, starting 1 to 2 days before symptom onset

Seasonal epidemics, typically fall to spring

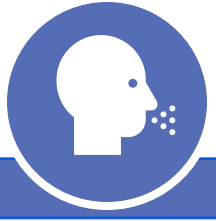
How RSV Spreads | RSV | CDC

RSV Communicability



Common respiratory virus

Spreads through respiratory droplets, direct contact, fomites

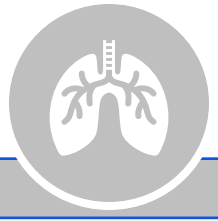


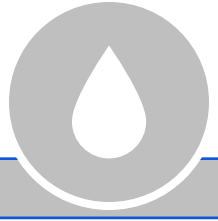
Most infected people are contagious for 3 to 8 days, starting 1 to 2 days before symptom onset

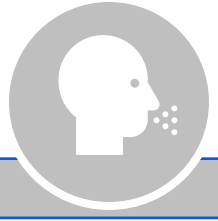
Seasonal epidemics, typically fall to spring

How RSV Spreads | RSV | CDC

RSV Temporal Pattern





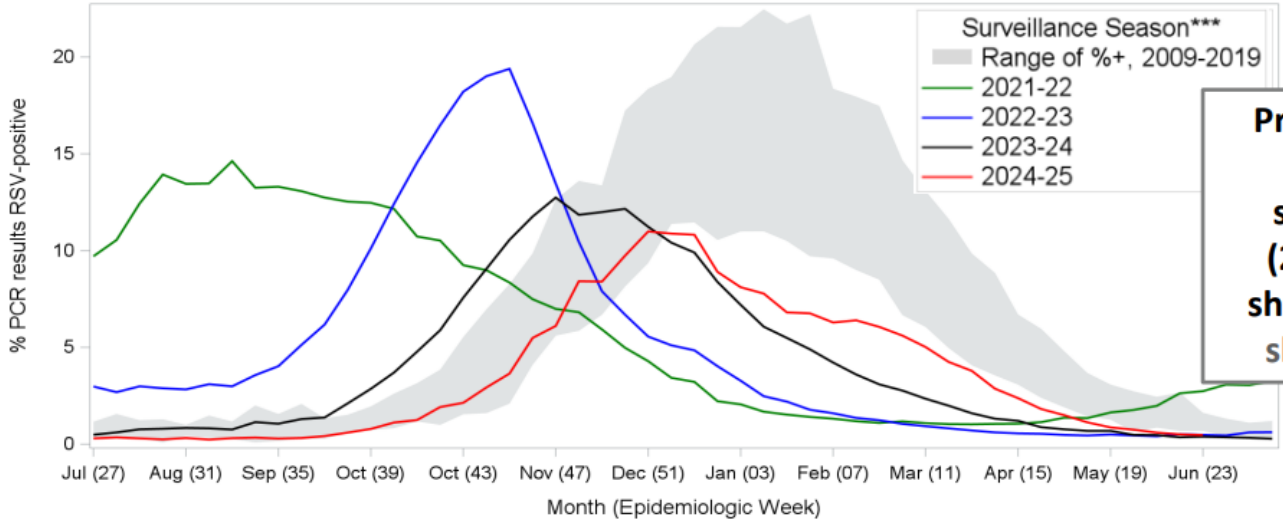


Common respiratory virus	Spreads through respiratory droplets, direct contact, fomites	Most infected people are contagious for 3 to 8 days, starting 1 to 2 days before symptom onset	Seasonal epidemics, typically fall to spring

How RSV Spreads | RSV | CDC

RSV Seasonality in the United States

Percentage* of polymerase chain reaction (PCR) test results positive for respiratory syncytial virus (RSV), by epidemiologic week — National Respiratory and Enteric Virus Surveillance System, United States, July 2009–June 2025**



Pre-COVID-19 pandemic seasonality (2009-2019) shown by grey shaded area

Notes: Report was last updated on 6/17/2025.

*All results presented are from polymerase chain reaction (PCR) tests, which represent >90% of the diagnostic tests reported to NREVSS. The last three weeks of data in 2024-25 may be less complete. NREVSS is an abbreviation for the National Respiratory
and Enteric Virus Surveillance System. For more information on NREVSS, please visit National Respiratory and Enteric Virus Surveillance System | CDC.

**Respiratory syncytial virus types A and B are not shown separately in this report.

***The NREVSS surveillance season runs from the first week in July through June of the following year

Respiratory Syncytial Virus Laboratory Data (NREVSS) | CDC; Interactive Dashboard | NREVSS | CDC. Adapted from: EtR: Clesrovimab

RSV Clinical Features in *Infants and Children*

- **Most infants with RSV infection are symptomatic.**
- **Early symptoms can include rhinorrhea (runny nose), nasal congestion, cough, and decreased appetite.**
- **Fever can occur early in illness.**
- **Very young infants can experience irritability, decreased activity, and apnea (pauses in breathing for more than 10 seconds).**

Clinical Overview of RSV | RSV | CDC, RSV in Infants and Young Children | RSV | CDC; Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases | RSV

Severe RSV Disease in *Infants and Children*

- **RSV disease can become severe a few days into illness.**
- **Lower respiratory tract infection:**
  - Bronchiolitis (inflammation of small airways in lung)
  - Pneumonia (infection and inflammation of the alveoli)
- **Can lead to hospitalization requiring supplemental oxygen, enteral or intravenous fluids, and mechanical ventilation.**
- **2–3% of young infants are hospitalized for RSV**
  - Highest rates in the first months of life; risk declines with increasing age
  - Majority of children aged <2 years had no underlying medical conditions

Clinical Overview of RSV | RSV | CDC, RSV in Infants and Young Children | RSV | CDC, Hall et al. Pediatrics. 2013, Langley & Anderson. PIDJ. 2011, CDC NVSN data

Annual RSV Burden Among U.S. *Infants and Children*

Among children younger than 5 years of age, before maternal RSV vaccine or infant RSV antibody recommendations:

~2,000,000

medical encounters

58,000–80,000

hospitalizations

Leading cause of infant hospitalizations

100–300 deaths

Hall et al, NEJM (2009): https://doi.org/10.1056/NEJMoa0804877; McLaughlin et al, J Infect Dis (2022): https://doi.org/10.1093/infdis/jiaa752; CDC RSV-NET, unpublished data; Thompson et al, JAMA (2003): https://doi.org/10.1001/jama.289.2.179; Matias et al, Influenza Other Respi Viruses (2014): https://doi.org/10.1111/irv.12258 Hansen et al, JAMA Network Open (2022): https://doi.org/10.1001/jamanetworkopen.2022.0527; Adapted from: Evidence to Recommendation Framework: Clesrovimab

Risk Factors for Severe RSV Disease in *Infants and Children*

- **Infants and young children (the younger the age, the higher the risk)**
- **Premature infants**
- **American Indian and Alaska Native children**
- **Children with:**
  - Chronic lung disease
  - Congenital (present from birth) heart disease
  - Weakened immune systems
  - Severe cystic fibrosis
  - Neuromuscular disorders, especially those with difficulty swallowing or clearing mucus secretions

RSV in Infants and Young Children | RSV | CDC, Clinical Overview of RSV | RSV | CDC

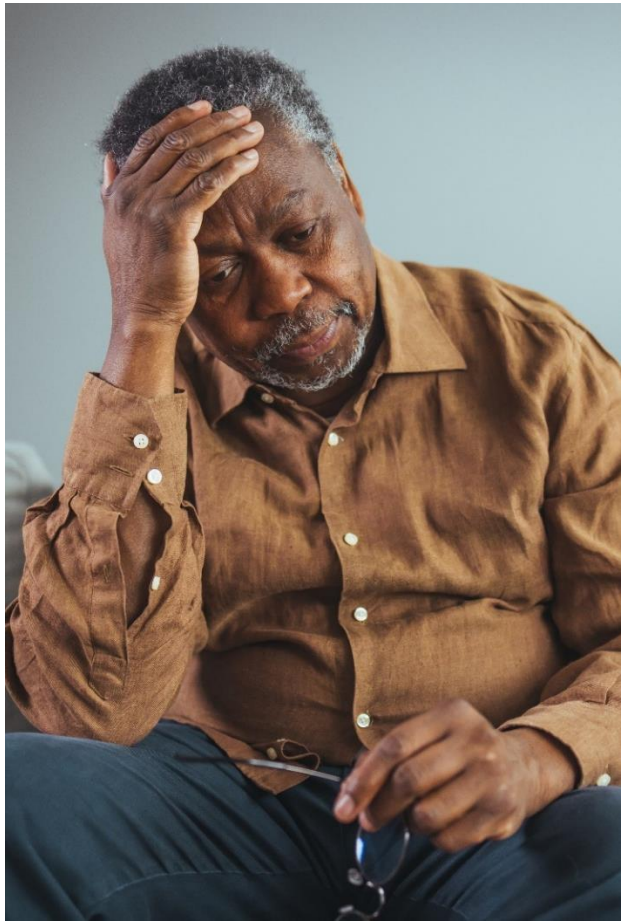
RSV Clinical Features in *Adults*

- **In adults, RSV usually causes mild symptoms but can also cause more severe disease.**
- **Symptoms usually consistent with an upper respiratory tract infection:**
  - Rhinorrhea, pharyngitis (sore throat), cough, headache, fatigue, fever
- **Milder illness will resolve in 1 to 2 weeks.**
- **Adults with certain risk factors are at higher risk of developing severe RSV disease.**

Clinical Overview of RSV | RSV | CDC, RSV in Adults | RSV | CDC

RSV Complications in *Adults*

- **In older adults and adults with certain medical conditions, RSV can lead to hospitalization due to:**
  - Lower respiratory tract RSV disease (e.g., pneumonia)
  - Exacerbation of medical conditions including asthma, chronic obstructive pulmonary disease (COPD), heart failure
- **Among unvaccinated adults, disease severity is similar to COVID-19 and influenza.**
- **Often require follow-up care and skilled nursing after hospital discharge.**



Clinical Overview of RSV | RSV | CDC, RSV in Adults | RSV | CDC, Surie et al. JAMA 2024. , Walsh et al. Health Sci Rep. 2022

Annual RSV Burden Among *Adults Ages 50 Years and Older* in the United States

~2,400,000
outpatient visits

~1,800,000
emergency department visits

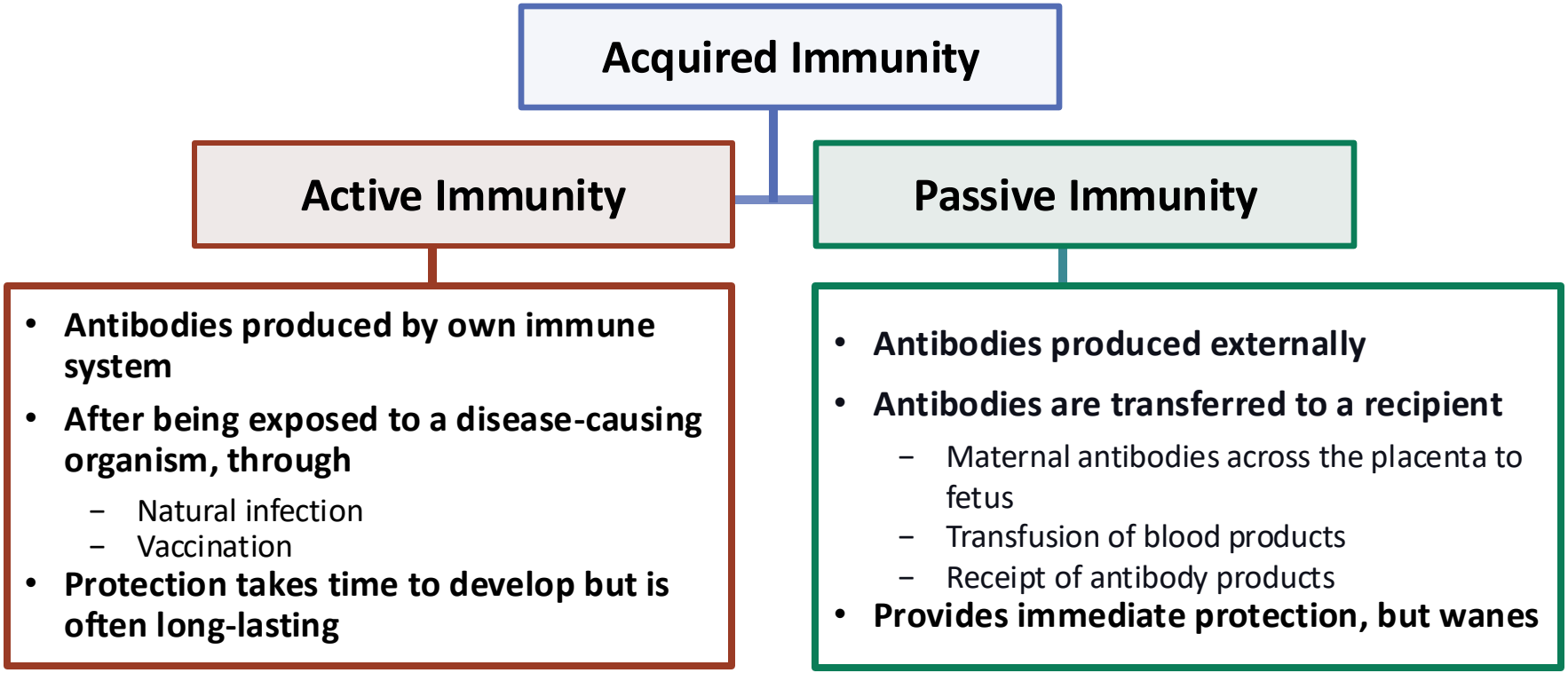
~200,000
hospitalizations

Rates of Medically Attended RSV Among US Adults: A Systematic Review and Meta-analysis | Open Forum Infectious Diseases | Oxford Academic. For up-to-date rates, please see: Surveillance of RSV | RSV | CDC

2

Immunization Products for Prevention of Severe RSV Disease in Infants

Active and Passive Immunity



Chapter 1: Principles of Vaccination | Pink Book | CDC

Choose One Product to Prevent Severe RSV Disease in Infants

Maternal RSV vaccination
- Pfizer Abrysvo

- or -

Infant RSV antibody
- Nirsevimab
- Clesrovimab

Most infants will *not* need both maternal vaccination and an RSV antibody.

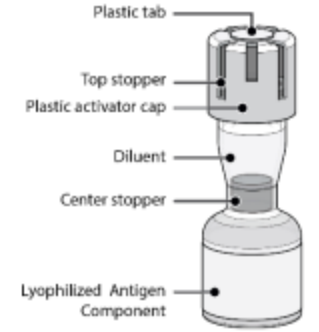
Maternal RSV Vaccination: Pfizer Abrysvo

- **Pfizer's bivalent RSV prefusion (RSVpreF) vaccine**
  - Protein subunit vaccine
- **Requires reconstitution**
- **Single dose, 0.5mL**
- **Antibodies are transferred transplacentally to fetus**
  - At least 14 days are needed for development and transplacental transfer of maternal antibodies
  - Protects infants from birth through 6 months of age from lower respiratory tract disease (LRTD) and severe LRTD

Pfizer Abrysvo Package Insert (fda.gov), RSV Vaccine Guidance for Pregnant Women | RSV | CDC, Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR

Pfizer Abrysvo Requires Reconstitution

- Each **Act-O-Vial** contains lyophilized antigen powder (a sterile white powder) and sterile water diluent.



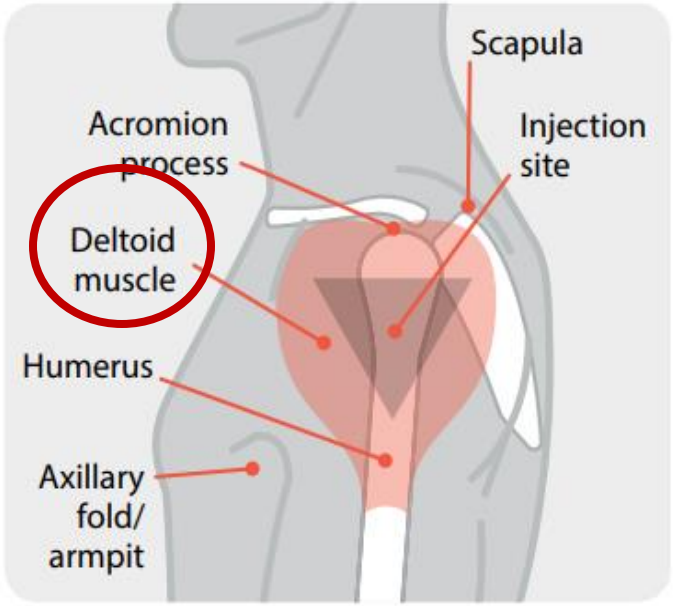
Act-O-Vial presentation

- Each **vial and prefilled syringe kit** includes a vial of lyophilized antigen powder, a prefilled syringe containing sterile water diluent, and a vial adapter.

Refer to the vaccine package insert for specific preparation details.

Pfizer Abrysvo Package Insert (fda.gov)

Pfizer Abrysvo Administration



- **Route**
  - Intramuscular injection
- **Site**
  - Deltoid region of the upper arm
  - Alternate: Vastus lateralis muscle of anterolateral thigh
- **Coadministration**
  - Simultaneous administration with other recommended vaccinations is appropriate.

Vaccine Administration: Intramuscular (IM) injections: Adults 19 years of age and older

Pfizer Abrysvo Efficacy During Clinical Trials

- **Maternal RSV vaccine at 32 to 36 weeks of gestation reduced the infant's risk of developing RSV lower respiratory tract disease (LRTD) associated with:**

	Having Health Care Visit	Hospitalization	Severe RSV
Within 3 months after birth	57%	68%	82%
Within 6 months after birth	51%	57%	69%

Pfizer Abrysvo Package Insert (fda.gov); RSV Vaccine Guidance for Pregnant Women | RSV | CDC

Infant RSV Antibody – Nirsevimab

- **Long-acting monoclonal antibody manufactured by AstraZeneca, distributed by Sanofi**
  - Passive immunization; not a vaccine
  - Beyfortus is trade name
- **Approved for prevention of RSV LRTD:**
  - In infants during or entering their first RSV season
  - During second RSV season, infants and young children at high risk for severe RSV disease
- **50 mg/0.5 mL and 100 mg/1.0 mL**

Beyfortus Prescribing Information (fda.gov)

Nirsevimab Dosage

RSV Season	Age	Body Weight the Day of Immunization	Number of Injections	Recommended Total Dosage
1st Season	Birth through 7 months	Less than 5 kg (11 lb)	**One 50 mg** prefilled syringe - **purple plunger rod**	0.5 mL (50 mg)
1st Season	Birth through 7 months	5 kg (11 lb) and greater	**One 100 mg** prefilled syringe - **light blue plunger rod**	1 mL (100 mg)
2nd Season	8 through 19 months	N/A	**Two 100 mg** prefilled syringes - **light blue plunger rod**	2 mL (200 mg total)

Beyfortus Prescribing Information (fda.gov)

Infant RSV Antibody – Clesrovimab

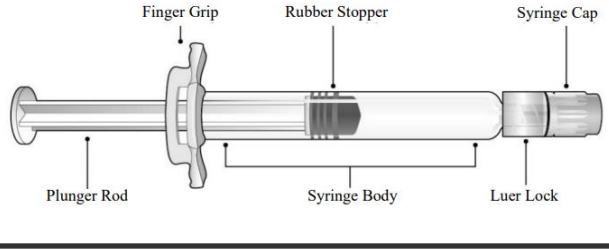
- **Long-acting monoclonal antibody manufactured by Merck**
  - Passive immunization; not a vaccine
  - Enflonsia is trade name
- **Approved for prevention of RSV LRTD in infants during or entering their first RSV season.**
- **Single dose, manufacturer-filled syringe**
  - 105 mg/0.7 mL
  - Same dose for all infants regardless of weight

Enflonsia (clesrovimab) Prescribing Information

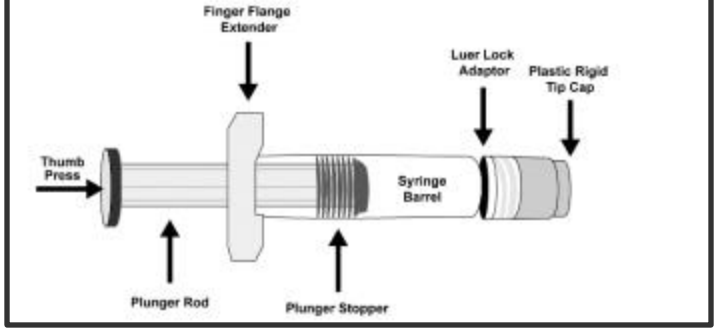
Infant RSV Antibody Preparation

- **Use the same best practices as with vaccines, including:**
  - Follow routine infection control procedures
  - Prepare medications for one patient at a time
  - Always triple-check the expiration date, correct product, and correct dose
  - Unscrew the syringe cap and attach a Luer lock needle to the syringe.

Nirsevimab

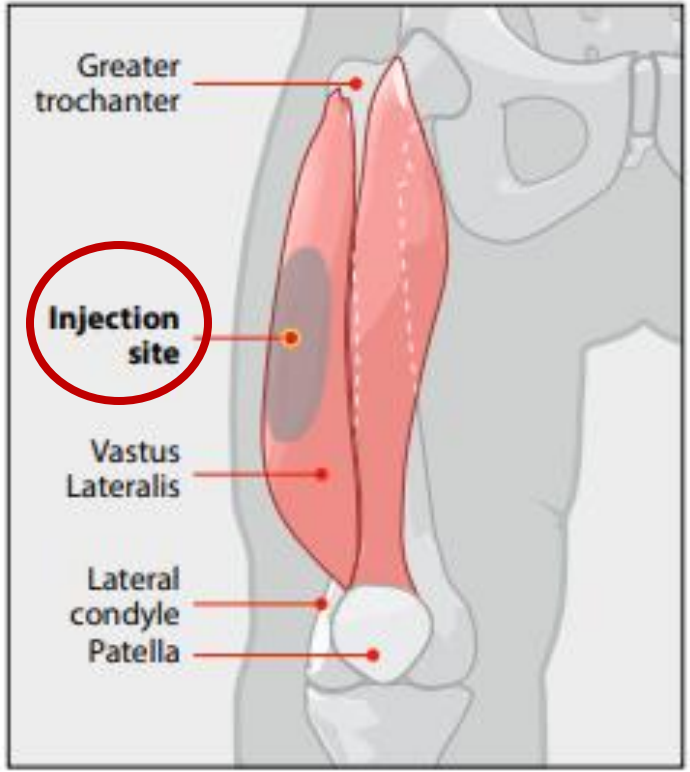


Clesrovimab



Beyfortus Prescribing Information (fda.gov), Enflonsia (clesrovimab) Prescribing Information

Infant RSV Antibody Administration

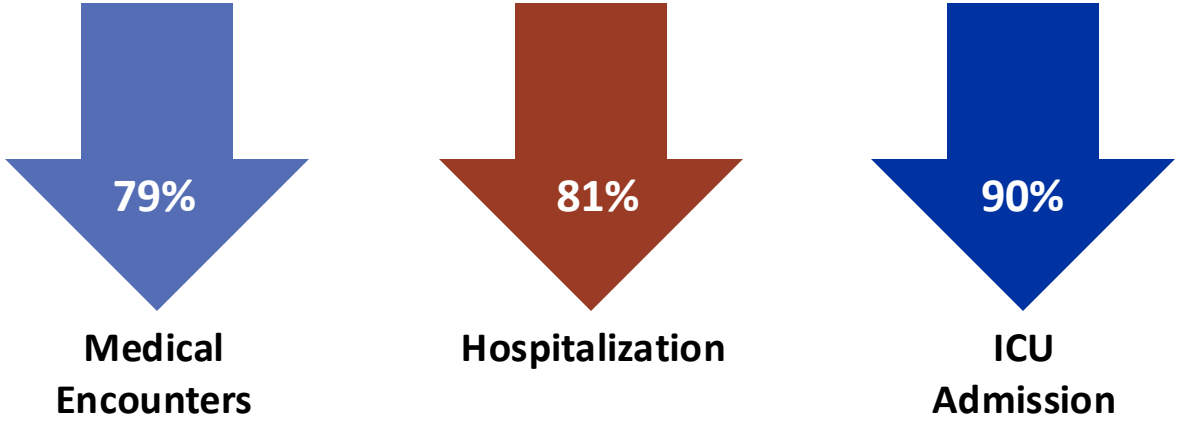


- **Route**
  - Intramuscular injection
- **Site**
  - Vastus lateralis muscle of anterolateral thigh
  - The gluteal muscle should **not** be used.
- **Coadministration**
  - Simultaneous administration with vaccines is acceptable.

Beyfortus Prescribing Information (fda.gov), Enflonsia (clesrovimab) Prescribing Information

Nirsevimab Efficacy During Clinical Trials

- **Nirsevimab reduced the risk of negative outcomes related to RSV-associated LRTI when given to infants younger than 8 months of age.**
- **Through the 5 months after their receipt of nirsevimab, infants born during or entering their first RSV season experienced:**

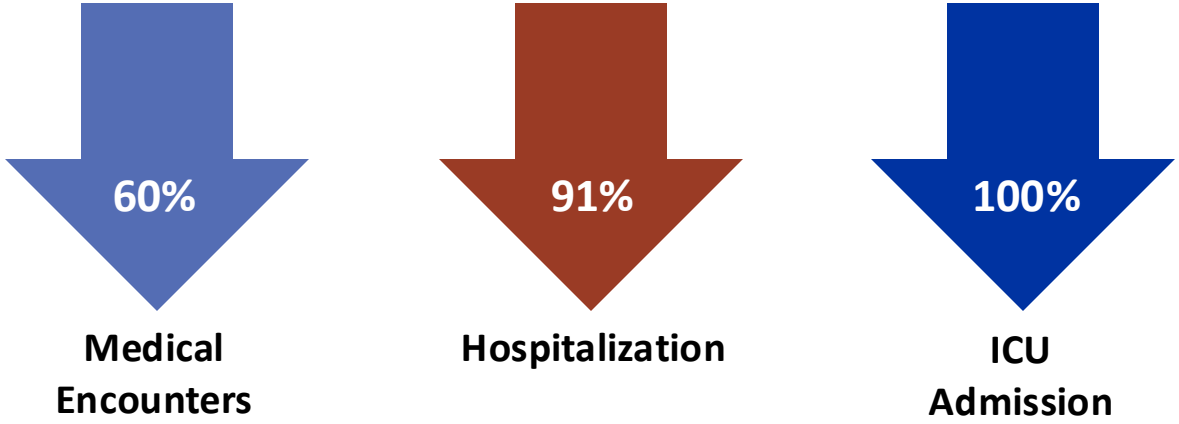


LRTI = Lower respiratory tract infection

Healthcare Providers: RSV Immunization for Infants and Young Children | 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 Prescribing Information (fda.gov)

Clesrovimab Efficacy During Clinical Trials

- **Clesrovimab reduced the risk of negative outcomes related to RSV-associated LRTI when given to infants younger than 8 months of age.**
- **Through the 5 months after their receipt of clesrovimab, infants born during or entering their first RSV season experienced:**



LRTI = Lower respiratory tract infection

Enflonsia (clesrovimab) Prescribing Information, Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR

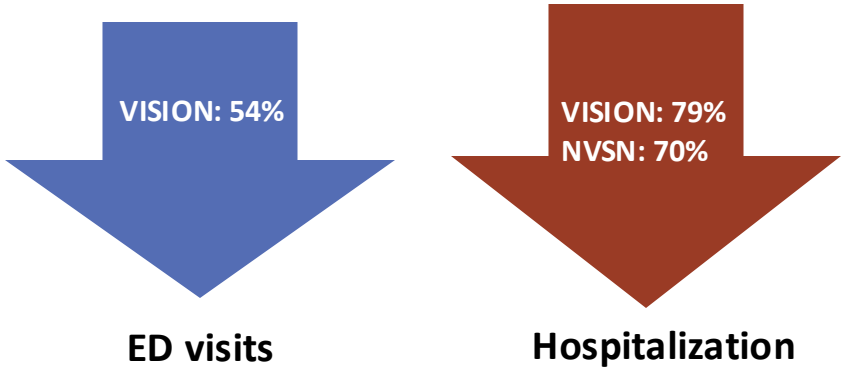
Real-World Effectiveness During 2024–25 RSV Season in the U.S.: Nirsevimab

- **Effective against RSV-associated ED encounters, hospitalization, and ICU admission among infants in their first RSV season.**

US Pediatric RSV Surveillance and Effectiveness and impact of RSV prevention products (ACIP, June 25, 2025);
NVSN: New Vaccine Safety Network; VISION: Virtual SARS-CoV-2, Influenza, and Other respiratory viruses Network; Overcoming: Overcoming Network

Real-World Effectiveness During 2024–25 RSV Season in the U.S.: Maternal RSV Vaccine

- **Effective against infant RSV-associated ED encounters and hospitalization.**



US Pediatric RSV Surveillance and Effectiveness and impact of RSV prevention products (ACIP, June 25, 2025);
NVSN: New Vaccine Safety Network; VISION: Virtual SARS-CoV-2, Influenza, and Other respiratory viruses Network

3

Immunization Recommendations for Prevention of Severe RSV Disease in Infants

Child and Adolescent Immunization Schedule: Pfizer Abrysvo During Pregnancy *to Protect the Infant*

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Respiratory syncytial virus vaccine (RSV [Abrysvo])														Seasonal administration during pregnancy, See Notes			

Range of recommended ages for certain high-risk groups

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger: 2025 U.S.

Adult Immunization Schedule: Pfizer Abrysvo During Pregnancy *to Protect the Infant*

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2025

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Respiratory syncytial virus (RSV)	Seasonal administration during pregnancy (See Notes)		60 through 74 years (See Notes)	≥75 years

Updated in June 2025
to 50 through 74 years

Recommended vaccination for adults with an additional risk factor or another indication

Recommended Adult Immunization Schedule for ages 19 years or older; 2025 U.S.

Maternal RSV Vaccination

- **Recommended during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants.**
  - One dose of the Pfizer Abrysvo vaccine
  - Recommended for use during September through January in most of the continental United States*

*In jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, tropical climates), providers should follow state, local, or territorial guidance on timing of maternal RSV vaccination. In addition, because the timing of RSV activity varies geographically, in other jurisdictions, public health authorities may provide revised guidance regarding the timing of RSV antibody administration based on local surveillance data and feasibility of implementation.

Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov), Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR

Pfizer Abrysvo Clinical Considerations

- **Maternal RSV vaccination is a one-time dose.**
  - There currently is no ACIP recommendation for RSV vaccination in subsequent pregnancies.
  - Infants born to mothers who received RSV vaccine during a previous pregnancy should receive RSV antibody after birth.
- **Maternal RSV vaccination is not recommended after 36 weeks and 6 days gestation.**
  - Infant should receive RSV antibody.

Pfizer Abrysvo Package Insert (fda.gov), RSV Vaccine Guidance for Pregnant Women | RSV | CDC

Rationale for Seasonal Administration

- **Infants born 1–2 months after their mother is vaccinated will have immediate protection against RSV.**
- **Protection provided by a maternal vaccine wanes over time.**

Infants born in months with low RSV transmission (e.g., April–September) are better protected by receiving RSV antibody just before or at the start of the RSV season.

RSV Vaccine Guidance for Pregnant Women | RSV | CDC

Child and Adolescent Immunization Schedule: RSV Antibody for Infants and Young Children

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Respiratory syncytial virus (RSV-mAb [Nirsevimab])	1 dose depending on maternal RSV vaccination status (See Notes)								1 dose (8 through 19 months), See Notes								

Clesrovimab also recommended starting in August 2025.

Range of recommended ages for all children

Range of recommended ages for certain high-risk groups

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger: 2025 U.S., ACIP Recommendations | ACIP | CDC

RSV Antibody Recommendations on Child and Adolescent Immunization Schedule Addendum

Child Immunization Schedule Addendum

Recommendations for Ages 18 Years or Younger, United States, 2025

Health Care Providers
AUG. 7, 2025

Addendum

In addition to the recommendations presented in the previous sections of this immunization schedule, CDC has approved the following ACIP recommendations since October 24, 2024.

Vaccines	Recommendations	Effective Date of Recommendation*
RSV monoclonal antibody (Clesrovimab)	ACIP recommends infants aged < 8 months born during or entering their first RSV season who are not protected by maternal vaccination receive one dose of clesrovimab.	August 4, 2025

Child Immunization Schedule Addendum | Vaccines & Immunizations | CDC

Recommendations for Use of RSV Antibody in Infants

- **One dose of clesrovimab *or* nirsevimab for infants younger than 8 months of age born during or entering their first RSV season (October–March in most of the continental U.S.) if:**
  - The mother did not receive RSV vaccine during the pregnancy
  - The mother's RSV vaccination status is unknown
  - The infant was born less than 14 days after maternal RSV vaccination

Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR

Timing of Infant RSV Antibody Administration

- **Recommended October through March in most of United States**
  - Optimal timing is shortly before the RSV season begins (i.e., October through November).
- **For infants born October through March**
  - Administer in the first week of life—ideally during the birth hospitalization.
  - Infants with prolonged birth hospitalizations due to prematurity or other causes should be immunized shortly before or promptly after discharge.
- **If not given in the hospital, administer in outpatient settings.**
  - For example, during newborn, 2-, 4-, or 6-month well-child visits, or other outpatient visits

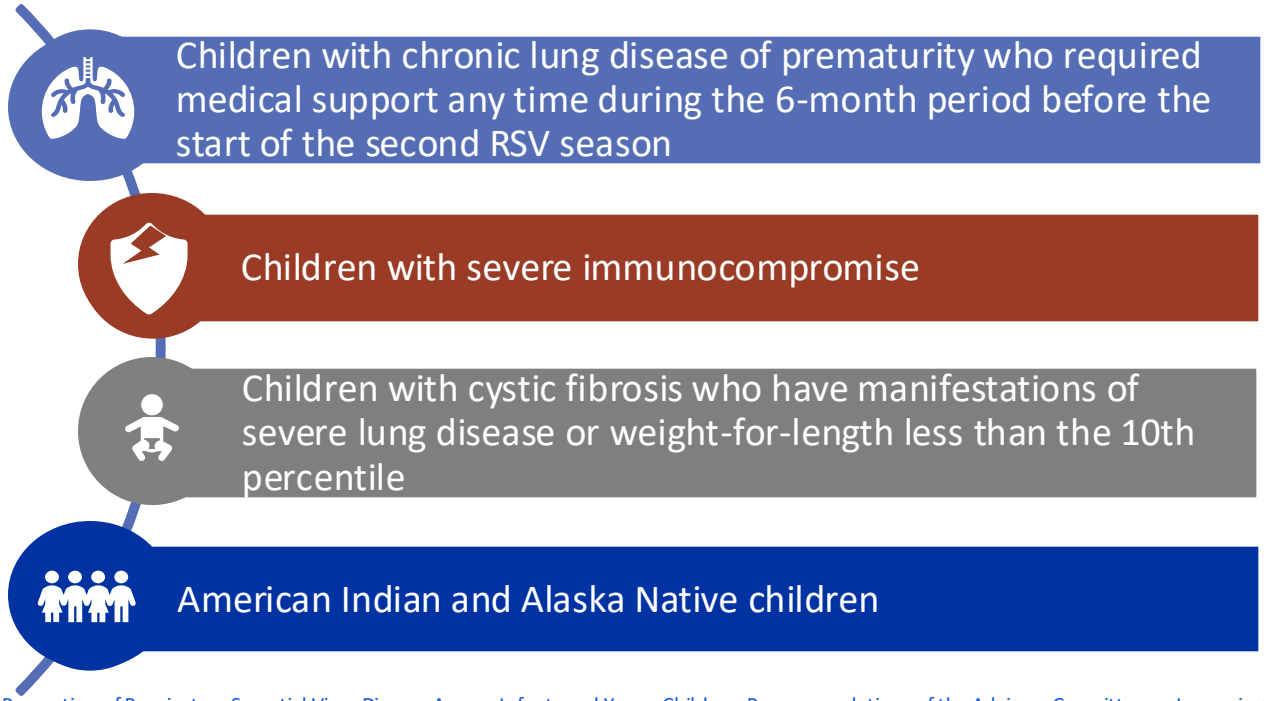
Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR; Beyfortus Prescribing Information (fda.gov), Enflonsia (clesrovimab) Prescribing Information

Recommendations for Infants and Young Children at Increased Risk for Severe RSV Disease

- **One dose of nirsevimab recommended for children ages 8 through 19 months at increased risk of severe RSV disease and entering their second RSV season**
  - *Only nirsevimab* is recommended for this age group and in the second RSV season.
  - Regardless of maternal RSV vaccination status *or* infant's receipt of RSV antibody during first RSV season
  - Could have received clesrovimab or nirsesvimab for first RSV season

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, Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR

Children Ages 8 Through 19 Months at *Increased Risk* for Severe RSV Disease



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

Knowledge Check

If the mother did *not* receive the Pfizer Abrysvo vaccine during 32 through 36 weeks gestation, should the infant receive RSV antibody (clesrovimab or nirsevimab) before or during their first RSV season?

A. Yes

B. No

Knowledge Check

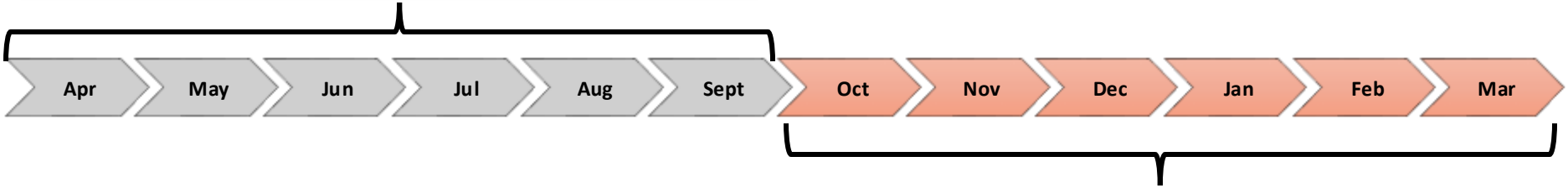
If the mother did *not* receive the Pfizer Abrysvo vaccine during 32 through 36 weeks gestation, should the infant receive RSV antibody (clesrovimab or nirsevimab) before or during their first RSV season?

A. Yes 

B. No

Infant RSV Antibody Timing by Birth Month: First RSV Season in Most of Continental U.S.

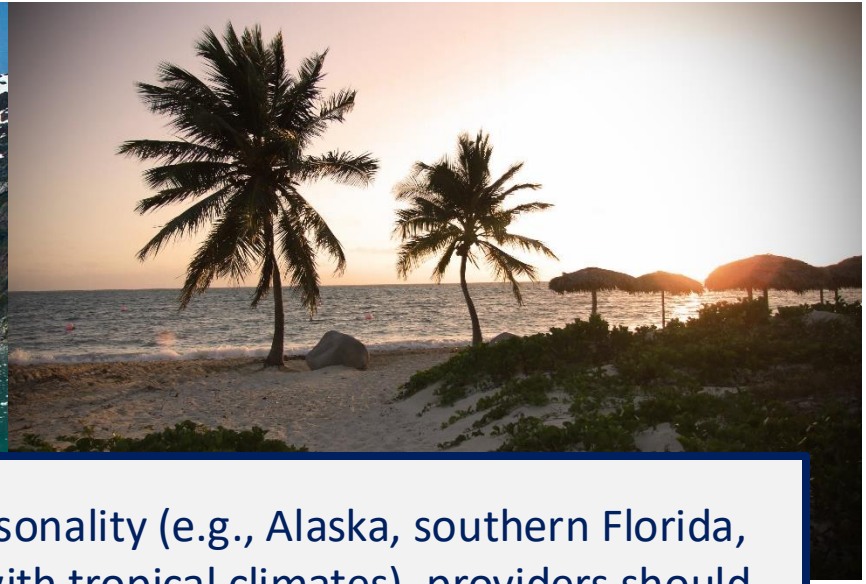
Infants born April through September are recommended to receive RSV antibody shortly before the RSV season begins (e.g., October or November).



Infants born October through March are recommended to receive RSV antibody within one week of birth, ideally during birth hospitalization.

Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR, Immunizations to Protect Infants | RSV | CDC

RSV Seasonality Differs Based on Climate



In jurisdictions with differing RSV seasonality (e.g., Alaska, southern Florida, Puerto Rico, and other jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on the timing of administration.

Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR, RSV Immunization Guidance for Infants and Young Children | RSV | CDC

Considerations for Counseling Patients Regarding Maternal RSV Vaccine and Infant RSV Antibody

Maternal RSV vaccine 	Immediate protection for baby after birth No injection for the infant Potentially reduced protection in some situations (e.g., mother is immunocompromised or infant born soon after vaccination) Potential risk for hypertensive disorders of pregnancy
Infant RSV antibody 	Direct receipt of antibodies rather than relying on transplacental transfer Protection may wane more slowly than maternal RSV vaccine Side effects are usually mild and resolve quickly; hypersensitivity reactions are uncommon but have been reported Delayed administration could leave the infant unprotected[1]

[1] Infants born during October through March should be administered RSV antibody in the first week of life – ideally during the birth hospitalization.

Clinical considerations for maternal RSVPreF vaccine and nirsevimab - September 2023 ACIP meeting ; Evaluation of Preterm Birth and SGA at Birth - October 2024 ACIP meeting

Timing of RSV Immunizations for Infants and Pregnant Women

Infants born April through September are recommended to receive RSV antibody shortly before the RSV season begins (e.g., October or November).

Infant RSV antibody recommended.

- Infants born October through March should receive within one week of birth, ideally during birth hospitalization.
- Infants born April through September should receive in October or November.

September through January, RSV vaccine (Abrysvo) is recommended during weeks 32-36 of pregnancy.

Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR, Immunizations to Protect Infants | RSV | CDC

Flexibility in Timing of RSV Immunizations

- **Recommendations for the timing of administration are flexible to improve patient access.**
- **Because timing of RSV activity varies geographically, public health authorities may provide jurisdiction-specific guidance based on local RSV surveillance data and feasibility of implementation.**
- **Providers should consult with state or territorial health departments before modifying recommendations for infant RSV antibody or maternal RSV vaccine administration.**

RSV Immunization Guidance for Infants and Young Children | RSV | CDC, Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR

Considerations for Modifying Timing of RSV Immunizations (1)

Starting administration of maternal vaccine before September or infant RSV antibody before October:

Advantages	Disadvantages
Maternal RSV vaccine: Protection to infants born before October and for infants who might experience a delay in receipt of RSV antibody **Infant RSV antibody**: Can provide more time for infants to receive an RSV antibody before start of the RSV season Potentially useful for jurisdictions with early RSV seasonality	Protection decreases over time. - For example, infants who receive RSV antibody in September or born to a mother vaccinated in August could be less protected by the peak of the RSV season and toward the end of the RSV season.

Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR

Considerations for Modifying Timing of RSV Immunizations (2)

Administering maternal RSV vaccine after January or infant RSV antibody after March:

Advantages	Disadvantages
Either product could protect infants during their first months of life when they are at highest risk for severe disease.	The risk for RSV exposure and infection during the end of the RSV season might be low. **Maternal RSV vaccine**: If administered in February or March, infant born in April or May would not be recommended to receive RSV antibody in October **Infant RSV antibody**: If administered in April, would not be recommended to receive a dose in October Administering a dose of infant RSV antibody in October instead could provide protection for an entire RSV season.

Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR

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Safety: Immunization Products for Prevention of Severe RSV Disease in Infants

Maternal RSV Vaccine (Pfizer Abrysvo): Contraindications and Precautions

Contraindications
Severe allergic reaction (e.g., anaphylaxis) to a vaccine component
Refer to “Section 11 Description” in the product’s package insert to review vaccine components.

Precautions
Moderate or severe acute illness with or without fever

RSV Vaccine Guidance for Pregnant Women | RSV | CDC; Pfizer ABRYSVO Package Insert (fda.gov)

RSV Vaccine Safety During Pregnancy

- **Among Abrysvo clinical trial participants at 24–36 weeks' gestation:**
  - More cases of preterm birth and hypertensive disorders of pregnancy among Abrysvo recipients versus placebo, but differences not statistically significant.
- **FDA approved Abrysvo for use during 32–36 weeks' gestation to avoid the potential risk for preterm birth at less than 32 weeks' gestation.**
- **2023–2024 Respiratory Season VSD analysis found that maternal RSV vaccination during 32–36 weeks' gestation:**
  - Not associated with increased risk of preterm birth, SGA at birth, or stillbirth
  - Small increased risk for hypertensive disorders of pregnancy
- **CDC and FDA will continue to monitor safety data.**

Pfizer ABRYSVO Package Insert (fda.gov); RSV Vaccine Guidance for Pregnant Women | RSV | CDC; Evaluation of Preterm Birth and SGA at Birth - October 2024 ACIP meeting, Prenatal RSVpreF Vaccine Safety 2023-24 Respiratory Season The Vaccine Safety Datalink (VSD) - June 2025 ACIP Meeting

Infant RSV Antibody Product Contraindications and Precautions

Contraindications
History of serious hypersensitivity reactions, including anaphylaxis, to an RSV antibody product, or to any of the product's components
Refer to "Section 11 Description" in the product's package insert to review product components.

Precautions
Moderate or severe acute illness with or without fever

Beyfortus Prescribing Information (fda.gov), Enflonsia (clesrovimab) Prescribing Information
Special Situations | Vaccinating Persons with Increased Bleeding Risk | CDC

Infant RSV Antibody Product Safety

- **Most common adverse reactions were rash and injection site reactions.**
- **Incidence of serious adverse events not significantly different between either clesrovimab or nirsevimab, and comparators (placebo or palivizumab)**
- **Postmarketing surveillance through FAERS and VSD are reassuring.**

Beyfortus Prescribing Information (fda.gov), Enflonsia (clesrovimab) Prescribing Information ; 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, Work group considerations and clinical considerations for clesrovimab . FAERS = FDA Adverse Event Reporting System.

How to Report Adverse Events

- **If an RSV antibody product is administered alone:**
  - Report suspected adverse events (AEs) to MedWatch
  - www.fda.gov/medwatch

- **If an RSV antibody product is administered simultaneously with any vaccine:**
  - Report suspected AEs to Vaccine Adverse Event Reporting System (VAERS)
  - vaers.hhs.gov
  - Specify that received RSV antibody product in Section 9 of VAERS form
  - Additional reporting to MedWatch is not necessary

RSV Immunization Guidance for Infants and Young Children | RSV | CDC, Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025 | MMWR

5

Prevention of Severe RSV Disease in Adults

RSV Vaccines for Prevention of Severe RSV Disease in Adults

- **RSVPreF3+AS01**
  - Brand name: Arexvy (GSK)
- **RSVpreF**
  - Brand name: Abrysvo (Pfizer)
- **mRNA-1345**
  - Brand name: mResvia (Moderna)

No preferential recommendation. Give whichever vaccine is available.

Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov)

Characteristics of GSK Arexvy RSV Vaccine

- **Recombinant prefusion F protein (preF) vaccine**
  - Protein subunit vaccine, adjuvanted (AS01)
- **Single dose, 0.5mL**
- **Requires reconstitution**
  - Follow package insert for guidance
- **Intramuscular injection**

- **Licensed for use in people ages 60 years and older, and people ages 50 through 59 years at increased risk of severe RSV disease**

Package Insert - AREXVY (fda.gov)

Characteristics of Pfizer Abrysvo RSV Vaccine

- **Recombinant prefusion F protein (preF) vaccine**
  - Protein subunit vaccine
- **Single dose, 0.5mL**
- **Requires reconstitution**
  - Follow package insert for guidance
- **Intramuscular injection**
- **Licensed for use in people ages 60 years and older, and people ages 18 through 59 years at increased risk of severe RSV disease**

[Pfizer ABRYSVO Package Insert (fda.gov)](). Note: Pfizer Abrysvo also licensed for use in pregnant women at 32 through 36 weeks gestation for prevention of RSV disease in infants.

Characteristics of Moderna mResvia RSV Vaccine

- **mRNA vaccine**
- **Supplied as a prefilled syringe**
  - Must be thawed
- **Single dose, 0.5mL**
- **Intramuscular injection**
- **Licensed for use in people ages 60 years and older, and people ages 18 through 59 years at increased risk of severe RSV disease**

Package Insert - MRESVIA (fda.gov)

Moderna mResvia Thawing Instructions

Configuration	Thaw in Refrigerator	Thaw at Room Temperature
Carton of one or two pre-filled syringe(s) in single blister pack **One syringe** (removed from carton)	Thaw between 2°C to 8°C (36°F to 46°F) for 100 minutes.	Thaw between 15°C to 25°C (59°F to 77°F) for 40 minutes.
Carton of **10** pre-filled syringes in blister packs	Thaw between 2°C to 8°C (36°F to 46°F) for 160 minutes.	Thaw between 15°C to 25°C (59°F to 77°F) for 80 minutes.

- **If thawed in the refrigerator, let each pre-filled syringe stand at room temperature for between 10 and 20 minutes before administering the vaccine.**
- **If thawed at room temperature, the vaccine is ready to be administered.**

Package Insert - mResvia (fda.gov); mResvia Product Information Quick Guide

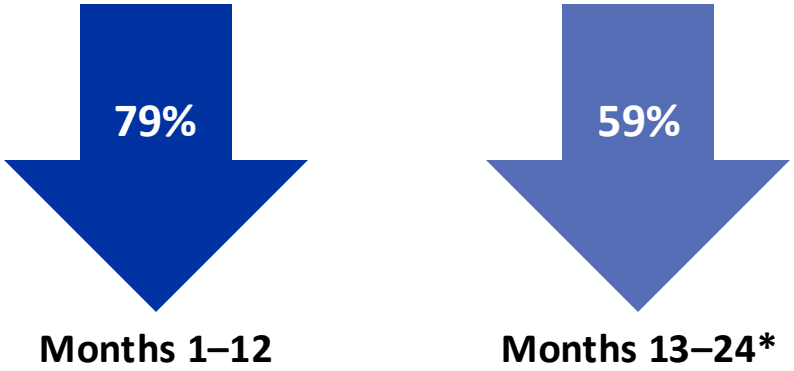
Vaccine Efficacy in Older Adults

- **GSK Arexvy, Pfizer Abrysvo, and Moderna mResvia were shown in clinical trials to reduce the risk of RSV-associated lower respiratory tract disease (LRTD) in adults 60 years and older.**
- **Vaccine efficacy (VE) cannot be directly compared across trials, due to different:**
  - Case definitions of lower respiratory disease
  - Follow-up time
  - Participant health status

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)
Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov)

Vaccine Efficacy in Older Adults: GSK Arexvy Clinical Trial

- **Randomized, double-blinded, placebo-controlled phase 3 clinical trial**
  - 17 countries
  - 24,973 immunocompetent participants
- **Reduced risk of RSV-associated LRTD by:**

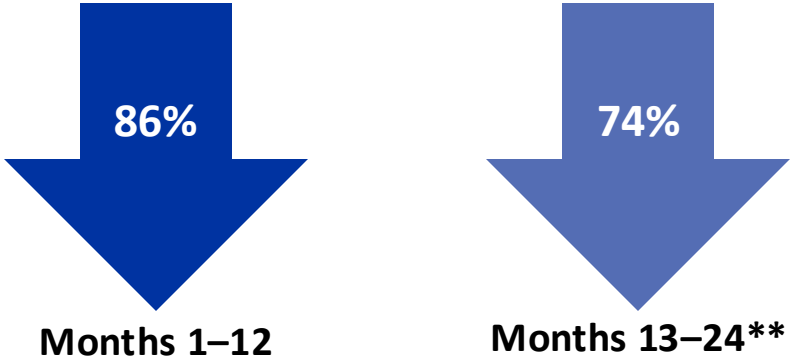


*Median follow-up time during this period was 12 months.

Evidence to Recommendations: RSV Vaccination in Older Adults (cdc.gov)

Vaccine Efficacy in Older Adults: Pfizer Abrysvo Clinical Trial

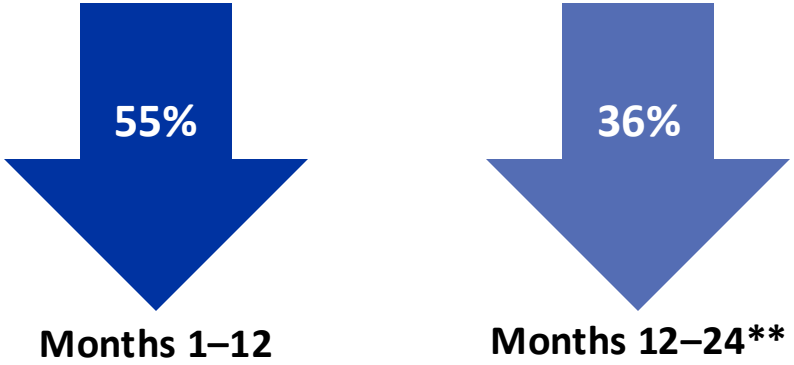
- **Randomized, double-blinded, placebo-controlled phase 3 clinical trial**
  - 7 countries
  - 36,863 immunocompetent participants
- **Reduced risk of RSV-associated lower respiratory tract infection (LRTI)* by:**



*Based on second primary outcome (RSV LRTI with at least three lower respiratory signs/symptoms)
**Median follow-up time during this period was 6 months.
Evidence to Recommendations: RSV Vaccination in Older Adults (cdc.gov)

Vaccine Efficacy in Older Adults: Moderna mResvia Clinical Trial

- **Phase 2/3 clinical trial**
  - 22 countries
  - 36,313 participants (healthy and with comorbidities)
- **Reduced risk of RSV-associated lower respiratory tract disease (LRTD)* by:**



*Based on second primary outcome (RSV LRTD with at least three lower respiratory symptoms)
**Median follow-up time during this period was 7 months.

MMWR, Use of Respiratory Syncytial Virus Vaccines for Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices, United States, 2024

Immunogenicity Data in Adults Ages 50–59 Years

- **Phase 3 clinical trials in adults ages 50–59 years at increased risk for severe RSV disease**
- **Non-inferior immunogenicity compared to adults 60 years of age and older for GSK Arexvy, Pfizer Abrysvo, and Moderna mResvia**

Evidence to Recommendations Framework (EtR) RSV Vaccination in Adults Aged 50-59 Years

Real-World Vaccine Effectiveness in Older Adults: GSK Arexvy and Pfizer Abrysvo

- **In the first season after vaccination, protein subunit vaccination reduced RSV-associated hospitalization 75% among adults ages 60 years and older.**
- **VE was similar across ages:**
  - 60–74 years
  - 75 years and older
- **RSV vaccine protection lasts at least 2 seasons, but wanes over time.**
  - CDC will continue to monitor real-world RSV vaccine effectiveness during each respiratory virus season.

RSV Vaccine Effectiveness Against Hospitalization Among US Adults 60 Years and Older | Vaccination | JAMA | JAMA Network, Estimated Vaccine Effectiveness for Respiratory Syncytial Virus–Related Acute Respiratory Illness in Older Adults: Findings From the First Postlicensure Season | Clinical Infectious Diseases | Oxford Academic, Respiratory syncytial virus (RSV) vaccine effectiveness against RSV-associated hospitalisations and emergency department encounters among adults aged 60 years and older in the USA, October, 2023, to March, 2024: a test-negative design analysis – ScienceDirect, Estimated Vaccine Effectiveness for Respiratory Syncytial Virus–Related Lower Respiratory Tract Disease | Infectious Diseases | JAMA Network Open | JAMA Network

6

RSV Vaccine Recommendations and Schedule in Adults

Adult Immunization Schedule: RSV Vaccination

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2025

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Respiratory syncytial virus (RSV)	Seasonal administration during pregnancy (See Notes)		60 through 74 years (See Notes)	≥75 years

Updated in June 2025 to 50 through 74 years

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity

Recommended Adult Immunization Schedule for ages 19 years or older: 2025 U.S., ACIP Recommendations | ACIP | CDC

Updated RSV Vaccine Recommendations for Adults

- **ACIP recommends that adults ages 50 through 59 years who are at increased risk of severe RSV disease receive a single dose of RSV vaccine.**
  - Recommended as a single dose only — people who have already received RSV vaccination are *not* recommended to receive another dose.
  - RSV vaccine can be administered with any product licensed in this age group.
- **In summary, RSV vaccination now recommended for:**
  - All adults ages 75 years and older
  - Adults ages *50 through 74 years* at increased risk of severe RSV disease.

Evidence to Recommendations Framework (EtR) RSV Vaccination in Adults Aged 50-59 Years, Package Insert – ABRYSVO, Package Insert – AREXVY, ACIP Recommendations | ACIP | CDC; RSV Vaccine Guidance for Adults | RSV | CDC

RSV Vaccination on Adult Immunization Schedule Addendum

Adult Immunization Schedule Addendum

Recommendations for Ages 19 Years or Older, United States, 2025

Health Care Providers
JULY 2, 2025

Addendum

In addition to the recommendations presented in the previous sections of this immunization schedule, CDC has approved the following ACIP recommendations since October 24, 2024.

Vaccines	Recommendations	Effective Date of Recommendation[†]
RSV (Abrysvo,Arexvy,mResvia)	ACIP recommends adults 50–59 years of age who are at increased risk of severe RSV disease[a] receive a single dose of RSV vaccine.[b,c] a. CDC will publish Clinical Considerations that describe chronic medical conditions and other risk factors for severe RSV disease for use in this risk-based recommendation. b. At this time, RSV vaccination is recommended as a single dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose. c. RSV vaccine can be administered with any product licensed in this age group.	June 25, 2025

Adult Immunization Schedule Addendum | Vaccines & Immunizations | CDC

RSV Vaccination Recommendations

- **CDC recommends a single dose of RSV vaccine for:**
  - Adults ages 75 years and older
  - Adults ages 50 through 74 who are at increased risk of severe RSV disease
- **Greatest benefit if administered in late summer or early fall**
  - Ideally, August through October in most of the continental U.S.

Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov), RSV Vaccine Guidance for Adults | RSV | CDC

Just One RSV Vaccine Dose Recommended for Adults

- **The RSV vaccine is not currently an annual vaccine.**
- **Adults who have received an RSV vaccine should not receive another dose.**
- **CDC is monitoring RSV vaccines to determine whether additional doses might be needed.**

Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov), RSV Vaccine Guidance for Adults | RSV | CDC

Adults Ages 50–74 at Increased Risk for Severe RSV Disease Should Receive a Single Dose of RSV Vaccine

Chronic lung or respiratory disease

Chronic cardiovascular disease

End-stage renal disease

Diabetes mellitus complicated by end-organ damage or requiring treatment with insulin or SGLT2 inhibitor*

Neurological or neuromuscular conditions (causing impaired airway clearance or respiratory muscle weakness)

Chronic liver disease

Chronic hematologic conditions

Severe obesity (body mass index ≥40 kg/m^2)

Moderate or severe immunocompromise

Residence in a nursing home

Other factors that a provider determines would increase risk of severe disease due to viral respiratory infection

*SGLT2=sodium-glucose co-transporter-2

Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov)

Self-Attestation Is Acceptable Evidence of a Risk Factor

- **Patient attestation is sufficient evidence of the presence of a risk factor.**
- **Vaccinators should not deny RSV vaccination because of a lack of medical documentation.**

Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov), RSV Vaccine Guidance for Adults | RSV | CDC

Knowledge Check

Should a 65-year-old patient with insulin-dependent diabetes receive RSV vaccination?

A. Yes

B. No

Knowledge Check

Should a 65-year-old patient with insulin-dependent diabetes receive RSV vaccination?

A. Yes

B. No

7

Prevention of Severe RSV Disease in Adults: Special Considerations

Coadministration of RSV and Other Vaccines in Adults

- **RSV and influenza vaccines may not produce as strong of an immune response if coadministered, but the clinical significance is unknown.**
- **Coadministration of multiple vaccines at the same visit may increase reactogenicity; evidence is mixed.**
- **If vaccines are not administered the same day, there is no required interval between vaccines.**

Coadministration with all other adult vaccines is acceptable

Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov), ACIP RSV Vaccination in Adults-Workgroup Interpretations-October 24, 2024

Considerations for Coadministration

- Whether the patient is up to date with recommended vaccines
- Likelihood of returning
- Risk for acquiring vaccine-preventable disease
- Vaccine reactogenicity profiles
- Patient preferences

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR

8

Prevention of Severe RSV Disease in Adults: Safety

Contraindications and Precautions to RSV Vaccines in Adults

Products: Moderna mResvia, Pfizer Abrysvo, GSK Arexvy

Contraindication
Severe allergic reaction (e.g., anaphylaxis) to a vaccine component
Refer to “Section 11 Description” in the product’s package insert to review vaccine components.

Precaution
Moderate or severe acute illness with or without fever

Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over | CDC, Pfizer ABRYSVO Package Insert (fda.gov), Package Insert - MRESVIA (fda.gov), Package Insert - AREXVY (fda.gov)

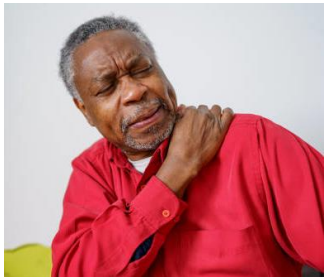
RSV Vaccine Safety in Adults (1)

- **Most common side effects are similar to other vaccines.**

Pain at injection site

Fatigue

Headache



Muscle pain

Joint pain

Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov)]; RSV Vaccine Guidance for Older Adults | RSV | CDC

RSV Vaccine Safety in Adults (2)

- **Protein subunit vaccines (GSK Arexvy and Pfizer Abrysvo):**
  - Pre-licensure clinical trials in older adults: a small number of Guillain-Barré syndrome (GBS) cases occurring within 42 days after vaccination were identified.
  - Post-licensure safety data in adults 65 years and older (FDA and CMS* partnership):
    - Suggested increased risk of GBS after vaccination
    - Estimated risk on the order of 10 excess GBS cases per 1 million vaccinated adults
  - ACIP and CDC continue to conclude that the benefits outweigh the risks.
- **mRNA vaccine (Moderna mResvia):**
  - Pre-licensure clinical trials: No GBS cases within 42 days after vaccination
  - Post-licensure safety data: Not yet available
- **CDC and FDA continue to monitor safety data.**

*Centers for Medicare and Medicaid Services

FDA/CMS Evaluation of GBS following RSV Vaccination Among Adults 64 Years and Older - October 2024 ACIP meeting; RSV Vaccination in Adults: Work Group Interpretations - October ACIP meeting; Pfizer ABRYSVO Package Insert (fda.gov), Package Insert - AREXVY (fda.gov)

V-safe Program

- **V-safe is one of several vaccine safety monitoring systems in the United States.**
- **Encourage vaccine recipients to sign up if they received RSV vaccine in the last 42 days.**
  - Adults ages 60 years and older
  - Pregnant women ages 16-49 years
- vsafe.cdc.gov

About V-safe | Vaccine Safety Systems | CDC

9

Storage and Handling of RSV Immunization Products

Nirsevimab Storage and Handling

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.

Nirsevimab Package Insert (fda.gov)

Clesrovimab Storage and Handling

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

Use within 48 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 48 hours.

Do *not* freeze.

Do *not* shake.

Protect from light.

Enflonsia (clesrovimab) Prescribing Information

Pfizer Abrysvo Storage and Handling

Before Reconstitution

- Store refrigerated between 2°C and 8°C (36°F and 46°F).
- Do *not* freeze.

After Reconstitution

- Store at room temperature 15°C to 30°C (59°F to 86°F).
- Do *not* refrigerate.
- Do *not* freeze.
- Use within 4 hours.

Pfizer ABRYSVO Package Insert (fda.gov)

GSK Arexvy Storage and Handling

Not approved for pregnant women.

Before Reconstitution

- Store refrigerated between 2°C and 8°C (36°F and 46°F).
- Do *not* freeze.
- Protect from light.

After Reconstitution

- Store refrigerated between 2°C and 8°C (36°F and 46°F) OR at room temperature, up to 25°C (77°F).
- Use within 4 hours.
- Do *not* freeze.
- Protect from light.

Package Insert - AREXVY (fda.gov)

Not approved for pregnant women.

Moderna mResvia Storage and Handling

Storage Before Thawing

Store frozen between -40°C and -15°C (-40°F and 5°F).

Protect from light.

Storage After Thawing

Store refrigerated between 2°C and 8°C (36°F and 46°F) for 90 days.

- or -

Store at room temperature up to 25°C (77°F) for 24 hours.

Do *not* refreeze once thawed. Do *not* refrigerate after thawing at room temperature.

Do not shake.

Protect from light.

Package Insert - mResvia (fda.gov)
mResvia Product Informaton Quick Guide

Administer the Correct RSV Immunization Product

Infants and Some Young Children

RSV monoclonal antibody* only

⚠ **Do not administer Abrysvo, Arexvy, or mResvia to infants or children.**

During Pregnancy

Abrysvo (Pfizer) only

⚠ **Do not administer RSV antibody, Arexvy, or mResvia during pregnancy.**

Older Adults and Adults with Risk Conditions

Abrysvo (Pfizer)
Arexvy (GSK)
mResvia (Moderna)

⚠ **Do not administer RSV antibody to adults.**

* Includes nirsevimab and clesrovimab

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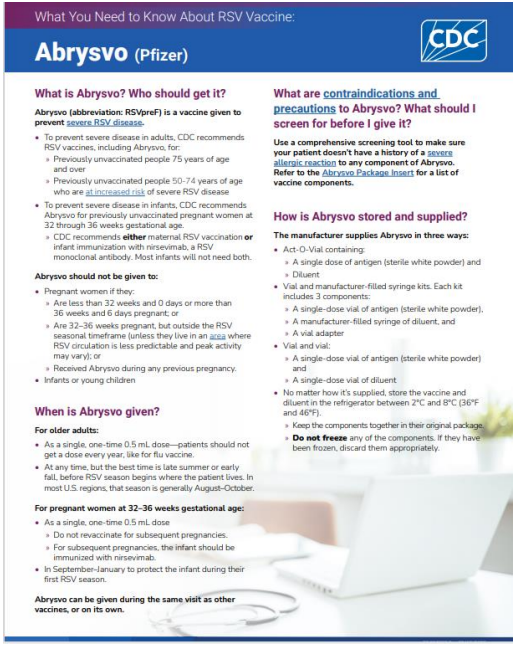
Clinical Resources

CDC RSV Resources (1)

- **RSV disease information:** www.cdc.gov/rsv/index.html
- **RSV immunization and vaccine resources:**
  - Infants and Young Children: www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/infants-young-children.html
  - Adults: https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/adults.html
- **RSV Immunization Information Statement:** https://www.cdc.gov/vaccines/vpd/rsv/immunization-information-statement.html
- **RSV Vaccine Information Statement (VIS):** https://www.cdc.gov/vaccines/hcp/current-vis/rsv.html

CDC RSV Resources (2)

- **RSV immunization information for health care providers:**
  - https://www.cdc.gov/vaccines/vpd/rsv/index.html



What You Need to Know About RSV Vaccine:

Abrysvo (Pfizer)

What is Abrysvo? Who should get it?

Abrysvo (abbreviation: RSVpreF) is a vaccine given to prevent severe RSV disease.

- To prevent severe disease in adults, CDC recommends RSV vaccines, including Abrysvo, for:
  - Previously unvaccinated people 75 years of age and over
  - Previously unvaccinated people 50–74 years of age who are at increased risk of severe RSV disease
- To prevent severe disease in infants, CDC recommends Abrysvo for previously unvaccinated pregnant women at 32 through 36 weeks gestational age.
  - CDC recommends **either** maternal RSV vaccination **or** infant immunization with nirsevimab, a RSV monoclonal antibody. Most infants will not need both.

Abrysvo should not be given to:

- Pregnant women if they:
  - Are less than 32 weeks and 0 days or more than 36 weeks and 6 days pregnant; or
  - Are 32–36 weeks pregnant, but outside the RSV seasonal timeframe (unless they live in an area where RSV circulation is less predictable and peak activity may vary); or
  - Received Abrysvo during any previous pregnancy.
- Infants or young children

When is Abrysvo given?

For older adults:

- As a single, one-time 0.5 mL dose—patients should not get a dose every year, like for flu vaccine.
- At any time, but the best time is late summer or early fall, before RSV season begins where the patient lives. In most U.S. regions, that season is generally August–October.

For pregnant women at 32–36 weeks gestational age:

- As a single, one-time 0.5 mL dose
  - Do not revaccinate for subsequent pregnancies.
  - For subsequent pregnancies, the infant should be immunized with nirsevimab.
- In September–January to protect the infant during their first RSV season.

Abrysvo can be given during the same visit as other vaccines, or on its own.

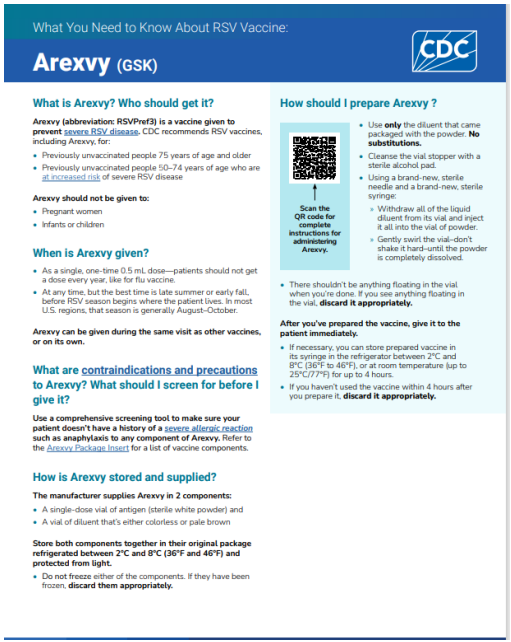
What are contraindications and precautions to Abrysvo? What should I screen for before I give it?

Use a comprehensive screening tool to make sure your patient doesn't have a history of a severe allergic reaction to any component of Abrysvo. Refer to the Abrysvo Package Insert for a list of vaccine components.

How is Abrysvo stored and supplied?

The manufacturer supplies Abrysvo in three ways:

- Act-O-Vial containing:
  - A single dose of antigen (sterile white powder) and
  - Diluent
- Vial and manufacturer-filled syringe kits. Each kit includes 3 components:
  - A single-dose vial of antigen (sterile white powder),
  - A manufacturer-filled syringe of diluent, and
  - A vial adapter
- Vial and vial:
  - A single-dose vial of antigen (sterile white powder) and
  - A single-dose vial of diluent
- No matter how it's supplied, store the vaccine and diluent in the refrigerator between 2°C and 8°C (36°F and 46°F).
  - Keep the components together in their original package.
  - **Do not freeze** any of the components. If they have been frozen, discard them appropriately.



What You Need to Know About RSV Vaccine:

Arexvy (GSK)

What is Arexvy? Who should get it?

Arexvy (abbreviation: RSVPref3) is a vaccine given to prevent severe RSV disease. CDC recommends RSV vaccines, including Arexvy, for:

- Previously unvaccinated people 75 years of age and older
- Previously unvaccinated people 50–74 years of age who are at increased risk of severe RSV disease

Arexvy should not be given to:

- Pregnant women
- Infants or children

When is Arexvy given?

- As a single, one-time 0.5 mL dose—patients should not get a dose every year, like for flu vaccine.
- At any time, but the best time is late summer or early fall, before RSV season begins where the patient lives. In most U.S. regions, that season is generally August–October.

Arexvy can be given during the same visit as other vaccines, or on its own.

What are contraindications and precautions to Arexvy? What should I screen for before I give it?

Use a comprehensive screening tool to make sure your patient doesn't have a history of a severe allergic reaction such as anaphylaxis to any component of Arexvy. Refer to the Arexvy Package Insert for a list of vaccine components.

How is Arexvy stored and supplied?

The manufacturer supplies Arexvy in 2 components:

- A single-dose vial of antigen (sterile white powder) and
- A vial of diluent that's either colorless or pale brown

Store both components together in their original package refrigerated between 2°C and 8°C (36°F and 46°F) and protected from light.

- Do not freeze either of the components. If they have been frozen, **discard them appropriately.**

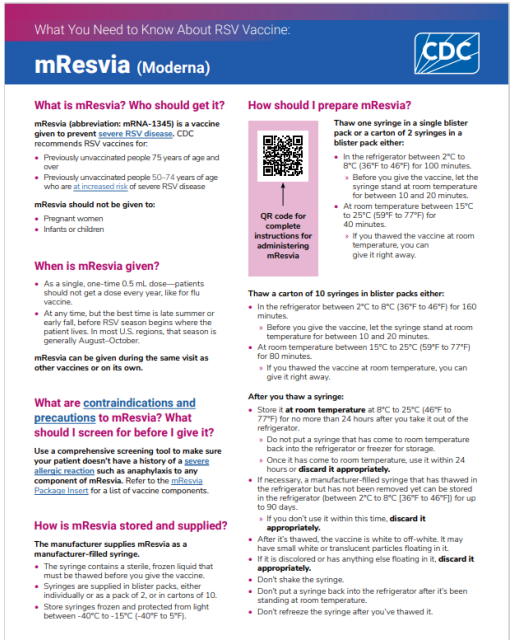
How should I prepare Arexvy ?

Scan the QR code for complete instructions for administering Arexvy.

- Use **only** the diluent that came packaged with the powder. **No substitutions.**
- Cleanse the vial stopper with a sterile alcohol pad.
- Using a brand-new, sterile needle and a brand-new, sterile syringe:
  - Withdraw all of the liquid diluent from its vial and inject it all into the vial of powder.
  - Gently swirl the vial–don't shake it hard–until the powder is completely dissolved.
- There shouldn't be anything floating in the vial when you're done. If you see anything floating in the vial, **discard it appropriately.**

After you've prepared the vaccine, give it to the patient immediately.

- If necessary, you can store prepared vaccine in its syringe in the refrigerator between 2°C and 8°C (36°F to 46°F), or at room temperature (up to 25°C/77°F) for up to 4 hours.
- If you haven't used the vaccine within 4 hours after you prepare it, **discard it appropriately.**



What You Need to Know About RSV Vaccine:

mResvia (Moderna)

What is mResvia? Who should get it?

mResvia (abbreviation: mRNA-1345) is a vaccine given to prevent severe RSV disease. CDC recommends RSV vaccines for:

- Previously unvaccinated people 75 years of age and over
- Previously unvaccinated people 50–74 years of age who are at increased risk of severe RSV disease

mResvia should not be given to:

- Pregnant women
- Infants or children

When is mResvia given?

- As a single, one-time 0.5 mL dose—patients should not get a dose every year, like for flu vaccine.
- At any time, but the best time is late summer or early fall, before RSV season begins where the patient lives. In most U.S. regions, that season is generally August–October.

mResvia can be given during the same visit as other vaccines or on its own.

What are contraindications and precautions to mResvia? What should I screen for before I give it?

Use a comprehensive screening tool to make sure your patient doesn't have a history of a severe allergic reaction such as anaphylaxis to any component of mResvia. Refer to the mResvia Package Insert for a list of vaccine components.

How is mResvia stored and supplied?

The manufacturer supplies mResvia as a manufacturer-filled syringe.

- The syringe contains a sterile, frozen liquid that must be thawed before you give the vaccine.
- Syringes are supplied in blister packs, either individually or as a pack of 2, or in cartons of 10.
- Store syringes frozen and protected from light between -40°C to -15°C (-40°F to 5°F).

How should I prepare mResvia?

QR code for complete instructions for administering mResvia

Thaw one syringe in a single blister pack or a carton of 2 syringes in a blister pack either:

- In the refrigerator between 2°C to 8°C (36°F to 46°F) for 100 minutes.
  - Before you give the vaccine, let the syringe stand at room temperature for between 10 and 20 minutes.
- At room temperature between 15°C to 25°C (59°F to 77°F) for 40 minutes.
  - If you thawed the vaccine at room temperature, you can give it right away.

Thaw a carton of 10 syringes in blister packs either:

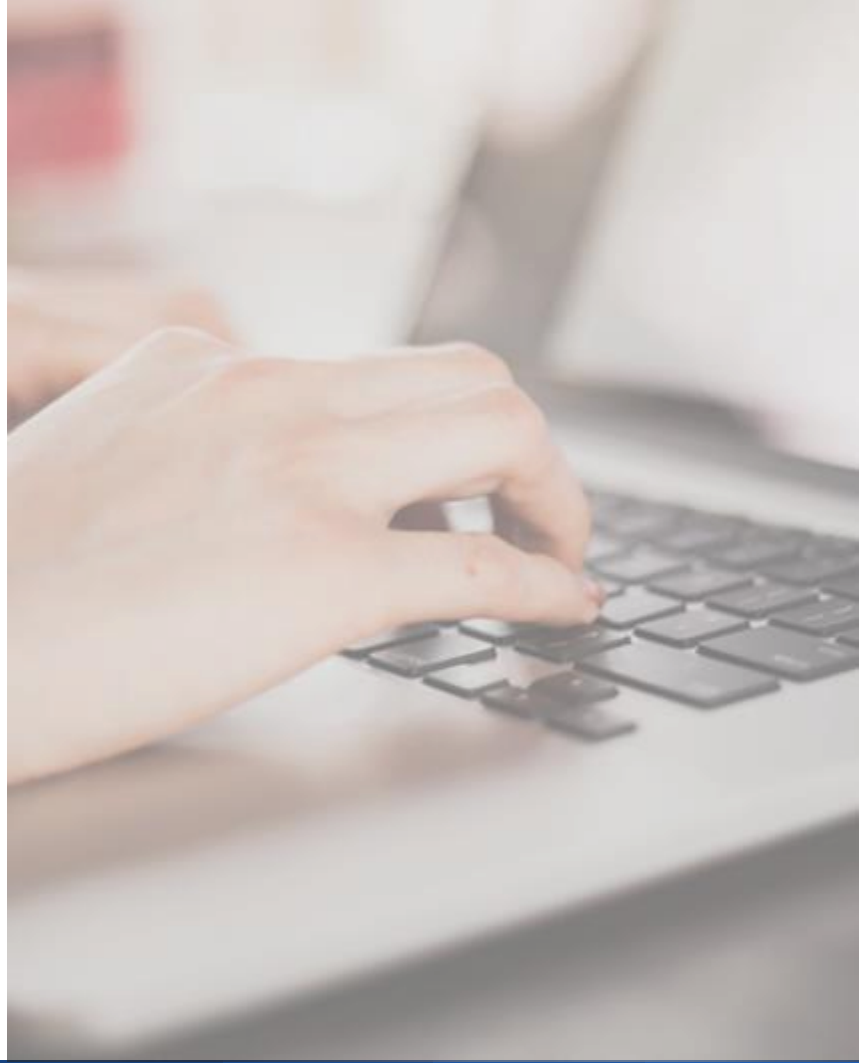
- In the refrigerator between 2°C to 8°C (36°F to 46°F) for 160 minutes.
  - Before you give the vaccine, let the syringe stand at room temperature for between 10 and 20 minutes.
- At room temperature between 15°C to 25°C (59°F to 77°F) for 80 minutes.
  - If you thawed the vaccine at room temperature, you can give it right away.

After you thaw a syringe:

- Store it **at room temperature** at 8°C to 25°C (46°F to 77°F) for no more than 24 hours after you take it out of the refrigerator.
  - Do not put a syringe that has come to room temperature back into the refrigerator or freezer for storage.
  - Once it has come to room temperature, use it within 24 hours or **discard it appropriately.**
- If necessary, a manufacturer-filled syringe that has thawed in the refrigerator but has not been removed yet can be stored in the refrigerator (between 2°C to 8°C [36°F to 46°F]) for up to 90 days.
  - If you don't use it within this time, **discard it appropriately.**
- After it's thawed, the vaccine is white to off-white. It may have small white or translucent particles floating in it.
- If it is discolored or has anything else floating in it, **discard it appropriately.**
- Don't shake the syringe.
- Don't put a syringe back into the refrigerator after it's been standing at room temperature.
- Don't refreeze the syringe after you've thawed it.

CDC Clinical Resources

- www.cdc.gov/vaccines/
  - Advisory Committee on Immunization Practices (ACIP) Vaccine Recommendations and Guidelines
  - Recommended Immunization Schedules
  - Vaccine Administration Resources
  - Vaccine Storage and Handling Toolkit
  - Vaccine Information Statements



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- To claim continuing education (CE) for this course, please follow the steps below by July 1, 2026.
- Search and register for course **WD4810-082924** in **CDC TRAIN**.
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- If you have any questions, contact **CDC TRAIN** at train@cdc.gov or IZLearn@cdc.gov

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Email us your immunization questions:

nipinfo@cdc.gov

Thank You From Atlanta!

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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.