

# Looking for Air? All About Respiratory Syncytial Virus

Gilmary Betancourt Marrero, PharmD, HIVPCP

Pharmacist Local Specialty

Walgreens

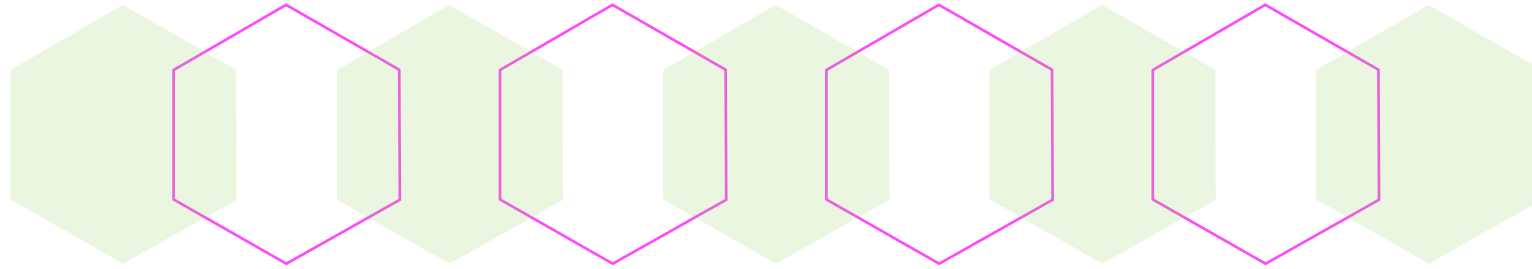
Saturday, August 24<sup>th</sup>, 2024



**COLEGIADOS...UNIDOS  
SOMOS MÁS FUERTES**

**CONVENCIÓN ANUAL  
CFPR 2024**

# Disclosure to Learners



Gilmary Betancourt Marrero, faculty for this CE activity,  
has no relevant financial relationship(s) with ineligible  
companies to disclose.



**“The Colegio de Farmacéuticos de Puerto Rico is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.”**

**Provider Number: 0151**

# Objectives

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**At the end of the activity, pharmacists should be able to:**

- ✓ Discuss differences between RSV and other respiratory infections.
- ✓ Describe the epidemiology of RSV and clinical outcomes.
- ✓ Outline prevention strategies available.
- ✓ Classify available and emerging RSV vaccines for older adults including mechanisms of action and safety and efficacy data.
- ✓ Identify differences between the management of RSV based on age.

# Objectives

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**At the end of the activity, pharmacists should be able to:**

- ✓ Explain evidence-based recommendations for the appropriate use of RSV vaccines, considering factors such as age, medical history, and other risk factors.
- ✓ Discuss management of RSV infection in adults and children.
- ✓ Describe regulations related to the vaccinations for RSV.
- ✓ Value the role of the pharmacy team in caring for patients at risk for RSV.

# Objectives

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**At the end of the activity, pharmacy technicians should be able to:**

- ✓ List the differences between RSV and other respiratory infections.
- ✓ Describe the epidemiology of RSV and clinical outcomes.
- ✓ List prevention strategies available.
- ✓ Identify available and emerging RSV vaccines for older adults including mechanisms of action and safety and efficacy data.

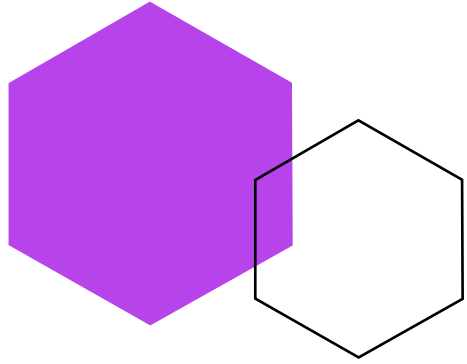
# Objectives

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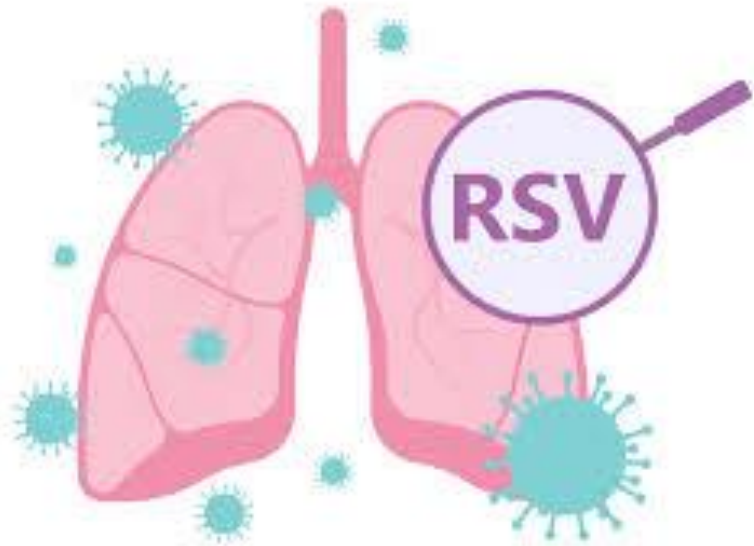
**At the end of the activity, pharmacy technicians should be able to:**

- ✓ Identify differences between the management of RSV based on age.
- ✓ Mention the medications used for RSV infection in adults and children.
- ✓ Describe regulations related to the vaccinations for RSV.
- ✓ Value the role of the pharmacy team in caring for patients at risk for RSV





# Respiratory Syncytial Virus: Old Virus or New Virus?

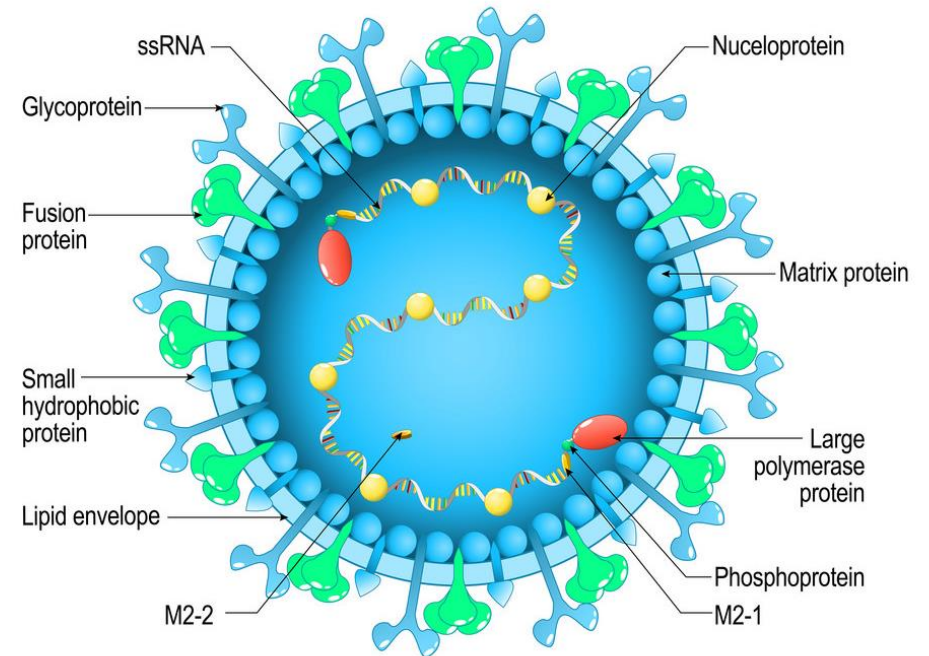




# RSV Overview

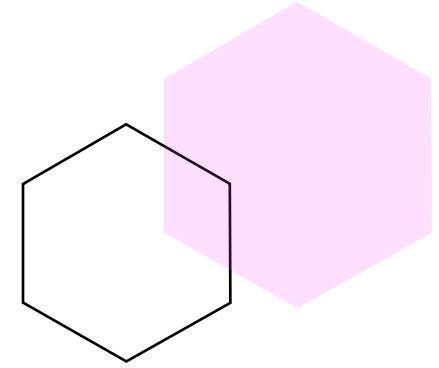
- **Respiratory Syncytial Virus**
  - Virus that infects nose, throat, lung, and breathing passages
  - A common cause of bronchiolitis
  - Negative-sense, single-strand, enveloped RNA virus
  - Scientific name: human orthopneumovirus
- **Transmission**
  - Respiratory droplets
  - Contaminated surfaces

**RSV**  
(respiratory syncytial virus)



Retrieved from <https://www.vectorstock.com/royalty-free-vector/respiratory-syncytial-virus-rsv-structure-vector-49872858>

# RSV Overview



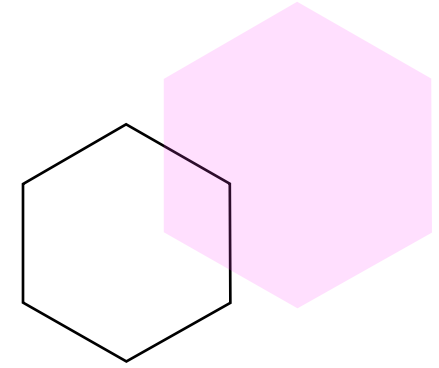
- **Symptoms**

- Runny nose or congestion
- Dry cough
- Sore throat
- Headache
- In young infants, irritability, decreased activity, and breathing difficulties can occur.

- **Diagnosis**

- Blood test
- Chest X-ray
- Swab of secretions
- Pulse oximetry

# Cold vs Flu vs RSV: Know the difference



## COLD

- ✓ Cough
- ✓ Stuffy or runny nose
- ✓ Sneezing
- ✓ Sore throat and sore ears
- ✓ Headache
- ✓ Red eyes
- ✓ Loss of appetite
- ✓ Irritability
- ✓ Some children may develop a fever

## FLU

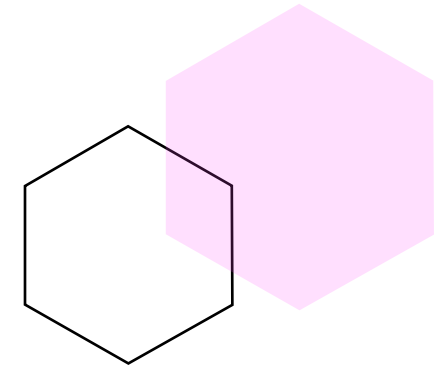
- ✓ Cough
- ✓ Stuffy or runny nose
- ✓ Sore throat
- ✓ Body ache
- ✓ Shivering
- ✓ Feeling hot or cold
- ✓ Diarrhoea or vomiting
- ✓ Fatigue
- ✓ Symptoms can be more severe than a cold

## RSV

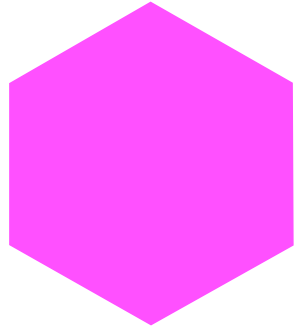
- ✓ Cough
- ✓ Stuffy or runny nose
- ✓ Sneezing
- ✓ Wheezing
- ✓ Fever
- ✓ Can cause severe illness such as bronchiolitis or pneumonia

Retrieved from  
<https://www.pregnancybirthbaby.org.au/respiratory-syncytial-virus-rsv-in-babies-and-children>

# RSV Overview

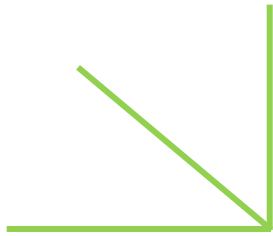


- **Complications in infants/children**
  - Severe breathing illness
  - Pneumonia
- **Complications in adults**
  - Worsening of conditions like asthma, congestive heart failure
  - Pneumonia
  - Acute bronchiolitis
  - Respiratory failure
- Infants < 5 years and adults >65 years with chronic medical conditions are at increased risk of severe complication caused by RSV



# RSV Epidemiology





## Each year in the United States, RSV leads to approximately:

- 2.1 million outpatient (non-hospitalization) visits among children younger than 5 years old
- 58,000-80,000 hospitalizations among children younger than 5 years old
- 60,000-160,000 hospitalizations among adults 65 years and older
- 6,000-10,000 deaths among adults 65 years and older
- 100–300 deaths in children younger than 5 years old

Centers for Disease Control and Prevention. Surveillance of RSV. Published June 2024. Accessed July 29, 2024. <https://www.cdc.gov/rsv/php/surveillance/index.html>

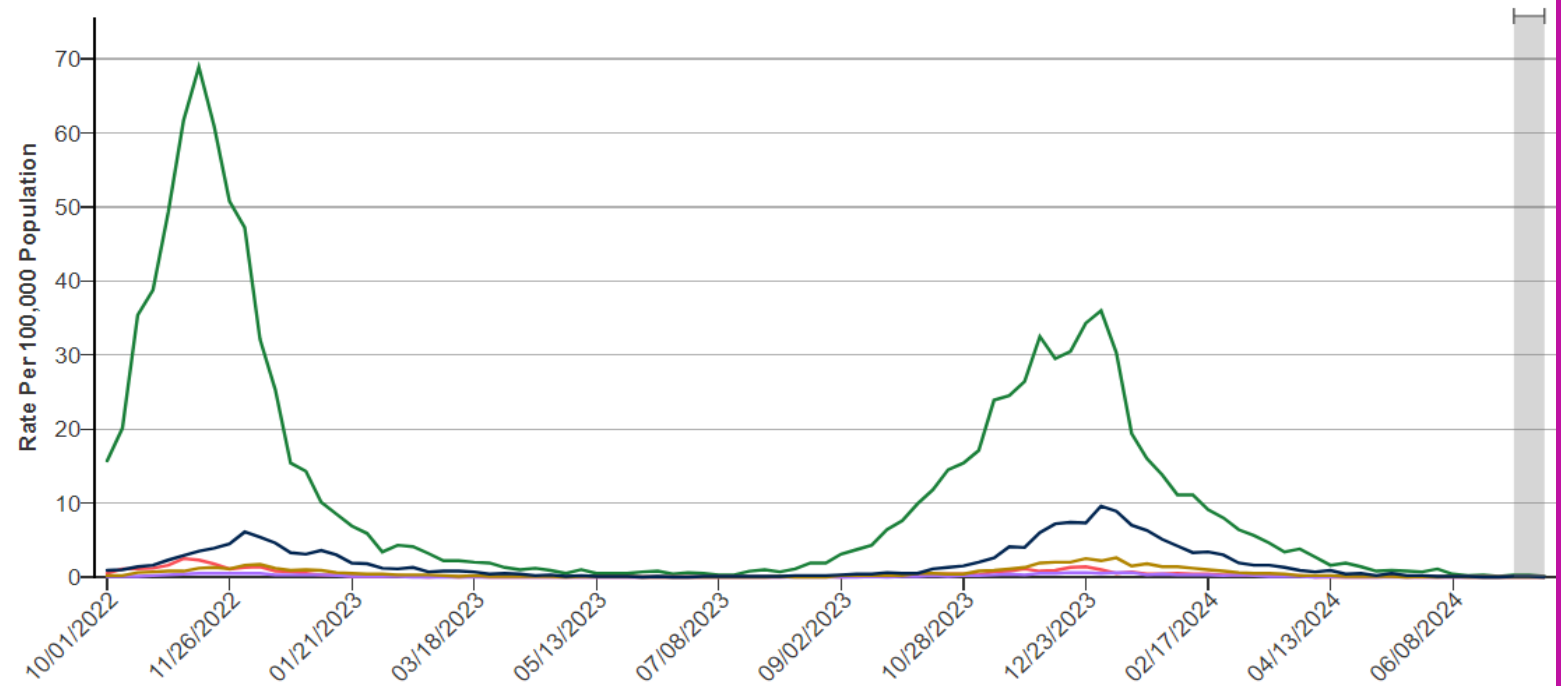
Retrieved from <https://www.cdc.gov/respiratory-viruses/data-research/dashboard/most-impacted-hospitalizations.html>

## Hospitalization Rates for Viral Respiratory Illness, by Age

Weekly hospitalization rates for COVID-19, influenza, and RSV per 100,000 population. Preliminary data are shaded in gray.

Respiratory Illness

RSV





VIGILANCIA EPIDEMIOLÓGICA  
VIRUS SINCITAL RESPIRATORIO  
PUERTO RICO, 2024  
ACTUALIZADO 18 DE JULIO DE 2024

Acumulado, año 2024



Total de casos reportados a la vigilancia  
328



Distribución de casos por sexo  
Hombre: 63%  
Mujer: 37%



Grupos de edad con mayor cantidad de casos  
<1: 40%  
1-4 años: 33%



Región de salud con tasa de incidencia más alta por cada 100,000 habitantes  
Fajardo: 13  
Metro: 13  
Arecibo: 11.8



Hospitalizaciones  
110

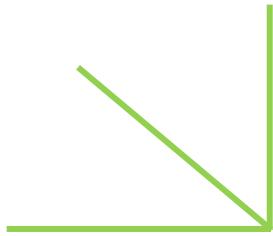


Fatalidades asociadas  
0

Retrieved from  
<https://www.salud.pr.gov/CMS/DOWNLOAD/8610>

\*Semana Epidemiológica 28 - 7 al 13 de julio de 2024.

Fuente: Sistema de Vigilancia de Virus Respiratorio Sincital. División de Epidemiología e Investigación del Departamento de Salud. Informe semanal Situación de Virus Respiratorio Sincital en Puerto Rico. Disponible en [https://www.salud.pr.gov/virus\\_sincital](https://www.salud.pr.gov/virus_sincital)

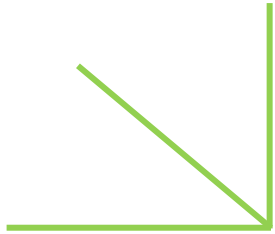


- RSV is one of the leading causes of acute respiratory tract infections worldwide.
- Historically, in the the United States and other areas, RSV season typically starts during the fall and peaks in the winter, with the following pattern:
  1. RSV season onset: mid-September to mid-November
  2. RSV season peak: late December to mid-February
  3. RSV season offset: mid-April to mid-May

Centers for Disease Control and Prevention. Surveillance of RSV. Published June 2024. Accessed July 29, 2024. <https://www.cdc.gov/rsv/php/surveillance/index.html>

Rios-Guzman, E., Simons, L.M., Dean, T.J. et al. Deviations in RSV epidemiological patterns and population structures in the United States following the COVID-19 pandemic. *Nat Commun* 15, 3374 (2024). <https://doi.org/10.1038/s41467-024-47757-9>

# RSV and the COVID-19 Pandemic



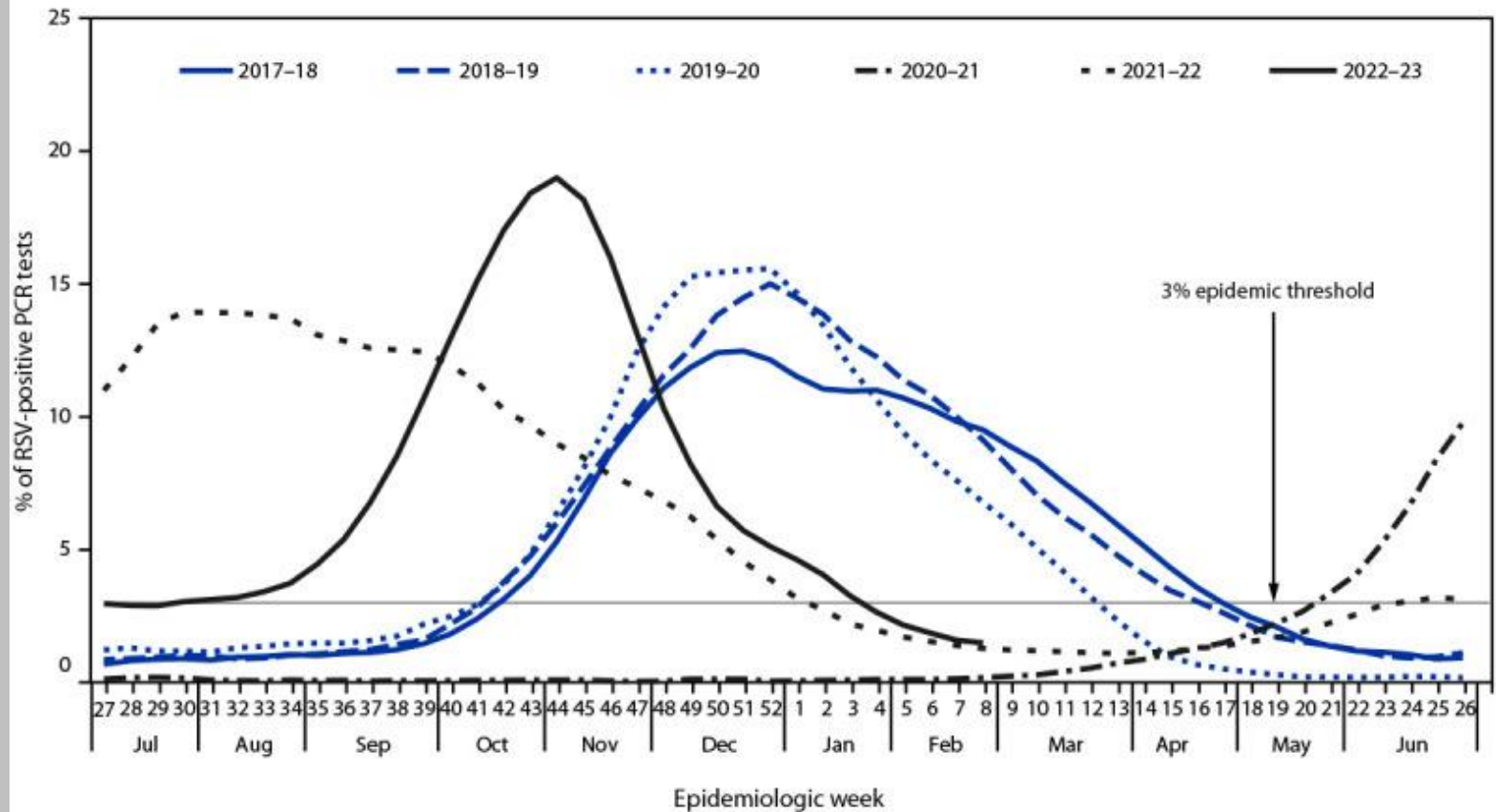
- RSV prevalence decreased substantially in the United States (US) following the implementation of COVID-19-related non-pharmaceutical interventions but later rebounded with abnormal seasonality.
- Some factors that may contribute to changes in the RSV epidemic in recent years can be but not limited to:
  1. Lack of immune stimulation by virus for prolonged periods
  2. Increase in viral co-infections
  3. Temporal variations in testing practices
  4. Societal and health system factors

Rios-Guzman, E., Simons, L.M., Dean, T.J. et al. Deviations in RSV epidemiological patterns and population structures in the United States following the COVID-19 pandemic. *Nat Commun* 15, 3374 (2024).

<https://doi.org/10.1038/s41467-024-47757-9>

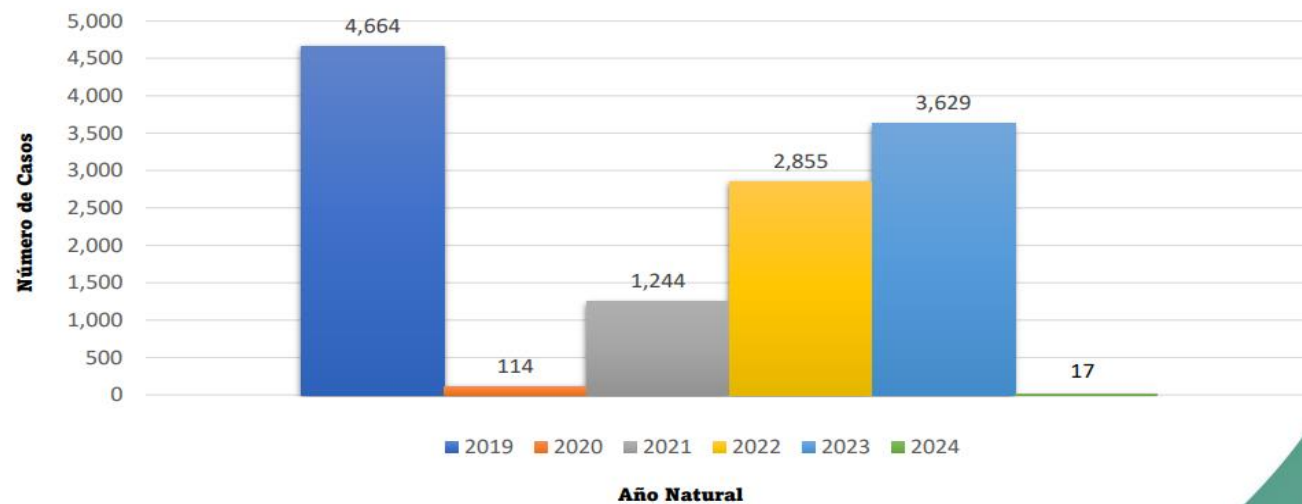
Abu-Raya B, Vineta Paramo M, Reicherz F, Michel Lavoie P. Why has the epidemiology of RSV changed during the COVID-19 pandemic? *The Lanc Disc Scien.* 2023;61(102089):1-6. doi:<https://doi.org/10.1016/j.eclinm.2023.102089>

**FIGURE 1. Percentage of polymerase chain reaction test results positive for respiratory syncytial virus, by epidemiologic week — National Respiratory and Enteric Virus Surveillance System, United States, July 2017–February 2023**



Hamid S, Winn A, Parikh R, et al. Seasonality of Respiratory Syncytial Virus - United States, 2017-2023. *MMWR Morb Mortal Wkly Rep.* 2023;72(14):355-361. Published 2023 Apr 7. doi:10.15585/mmwr.mm7214a1

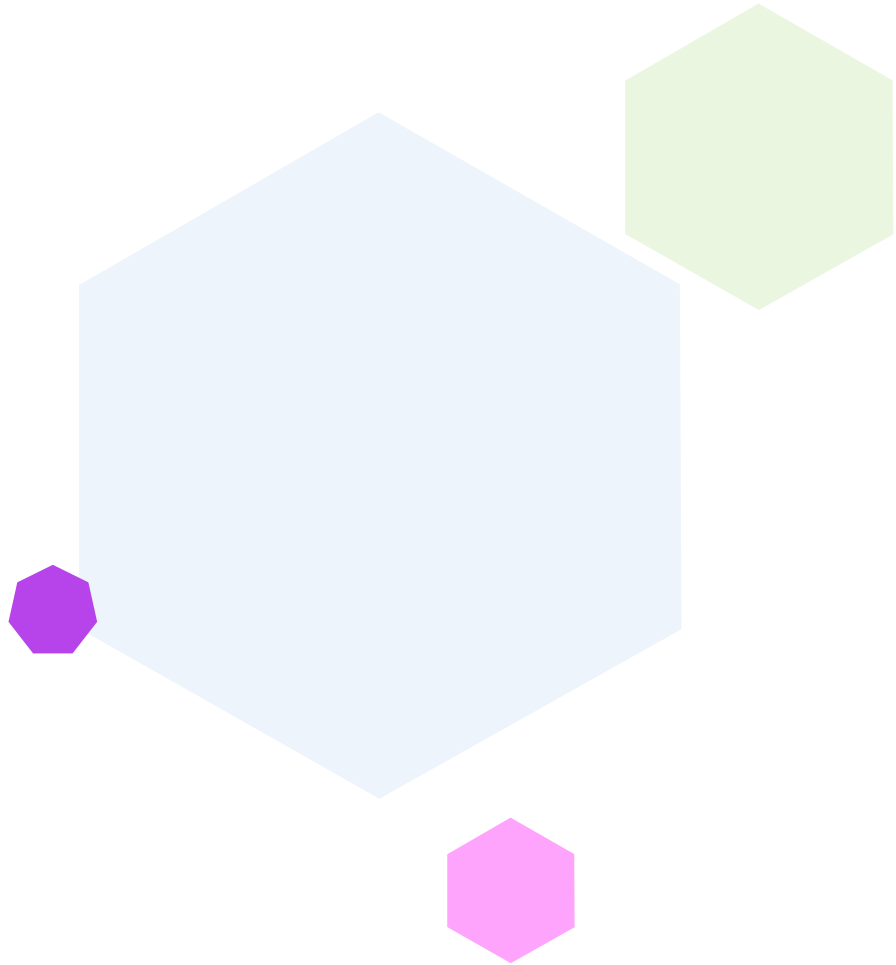
## Casos RSV Puerto Rico, 2019 - 2024



División de Epidemiología e Investigación  
Datos actualizados al 1/4/2024



Vigilancia Epidemiológica VPD y RSV. Departamento de Salud de Puerto Rico  
<https://www.salud.pr.gov/CMS/DOWNLOAD/8433>



# RSV MANAGEMENT



# RSV GOAL OF THERAPY

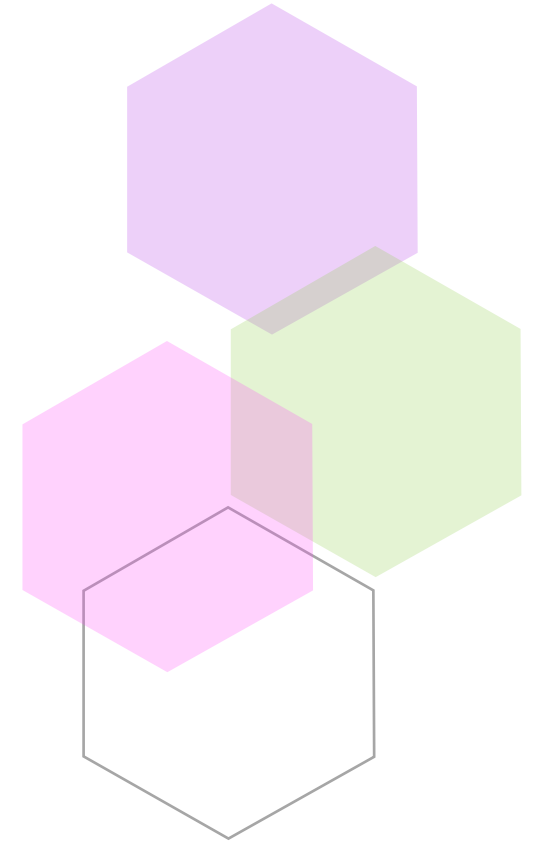
1. **Alleviate symptoms**
2. **Decrease the duration and severity of the illness**
3. **Decrease the risk of transmission**

Gatt D, Martin I, AlFouzan R, Moraes TJ. Prevention and Treatment Strategies for Respiratory Syncytial Virus (RSV). *Pathogens*. 2023;12(2):154. Published 2023 Jan 17. doi:10.3390/pathogens12020154



# NON-PHARMACOLOGICAL THERAPY

- Rest
- Supportive Care (mainstay treatment for RSV bronchiolitis): hydration, saline nose drops to clear nasal obstruction
- Hygiene measurements: washing hands, maintaining 6 feet apart to avoid transmission
- Oxygen therapy for those struggling to keep a saturation >90%



Eiland LS. Respiratory syncytial virus: diagnosis, treatment and prevention. *J Pediatr Pharmacol Ther.* 2009;14(2):75-85.  
doi:10.5863/1551-6776-14.2.75

# PHARMACOLOGICAL THERAPY

## Over-the counter medicine

- Acetaminophen or Ibuprofen to reduce fever and relive pain
- Cold medicine for cough suppression such as Dextromethorphan

Talk to a health provider before giving a child non-prescription cold medicine.

## Prescription medicine

- Ribavirin oral systemic (tablets, capsules) in adults
- Ribavirin oral inhalation (Virazole®) in children and infants



Centers for Disease Control and Prevention. Symptoms of RSV. Accessed July 30, 2024.

[https://www.cdc.gov/rsv/symptoms/index.html#:~:text=Manage%20fever%20and%20pain%20with,\(loss%20of%20body%20fluids\).](https://www.cdc.gov/rsv/symptoms/index.html#:~:text=Manage%20fever%20and%20pain%20with,(loss%20of%20body%20fluids).)

# PHARMACOLOGICAL THERAPY

## Adults:

- Off-label use in RSV infection for immunocompromised patients
- Dosage: 600-800mg 2 to 3 times daily OR a single 10mg/kg loading dose followed by 20mg/kg/day in 3 divided doses

# RIBAVIRIN



Ribavirin capsules

# PHARMACOLOGICAL THERAPY

## Children:

- FDA-approved for RSV infection
- Administration: reconstitute 6g of vial in 300mL sterile water.

### Dosage:

1. Continuous aerosolization: 6g for 12-18 hours for 3-7 days
2. Intermittent aerosolization: 2,000 mg over 2 to 3 hours 3 times daily for 2 to 10 days

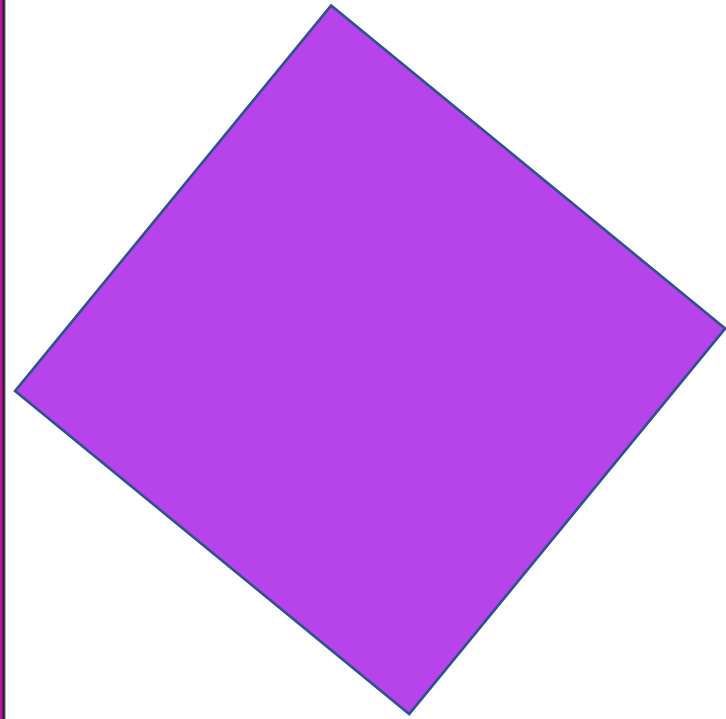
## RIBAVIRIN



# RIBAVIRIN

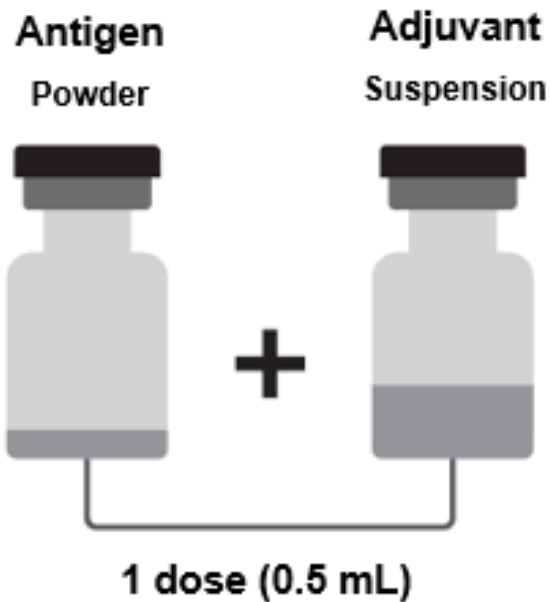
- Adverse Reactions:
  - Oral (systemic): constipation, diarrhea, muscle or joint pain, dry skin, dry mouth, change in taste
  - Oral inhalation: skin rash, bradycardia, chest pain, hypotension
- Warnings and Precautions:
  - a. Hypersensitivity to ribavirin or any component
  - b. Hemolytic anemia
- Monitoring parameters: Respiratory function, hemoglobin, reticulocyte count, CBC with differential

Lexicomp Database. Ribavirin. 2024



# RSV PREVENTION: VACCINES

# RSVPreF3 (Arexvy<sup>®</sup>, GSK)

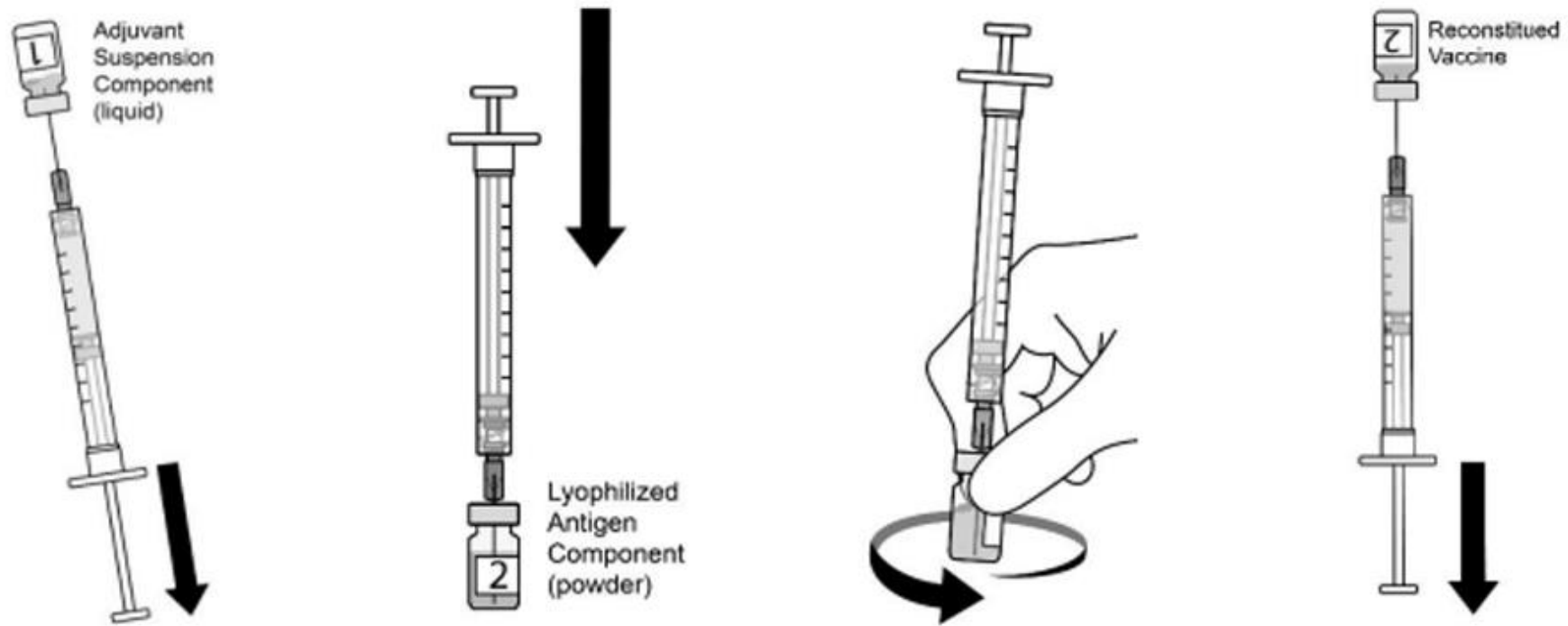


- Adjuvated recombinant prefusion F protein vaccine
- FDA approved in May 2023
- Indicated for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in:
  1. Individuals 60 years or older
  2. Individuals 50-59 years with increased risk of LRTD caused by RSV
- A single dose of 0.5mL administered via intramuscular injection after reconstitution

FDA. Arexvy Package Insert. Published June 2024. Accessed July 30, 2024.  
<https://www.fda.gov/media/167805/download?attachment>



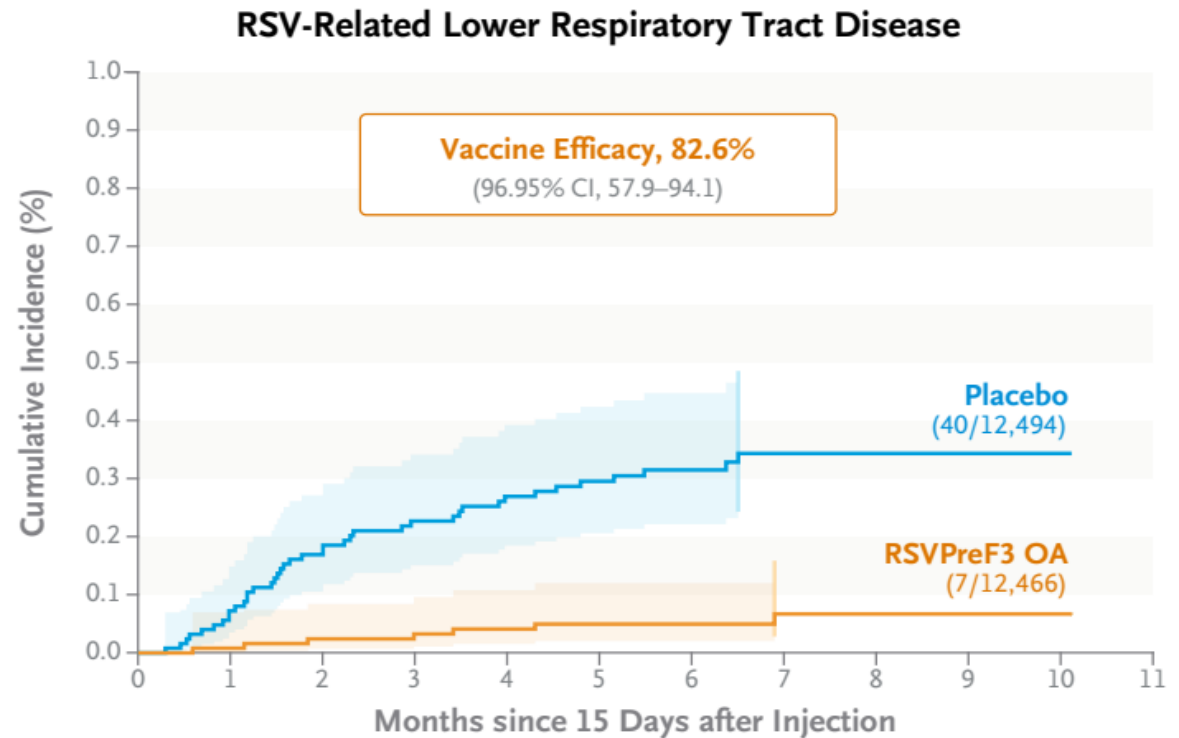
# RSVPreF3 (Arexvy<sup>®</sup>, GSK) Preparation



Retrieved from  
<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents/SORSV.pdf> title

# Vaccine Efficacy of RSVPreF3 (Arexvy<sup>®</sup>, GSK) in Patients 60 years and older

- Randomized, placebo-controlled, phase 3 clinical trial in 17 countries
- **Primary endpoint:** evaluate efficacy of a single dose of RSVPreF3 vaccine in adults 60 years or older to prevent RSV-related LRTD
- 24, 966 participants



Papi A, Ison MG, Langley JM, et al. Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults. *N Engl J Med*. 2023;388(7):595-608. doi:10.1056/NEJMoa2209604

# Vaccine Efficacy of RSVPreF3 (Arexvy<sup>®</sup>, GSK) in Patients 50-59 years

- Randomized, placebo-controlled, phase 3 clinical trial
- **Primary endpoint:** evaluate efficacy of a RSVPreF3 vaccine in adults 50-59 years and demonstrate non-inferiority in immune responses compared to adults 60 years and older
- 958 participants

| RSV-A Neutralizing Titers   |  |                                  |
|-----------------------------|--|----------------------------------|
|                             | Adjusted Geometric Mean Titer (GMT) (95% CI) | Seroresponse Rate (SRR) (95% CI) |
| Patients 50-59 years        | 8,922.7 (8,118.2, 9,806.9)                   | 86.9 (82.8, 90.3)                |
| Patients 60 years and older | 7,440.1 (6,768.4, 8,178.5)                   | 80.4 (75.8, 84.5)                |

FDA. Arexvy Package Insert. Published June 2024. Accessed July 30, 2024. <https://www.fda.gov/media/167805/download?attachment>

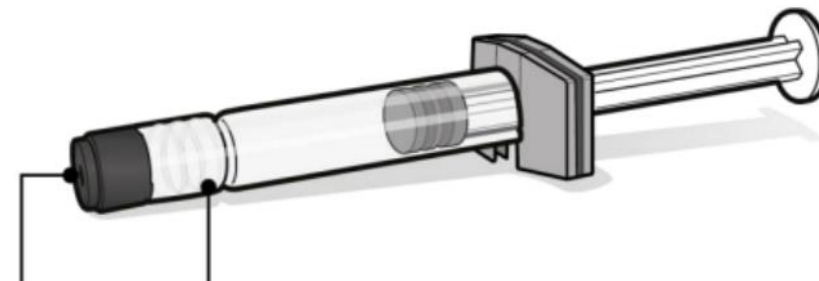
# RSVPreF (Abrysvo<sup>®</sup>, Pfizer)

- Adjuvated recombinant prefusion F protein vaccine
- FDA approved in May 2023
- Active immunization indicated for the prevention of LRTD caused by RSV in:
  1. Individuals 60 years of age and older
  2. Pregnant individuals at 32 through 36 weeks gestational age
- A single dose of 0.5mL administered via intramuscular injection after reconstitution

Vial of Lyophilized Antigen Component



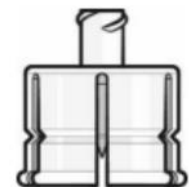
Syringe of Sterile Water Diluent Component



Syringe cap

Luer lock adapter

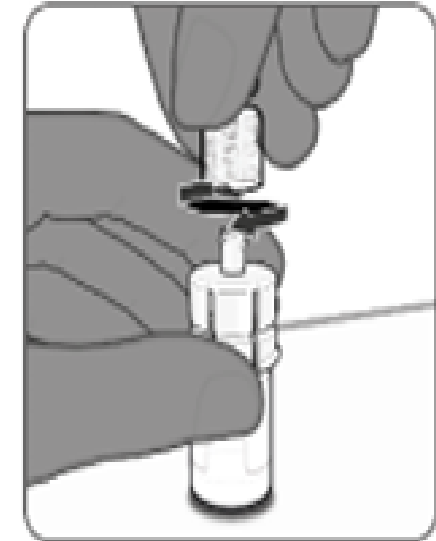
Vial Adapter



FDA. Abrysvo Package Insert. Accessed July 30, 2024.

<https://www.fda.gov/media/168889/download?attachment>

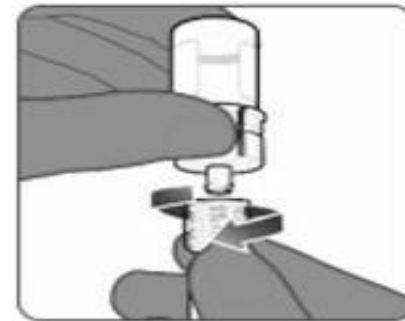
# RSVPreF (Abrysvo<sup>®</sup>, Pfizer) Preparation



Retrieved from

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents/SORSV.pdf> title

# RSVPreF (Abrysvo<sup>®</sup>, Pfizer) Preparation



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<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINES/IMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents/SORSV.pdf> title

# RSVPreF (Abrysvo<sup>®</sup>, Pfizer) Preparation

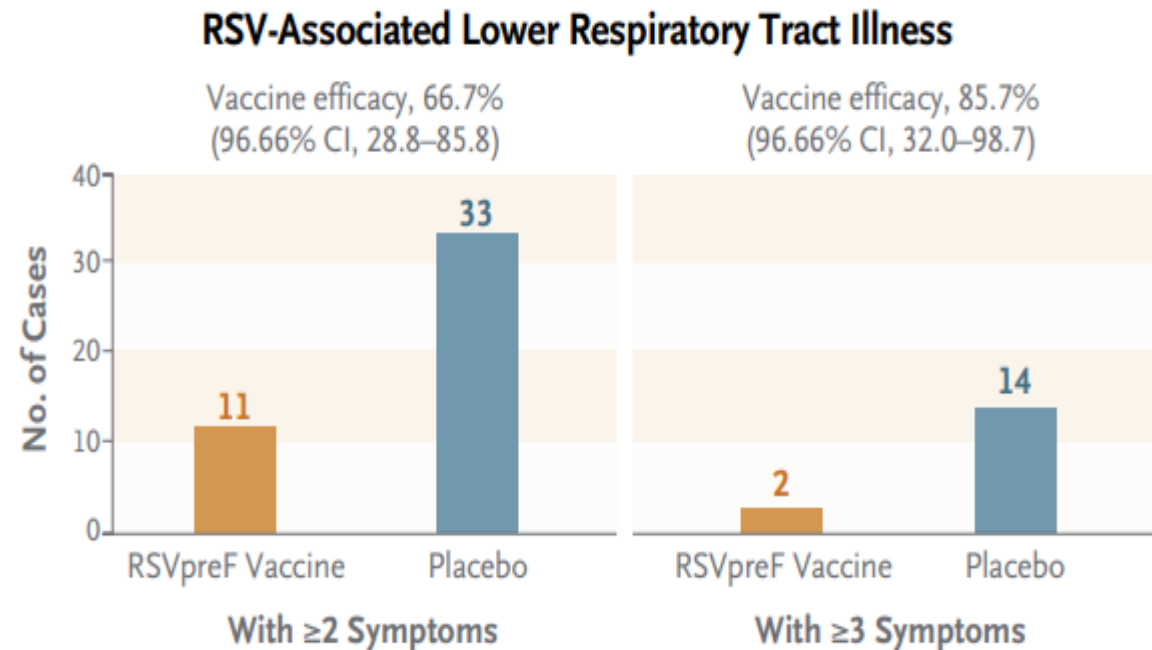


Retrieved from  
<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents/SORSV.pdf> title



## Vaccine Efficacy of RSVPreF (Abrysvo<sup>®</sup>, Pfizer) in Patients 60 years and older

- Randomized, multicenter placebo-controlled, phase 3 clinical trial
- **Primary endpoint:** evaluate the efficacy and safety of RSVpreF vaccine in adults  $\geq 60$  years of age during a single RSV season
- 34,284 participants



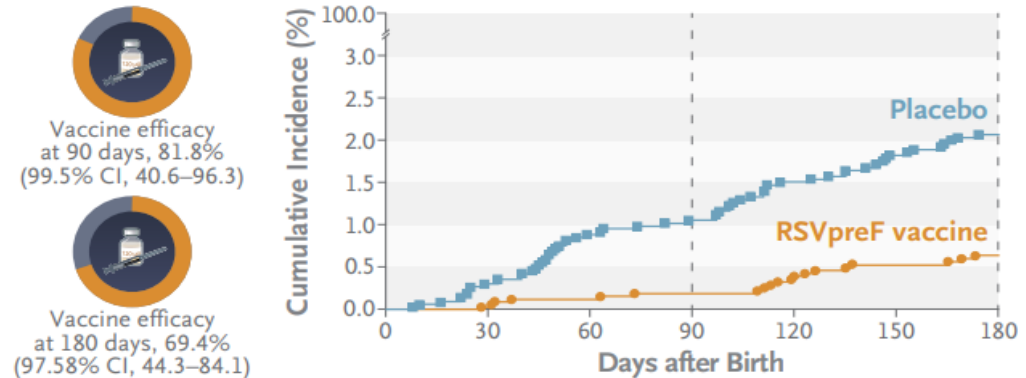
Walsh EE, Pérez Marc G, Zareba AM, et al. Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults. *N Engl J Med*. 2023;388(16):1465-1477. doi:10.1056/NEJMoa2213836

# Vaccine Efficacy of RSVPreF (Abrysvo<sup>®</sup>, Pfizer) During Pregnancy

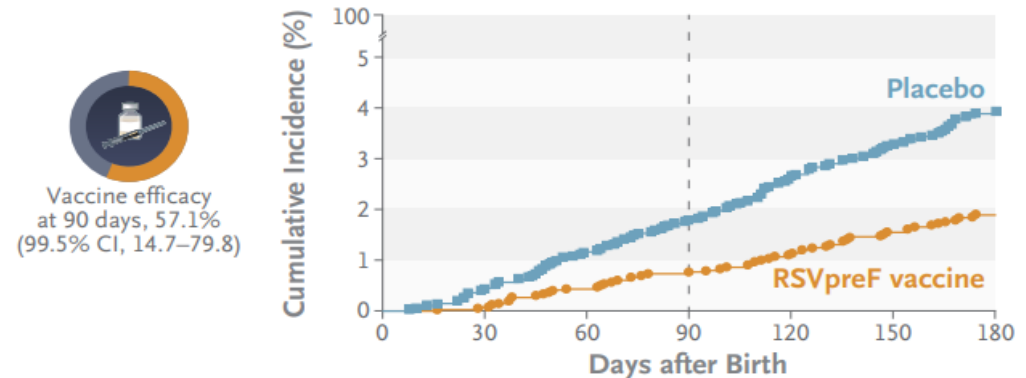
- Double-blind, randomized, multicenter placebo-controlled, phase 3 clinical trial conducted in 18 countries over 4 RSV seasons
- **Primary endpoint:** examine the efficacy and safety of vaccinating women with uncomplicated pregnancy at 24 through 36 weeks' gestation to prevent RSV-associated illness in infants
- 7,392 women

Kampmann B, Madhi SA, Munjal I, et al. Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants. *N Engl J Med.* 2023;388(16):1451-1464. doi:10.1056/NEJMoa2216480

## Severe RSV-Associated Lower Respiratory Tract Illness



## RSV-Associated Lower Respiratory Tract Illness



# mRNA (mRESVIA<sup>®</sup>, Moderna)

- mRNA vaccine that encodes the stabilized prefusion F glycoprotein
- FDA approved in May 2024
- Active immunization indicated for the prevention of LRTD caused by RSV in:
  1. Individuals 60 years of age and older.
- A prefilled syringe of 0.5mL administered via intramuscular injection

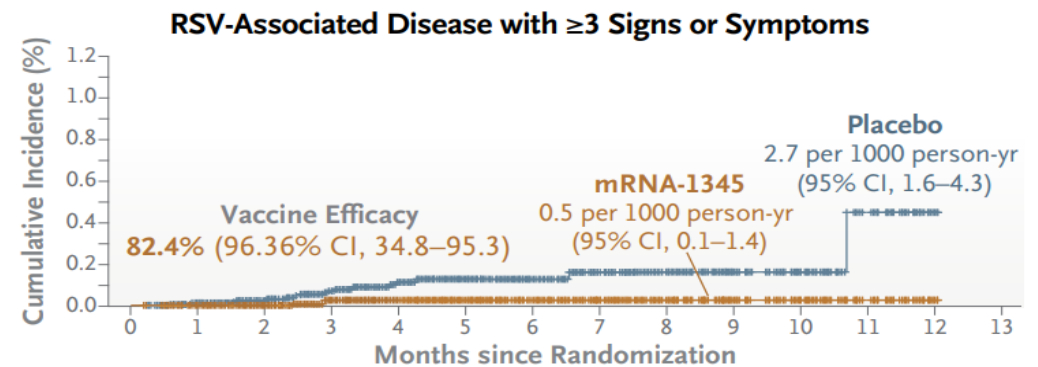
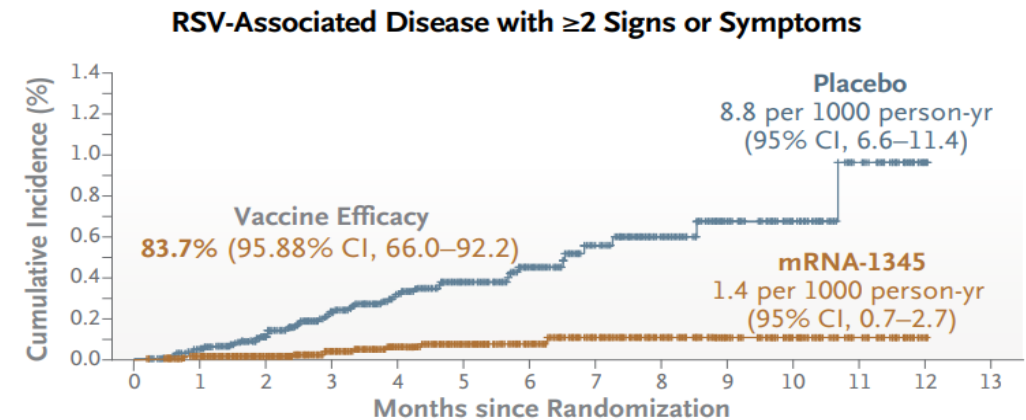


New & Approved: Updates from FDA. Pharmacy Today. July 2024; 20 (7): 12-13.

# Vaccine Efficacy of mRNA (mRESVIA<sup>®</sup>, Moderna) in Patients 60 years and older

- Randomized, double-blind, placebo-controlled, phase 2–3 trial in 22 countries
- **Primary endpoint:** evaluate efficacy in preventing RSV-associated LRTD with at least two signs or symptoms and with at least three signs or symptoms.
- 35,541 participants

Wilson E, Goswami J, Baqui AH, et al. Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults. *N Engl J Med*. 2023;389(24):2233-2244. doi:10.1056/NEJMoa2307079



# Vaccines Storage and Handling

| Vaccine  | Temperature                      | Storage Issues  | Notes   |
|----------|----------------------------------|---|---|
| Arexvy®  | 2°C to 8°C<br>(36°F to 46°F)     | Protect from light. Do not freeze. Discard if carton has been frozen. | Reconstituted vaccine may be stored in the refrigerator for up to 4 hours prior to use.   |
| Abrysvo® |                                  |   | Reconstituted vaccines may be stored at room temperature only. Use within 4 hours   |
| mRESVIA® | -40°C to -15°C<br>(-40°F to 5°F) | Thaw prior to use. Do not refreeze once thawed.                       | To thaw a prefilled syringe: <ul style="list-style-type: none"> <li>- Refrigerator for 60 mins, then room temperature for 10-20 mins</li> <li>- Room temperature for 45 mins</li> </ul> |

Oregon Health Authority. Interim Immunization Protocol. Published July 2024. Accessed August 1, 2024.

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents/SORSV.pdf>

# Additional Considerations

- All three vaccines are well tolerated with safety profile like other vaccines
- Vaccine administration timing:  
Optimally prior to the onset of RSV season (September-March)
- Coadministration of RSV vaccines with other vaccines is acceptable.
- No minimum interval between vaccines

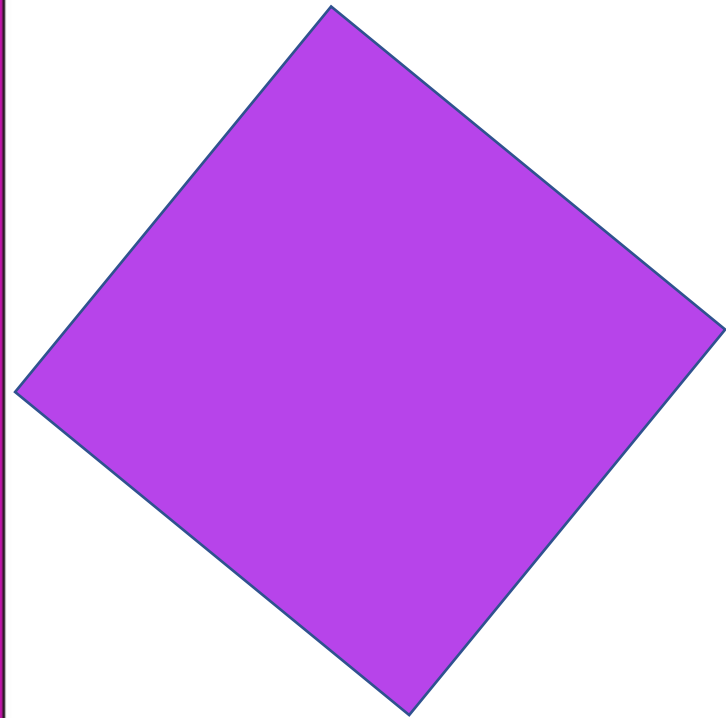


# Additional Considerations

- **Ongoing studies and surveillance:**
  - Preliminary data from VAERS suggest a potential increased risk of Guillain-Barré Syndrome (GBS)
    1. Six cases of inflammatory neurologic events reported in Arexvy® and Abrysvo® clinical trials
  - June 2024 ACIP meeting: CDC and FDA presented new data from ongoing safety monitoring that suggest potential increased risk of GBS and RSV vaccination with Arexvy and Abrysvo vaccine
  - Ongoing monitoring for more data

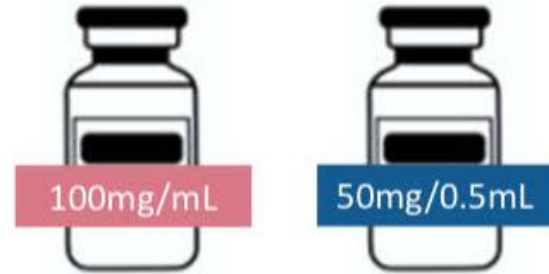
Centers for Disease Control and Prevention. Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Older. Accessed August 1, 2024. <https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html#vaccine-efficacy>





# RSV PREVENTION: MONOCLONAL ANTIBODIES





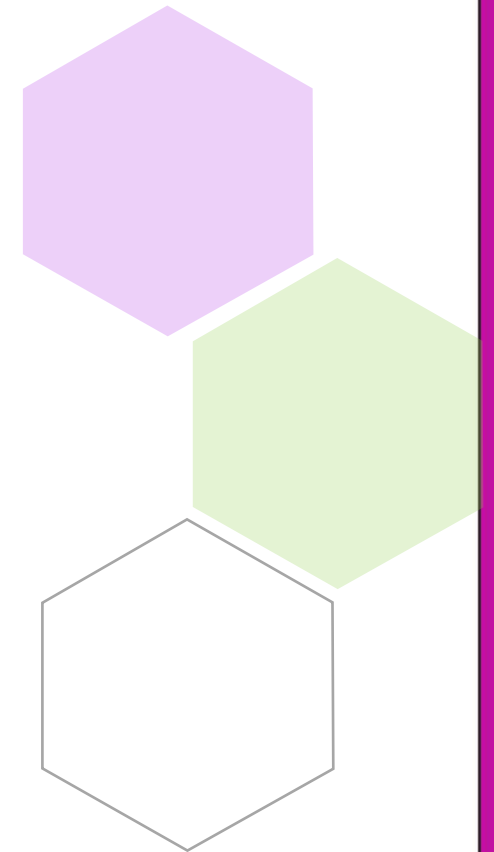
### Palivizumab (Synagis®):

- Monoclonal antibody
- Single dose vial
- 50mg/0.5mL and 100mg/mL



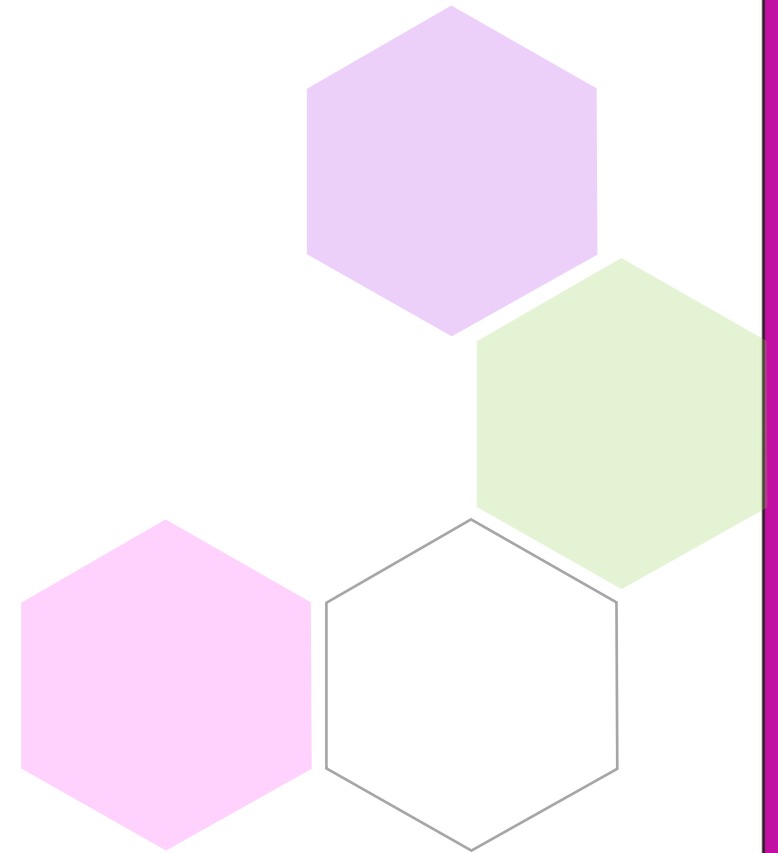
### Nirsevimab (Beyfortus®):

- Long-acting monoclonal antibody
- Single prefilled syringe
- 50mg/0.5mL and 100mg/mL



# Palivizumab

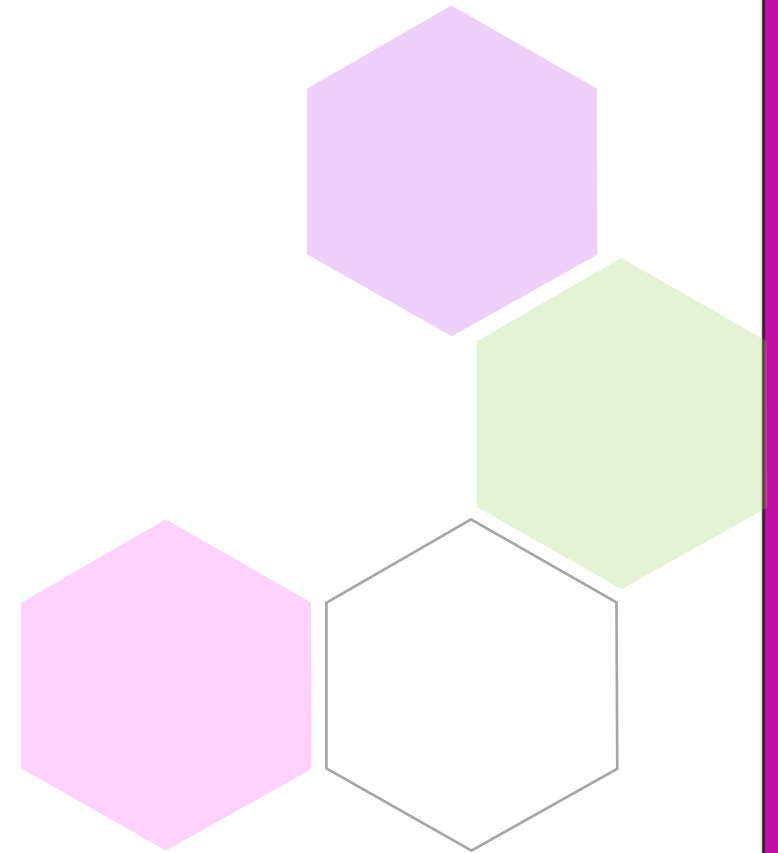
- First monoclonal antibody approved in 1998
- Indicated for preventing LRTD caused by RSV in children at high risk for severe RSV
- Dosage: 15mg/kg IM monthly.
  - First dose is recommended prior to onset of RSV season.
  - Remaining doses administered monthly during RSV season



Caserta MT, O'Leary ST, Munoz FM, Ralston SL; COMMITTEE ON INFECTIOUS DISEASES . Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics*. 2023;152(1):e2023061803. doi:10.1542/peds.2023-061803

# Palivizumab

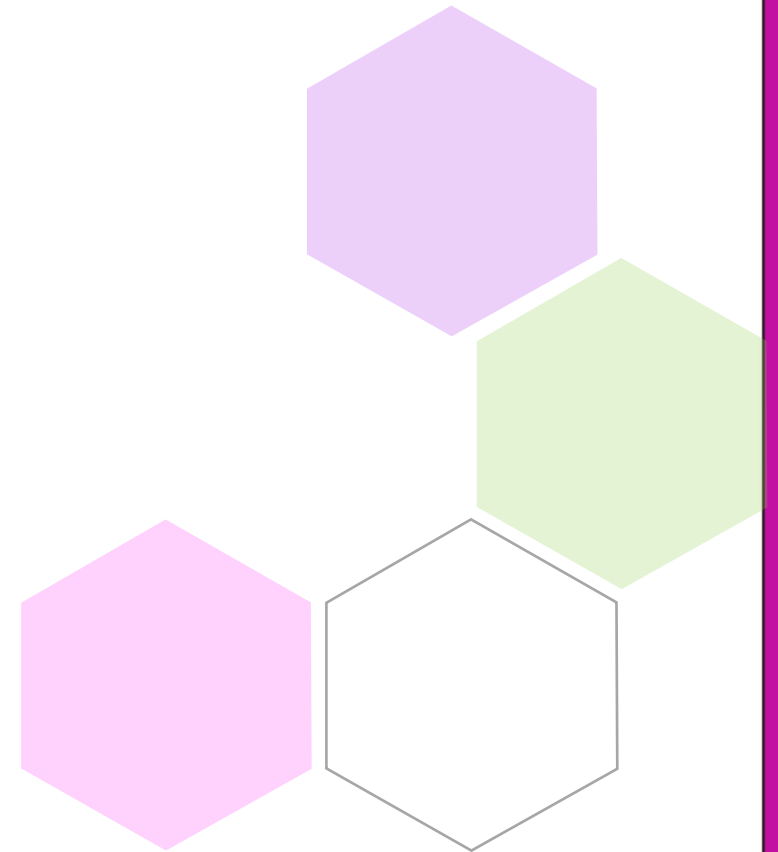
- Infants eligible for Palivizumab during the first year of life:
  1. Premature infants born at <29 weeks gestation
  2. Premature infants born <32 weeks gestation with chronic lung disease
  3. Infants <12 months with certain heart conditions



Respiratory Syncytial Virus (RSV) In RX PreP 2023.

# Nirsevimab

- FDA approved in 2023
- Long-acting monoclonal antibody with extended half-life for up to 71 days
- Indicated for preventing LRTD due to RSV in:
  1. Neonates and infants born during or entering their first RSV season
  2. Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.



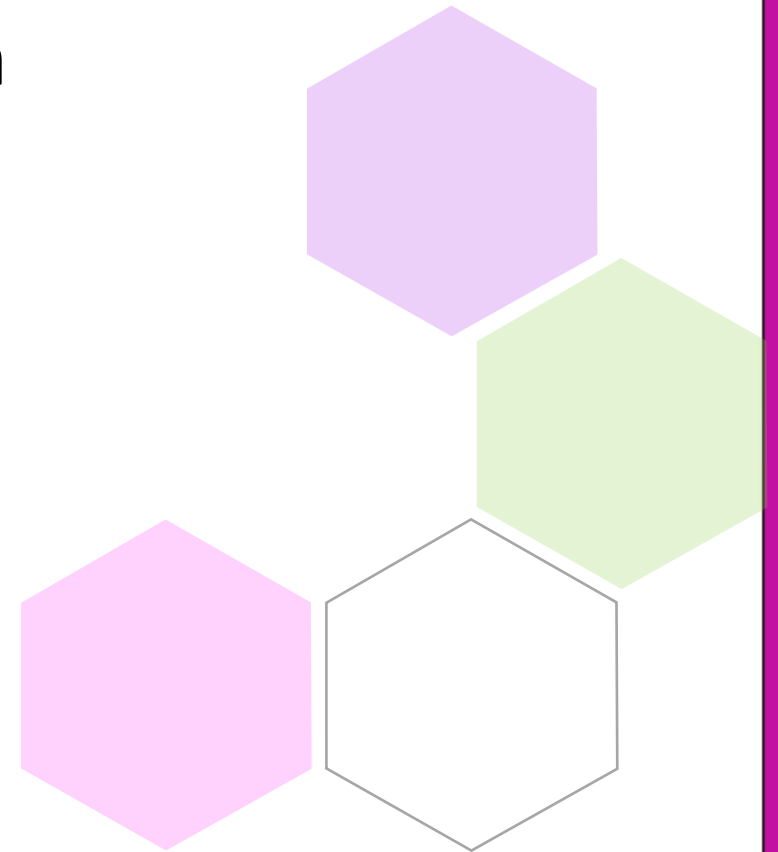
Food and Drug Administration. FDA Approves New Drug to Prevent RSV in Babies and Toddlers. Published July 2023. Accessed August 1, 2024. <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-prevent-rsv-babies-and-toddlers>

## Nirsevimab Dosage in Neonates and Infants for First RSV Season

| Body Weight     | Recommended Dosage |
|-----------------|--------------------|
| Less than 5kg   | 50mg IM injection  |
| 5kg and greater | 100mg IM injection |

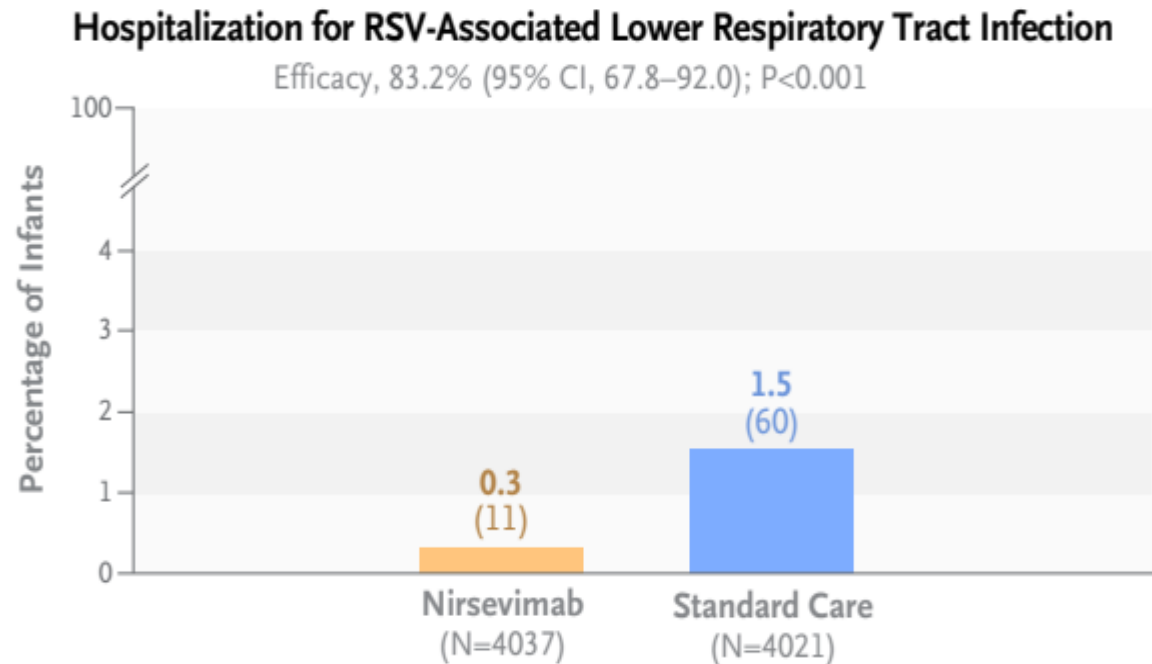
- If children up to 24 months still have increased risk of severe RSV during second RSV season, two injections of Nirsevimab 100mg IM at different sites (total of 200mg) is recommended.

FDA. Nirsevimab Package Insert. Published July 2023. Accessed August 1, 2024.  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/761328s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf)



# Efficacy of Nirsevimab

- Phase 3b, open-label, pragmatic, randomized trial
- **Primary endpoint:** safety of nirsevimab and its effect on RSV-associated hospitalizations in infants who were  $\leq 12$  months of age, born at gestational age of  $\geq 29$  weeks and entering first RSV season
- 8,058 infants 12 months or younger



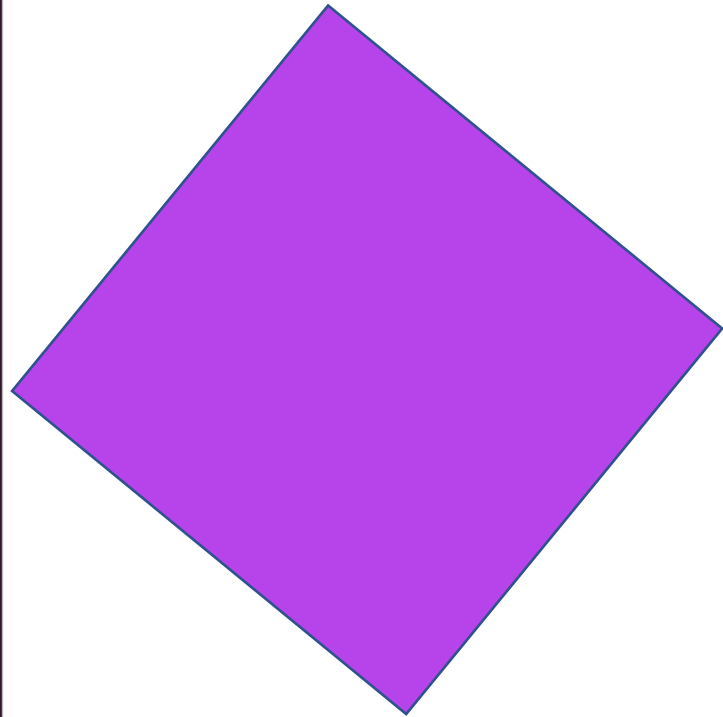
Drysdale SB, Cathie K, Flamein F, et al. Nirsevimab for Prevention of Hospitalizations Due to RSV in Infants. *N Engl J Med*. 2023;389(26):2425-2435. doi:10.1056/NEJMoa2309189

| Additional Information | Palivizumab   | Nirsevimab   |
|------------------------|---|--|
| <b>Storage</b>         | 2°C and 8°C (36°F and 46°F) in its original container. Do not freeze. | 36°F to 46°F (2°C to 8°C). May be kept at room temperature 68°F to 77°F (20°C to 25°C) for a maximum of 8 hours. |
| <b>Adverse Events</b>  | Rash and injection site reactions                                     |  |

FDA. Nirsevimab Package Insert. Published July 2023. Accessed August 1, 2024.

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/761328s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf)

Sobi, What is Synagis? Accessed August 1, 2024. <https://www.synagis.com/what-is-synagis.html#HowSynagisgiven>



# ACIP AND CDC RSV IMMUNIZATION RECOMMENDATIONS



# 2024 CDC Immunization Schedules

## Child/Adolescent

Retrieved from  
<https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

**Table 1** Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2024

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 |        |  |                          |           |  |                      |                                |   |           |                      |                      |  |  |
| Hepatitis B (HepB)                                       | 1 <sup>st</sup> dose   | ← 2 <sup>nd</sup> dose → |                      | ← 3 <sup>rd</sup> dose → |                          |   |        |  |                          |           |  |                      |                                |   |           |                      |                      |  |  |
| Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series) |  |                          | 1 <sup>st</sup> dose | 2 <sup>nd</sup> dose     | See Notes                |   |        |  |                          |           |  |                      |                                |   |           |                      |                      |  |  |
| Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)   |  |                          | 1 <sup>st</sup> dose | 2 <sup>nd</sup> dose     | 3 <sup>rd</sup> dose     |   |        |  | ← 4 <sup>th</sup> dose → |           |  | 5 <sup>th</sup> dose |                                |   |           |                      |                      |  |  |
| Haemophilus influenzae type b (Hib)                      |  |                          | 1 <sup>st</sup> dose | 2 <sup>nd</sup> dose     | See Notes                |   |        | ← 3 <sup>rd</sup> or 4 <sup>th</sup> dose, See Notes → |                          |           |  |                      |                                |   |           |                      |                      |  |  |
| Pneumococcal conjugate (PCV15, PCV20)                    |  |                          | 1 <sup>st</sup> dose | 2 <sup>nd</sup> dose     | 3 <sup>rd</sup> dose     | ← 4 <sup>th</sup> dose →                |        |  |                          |           |  |                      |                                |   |           |                      |                      |  |  |
| Inactivated poliovirus (IPV <18 yrs)                     |  |                          | 1 <sup>st</sup> dose | 2 <sup>nd</sup> dose     | ← 3 <sup>rd</sup> dose → |   |        |  |                          |           |  | 4 <sup>th</sup> dose |                                |   |           |                      |                      |  |  |
| COVID-19 (1vCOV-mRNA, 1vCOV-aPS)                         | 1 or more doses of updated (2023–2024 Formula) vaccine (See Notes) |                          |                      |                          |                          |   |        |  |                          |           |  |                      |                                |   |           |                      |                      |  |  |
| Influenza (IIV4)<br>or<br>Influenza (LAIV4)              | Annual vaccination 1 or 2 doses                                    |                          |                      |                          |                          |   |        |  |                          |           | Annual vaccination 1 or 2 doses                  |                      | Annual vaccination 1 dose only |   |           |                      |                      |  |  |
| Measles, mumps, rubella (MMR)                            |  |                          |                      |                          |                          | See Notes                               |        | ← 1 <sup>st</sup> dose →                               |                          |           |  | 2 <sup>nd</sup> dose |                                |   |           |                      |                      |  |  |
| Varicella (VAR)  |  |                          |                      |                          |                          |   |        | ← 1 <sup>st</sup> dose →                               |                          |           |  | 2 <sup>nd</sup> dose |                                |   |           |                      |                      |  |  |
| Hepatitis A (HepA)                                       |  |                          |                      |                          |                          | See Notes                               |        | 2-dose series, See Notes                               |                          |           |  |                      |                                |   |           |                      |                      |  |  |
| Tetanus, diphtheria, acellular pertussis (Tdap ≥7 yrs)   |  |                          |                      |                          |                          |   |        |  |                          |           |  |                      | 1 dose                         |   |           |                      |                      |  |  |
| Human papillomavirus (HPV)                               |  |                          |                      |                          |                          |   |        |  |                          |           |  |                      | See Notes                      |   |           |                      |                      |  |  |
| Meningococcal (MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years)   |  |                          | See Notes            |                          |                          |   |        |  |                          |           |  |                      |                                |   |           | 1 <sup>st</sup> dose | 2 <sup>nd</sup> dose |  |  |
| Meningococcal B (MenB-4C, MenB-FHbp)                     |  |                          |                      |                          |                          |   |        |  |                          |           |  |                      |                                |   |           | See Notes            |                      |  |  |
| Respiratory syncytial virus vaccine (RSV [Abrysvo])      |  |                          |                      |                          |                          |   |        |  |                          |           |  |                      |                                | Seasonal administration during pregnancy, See Notes |           |                      |                      |  |  |
| Dengue (DEN4CYD; 9–16 yrs)                               |  |                          |                      |                          |                          |   |        |  |                          |           | Seropositive in endemic dengue areas (See Notes) |                      |                                |   |           |                      |                      |  |  |
| Mpox   |  |                          |                      |                          |                          |   |        |  |                          |           |  |                      |                                |   |           |                      |                      |  |  |

Range of recommended ages for all children
  Range of recommended ages for catch-up vaccination
  Range of recommended ages for certain high-risk groups
  Recommended vaccination can begin in this age group
  Recommended vaccination based on shared clinical decision-making
  No recommendation/not applicable

# 2024 CDC Immunization Schedules Child/Adolescent

Retrieved from  
<https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

**Table 3** Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2024

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions are often not mutually exclusive. If multiple conditions are present, refer to guidance in all relevant columns. See Notes for medical conditions not listed.

| Vaccine and other immunizing agents | Pregnancy                           | Immunocompromised (excluding HIV infection) | HIV infection CD4 percentage and count*                        |                 | CSF leak or cochlear implant | Asplenia or persistent complement component deficiencies | Heart disease or chronic lung disease               | Kidney failure, End-stage renal disease or on Dialysis         | Chronic liver disease                    | Diabetes |  |
|-------------------------------------|-------------------------------------|---|--|-----------------|------------------------------|--|---|--|--|----------|--|
|                                     |                                     |   | <15% or <200mm   | ≥15% and >200mm |                              |  |   |  |  |          |  |
| RSV-mAb (nirsevimab)                |                                     | 2nd RSV season                              | 1 dose depending on maternal RSV vaccination status, See Notes |                 |                              |  | 2nd RSV season for chronic lung disease (See Notes) | 1 dose depending on maternal RSV vaccination status, See Notes |  |          |  |
| Hepatitis B                         |                                     |   |  |                 |                              |  |   |  |  |          |  |
| Rotavirus                           |                                     | SCID <sup>b</sup>                           |  |                 |                              |  |   |  |  |          |  |
| DTaP/Tdap                           | DTaP<br>Tdap: 1 dose each pregnancy |   |  |                 |                              |  |   |  |  |          |  |
| Hib                                 |                                     | HSCT: 3 doses                               | See Notes  |                 |                              | See Notes  |   |  |  |          |  |
| Pneumococcal                        |                                     |   |  |                 |                              |  |   |  |  |          |  |
| IPV                                 |                                     |   |  |                 |                              |  |   |  |  |          |  |
| COVID-19                            |                                     | See Notes                                   |  |                 |                              |  |   |  |  |          |  |
| IIV4                                |                                     |   |  |                 |                              |  |   |  |  |          |  |
| LAIV4                               |                                     |   |  |                 |                              |  |   |  | Asthma, wheezing: 2–4 years <sup>c</sup> |          |  |
| MMR                                 | *                                   |   |  |                 |                              |  |   |  |  |          |  |
| VAR                                 | *                                   |   |  |                 |                              |  |   |  |  |          |  |
| Hepatitis A                         |                                     |   |  |                 |                              |  |   |  |  |          |  |
| HPV                                 | *                                   | 3 dose series, See Notes                    |  |                 |                              |  |   |  |  |          |  |
| MenACWY                             |                                     |   |  |                 |                              |  |   |  |  |          |  |
| MenB                                |                                     |   |  |                 |                              |  |   |  |  |          |  |
| RSV (Abrysvo)                       | Seasonal administration, See Notes  |   |  |                 |                              |  |   |  |  |          |  |
| Dengue                              |                                     |   |  |                 |                              |  |   |  |  |          |  |
| Mpox                                | See Notes                           |   |  |                 |                              |  |   |  |  |          |  |

Recommended for all age-eligible children who lack documentation of a complete vaccination series
Not recommended for all children, but is recommended for some children based on increased risk for or severe outcomes from disease
Recommended for all age-eligible children, and additional doses may be necessary based on medical condition or other indications. See Notes.
Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction
Contraindicated or not recommended  
\*Vaccinate after pregnancy, if indicated
No Guidance/Not Applicable

# 2024 CDC Immunization Schedules

## Adult

Retrieved from  
<https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>

**Table 1** Recommended Adult Immunization Schedule by Age Group, United States, 2024

| Vaccine   | 19–26 years   | 27–49 years   | 50–64 years | ≥65 years                           |
|---|---|---|-------------|-------------------------------------|
| COVID-19  | 1 or more doses of updated (2023–2024 Formula) vaccine (See Notes)          |   |             |                                     |
| Influenza inactivated (IIV4) or Influenza recombinant (RIV4) <b>OR</b> Influenza live, attenuated (LAIV4) | 1 dose annually   |   |             |                                     |
| Respiratory Syncytial Virus (RSV)   | Seasonal administration during pregnancy. See Notes.                        |   |             | ≥60 years                           |
| Tetanus, diphtheria, pertussis (Tdap or Td)   | 1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes) |   |             |                                     |
|   | 1 dose Tdap, then Td or Tdap booster every 10 years                         |   |             |                                     |
| Measles, mumps, rubella (MMR)   | 1 or 2 doses depending on indication (if born in 1957 or later)             |   |             | For healthcare personnel, see notes |
| Varicella (VAR)   | 2 doses (if born in 1980 or later)  |   | 2 doses     |                                     |
| Zoster recombinant (RZV)  | 2 doses for immunocompromising conditions (see notes)                       |   | 2 doses     |                                     |
| Human papillomavirus (HPV)  | 2 or 3 doses depending on age at initial vaccination or condition           | 27 through 45 years   |             |                                     |
| Pneumococcal (PCV15, PCV20, PPSV23)   |   |   |             | See Notes                           |
|   |   |   |             | See Notes                           |
| Hepatitis A (HepA)  | 2, 3, or 4 doses depending on vaccine                                       |   |             |                                     |
| Hepatitis B (HepB)  | 2, 3, or 4 doses depending on vaccine or condition                          |   |             |                                     |
| Meningococcal A, C, W, Y (MenACWY)  | 1 or 2 doses depending on indication, see notes for booster recommendations |   |             |                                     |
| Meningococcal B (MenB)  | 19 through 23 years   | 2 or 3 doses depending on vaccine and indication, see notes for booster recommendations |             |                                     |
| Haemophilus influenzae type b (Hib)   | 1 or 3 doses depending on indication  |   |             |                                     |
| Mpox  |   |   |             |                                     |

  Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity
   Recommended vaccination for adults with an additional risk factor or another indication
   Recommended vaccination based on shared clinical decision-making
   No recommendation/Not applicable

# 2024 CDC Immunization Schedules

## Adult

Retrieved from  
<https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>

**Table 2** Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2024

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions or indications are often not mutually exclusive. If multiple medical conditions or indications are present, refer to guidance in all relevant columns. See Notes for medical conditions or indications not listed.

| VACCINE      | Pregnancy                          | Immunocompromised (excluding HIV infection)         | HIV infection CD4 percentage and count |                              | Men who have sex with men | Asplenia, complement deficiency    | Heart or lung disease | Kidney failure, End-stage renal disease or on dialysis | Chronic liver disease; alcoholism* | Diabetes         | Healthcare Personnel <sup>b</sup> |
|--------------|------------------------------------|---|--|------------------------------|---------------------------|------------------------------------|-----------------------|--|------------------------------------|------------------|-----------------------------------|
|              |                                    |   | <15% or <200mm <sup>3</sup>            | ≥15% and ≥200mm <sup>3</sup> |                           |                                    |                       |  |                                    |                  |                                   |
| COVID-19     | See Notes                          |   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| IIV4 or RIV4 | 1 dose annually                    |   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| LAIV4        | 1 dose annually if age 19–49 years |   |  |                              |                           | 1 dose annually if age 19–49 years |                       |  |                                    |                  |                                   |
| RSV          | Seasonal administration. See Notes | See Notes   |  |                              |                           |                                    |                       |  |                                    |                  | See Notes                         |
| Tdap or Td   | Tdap: 1 dose each pregnancy        | 1 dose Tdap, then Td or Tdap booster every 10 years |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| MMR          | *                                  |   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| VAR          | *                                  | See Notes   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| RZV          |                                    | See Notes   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| HPV          | *                                  | 3 dose series if indicated                          |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| Pneumococcal |                                    |   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| HepA         |                                    |   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| Hep B        | See Notes                          |   |  |                              |                           |                                    |                       |  |                                    |                  | Age ≥ 60 years                    |
| MenACWY      |                                    |   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| MenB         |                                    |   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |
| Hib          |                                    | HSCT: 3 doses <sup>c</sup>                          |  |                              |                           |                                    |                       |  |                                    | Asplenia: 1 dose |                                   |
| Mpox         | See Notes                          |   |  |                              |                           |                                    |                       |  |                                    |                  |                                   |

  Recommended for all adults who lack documentation of vaccination, OR lack evidence of immunity  
  Not recommended for all adults, but recommended for some adults based on either age OR increased risk for or severe outcomes from disease  
  Recommended based on shared clinical decision-making  
  Recommended for all adults, and additional doses may be necessary based on medical condition or other indications. See Notes.  
  Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction  
  Contraindicated or not recommended  
<sup>a</sup>Vaccinate after pregnancy, if indicated  
  No Guidance/Not Applicable

# RSV Immunization in Older Adults

- ACIP Recommendation (June 2024): single dose of RSV vaccines for:
  1. All adults 75 years and older
  2. Adults 60-74 years with increased risk of severe RSV.
- Benefits are highest when RSV vaccination is given in the late summer or early fall, just before the onset of RSV season
- ACIP does not recommend for now the vaccine for adults 50-59 years as they concluded there was not enough data on benefits versus risks.



Advisory Committee on Immunization Practices. ACIP recommendations. Published June 2024. Accessed August 1, 2024.  
<https://www.cdc.gov/vaccines/acip/recommendations.html>

# RSV Immunization in Older Adults

- Shared clinical decision-making considerations:
  1. Patient's medical conditions
  2. Patient preference
  3. Risk of exposure and disease severity

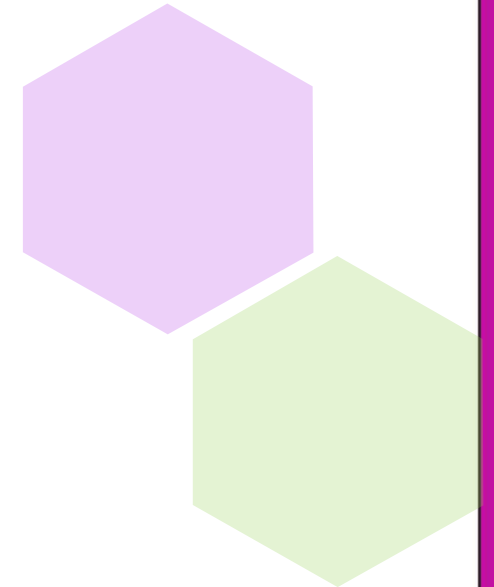


Retrieved from  
<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-02-28-29/08-RSV-Adults-Britton-508.pdf>



# RSV Immunization During Pregnancy

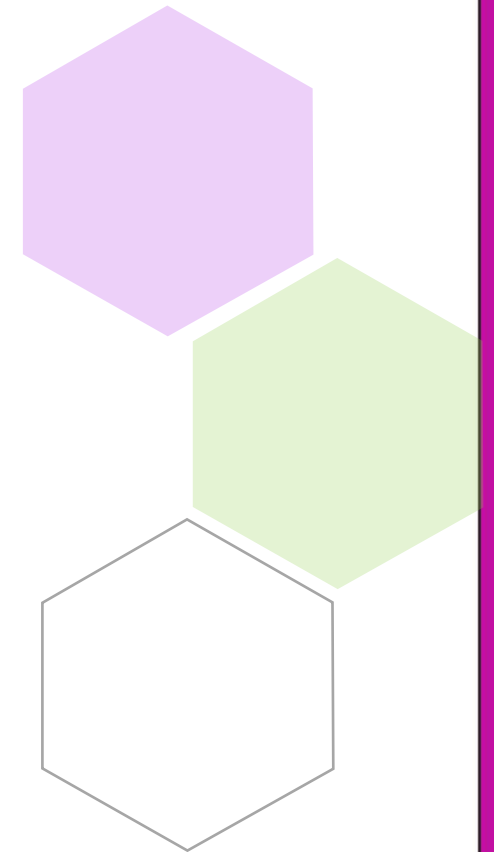
- ACIP Recommendation (September 2023): single one-time dose of RSVPreF (Abrysvo<sup>®</sup>) vaccine in pregnant persons at 32-36 weeks gestation during RSV season (September-January)
- Co-administration with other vaccines recommended during pregnancy is a best practice.
- Shared clinical decision-making if person is not 32-36 weeks pregnant during RSV season.



Fleming-Dutra KE, Jones JM, Roper LE, et al. 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 Morb Mortal Wkly Rep* 2023;72:1115–1122. DOI: <http://dx.doi.org/10.15585/mmwr.mm7241e1>

# RSV Immunization in Infants

- ACIP Recommendation (August 2023):
  1. All infants aged <8 months born during or entering their first RSV season should receive 1 dose of nirsevimab if maternal vaccination with Abrysvo® was not completed before birth.
  2. Infants and children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season should receive 1 dose of nirsevimab
- Administration of nirsevimab should be before RSV season begins or within 1 week of birth for those born during RSV season



Jones JM, Fleming-Dutra KE, Prill MM, et al. 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 Morb Mortal Wkly Rep* 2023;72:920–925. DOI: <http://dx.doi.org/10.15585/mmwr.mm7234a4>



# RSV Immunization Summary

Adults  $\geq 60$  years

One dose of:  
RSVPreF3 (Arexvy®)  
Or  
RSVPreF (Abrysvo®)  
Or  
mRNA (mRESVIA®)

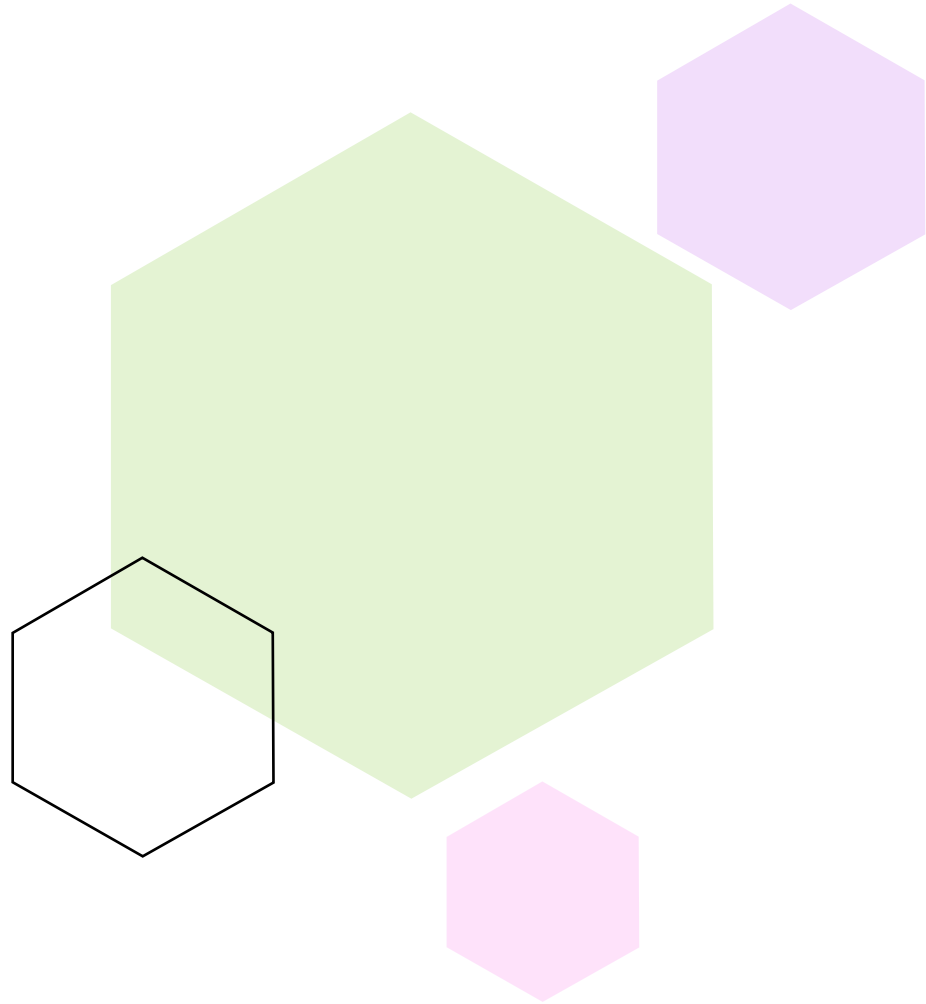
Maternal  
Vaccination

One dose of  
RSVPreF (Abrysvo®)  
at 32-36 weeks  
gestation during  
RSV season

Passive immunization of  
infants and young children

Age <8 months WITH no maternal  
RSV vaccination: one dose of  
nirsevimab after birth or soon  
before RSV season

Age 8-19 months at increased  
risk: one dose of nirsevimab prior  
beginning 2<sup>nd</sup> RSV season



# RSV Vaccine Update

# Pfizer Announces Positive Top-Line Results from Phase 3 Study of ABRYSVO® in Adults Aged 18 to 59 at Increased Risk for RSV Disease

Tuesday, April 09, 2024 - 06:45am

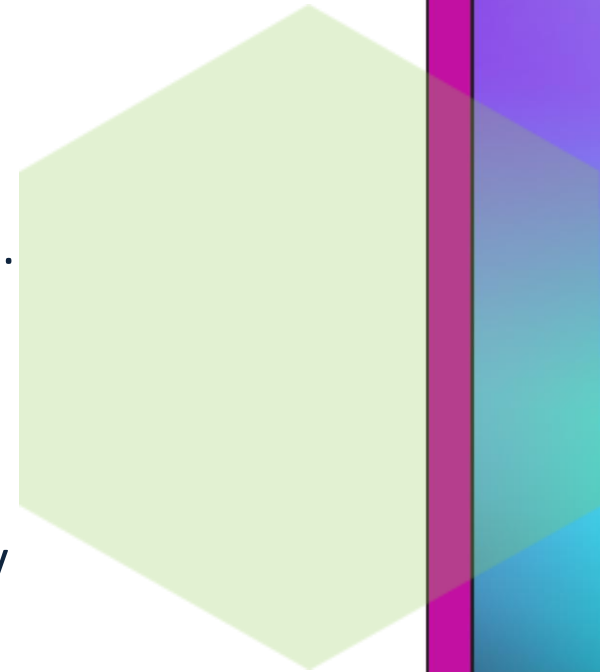


- *ABRYSVO met its trial primary endpoints in adults aged 18 to 59 with an increased respiratory syncytial virus (RSV) disease risk. The vaccine was well-tolerated and demonstrated an immune response non-inferior to adults aged 60 years and older*
- *Pfizer intends to submit these findings to regulatory agencies to seek approval of ABRYSVO in adults 18 to 59 years of age*

Retrieved from <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-positive-top-line-results-phase-3-study-1>

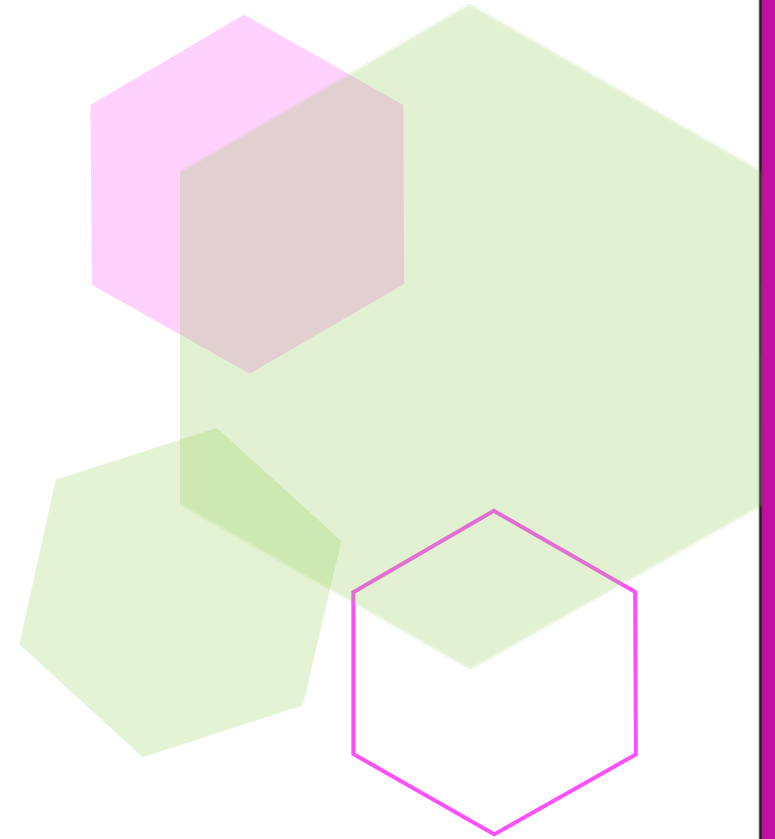
# Summary

- RSV is a respiratory infection that has increased risk of severity in infants and older adults.
- The COVID-19 pandemic has shifted the patterns of RSV season in recent years.
- Over-the-counter medication for symptom relief and ribavirin can be used for RSV management.
- New products have been approved to prevent RSV since 2023: three RSV vaccines and one monoclonal antibody.
- Adults 60 years and older are recommended to administer a single dose of RSV vaccine prior to the onset of RSV season.
- Abrysvo® is the only RSV vaccine approved for use in pregnant persons.
- RSV protection for newborn infants can be provided through maternal vaccination or a dose of nirsevimab or pailvizumab.

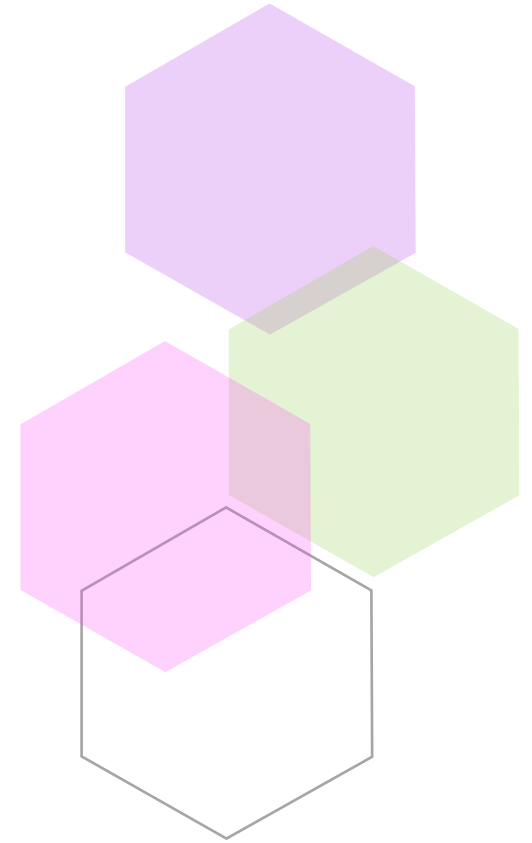


# Key Takeaways

- Pharmacists and the rest of the pharmacy team play an important role in educating eligible patients of the RSV vaccines and their effectiveness in preventing LRTD due to RSV.
- Patient factors (medical conditions, beliefs, patient preference, etc.) must be considered in the shared clinical decision-making for vaccine administration.
- With the upcoming respiratory season coming, pharmacy team members will have the opportunity to update patients with routine vaccinations, including for RSV.



POST TEST



# POST TEST

## QUESTIONS

- Clinical symptoms of RSV are very specific and does not overlap with other viral respiratory infections, as well as some bacterial infections.
  - a. True
  - b. False
- Adults 60 and older who are at increased risk include those with certain chronic medical conditions such as chronic lung or heart disease, immune compromise, those who are elderly or frail, or those living in nursing homes.
  - a. True
  - b. False

# POST TEST

## QUESTIONS

- There are two RSV vaccines approved for adults ages 60 years and older and both vaccines are recombinant protein vaccines that cause the immune system to produce RSV antibodies.
  - a. True
  - b. False
- To protect infants from severe RSV, CDC recommends an RSV vaccine for people who are 32–36 weeks pregnant or a monoclonal antibody given to the baby after birth.
  - a. True
  - b. False



# POST TEST

## QUESTIONS

- CDC encourages healthcare providers to maximize the benefit of RSV vaccination by giving them the RSV vaccine in winter and spring, just prior to the RSV season.
  - a. True
  - b. False

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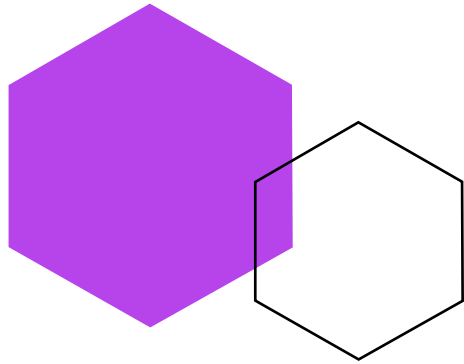
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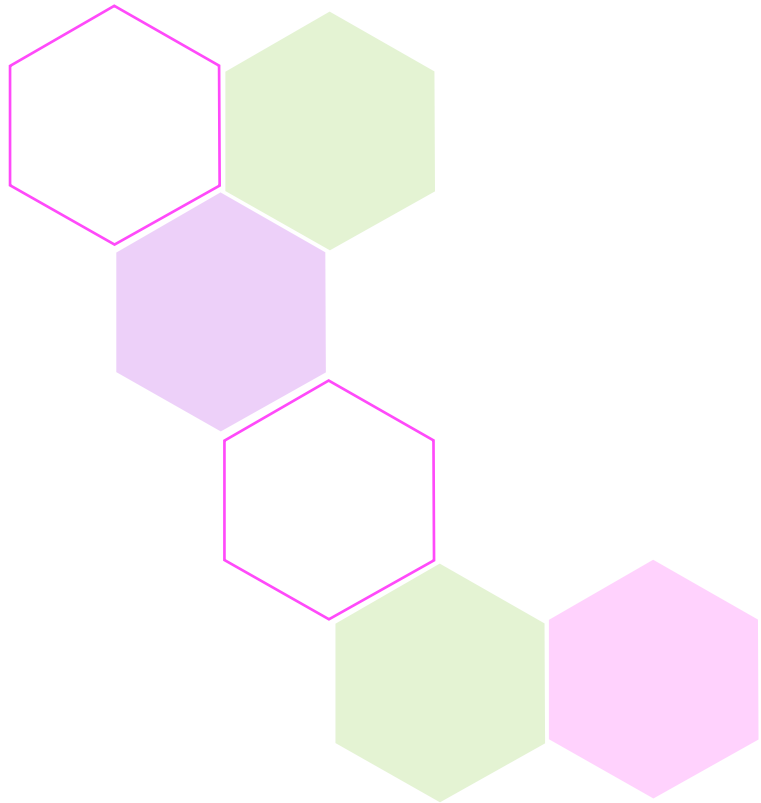


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# Thank you

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