

Respiratory Vaccines Update

Webinar 3

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Webinar

- If you have a question during or after the webinar, please ask your question in the chat.
 - I will do my best to answer all questions before the end of the webinar.
- If you have a question after the webinar, please email Allie Staton.
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Objectives

- Interpret current guidelines for respiratory vaccines.
- Recommend appropriate respiratory vaccines to patients and community members.
- Discuss current respiratory vaccine guidelines and recommendations.

Topics

- Review RSV vaccine products
- Review RSV vaccine recommendations for ages 60 and older
- Review RSV vaccine for pregnant patients
- Discuss current guidance for infant RSV immunizations

Information on Respiratory Syncytial Virus (RSV) Vaccine Administration Errors in Young Children and Pregnant People

Vaccine administration errors are known to occur and are routinely monitored through the Vaccine Adverse Event Reporting System¹ ([VAERS](#)). Since approval of RSV vaccines and the monoclonal antibody nirsevimab, **the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have received reports of the Pfizer (Abrysvo) or GSK (Arexvy) RSV vaccines being administered in error to young children. CDC and FDA have also received reports of the GSK RSV vaccine (Arexvy) being administered in error to pregnant people.** As of January 17, 2024, the number of reports received by VAERS suggests that these types of errors are uncommon in young children less than 2 years of age (25 reports) and pregnant people (128 reports) relative to an estimated 1 million infants protected from RSV either through infant receipt of nirsevimab or through vaccination of pregnant people.²

In August and September 2023, CDC and the Advisory Committee on Immunization Practices recommended two RSV prevention products to prevent RSV-associated lower respiratory tract disease in infants. Nirsevimab (Beyfortus, Sanofi, and AstraZeneca) is only [recommended for infants and some young children at increased risk for severe RSV disease](#). **RSV vaccines (Pfizer Abrysvo, GSK Arexvy) are NOT approved for use in infants or young children.** Pfizer (Abrysvo) is the **only [RSV vaccine recommended for pregnant people](#)**. **The GSK RSV vaccine (Arexvy) is NOT approved for use during pregnancy.**

Most reports of administration errors in young children occurred in infants younger than 8 months. Administration errors for both young children and pregnant people occurred in outpatient settings, including doctor's offices; administration errors of the GSK RSV vaccine (Arexvy) in pregnant people also occurred in pharmacies. Most of these administration error reports described no adverse event. When an adverse event was concurrently reported to VAERS, most reports were classified as nonserious¹. CDC, FDA, and other federal agencies continue to monitor the safety of RSV vaccines and reports of vaccine administration errors and will share information with the public as it becomes available.

IMPORTANT NOTE...

Insurance plans are **not required** to pay for vaccines if they are administered outside of the ACIP/CDC guidelines.

If you prescribe and/or administer an immunization outside of ACIP/CDC guidelines...

- Please document the clinical reason for prescribing outside of guidelines
- Counsel the patient on why you recommend it
- Counsel the patient that they may have to pay out of pocket

IMPORTANT NOTE...

As providers, it is our responsibility to make sure we are up to date on current recommendations and best practices.

Insurance companies are not responsible for “stopping us” from doing something that is wrong.

DON'T FORGET!

A strong recommendation from a healthcare provider is important!

Patients are more likely to choose to vaccinate if their healthcare providers make a **strong** recommendation for vaccination.

RSV

Disease

RSV Disease

- Common respiratory virus
- Usually causes mild, cold-like symptoms
- Most people recover in a week or two
- Humans do not develop lasting immunity from infection

**Infants and older adults are more likely to develop severe RSV.
This may require hospitalization.**

RSV season in the continental U.S. is typically October through March.

RSV Disease (*adults*)

- Most adult cases occur among older adults
- Severe cases usually involve lower respiratory tract disease (LRTD)
- Among adults ages 65 years and older:
 - Hospitalizations: 60,000 – 160,000 annually
 - Deaths: 6,000 – 10,000 annually

RSV Disease (*adults*)

Adults with certain medical conditions are at increased risk for RSV-associated hospitalization.

In general:

- Older adults, especially those 65 years and older
- Adults with chronic heart or lung disease
- Adults with weakened immune systems

RSV Disease (*adults*)

Adults with certain medical conditions are at increased risk for RSV-associated hospitalization.

- Lung diseases
- Cardiovascular diseases
- Neurologic or neuromuscular conditions
- Cerebrovascular disease
- Diabetes Mellitus
- Kidney disorders
- Liver disorders
- Hematologic disorders
- Residents of long-term care facilities
- Persons who are frail or of advanced age
- Persons with moderate to severe immune compromise:
 - Medical condition
 - Medical treatment
 - Immunosuppressive medications

RSV Disease (*children*)

- RSV infection is the leading cause of hospitalization among U.S. infants
- Most children are infected during first year of life
- Almost all children infected by age 2 years
 - ~79% of children under the age of 2 years who are hospitalized from RSV have no underlying medical conditions
- In children aged 5 years and younger in the U.S.:
 - Hospitalizations: 50,000 – 80,000 annually
 - Deaths: 100 – 300 annually

RSV

Immunization Products

	Abrysvo (RSVpreF) <i>Pfizer</i>	Arexvy (RSVpreF3) <i>GSK</i>	Beyfortus (nirsevimab) <i>Sanofi and AstraZeneca</i>
FDA approved for: Ages 60 and older	✓	✓	✗
ACIP/CDC recommended for: Ages 60 and older	✓	✓	✗
<hr/>			
FDA approved for: Use in pregnancy	✓	✗	✗
ACIP/CDC recommended for: Use in pregnancy	✓	✗	✗
<hr/>			
FDA approved for: Use in infants	✗	✗	✓
ACIP/CDC recommended for: Use in infants	✗	✗	✓

Abrysvo & Arexvy MMWR (*older adults*)

What is already known about this topic?

- RSV causes substantial morbidity and mortality in older adults.
- In May 2023, FDA approved the first two vaccines for prevention of RSV lower respiratory tract disease (LRTD) for use in adults aged 60 years and older.

What is added by this report?

- For both vaccine products, Abrysvo and Arexvy, vaccination with a single RSV vaccine dose demonstrated moderate to high efficacy in preventing symptomatic RSV-associated LRTD among adults aged 60 years and older.
- On June 21, 2023, **the Advisory Committee on Immunization Practices (ACIP) recommended that all persons aged 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision making.**

What are the implications for public health practice?

- RSV vaccination might prevent substantial morbidity in older adults at risk for severe RSV disease.
- Post-marketing surveillance for safety and effectiveness will direct future guidance.

Abrysvo MMWR (*pregnancy*)

What is already known about this topic?

- Nirsevimab is recommended in infants to prevent respiratory syncytial virus (RSV)-associated lower respiratory tract infection (LRTI).
- In August 2023, the FDA approved Pfizer RSV vaccine for pregnant persons at 32-36 weeks' gestation to prevent RSV-associated LRTI in infants <6 months.

What is added by this report?

- On September 22, 2023, CDC's **Advisory Committee on Immunization Practices (ACIP)** recommended RSV vaccine for **pregnant persons at 32-26 weeks' gestation using seasonal administration (meaning September thru January in most of the United States)** to prevent RSV-associated LRTI in infants aged <6 months.

What are the implications for public health practice?

- CDC recommends protecting all infants against RSV-associated LRTI through use of either the maternal RSV vaccine or through infant receipt of nirsevimab.

Beyfortus (nirsevimab) MMWR (*infants*)

What is already known about this topic?

- In July 2023, FDA approved nirsevimab, a long-acting monoclonal antibody, for prevention of RSV lower respiratory tract disease in infants.

What is added by this report?

- In August 2023, **the Advisory Committee for Immunization Practices (ACIP), recommended nirsevimab for infants aged <8 months born during or entering their first RSV season and children aged 8-19 months who are at increased risk for severe RSV disease entering their second RSV season.**

What are the implications for public health practice?

- Nirsevimab can prevent severe RSV disease among infants and children aged <20 months at increased risk for severe RSV disease.

RSV

Immunizations for Older Adults

RSV (*adults*)

Two RSV vaccines approved for adults ages 60 years and older.

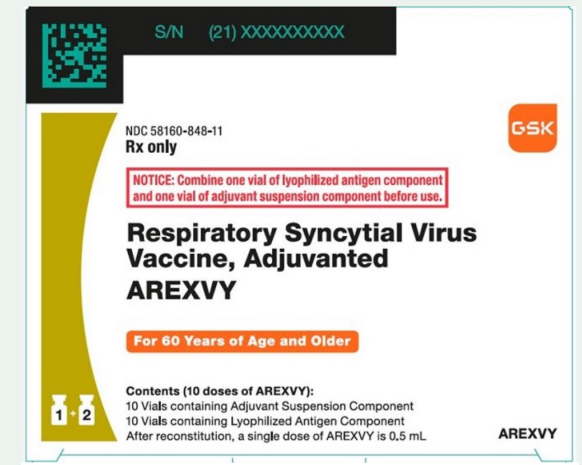
	Abrysvo (RSVpreF) <i>Pfizer</i>	Arexvy (RSVpreF3) <i>GSK</i>
FDA-approved use	<ul style="list-style-type: none">• Patients ages 60 years and older• <i>Pregnant patients 32 – 36 weeks gestational age</i>	<ul style="list-style-type: none">• Patients ages 60 years and older
ACIP/CDC Recommendations	<ul style="list-style-type: none">• Administer one dose to patients ages 60 years and older, using shared clinical decision making• <i>Administer one dose to pregnant patients during weeks 32 – 36 weeks of pregnancy during September through January.</i>	<ul style="list-style-type: none">• Administer one dose to patients 60 years and older, using shared clinical decision making

NOTE: These vaccines are NOT approved or authorized for use in older adults under the age of 60 years.

Abrysvo & Arexvy

Similarities:

- Both have similar efficacy
 - “Moderately to highly” effective in preventing symptomatic RSV-associated LRTD among patients 60 years and older
 - Studies not powered to show decrease in RSV-associated hospitalizations or deaths
- Both require reconstitution
- Both stored at refrigerated temperature
- Both good for 4 hours after reconstitution
- Both administered intramuscularly
- Both approved for one dose for patients ages 60 and older



Differences:

- Currently available in different package sizes
- Different mechanisms for reconstitution
- Arexvy has an adjuvant, Abrysvo does not
- Abrysvo has an indication for pregnancy

RSV Vaccines (*adults ages 60 years and older*)

- **Abrysvo and Arexvy approved for patients 60 years and older.**
- **Currently, only one dose is recommended.**
 - Administer prior to RSV season, if possible.
 - RSV season is typically October thru March.
 - This is NOT a yearly recommendation. It is currently a “one and done” recommendation.
- **Coadministration with other vaccines is acceptable.**
 - Efficacy of coadministration is not expected to be an issue.
 - Studies are ongoing.
 - Patients *may* experience more side effects when Abrysvo or Arexvy are administered with other vaccines.
 - Counsel appropriately.
 - Use your clinical judgment when deciding to coadminister.
 - Will the patient return for other vaccines?

RSV

Immunizations to Protect Infants

RSV Immunizations *(to protect infants)*

There are two immunizations recommended to prevent RSV lower respiratory tract infection in infants.

1. Abrysvo (RSVpreF): *maternal vaccination*

- Administered to pregnant patient during 32 – 36 weeks gestation (during the months of September through January)

2. Beyfortus (nirsevimab): *long-lasting monoclonal antibody*

- Administered to infant after birth

Either maternal vaccination *or* monoclonal antibody is recommended, in most situations for newborns.

Administration of both is not needed for most infants.

RSV

Immunizations for Pregnant Patients

RSV (*pregnancy*)

One RSV vaccine approved for pregnant patients.

	Abrysvo (RSVpreF) <i>Pfizer</i>
FDA-approved use	<ul style="list-style-type: none">• Pregnant patients 32 – 36 weeks gestational age
ACIP/CDC Recommendations	<ul style="list-style-type: none">• Administer one dose to pregnant patients during weeks 32 – 36 weeks of pregnancy during <i>September through January</i><ul style="list-style-type: none">• It is not currently recommended to administer Abrysvo to pregnant patients after January

RSV

Immunizations for Infants

RSV (*infants*)

One RSV immunization recently approved for infants.

	Beyfortus (nirsevimab) <i>Sanofi and AstraZeneca</i>
FDA-approved use	<ul style="list-style-type: none">• Neonates and infants born during or entering their first RSV season• Children up to 24 months who remain vulnerable to severe RSV disease through their second RSV season
ACIP/CDC Recommendations	<ul style="list-style-type: none">• One dose for infants younger than 8 months, born during or entering their first RSV season if:<ul style="list-style-type: none">• The mother did not receive RSV vaccine during pregnancy• The mother's RSV vaccination status is unknown• The infant was born within 14 days of maternal vaccination• A second dose, shortly before or during their second RSV season, is recommended for some children ages 8 – 19 months who are at increased risk for severe RSV disease

RSV (*infants*)

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

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have severe disease
- American Indian or Alaskan Native children

RSV (*infants*)

Administration Guidance

- Administer shortly before RSV season, if possible.
 - This is optimal.
- Infants born shortly before or during RSV season should receive nirsevimab within 1 week of birth.
- Nirsevimab may be administered either during the birth hospitalization or in the outpatient setting.
- Nirsevimab may be administered to eligible infants or children who have not yet received a dose at any time during the season.
 - Only one dose is recommended for an RSV season.
- Infants with prolonged birth hospitalizations related to prematurity or other causes should receive nirsevimab shortly before or promptly after hospital discharge.
- Coadministration with other age-appropriate vaccines is recommended.

RSV

Common Questions

Is either Abrysvo or Arexvy better than the other to protect patients ages 60 years and older from severe RSV?

- There is no preferential recommendation of either Abrysvo or Arexvy.
- Both products are recommended for patients over the age of 60, based on shared clinical decision making.
- Efficacy was similar in clinical trials.

Is either Abrysvo or nirsevimab better than the other to protect infants from severe RSV?

- To protect an infant from severe RSV, there is no preferential recommendation of either Abrysvo (administered during pregnancy) or nirsevimab (administered to infant).
- Abrysvo may only be administered during the months of September through January to patients 32 – 36 weeks gestation.
- Nirsevimab may be administered shortly before and throughout RSV season.
 - RSV season is typically October through March.

Should I keep prescribing Abrysvo to pregnant patients even though it's past January?

- CDC says no.
- Be on the lookout in case there are any updates to this from official resources.

Should I administer RSV immunizations with other vaccines?

- Coadministration of RSV vaccines with other vaccines during the same visit is acceptable.
- When deciding about coadministration, consider:
 - Is the patient up to date with other vaccines?
 - Will the patient return for other vaccines?
 - What is the patient's risk for RSV?
 - Are you administering another vaccine with a high reactogenicity profile?
 - Patient preference.

Note: Regardless of your decision to administer RSV with other vaccines at the same time, be sure to always counsel appropriately.

Atrial Fibrillation and RSV vaccines. Is this safe?

From the MMWR:

GSK Vaccine (Arexvy)

A higher number of participants in the intervention group than in the control group reported atrial fibrillation as an unsolicited event within the 30 days after injection (intervention = 10 events [0.1%]; control = four events [$<0.1\%$]), eight of which were SAEs [intervention = seven; control = one]; three of the SAEs corresponded to new onset atrial fibrillation (intervention = two; control = one) (22).

Pfizer Vaccine (Abrysvo)

A higher number of participants in the intervention group than in the control group reported atrial fibrillation as an unsolicited event within the 30 days after injection (intervention = 10 events [$<0.1\%$]; control = four events [$<0.1\%$], of which seven were SAEs [intervention = four; control = three]). Among participants who reported atrial fibrillation, a medical history of atrial fibrillation was reported by six of 10 Pfizer vaccine recipients and two of four placebo recipients (26).

Please note:

- There are no precautions or contraindications regarding atrial fibrillation for either Absrysvo or Arexvy.
- This will continue to be monitored.

IMPORTANT NOTE...

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- Please document the clinical reason for prescribing outside of guidelines
- Counsel the patient on why you recommend it
- Counsel the patient that they may have to pay out of pocket

Thank you!

Questions?

Resources

- RSV Vaccines in Older Adults – MMWR
 - <https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm>
- Use of Pfizer RSV vaccine during pregnancy – MMWR
 - <https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm>
- Use of nirsevimab for prevention of RSV in infants and young children – MMWR
 - <https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm>
- Abrysvo Package Insert
 - <https://www.fda.gov/media/168889/download>
- Arexvy Package Insert
 - <https://www.fda.gov/media/167805/download>
- Beyfortus (nirsevimab) Package Insert
 - https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf
- American Academy of Pediatrics Resources:
 - <https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-administration/>
 - <https://www.aap.org/en/patient-care/respiratorysyncytial-virus-rsv-prevention/>
 - <https://www.aap.org/en/patient-care/respiratorysyncytial-virus-rsv-prevention/nirsevimab-administration/>
 - https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-frequently-askedquestions/?_ga=2.232011547.541786410.1696354732-1748098428.1612884933