Respiratory Vaccines Update

Webinar 1

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- **You must complete the Evaluation Survey following this webinar.**
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    - No late evaluations will be accepted. Please complete the survey ASAP.
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- **Certificates of Completion for attending this course will be available after you complete the Evaluation Survey.**
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  - A link to the Certificates of Completion will also be sent out tomorrow afternoon in a follow-up email.

Webinar

- If you have a question during or after the webinar, please post your question in the chat.
  - We will do our best to answer all questions before the end of the webinar.

- If you have a question after the webinar, please email Allie Staton.
  - allie@immunizear.org

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

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.

https://www.cdc.gov/rsv/index.html

RSV Season

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

- Because the timing of the onset, peak, and decline of RSV might vary geographically, providers can adjust RSV vaccine administration schedules based on local epidemiology.
  - RSV seasonality in tropical climates (including southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands) might differ from that of most of the continental U.S. or be unpredictable.
  - In Alaska, RSV seasonality is less predictable and duration may last longer than the national average for duration.
  - Providers in the jurisdictions mentioned above should consult state, local, or territorial guidance on timing of nirsevimab administration.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

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

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

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

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

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

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

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

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

RSV

Immunization Products

Green check mark required for FDA approval and ACIP/CDC recommended for administration.	**Abrysvo** (RSVpreF) *Pfizer*	**Arexvy** (RSVpreF3) *GSK*	**Beyfortus** (nirsevimab) *Sanofi and AstraZeneca*
FDA approved for: Ages 60 and older	✓	✓	X
ACIP/CDC recommended for: Ages 60 and older	✓	✓	X
FDA approved for: Use in pregnancy	✓	X	X
ACIP/CDC recommended for: Use in pregnancy	X	X	X
FDA approved for: Use in infants	X	X	✓
ACIP/CDC recommended for: Use in infants	X	X	✓

Abrysvo & Arexvy MMWR

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.

Beyfortus (nirsevimab) MMWR

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 vaccines recently FDA approved for adults*.

	Abrysvo (RSVpreF) *Pfizer*	**Arexvy (RSVpreF3) *GSK***
FDA-approved use	• Patients ages 60 years and older • *Pregnant patients 32 – 36 weeks gestational age***	• Patients ages 60 years and older
ACIP/CDC Recommendations	• Administer one dose to patients ages 60 years and older, using shared clinical decision making • *ACIP has not met to give guidance on the use of Abrysvo for patients who are pregnant*	• Administer one dose to patients 60 years and older, using shared clinical decision making

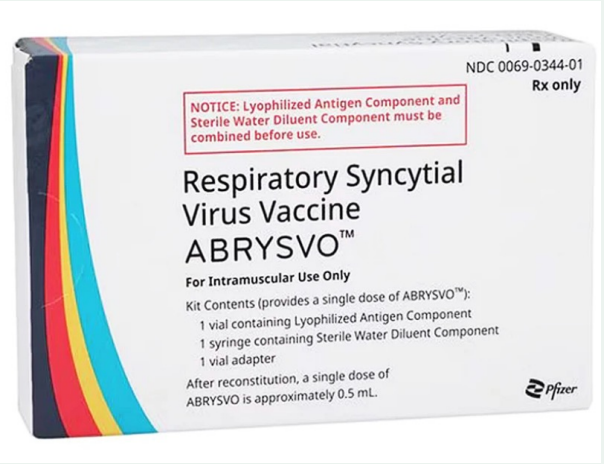
*Pregnancy indication for Abrysvo is <u>not</u> limited to patients 18 years and older, per FDA and the package insert.

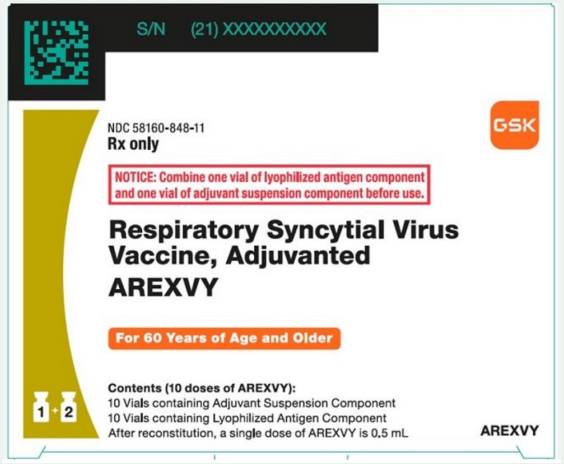
**Recommendations for use have NOT been made by ACIP/CDC yet.

https://www.fda.gov/vaccines-blood-biologics/arexvy

https://www.fda.gov/vaccines-blood-biologics/abrysvo

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

Abrysvo & Arexvy: Adverse Effects

Abrysvo:

- Fatigue (15.5%)
- Headache (12.8%)
- Pain at injection site (10.5%)
- Muscle pain (10.1%)

Arexvy:

- Injection site pain (60.9%)
- Fatigue (33.6%)
- Myalgia – muscle pain (28.9%)
- Headache (27.2%)
- Arthralgia – joint pain (18.1%)

For reference…

Shingrix:

- Pain at injection site (78%)
- Redness at injection site (38%)
- Swelling at injection site (26%)
- Myalgia (45%)
- Fatigue (45%)
- Headache (38%)
- Shivering (27%)
- Fever (21%)
- GI symptoms (17%)

https://media.pfizerpro.com/?media=6331190342112

https://arexvyhcp.com/administration/

RSV Vaccines: 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.
- **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 for Pregnant Patients

RSV *(pregnancy)*

One vaccine recently FDA approved for pregnant patients*.

	Abrysvo **(RSVpreF)** ***Pfizer***
FDA-approved use	• Patients ages 60 years and older • *Pregnant patients 32 – 36 weeks gestational age***
ACIP/CDC Recommendations	• Administer one dose to patients ages 60 years and older, using shared clinical decision making • *ACIP has not met to give guidance on the use of Abrysvo for patients who are pregnant*

*Pregnancy indication for Abrysvo is not limited to patients 18 years and older, per FDA and the package insert.

**Recommendations for use have NOT been made by ACIP/CDC yet.

https://www.fda.gov/vaccines-blood-biologics/abrysvo

RSV

Immunizations for Infants

RSV *(infants)*

One immunization recently FDA approved for infants.

	Beyfortus **(nirsevimab)** ***Sanofi and AstraZeneca***
FDA-approved use	• 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	• One dose for infants younger than 8 months, born during or entering their first RSV season • A second dose, during their second RSV season, is recommended for some children ages 8 – 19 months who are severely immunocompromised

IMPORTANT NOTE: Recommendations for use of Beyfortus may change after ACIP reviews data and makes recommendations for pregnant patients who receive Abrysvo during pregnancy.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

RSV Vaccines: 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 either:
    - 1) Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) OR
    - 2) Weight-for-length less than 10th percentile
- American Indian or Alaskan Native children

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

RSV Vaccines: 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 age-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.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

RSV

Common Questions

Is either Abrysvo or Arexvy better than the other?

- 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.

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

Should I administer Abrysvo or Arexvy 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.

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

What’s going on with COVID-19 vaccines????

- ACIP is meeting next week!
- I’ll be giving a COVID-19 update next Thursday evening.
- More info soon! Stay tuned!

Thank you!

Questions?

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.

Resources

- RSV Vaccines in Older Adults – MMWR
  - https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.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