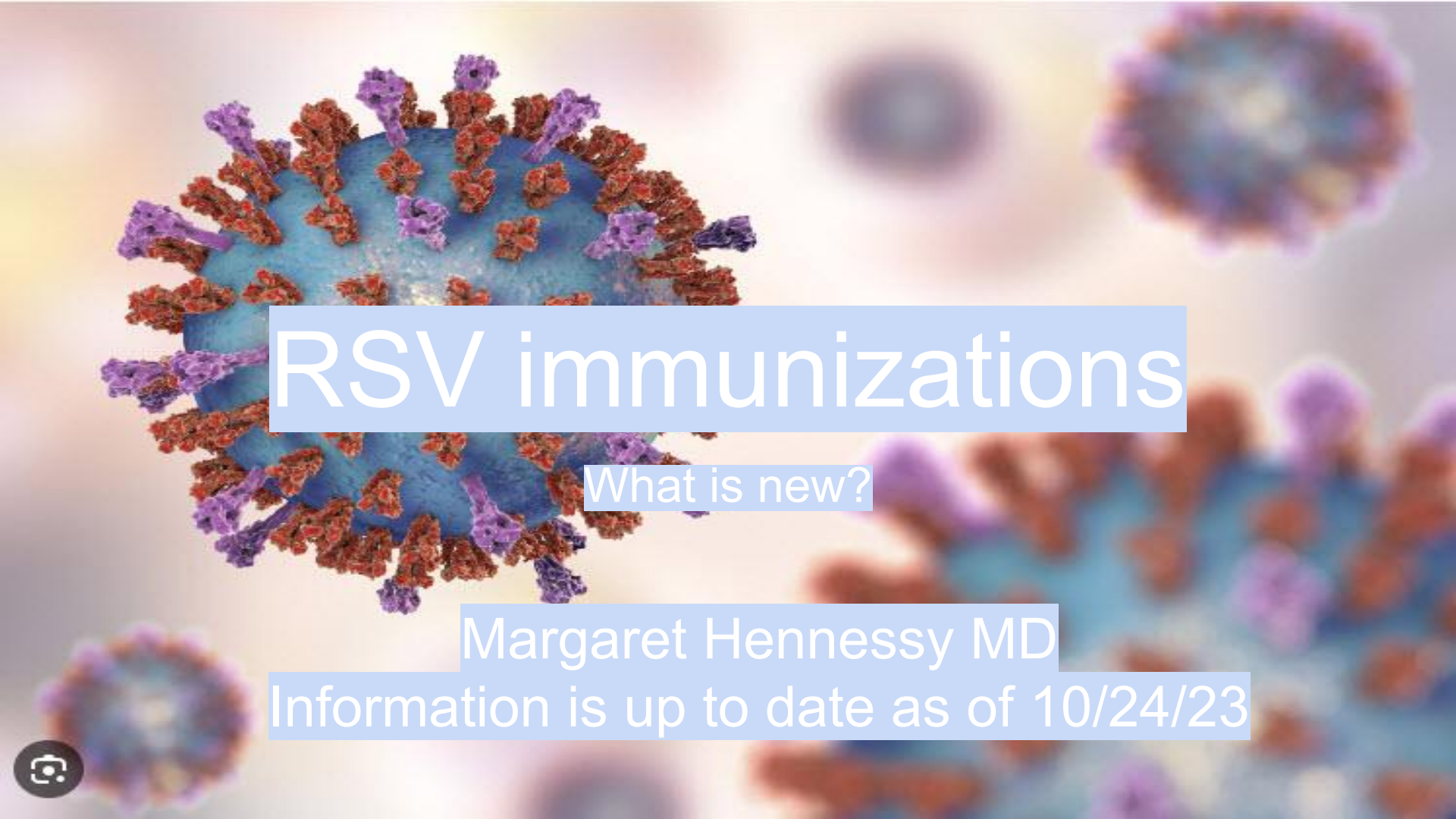


RSV immunizations

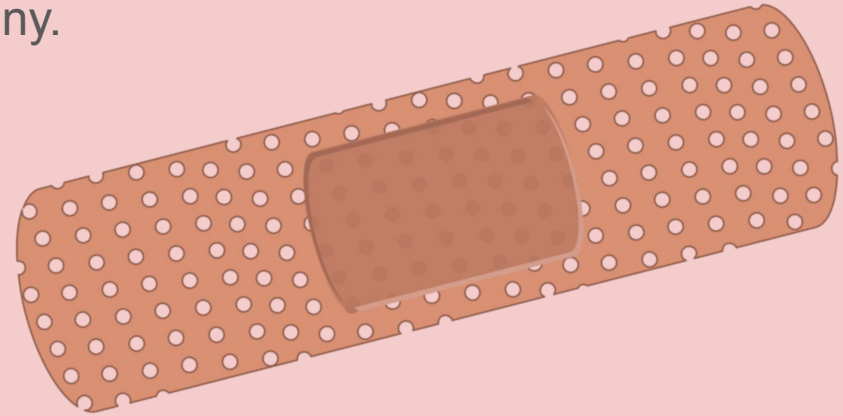
What is new?

Margaret Hennessy MD

Information is up to date as of 10/24/23

Disclosure statement

- Presentation is for educational purposes only and does not replace individual medical judgment.
- I have no financial disclosures related to this presentation.
- I will be using brand names when it simplifies the discussion but this is not an endorsement of any company.



I told my spouse I'll never vaccinate our kids.

She freaked out and shouted "What?! Why?!"

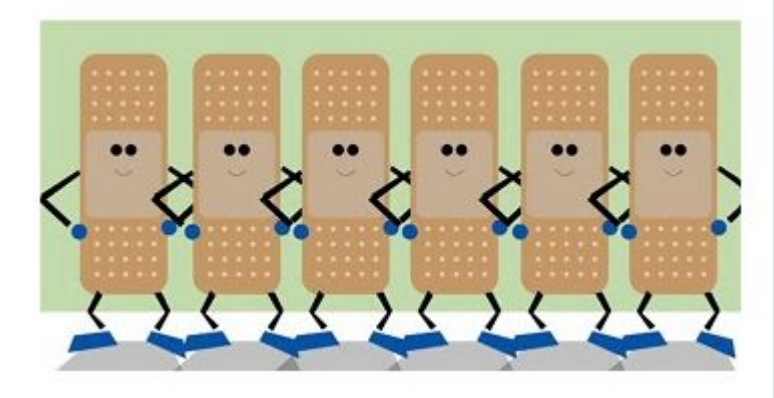
I told her, "I would rather have a doctor do that."

RSV is yucky for young children!

- Major cause of severe lower respiratory tract disease such as bronchiolitis or pneumonia.
- Approximately 58,000 to 80,000 hospitalizations in young children each year in US.
- More than half a million ER visits in children because of RSV and 1.5 million outpatient visits each year.
- 100 to 300 deaths each year in children under 5 years.
- There are no ***vaccines*** are licensed in the U.S. to prevent RSV in children.
- The vast majority (79%) of RSV hospitalizations are in previously healthy infants born at term.

Side track on terms-- immunization vs vaccine

- Passive immunization
  - Antibodies
  - Immunization does the “work” for you
- Active immunization
  - Vaccines
  - Immunization trains your body to make the antibodies
- All vaccines are immunizations but not all immunizations are vaccines.

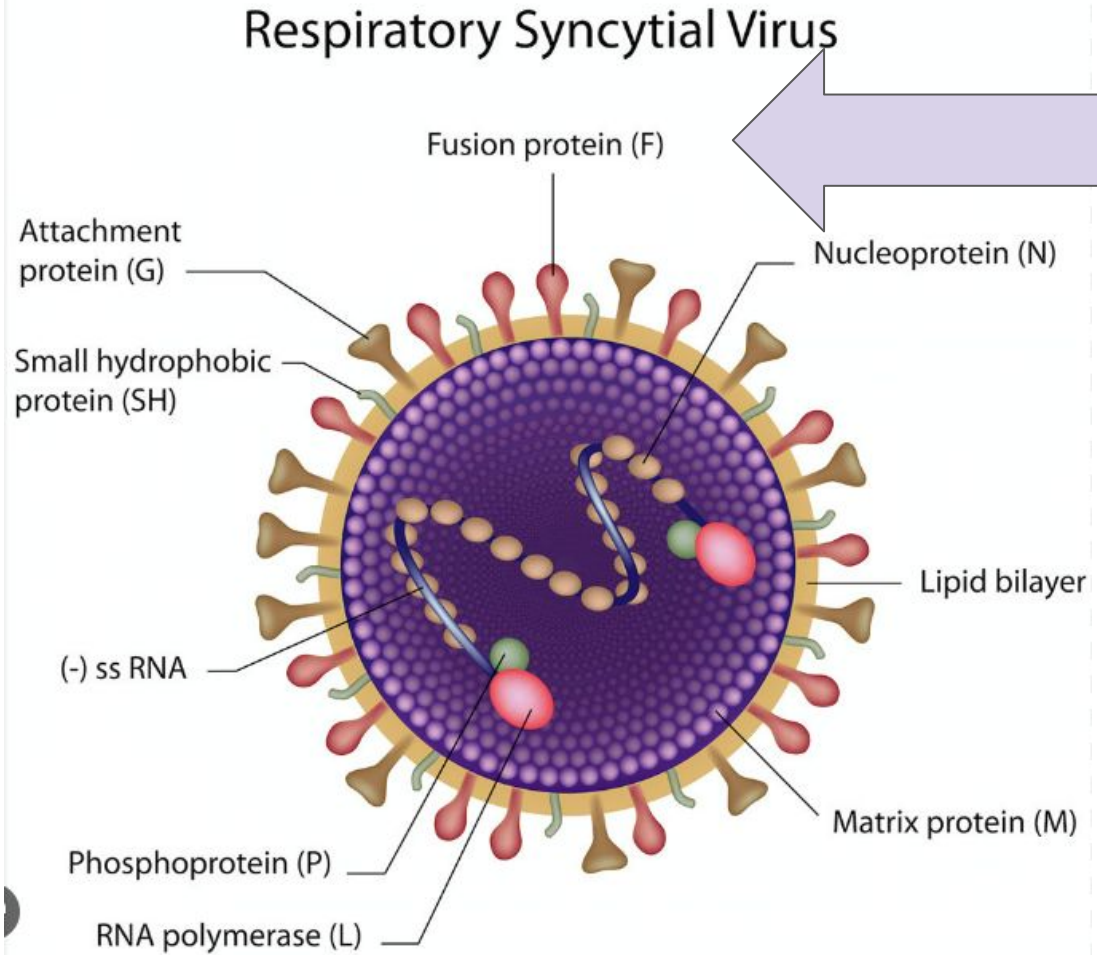


Previous Option for infants

Synagis (Palivizumab) is monoclonal antibody (passive immunization)

Drawbacks

- Limited indications for high-risk infants and young children
- Cost
- Requires monthly visit to clinic
- Requires PA from insurance
- No ACIP recommendations
- Not added to WIR automatically from EHR



New options using the F protein as a target

Nirsevimab (brand name is Beyfortus)

- From Sanofi and AstraZeneca (AstraZeneca also produces Synagis)
- RSV F protein inhibitor monoclonal antibody (passive immunization)
- One dose for the season
- FDA approved in June 2023, ACIP recommended August 2023
  - ACIP/CDC had not provided a recommendation Synagis, it came from AAP
- AAP recommendations are in line with ACIP recommendations.

Beyfortus (nirsevimab)

- All infants < 8 months from October 1st through March 31st-->Use age at time of immunization
- Ideally at birth but recommended within 7 days of life
- High risk babies and young children would get second dose at start of second season
- Dosed by weight/age
  - 50 mg if <5 kg
  - 100 mg if ≥5 kg
  - 200 mg (2x100 mg) for high-risk children entering 2nd RSV season
- Can be administered simultaneously with other childhood vaccines--interference with other immunizations is not expected
- Stored in refrigerator at 2-8 ◦ C, May be kept at room temperature (20-25◦ C) for up to 8 hours
- SAFETY--No significant increase in adverse effects seen in immunized children in the studies compared with children receiving placebo, except rash occurring within 14 days of injection and injection site reactions occurring within 7 days of injection

High Risk Conditions for 2nd season dose (8 to 19 months)

- American Indian and Alaska Native Children
- CLD of prematurity who required medical support any time within 6-month period before the start of the RSV season
- Severe immunocompromising conditions
- Cystic fibrosis PLUS at least one
    - Weight-for-length <10th percentile
    - Manifestations of severe lung disease
        - Previous hospitalization for pulmonary exacerbation in the first year of life
        - Abnormalities on chest imaging that persist when stable

Even if a child with high risk condition is not quite 8 months in their second RSV season, they should still get this second dose.

Infants/toddlers who get Beyfortus would not also get Synagis.
High-risk toddlers who got Synagis last season could get Beyfortus this season.

BOX. Infants and children aged 8–19 months with increased risk for severe disease who are recommended to receive nirsevimab when entering their second respiratory syncytial virus 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 <10th percentile
- American Indian or Alaska Native children

Abbreviation: RSV = respiratory syncytial virus.

https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7234a4-H.pdf

IMMUNIZATION INFORMATION STATEMENT

Respiratory Syncytial Virus (RSV) Preventive Antibody:

What You Need to Know

Why get immunized with a RSV preventive antibody?

A respiratory syncytial virus (RSV) preventive antibody can prevent severe lung disease caused by RSV.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also affect the lungs. Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing.

Anyone can become infected by RSV, and almost all children get an RSV infection by the time they are 2 years old. While most children recover from an RSV infection in a week or two, RSV infection can be dangerous for infants and some young children, causing difficulty breathing, low oxygen levels, and dehydration. In the United States, RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (infection of the lungs) in children younger than 1 year of age. Children who get sick from RSV may need to be hospitalized, and some might even die.

RSV Preventive Antibodies

The RSV preventive antibody (generic name nirsevimab, trade name Beyfortus) is a shot that prevents severe RSV disease in infants and young children. Antibodies are proteins that the body's immune system uses to fight off harmful germs. Like traditional vaccines, preventive antibodies are immunizations that provide protection against a specific pathogen. While both are immunizations, the way they provide immunity is different. Nirsevimab is an immunization that provides antibodies directly to the recipient. Traditional vaccines are immunizations that stimulate the recipient's immune system to produce antibodies.

Infants born during the RSV season (typically fall through spring) should receive a single dose of the RSV Immunization within 1 week after birth. Most infants whose mothers got the RSV vaccine don't need to get nirsevimab, too. Both protect infants from severe RSV by providing antibodies, either from the mother to the infant or directly to the infant. Most infants will likely only need protection from either the maternal RSV vaccine or nirsevimab (not both). However, there may be some situations in which nirsevimab would be recommended for an infant after the mother received an RSV vaccine.

Infants born outside of the RSV season who are younger than 8 months should receive a single dose of the RSV Immunization shortly before their first RSV season (typically the fall), but infants who are younger than 8 months who have not yet received a dose may receive a dose at any time during the season.

Some infants and young children who are at increased risk for severe RSV disease may need a single dose of the RSV antibody before or during their second RSV season.

RSV preventive antibodies can be given at the same time as vaccines routinely recommended for infants and young children.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Talk with your health care provider

Tell your health care provider if the person getting the preventive antibody has a:

- History of serious allergic reactions to an RSV preventive antibody (nirsevimab) or any of its components,
- Bleeding disorder, or
- Moderate or severe acute illness.

In some cases, your child's health care provider may decide to postpone giving RSV preventive antibodies until a future visit.

People who have a minor illness, such as a cold, can safely receive an RSV preventive antibody. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

Risks of a reaction to RSV preventive antibodies

After getting an RSV preventive antibody, your child might have temporary pain, redness, swelling where the injection was given, or a rash.

As with any medicine, there is a very remote chance that RSV Immunization could cause a severe allergic reaction, other serious injury, or death.

An allergic reaction could occur after your child leaves the hospital or clinic. If you see signs of a severe allergic reaction (for example, hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get your child to the nearest hospital.

Call your health care provider if you see any other symptoms that concern you.

What if there is a serious problem?

If your child got an RSV preventive antibody without getting a vaccine at the same time, and you suspect an adverse reaction, you or your health care provider can submit a report through https://www.fda.gov/medwatch or by phone at 1-800-FDA-1088.

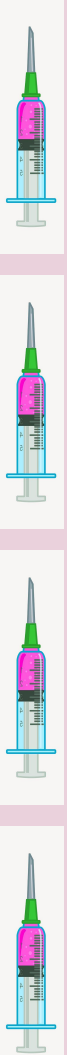
If your child got an RSV preventive antibody and a vaccine at the same time and you suspect an adverse reaction, you or your health care provider should report it to the Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov/ or call 1-800-822-7967. In your report, note that your child got an RSV Immunization along with a vaccine.

Note: MedWatch and VAERS are only for reporting reactions. MedWatch and VAERS staff members do not give medical advice.

How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit U.S. Food and Drug Administration website at Drugs@FDA: FDA-Approved Drugs.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit the CDC website https://www.cdc.gov/rsv/about/prevention.html

IIS not VIS



Efficacy

- 1st season Randomized studies using 2:1 immunization to placebo
  - Phase 2b trial-1,453 infant GA 29-34 weeks
  - Phase 3 trial-3,012 infants born 35 weeks and later
- High risk children entering their 2nd RSV season
  - Extrapolation done based on nirsevimab concentrations
  - One study with 615 children born <35 weeks + 310 children with CLD or heart dz
  - Randomized to get nirsevimab or palivizumab

- Pooled efficacy of nirsevimab in term and late preterm infants 79.0% (95% CI = 68.5%–86.1%) in preventing medically-attended RSV-associated LRTI
- Efficacy in preventing RSV-associated hospitalization was 80.6%(95% CI = 62.3%–90.1%)
- Efficacy on preventing RSV-associated ICU was 90.0% (95% CI = 16.4%–98.8%)

Other notes on Nirsevimab (Beyfortus)

- Available on VFC (VFC is for uninsured, underinsured*, Medicaid eligible, and American Indian or Alaska Native children)
- Issues with bundling with newborn hospitalization charges
- Not clear if private insurance will cover immediately-may take up to a year (ACA)
- Categorized as drug not vaccine, may limit who gives injection in some jurisdictions in the US--fortunately not an issue for us in Wisconsin
- Adverse Event reporting can be different
    - If just giving RSV then report to MedWatch (www.fda.gov/medwatch or by phone at 1-800-FDA-1088)
    - If given with other vaccines then report to VAERS only (https://vaers.hhs.gov or by phone 1-800-822-7967

*need to use a FQHC or RHS

- Wholesale Cost is $495 per 50 mg or 100 mg dose ($990 for the second season 200 mg dose)
- Coding for Nirsevimab administration--see supplemental information for more details
  - 96380 Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified healthcare professional
  - 96381 Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection
- The product codes for nirsevimab are:
  - 90380 Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use
  - 90381 Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use
- Contraindication--history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab or any of its ingredients
- Precaution--”Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human IgG1 monoclonal antibodies. Initiate appropriate medications and/or supportive therapy.”

From FAQs from AAP

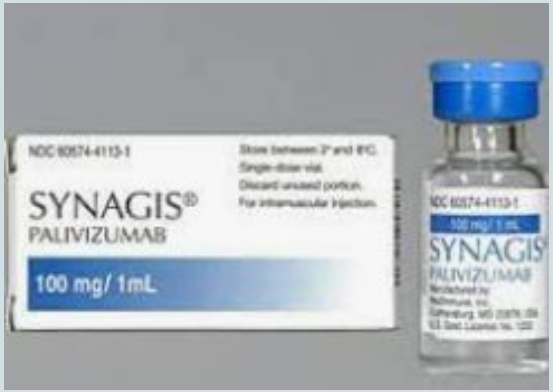
Is nirsevimab financially feasible for my practice? What flexibilities are available when I implement nirsevimab in my practice?

- Payment terms for this season for those ordering direct from Sanofi are 150 days from time of shipment.
- There is no minimum order size. Nirsevimab is packaged as five single dose prefilled syringes per carton in both formulations.
- Nirsevimab is fully returnable upon expiration. Sanofi offers credit (credit based on exact amount returned and the invoice purchase price that is net of prompt pay or other discount(s)) upon expiration on all full and open box Sanofi product(s) directly purchased from Sanofi that are returned within 1 year after the expiration date.

Great information available from AAP
https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-frequently-asked-questions/

What about Synagis?

SYNAGIS®
PALIVIZUMAB



- Synagis is palivizumab, it is usually given once a month during RSV season for infants and children with high risk conditions
- Nirsevimab (Beyfortus) may not be available at the start of this RSV season, therefore, infants who qualify for palivizumab (Synagis) should start the series.
- If nirsevimab becomes available then the child who has received fewer than 5 doses of for the palivizumab 2023-2024 RSV season may get a dose of nirsevimab 30 days later. They would not get any more doses of palivizumab.
- That is to say, once you get a dose of nirsevimab then you are done for the season even if you have a high risk condition

WHO gets Synagis?

Condition	Age
Born before 29 weeks, 0 days	First year of life
Hemodynamically significant congenital heart disease, Includes • Acyanotic heart disease on meds to control CHF and will require need cardiac surgery • moderate to severe pulmonary hypertension • If surgically corrected condition but still meds for CHF	First year of life
Cardiac transplant	Up to age 24 months
Neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough	First year of life
"Profoundly" immunocompromised, solid organ transplant, bone marrow transplant, on chemo	Up to age 24 months
Cystic fibrosis AND CLD and/or nutritional compromise in 1st year of life	First year of life
Cystic fibrosis AND manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile	Up to 24 months
Born before 32 weeks, 0 days AND O2 for at least 28 days after birth AND continue to need supplemental O2, chronic systemic steroids, or bronchodilators within the 6 months of the start the RSV season	Up to 24 months
Navajo or White Mountain Apache	First year of life
Alaska Native determination depends on epidemiology in Alaska (this state is treated differently than the rest of the US)	First year of life

If any infant is born during the season, they may not get all 5 doses since Synagis is only given during the set months of the RSV season as determined by the state.

Recommendations are from AAP

THE AMERICAN ACADEMY OF PEDIATRICS®

I rang the doctor and said, “Quick! My pregnant wife’s going into labor, what should I do?”

The doc asked, “Is this her first child?”

I said, “No, this is her husband.”

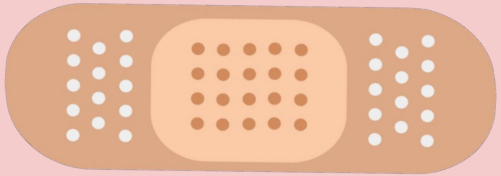
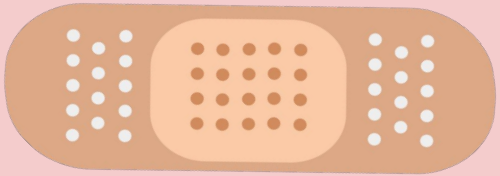
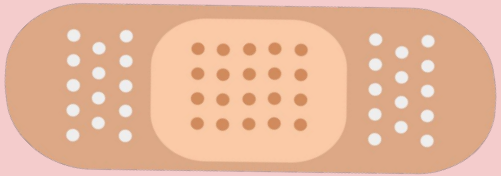
Protecting all infants

NEW OPTIONS

- Pfizer RSV vaccine will be available for pregnant persons-FDA-approved and ACIP-recommended, expected to be given at least 14 days prior to birth.
- Nirsevimab for all infants if prenatal dose of RSV vaccine not received
- Most infants would not get both types of protection

FDA-approval for RSVpreF vaccine- for persons during pregnancy

- Brand name is Abrysvo
- Manufacturer is Pfizer, maybe referred to as the “Pfizer RSV vaccine”
- 8/21/23--FDA approved for persons during pregnancy, ACIP recommended 9/22/23
- “Indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.”

ACIP Recommendations

- One dose at 32 0/7 weeks through 36 6/7 weeks using a seasonal pattern of September (1-2 months before season) through January (2-3 months before end of season).
- Infants born outside of this window, will then be recommended to get nirsevimab.
- Some parts of US (Alaska, southern Florida, Guam, Hawaii, Puerto Rico, Pacific Islands, and US Virgin Islands) will follow a different patterns.
- Maybe given at same time with other vaccines recommended during pregnancy (Tdap, Flu, COVID-19) but use a separate site (1 inch).
- No data on repeating in subsequent pregnancies--will have to wait on further recommendations.

Efficacy and Safety of RSVpreF Vaccine in Pregnancy

- Studied in 1:1 trial-- about 3,500 persons in each group-vaccine vs placebo
  - Reduced risk of severe LRTD in infants by 81.8% within 90 days after birth, and 69.4% within 180 days after birth.
- Another study in persons who are pregnant 32-36 weeks, 1,500 vaccine vs 1,500 placebo
  - Reduced the risk of LRTD by 57.3% and risk of severe LRTD by 76.5% within 180 days after birth
- Most common side effects-pain at the injection site, headache, myalgias, and nausea.
- More serious concerns seen in studies had slight increase in vaccine group vs placebo group
  - Not statistically significant
  - Pre-eclampsia 1.8% vs 1.4%
  - Preterm births 5.7% vs 4.7%
  - Data insufficient to determine causal impact

LRTD=lower respiratory tract disease

Summary of Key Recommendations

- The American College of Obstetricians and Gynecologists (ACOG) recommends a single dose of maternal RSV vaccination for pregnant individuals between 32 0/7 and 36 6/7 weeks of gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants. For most of the United States, RSV season occurs from September through January.
- Clinicians should counsel patients about the maternal RSV vaccine and the monoclonal antibody, nirsevimab, as safe and effective ways to prevent severe LRTI caused by RSV in infants.
- Patient preferences should be considered when determining whether to administer the maternal RSV vaccine or not to administer the maternal RSV vaccine and rely on administration of nirsevimab to the infant after birth.
- Maternal RSV vaccine can be administered at the same time as other vaccines routinely recommended during pregnancy.
- Clinicians should document receipt or declination of maternal RSV vaccination in the patient's medical chart.

ACOG | Clinical
The American College of Obstetricians and Gynecologists

Source--
https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/09/maternal-respiratory-syncytial-virus-vaccination

Relative risks and benefits of maternal vaccination and nirsevimab

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

Maternal RSV vaccine	Nirsevimab
Benefits • Provides protection immediately after birth • May be more resistant to virus mutation • Avoids injection of infant **Risks** • Protection reduced if fewer antibodies produced or are transferred from mother to baby (e.g., mother immunocompromised or infant born soon after vaccine) • Potential risk of preterm birth	**Benefits** • Studies of antibody levels suggest that protection might wane more slowly • Can provide antibodies directly if infant receives less antibodies from mother • No risk of adverse pregnancy outcomes **Risks** • Potentially limited availability during 2023-2024 RSV season

Source: CDC

Maternal vaccination and considerations for use of nirsevimab in infants born <34 weeks gestation

- As proposed, maternal RSV vaccine recommendation is for administration beginning at 32 weeks gestation
- From time of maternal vaccination, 14 days or more likely needed for development and transplacental transfer of maternal antibodies to protect the infant,[1] and nirsevimab is recommended for infants born within 14 days of vaccination
- Therefore, the earliest an infant can be born and have maternal vaccine-induced protection is at 34 weeks gestation
- Infants born <34 weeks gestation will be recommended to receive nirsevimab

[1] https://www.cdc.gov/vaccines/pregnancy/vacc-during-after.html.

What about infants born early?

Circumstances for which nirsevimab can be considered when mother has received RSV vaccine ≥14 days prior to birth

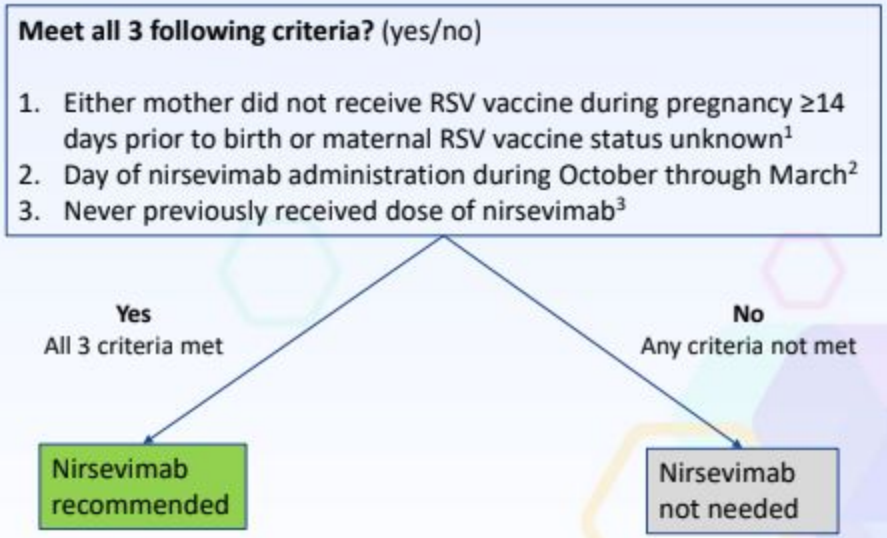
- Nirsevimab can be considered in rare circumstances when, per the clinical judgment of the healthcare provider, the potential incremental benefit of administration is warranted
  - Infants born to pregnant people who may not mount an adequate immune response to vaccination (e.g., people with immunocompromising conditions) or have conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)[1]
  - Infants with cardiopulmonary bypass, leading to loss of maternal antibodies
  - Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission and requiring oxygen at discharge)

[1] Palmerira Clin Dev Immunol 2012.

for the infant

Overview

Nirsevimab administration algorithm for children aged <8 months on the day of administration



Insurance coverage for RSV vaccine during pregnancy

- Private health insurance
- Medicaid-Beginning October 1, 2023, most people with coverage from Medicaid and Children's Health Insurance Program (CHIP) will be guaranteed coverage of all vaccines recommended by the Advisory Committee on Immunization Practice at no cost to them.
- Vaccines for Children (VFC) program--Pregnant teens <19 years enrolled in Medicaid will not be charged for the vaccine or administration. VFC-eligible teens not enrolled in Medicaid will get the vaccine at no charge but may be charged an administration fee.

The doctor said to me, “Your brain seems to have deleted all information about 80s pop music!”

I said, “Yikes, what’s The Cure?”

He said, “Oh my God, it’s worse than I thought!”

RSV is also yucky for adults!

- Can cause serious disease in older adults (≥65 years), adults with chronic heart or lung disease (asthma/COPD, CHF), adults with immunocompromised immune systems.
- Around 60,000–160,000 older adults are hospitalized each year due to RSV in the US
- Around 6,000–10,000 older adults die due to RSV infection.
- We don’t have antivirals to treat RSV infections
- Prevention is the key.

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 72 / No. 40
October 6, 2023

Characteristics and Outcomes Among Adults Aged ≥60 Years Hospitalized with Laboratory-Confirmed Respiratory Syncytial Virus — RSV-NET, 12 States, July 2022–June 2023

Summary

What is already known about this topic?

Respiratory syncytial virus (RSV) causes substantial morbidity and mortality in older adults. In June 2023, CDC recommended RSV vaccination for adults aged ≥60 years, using shared clinical decision-making and prioritizing those at highest risk for severe disease.

What is added by this report?

Among 1,634 patients aged ≥60 years hospitalized with RSV, 54% were aged ≥75 years, and 17% resided in long-term care facilities (LTCFs). Obesity, chronic obstructive pulmonary disease (COPD), and congestive heart failure (CHF) were common underlying conditions.

What are the implications for public health practice?

Clinicians and patients should consider age (particularly age ≥75 years), LTCF residence, and underlying medical conditions, including COPD and CHF, in shared decision-making regarding RSV vaccination to prevent severe RSV-associated outcomes.

Summary

What is already known about this topic?

In June 2023, CDC recommended the first respiratory syncytial virus (RSV) vaccines for adults aged ≥60 years using shared clinical decision-making. Understanding the severity of RSV disease is needed to guide this clinical decision-making.

What is added by this report?

During February 2022–May 2023, hospitalizations for RSV were less frequent but were associated with more severe disease than were hospitalizations for COVID-19 or influenza, including receipt of standard flow oxygen therapy, high-flow nasal cannula or noninvasive ventilation, and intensive care unit admission.

What are the implications for public health practice?

The potential for severe RSV disease among older adults is important to consider as part of shared clinical decision-making when assessing the benefit of RSV vaccination among adults aged ≥60 years.

Summary

What is already known about this topic?

Adults aged ≥65 years have increased risk for COVID-19–associated hospitalization and other severe outcomes compared with younger age groups.

What is added by this report?

During January–August 2023, adults aged ≥65 years accounted for 62.9% of all COVID-19–associated hospitalizations. Most hospitalized adults aged ≥65 had multiple underlying conditions. Only 23.5% had received the recommended COVID-19 bivalent vaccine.

What are the implications for public health practice?

Adults with increased risk for COVID-19–associated hospitalization, including all adults aged ≥65 years, should reduce their risk for severe COVID-19 by receiving recommended COVID-19 vaccinations, adopting measures to reduce risk for contracting COVID-19, and seeking prompt outpatient antiviral treatment after a positive SARS-CoV-2 test result.

CDC recommendations--SHARED DECISION-MAKING

ACIP recommended that adults aged ≥60 years may receive a single dose of RSV vaccine, using shared clinical decision-making

- Decision to vaccinate should be made with a discussion between the clinician and the patient.
  - Consider patients at high risk from severe disease from RSV--COPD, asthma, CHF, coronary artery disease, moderate to severe immunocompromised condition, diabetes, neurologic disease, kidney disease, liver disease, blood disease
  - Persons who are “frail”
  - Persons living in LTC/nursing homes
- One dose
- No recommendation for repeated dose or boosters
- No set season for vaccines
- May give concomitantly with other vaccines.

*Frailty-no consensus definition, one frequently used tool is the Fried frailty phenotype in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10 lbs [4.5 kg] in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity. Source- CDC

VACCINE INFORMATION STATEMENT

RSV (Respiratory Syncytial Virus) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

RSV vaccine can prevent lower respiratory tract disease caused by **respiratory syncytial virus (RSV)**. RSV is a common respiratory virus that usually causes mild, cold-like symptoms.

RSV can cause illness in people of all ages but may be especially serious for infants and older adults.

- Infants up to 12 months of age (especially those 6 months and younger) and children who were born prematurely, or who have chronic lung or heart disease or a weakened immune system, are at increased risk of severe RSV disease.
- Adults at highest risk for severe RSV disease include older adults, adults with chronic medical conditions such as heart or lung disease, weakened immune systems, or certain other underlying medical conditions, or who live in nursing homes or long-term care facilities.

RSV spreads through direct contact with the virus, such as droplets from another person's cough or sneeze contacting your eyes, nose, or mouth. It can also be spread by touching a surface that has the virus on it, like a doorknob, and then touching your face before washing your hands.

Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing. In very young infants, symptoms of RSV may also include irritability (fussiness), decreased activity, or apnea (pauses in breathing for more than 10 seconds).

Most people recover in a week or two, but RSV can be serious, resulting in shortness of breath and low oxygen levels. RSV can cause bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs). RSV can sometimes lead to worsening of other medical conditions such as asthma, chronic obstructive pulmonary disease (a chronic disease of the lungs that makes it hard to breathe), or congestive heart failure (when the heart can't pump enough blood and oxygen throughout the body).

Older adults and infants who get very sick from RSV may need to be hospitalized. Some may even die.

2. RSV vaccine

CDC recommends **adults 60 years of age and older** have the option to receive a single dose of RSV vaccine, based on discussions between the patient and their health care provider.

There are two options for protection of infants against RSV: maternal vaccine for the pregnant person and preventive antibodies given to the baby. Only one of these options is needed for most babies to be protected. CDC recommends a single dose of RSV vaccine for **pregnant people from week 32 through week 36 of pregnancy** for the prevention of RSV disease in infants under 6 months of age. This vaccine is recommended to be given from September through January for most of the United States. However, in some locations (the territories, Hawaii, Alaska, and parts of Florida), the timing of vaccination may vary as RSV circulating in these locations differs from the timing of the RSV season in the rest of the U.S.

RSV vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of RSV vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone RSV vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting RSV vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Pain, redness, and swelling where the shot is given, fatigue (feeling tired), fever, headache, nausea, diarrhea, and muscle or joint pain can happen after RSV vaccination.

Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported after RSV vaccination in clinical trials of older adults. It is unclear whether the vaccine caused these events.

Preterm birth and high blood pressure during pregnancy, including pre-eclampsia, have been reported among pregnant people who received RSV vaccine during clinical trials. It is unclear whether these events were caused by the vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at www.cdc.gov/vaccines.

https://www.cdc.gov/vaccines/hcp/vis/vis-statements/rsv.html

Latest version is 10/19/23

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

RSV Vaccines for adults- one dose IM, CPT code is 90678

Abrysvo, FDA approval 05/31/23

- Pfizer
- Bivalent RSV prefusion F protein–based vaccine
- 120 mcg, 0.5 ml
- Kit contains a vial of Lyophilized Antigen Component, a pre-filled syringe containing Sterile Water Diluent Component, and a vial adapter, no latex
- Study (RENOIR) using >38,000 participants with randomized 1:1 with placebo buffer, monitored for one RSV season in North and South Hemispheres and part of a second season for the North
- Monitored participants for 12 months
- Side effects:injection site pain, fatigue, H/A, myalgias, arthralgias
- Rare-N/V/D, fever, redness, swelling
- Studied with coadmin with Fluad-non-inferior response

Arexvy, FDA approval 05/03/23

- GSK
- Adjuvanted RSV prefusion F protein-based vaccine with AS01E adjuvant
- 120 mcg, 0.5 ml
- Must be reconstituted-powder plus diluent, no preservative, no latex
- Study using almost 25,000 participants randomized 1:1 with saline placebo-2 RSV seasons for Northern Hemisphere and 1 complete RSV season for Southern Hemisphere
- Monitored participants for 15 months
- Side effects:injection site pain, fatigue, H/A, myalgias, arthralgias
- Rare-redness, swelling,fever
- Studied co-admin with all types of flu vaccines

Other potential side effects?

- GSK vaccine-
  - 3 of 17,922 persons
    - 1 case of GBS
    - 2 cases of ADEM with concomitant use of influenza vaccine
- Pfizer vaccine-
  - 3 of 20,255 person
    - 1 case of GBS
    - 1 care of Miller Fisher (GBS variant)
    - 1 case of polyneuropathy

Atrial fibrillation within 30 days after injection in both trials-each vaccine had same numbers of 10 cases in vaccine recipients and 4 cases in the placebo group--most persons had previously-known history of afib.

- <50,000 adults in trials received vaccines (this is typical numbers)
- Side effects that are one in million may not be identified until broader use of the vaccines
- Consider focusing on patients who are high-risk for serious infections related to RSV.

https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7229a4-H.pdf

RSVpreF vaccine (Abrysvo) data from CDC

TABLE 3. Efficacy of 1 dose of Pfizer respiratory syncytial virus RSVpreF vaccine against respiratory syncytial virus–associated disease among adults aged ≥60 years — multiple countries, 2021–2023

Return

Efficacy evaluation period	Vaccine efficacy against outcome, % (95% CI)*	
	RSV-associated LRTD†	RSV-associated medically attended LRTD§
Season 1¶	88.9 (53.6–98.7)	84.6 (32.0–98.3)
Season 2 (interim)**	78.6 (23.2–96.1)	—††
Combined seasons 1 and 2 (interim)§§	84.4 (59.6–95.2)	81.0 (43.5–95.2)

LRTD=RSV LRTI with ≥3 signs or symptoms lasting >1 day

- Lower respiratory signs and symptoms included new or worsened cough, sputum production, wheezing, shortness of breath, and tachypnea.
- Also reviewed RSV LRTI with ≥two signs or symptoms lasting >1 day--not included here

RSVPreF3 vaccine (Arexvy) data from CDC

TABLE 1. Efficacy of 1 dose of GSK respiratory syncytial virus RSVpreF3 vaccine against respiratory syncytial virus–associated disease among adults aged ≥60 years — multiple countries, 2021–2023

Return

Efficacy evaluation period	Vaccine efficacy against outcome*	
	RSV-associated LRTD†	RSV-associated medically attended LRTD§
Season 1¶	82.6 (57.9–94.1)**	87.5 (58.9–97.6)††
Season 2§§	56.1 (28.2–74.4)††	—¶¶
Combined seasons 1 and 2 (interim)***	74.5 (60.0–84.5)†††	77.5 (57.9–89.0)††

Key to notes

** 96.95% CI
†† 95% CI
††† 97.5% CI

LRTD=2 or more symptoms/signs PLUS one sign for ≥24 hours or 3 symptoms for ≥24 hours

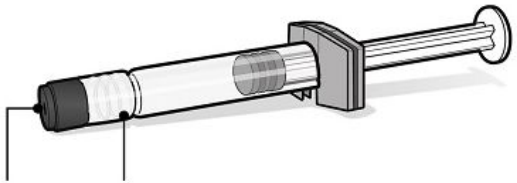
- lower respiratory symptoms-new or increased sputum, cough, and SOB
- signs-new or increased wheezing,rales, or rhonchi, RR ≥20 decreased pulse ox with need for O2 for ≥24 hours

Medically attended=inpatient or outpatient

ABRYSVO™
Respiratory Syncytial Virus Vaccine

Vial of Lyophilized Antigen Component

Syringe of Sterile Water Diluent Component



Vial Adapter

How supplied:

ABRYSVO is supplied in a kit that includes a vial of Lyophilized Antigen Component (NDC 0069-0207-01), a prefilled syringe containing Sterile Water Diluent Component (NDC 0069-0250-01) and a vial adapter.
ABRYSVO is supplied in cartons of 1, 5, and 10 kits.
Carton: 1 kit NDC 0069-0344-01
Carton: 5 kits NDC 0069-0344-05
Carton: 10 kits NDC 0069-0344-10

Storage and Handling

Storage Before Reconstitution: Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze. Discard if the carton has been frozen.
Storage After Reconstitution: After reconstitution, administer ABRYSVO immediately or store at room temperature [15ºC to 30ºC (59ºF to 86ºF)] and use within 4 hours. Do not store reconstituted vaccine under refrigerated conditions [2ºC to 8ºC (36ºF to 46ºF)]. Do not freeze reconstituted vaccine.

ABRYSVO™

Step 1. Preparation of vial and vial adapter

- Remove plastic flip off cap from vial and cleanse the rubber stopper.
- Without removing the vial adapter from its packaging, peel off the top cover.

Step 2. Attachment of vial adapter

- Hold the base of the vial on a flat surface.
- Keep the vial adapter in the packaging and orient it vertically over the center of the vial so that the adapter spike aligns with the center of the vial's rubber stopper.
- Connect the vial adapter to the vial with a straight downward push. The vial adapter will lock into place.
- Do not push vial adapter in at an angle as this may result in leaking during use.
- Remove the vial adapter packaging.

Step 3. Removal of syringe cap

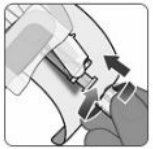
- For all syringe assembly steps, hold the syringe only by the Luer lock adapter located at the tip of the syringe. This will prevent the Luer lock adapter from detaching during use.
- Remove the syringe cap by slowly turning the cap counter-clockwise while holding the Luer lock adapter.

Step 4. Connection of syringe to vial adapter

- Hold the syringe's Luer lock adapter and connect it to the vial adapter by turning clockwise.
- Stop turning when you feel resistance, overtightening the syringe may result in leaking during use.
- Once the syringe is securely attached to the vial adapter, there will be a small space between the top of the vial adapter and the Luer lock adapter of the syringe.

Step 5. Reconstitution of Lyophilized Antigen Component to form ABRYSVO

- Inject the entire contents of the syringe containing the Sterile Water Diluent Component into the vial.
- Do not remove the empty syringe.
- While holding the plunger rod down, gently swirl the vial in a circular motion until the powder is completely dissolved (less than 1 minute).
- Do not shake.



Step 6. Withdrawal of reconstituted vaccine

- Invert the vial completely with the vial adapter and syringe still attached.
- Slowly withdraw the entire contents into the syringe to ensure an approximately 0.5 mL dose of ABRYSVO for administration.
- Do not pull the plunger rod out.

ABRYSVO™

Step 7. Disconnection of syringe

- Hold the Luer lock adapter of the syringe and disconnect the syringe from the vial adapter by turning counter-clockwise.

Step 8. Attachment of needle

- Attach a sterile needle suitable for intramuscular injection to the syringe containing ABRYSVO.

Step 9. Visual inspection

- ABRYSVO is a clear and colorless solution.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard if either condition is present.

Figure 1. Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) by slightly tilting the vial. Vial 1 of 2.

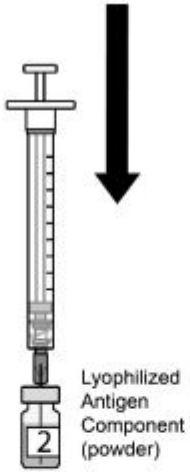


Figure 2. Slowly transfer entire contents of syringe into the lyophilized antigen component vial (powder). Vial 2 of 2.

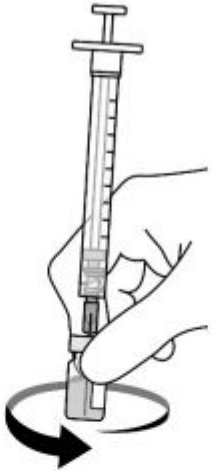


Figure 3. Gently swirl the vial until powder is completely dissolved. **Do not shake vigorously.**

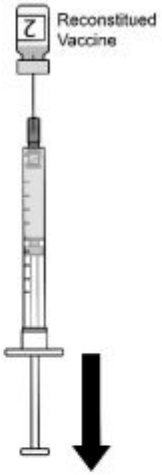


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly.

AREXVY
(RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED)

16 HOW SUPPLIED/STORAGE AND HANDLING

AREXVY is supplied as 2 components: A single-dose vial of lyophilized antigen component (powder) and a single-dose vial of adjuvant suspension component (liquid) (packaged without syringes or needles).

Table 3: Product Presentation for AREXVY

Presentation	Carton NDC Number	Components	
		Adjuvant Suspension Component (liquid)	Lyophilized Antigen Component (powder)
Outer carton of 10 doses	58160-848-11	10 vials NDC 58160-744-03	10 vials NDC 58160-723-03

16.1 Storage before Reconstitution

Adjuvant suspension component vials: Store refrigerated between 2°C and 8°C (36°F and 46°F). Store in the original package in order to protect vials from light. Do not freeze. Discard if the adjuvant suspension component has been frozen.

Lyophilized antigen component vials: Store refrigerated between 2°C and 8°C (36°F and 46°F). Store in the original package in order to protect vials from light. Do not freeze. Discard if the antigen component has been frozen.

Concerns

- Cost? ($200-300/vaccine), Insurance coverage
  - Covered under Medicare Part D
  - SeniorCare covers vaccines for RSV for members but only if given at a pharmacy
  - Non-SeniorCare Medicaid recipient coverage of RSV vaccines will begin on January 1, 2024
  - Adult BadgerCare Plus and Medicaid members is available through their medical benefit and must get the vaccine in the clinic
- Concomitant use with other vaccines (ok'd by CDC/ACIP)
- Both formulations require reconstitution
- Studies were underpowered to see efficacy in fragile adults and to see reduction in hospitalizations.
- Possible concerns with atrial fibrillation
- Contraindication for both RSV vaccines--History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine

Summary of RSV Immunizations

- Protecting infants/young toddlers
  - RSV vaccination for persons who are pregnant early in RSV season
  - RSV immunization-nirsevimab-for all infants < 8 months during RSV season
  - RSV immunization for children with high risk conditions during their 2nd RSV season
  - RSV immunization-palivizumab-for infants/toddlers with high risk conditions if nirsevimab is not available
- Protecting older adults
  - RSV vaccination for persons 60 years and older after shared decision-making with clinician and patient

New Immunizations to Protect Against Severe RSV

Who Does It Protect?	Type of Product	Is It for Everyone in Group?
 Adults 60 and over	RSV vaccine	Talk to your doctor first
 Babies	RSV antibody given to baby	All infants entering or born during RSV season. Small group of older babies for second season.
	OR	
 Babies	RSV vaccine given during pregnancy	Can get if you are 32–36 weeks pregnant during September–January

www.cdc.gov/rsv


THE END