Maryland
DEPARTMENT OF HEALTH

Public Health Services Administration

RSV Prevention for Infants and Children

A Toolkit for Healthcare Providers

Maryland Department of Health | Prevention and Health Promotion Administration
Infectious Disease Epidemiology and Outbreak Response Bureau | Center for Immunization

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1/6/2025: Based on feedback from the Maryland Chapter of the American Academy of Pediatrics, we are planning to make structural changes to the RSV prevention toolkit for the 2025-2026 RSV season.

If you have further feedback or suggestions to enhance this toolkit, please share them with us at mdh.izinfo@maryland.gov.

Counseling Parents of Infants and Pregnant Patients during RSV Season

As a healthcare provider, you are patients' most trusted source of information regarding immunizations. It is crucial that providers -including birthing hospitals, OBGYNs, and pediatricians - are equipped with the knowledge and tools necessary to effectively communicate about respiratory syncytial virus or RSV. Providers should tell patients about the risks of RSV, benefits of prevention strategies, and options for RSV prevention, including maternal vaccination (Abrysvo) or infant immunization with monoclonal antibodies (Nirsevimab). This toolkit provides resources to support health care providers to have informed conversations with patients about RSV prevention to mitigate the impact of RSV in vulnerable populations.

- **RSV is a leading cause of hospitalization among infants in the US** (Hall et al., 2013[1]; Langley & Anderson, 2011[2]; CDC NVSN data)
    - About 2-3% of young infants will be hospitalized for RSV
    - About 58,000-80,000 US children aged <5 years are hospitalized with RSV each year
    - RSV-associated hospitalization is highest in infants aged <3 months, and then decreases with age
    - Preterm infants experience higher hospitalization and ICU rates
- **The benefits of administration of either prevention product (Abrysvo, Nirsevimab) outweigh potential risks**
    - **Maternal RSV vaccine** during pregnancy is efficacious against severe RSV disease in infants up to 6 months (Fleming-Dutra KE, Jones JM, Roper LE et al, 2023[3]). The most common side effects were pain at the injection site, headache, myalgia, and nausea.
    - **Nirsevimab** is efficacious against severe RSV among infants entering their first RSV season (Jones JM, Fleming-Dutra KE, Prill MM et al, 2023[4]) The most common side effects were injection site reactions and rash.

Actions for health care providers

- ***Before seeing the patient***

[1] https://www.nejm.org/doi/10.1056/NEJMoa0804877?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200www.ncbi.nlm.nih.gov

[2] https://pubmed.ncbi.nlm.nih.gov/21487331/

[3] https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

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

- Review immunization history[5]
- Assess whether the patient has risk factors that elevate their risk level
- Determine what products you have available and/or what the patient is eligible to receive

- ***While seeing the patient***
  - Counsel the patient or caregiver. Recommend and offer immunizations or refer them to where they can receive vaccines.
  - If the patient is ineligible for a vaccine, explain the importance of testing and treatment early if they experience illness symptoms.
  - Explain the importance of other respiratory virus prevention tools such as:
    - Testing
    - Hand washing
    - Physical distancing and staying home when you are sick
    - Wearing a well-fitted mask
    - Improving airflow/ventilation where patients live and work

	 **For Birthing Hospitals Giving Beyfortus**	 **For ObGyns Giving Abrysvo**	 **For Pediatricians Giving Beyfortus**
During RSV reason, when administering immunizations.. .	• Before administering Beyfortus, check if birthing patient already received Abrysvo • Check if the child is VFC eligible • Assess weight and if high risk for dosage of Beyfortus	• Before administering Abrysvo, consider the health and pregnancy history and risk factors of the pregnant patient to assess risk • Check that the patient is the appropriate gestational age (32-36 weeks) • Check if the pregnant patient is VFC eligible	• Check if patient already received Befortus or if the parent received Abrysvo before birth • Check if the child is VFC eligible • Consider child's health history and risk factors • Assess weight and if high risk for dosage of Beyfortus
If your practice refers out...	If referring out for Beyfortus, check supply and ensure the other provider is taking patients/can take your patient	If referring out for Abrysvo, indicate pregnancy and gestation so the pharmacy or other practice can understand eligibility	If referring out for Beyfortus, check supply and ensure the other provider is taking patients/can take your patient

[5] https://www.cdc.gov/vaccines/hcp/admin/review-immunization-history.html

Use motivational interviewing when patients are hesitant or resistant

- **Be empathetic:** Approach the conversation with compassion. Show empathy, and be genuinely curious about the reasons why the patient feels the way they do. “It’s okay to want more information before making a decision.”
- **Ask permission:** If a patient is resistant to your strong recommendation, ask if you can discuss vaccines further. “Do you mind if we spend a few minutes talking about fall and winter respiratory vaccines?” Respect the patient’s decision if they say no, and ask if they would be willing to talk about vaccines at their next visit.
- **Respond to questions:** Answer questions within your expertise, ethics, and scope of practice. If you do not know an answer, tell your patient where they can find good sources of information.

Educate patients about how vaccination works

Vaccines help your immune system fight infections faster and more effectively. When you get a vaccine, it sparks your immune response. That helps your body fight off and remember the germ so it can attack if the germ ever invades again. Two types of immunity exist: active and passive.

- **Active immunity** occurs when our own immune system is responsible for protecting us from a pathogen. You can get active immunity through natural immunity (where the body is exposed to an illness and gets sick) or vaccine-induced immunity, where your body learns how to fight off infection as the result of a vaccine.
- **Passive immunity** occurs when we are protected from a pathogen by immunity gained from someone else. In this case, we are given antibodies to a disease rather than producing them through our immune system and the immunity is more immediate though may not last as long. **Maternal vaccination and products like nirsevimab rely on passive immunity.**

Explain how maternal vaccination works

Maternal immunization is a vaccination given during pregnancy that helps protect infants without the baby getting the shot themselves. A pregnant person who receives ABRSVO at 32-36 weeks gestational age will produce antibodies, which are passed through the placenta to the fetus. The infant will be born with maternal antibodies, which helps prevent RSV from birth through 6 months.

Explain how nirsevimab works

The immunization available for infants, called Nirsevimab or Befortus, is a long-acting monoclonal antibody injection which gives an infant (or high risk

toddler) RSV antibodies. The baby can then immediately be protected. It is similar to a vaccine, but monoclonal antibodies do not activate the immune system in the same way that a vaccine or infection does. Nirsevimab can be given alongside or between routine vaccinations and has been shown to reduce the risk of both RSV-related hospitalizations and health care visits in infants by about 80 percent.

Sample Script for Talking to Patients

> *At this point in your pregnancy, it is important that we talk about RSV, or* ***respiratory syncytial virus.*** *RSV is a common seasonal virus that can cause cold-like symptoms for many people, but it can cause babies to get very sick. RSV can make it hard for babies to breathe.*
>
> *We have two options for preventing severe RSV illness in babies. One option is a new vaccine that we give you during pregnancy. At 32-36 weeks gestation, you are eligible for this RSV vaccine.*
> *The vaccine causes you to make antibodies that you pass to your baby through the placenta. These antibodies help protect your baby early in their life.*
>
> *The other option called nirsevimab can be given to your baby after birth and also works to protect your baby from severe RSV.*
>
> *One or the other is recommended, but both are not needed for most babies.*

Co-administration can help avoid missed opportunities for vaccination

Co-administration of vaccines might be especially important when the patient has risk factors for severe respiratory illness (including but not limited to advanced age, cardiopulmonary disease, immunocompromising conditions, and residence in a long-term care facility) and there might not be an opportunity to vaccinate the patient with all their recommended vaccines in the near future.

> *Let's protect you from three respiratory viruses at the same visit! You can safely get all three vaccines today for flu, COVID-19, and RSV. You might experience some side effects, like fever and fatigue, but these are usually mild or moderate and only last a day or two.*
>
> *Getting all your vaccines today means you won't have to come back for another appointment - and it gives you protection against 3 respiratory viruses which can turn severe.*

As a provider, you can facilitate access for patients:

- Remind your patients if/when they are eligible for RSV immunization
- Consider joining the Vaccines for Children Program[6] which allows enrolled physicians to provide routinely recommended vaccines (including both products) free of cost to eligible children.
- If your practice does not carry these products or has insufficient supply, refer patients to local resources
    - Provide prescriptions for RSV vaccine for pregnant individuals who are 32-36 weeks gestation. Clearly indicate pregnancy on the prescription to ensure receipt of correct vaccine, such as with Abrysvo (Pfizer)
    - Call local pharmacies to assess availability of RSV-prevention products or check with your local health department

Informational Letter/Email Template

This letter template can be used to remind patients about RSV and other recommended fall respiratory virus vaccinations. Please customize it with your organization's specific information, including contact information and scheduling availability.

> **[ORGANIZATION LETTERHEAD]**
> **[DATE]**
> Subject: A Message from Our Practice Regarding RSV Prevention for Your Baby
>
> Dear Residents and Families,
>
> As the **[ROLE]** of **[YOUR ORGANIZATION NAME]**, I am reaching out to you with an important message to ensure the health of our patients against the respiratory viruses that commonly spread during the winter including COVID-19, flu, and RSV.
>
> As a provider invested in the health and safety of each resident under our care, I want to share information about immunizations that reduce the risk of RSV (Respiratory Syncytial Virus) for infants.
>
> **For pregnant patients**, maternal RSV vaccine (Abrysvo) is recommended during weeks 32 through 36 of pregnancy. Maternal vaccination protects infants by transferring antibodies during pregnancy.

[6] https://www.cdc.gov/vaccines-for-children/about/index.html

For infants, an immunization called nirsevimab (Beyfortus) is recommended for infants younger than 8 months of age who are entering their first RSV season. Nirsevimab is also recommended for high-risk children aged 8 through 19 months old who are at increased risk for severe RSV disease shortly before or during their second RSV season.

While I understand that there may be concerns about new vaccines and treatments, RSV in infants can be severe, resulting in thousands of children hospitalized every year. The RSV vaccines have been shown to be safe and effective. If you or your loved one has not yet received the RSV vaccine, I strongly encourage you to consider doing so to protect your baby's health.

Our staff is available to answer questions and schedule appointments if you are ready. You can reach our office at **[PHONE NUMBER]**

Sincerely,
[YOUR FULL NAME]
[YOUR ROLE] [YOUR ORGANIZATION NAME]

Resources for Talking to Parents

- Types of Immunity to a Disease | Centers for Disease Control (CDC)[7]
- Explaining How Vaccines Work | Centers for Disease Control (CDC)[8]
- RSV: When It's More Than Just a Cold | American Academy of Pediatrics (AAP)[9]

Frequently Asked Questions	
1. Is Nirsevimab a vaccine?	No. Nirsevimab is a monoclonal antibody product that offers long-lasting protection from RSV, with protection expected to last at least 5 months (about the length of a typical RSV season).
2. Should a pregnant person receive maternal RSV vaccine (Abrysvo) during pregnancy for the current season if they received maternal RSV vaccine during pregnancy in a previous season?	No. People who have received a maternal RSV vaccine during pregnancy should not receive additional doses during future pregnancies. Rather, that infant should receive nirsevimab.
3. Which product is better – nirsevimab or maternal RSV vaccine? Does one work better? Is	No studies have directly compared the two products. However, both products have been shown to provide

[7] https://www.cdc.gov/vaccines/vac-gen/immunity-types.htm
[8] https://www.cdc.gov/vaccines/hcp/conversations/understanding-vacc-work.html
[9] https://www.healthychildren.org/English/health-issues/conditions/chest-lungs/Pages/RSV-When-Its-More-Than-Just-a-Cold.aspx

one safer?	significant protection against severe RSV in young babies.
4. What is the maternal RSV vaccine made of and how does it work?	Abrysvo is a recombinant protein vaccine. It targets two F-proteins of the virus (RSVpreF A and RSVpreF B). If you get vaccinated during pregnancy, your body will build antibodies against these two RSV proteins and these antibodies will transfer across your placenta to your baby while pregnant. After birth, if your baby is exposed to RSV early in life, your baby will use the antibodies it got from you to recognize RSV and fight against it.
5. Can the RSV vaccine be given at the same time as other maternal vaccines?	Yes, you can receive the RSV vaccine at the same time as other routine vaccinations, like Tdap, COVID-19, and flu.
6. Can a baby receive nirsevimab if their mother received the RSV vaccine?	Both products protect babies from severe RSV by providing antibodies, either from the mother to the baby or directly to the baby. Most babies 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 a baby after the mother received an RSV vaccine.
7. Should I get the RSV vaccine if I've already had RSV before?	Even if you had RSV infection, RSV vaccination can help protect infants from severe RSV. There is no specific length of time that you need to wait after having RSV infection before you can receive an RSV vaccine. Generally, if you have a moderate or severe illness, you should wait until you recover before receiving an RSV vaccine. If you have a minor illness, such as a cold, you can get an RSV vaccine.
8. Are these covered by insurance and/or Medicaid?	Maternal RSV vaccine is covered ○ By Medicaid without cost-sharing for nearly all full-benefit adult beneficiaries with traditional Medicaid ○ By the Vaccines For Children (VFC) program for people younger than 19 years ○ By most private insurance plans Nirsevimab is covered ○ By the VFC program ○ By most private insurance plans

Clinical Considerations for Use of Maternal Vaccine or Infant Monoclonal Antibody for RSV Prevention

Product	Maternal RSV Vaccine (Abrysvo)		RSV Monoclonal Antibody (Beyfortus)	
Description	RSVPreF vaccine Trade name: Abrysvo™		Generic name: Nirsevimab Trade name: Beyfortus™	
Vaccine Codes[10]	**CVX**: 305	**CPT**: 90678	**CVX**: 306 (0.5 mL)	**CPT**: 90380 (0.5 mL)
			CVX: 307 ((1 mL))	**CPT**: 90381 (1 mL)
Duration of Protection	Approximately 3 to 6 months for infant		Approximately 5 months or more	
How Supplied	A kit that includes a vial of lyophilized antigen component, a prefilled syringe containing sterile water diluent, and a vial adapter. The lyophilized antigen component is reconstituted with the sterile water diluent to form a single dose.		Single dose pre-filled syringe with a purple (for 50 mg dosage) or light blue (for 100 mg dosage) plunger rod. No reconstitution needed.	
Storage and Handling	Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F). Store these components in their original package and keep them together in the refrigerator to optimize organization. Administer ABRYSVO immediately or store at room temperature [15°C to 30°C (59°F to 86°F)] and use within 4 hours. Discard reconstituted vaccine if not used within 4 hours. **Do not freeze before or after**		The pre-filled syringes should be stored refrigerated between 36°F to 46°F (2°C to 8°C) and may be kept at room temperature 68°F to 77°F (20°C to 25°C) for a maximum of 8 hours. • They should be stored in the original carton to protect from light until time of use. **Do not freeze or expose to heat**. After removal from the	

[10] https://www.cdc.gov/iis/code-sets/fall-season-respiratory-codes.html#cdc_data_surveillance_section_4-respiratory-syncytial-virus-rsv-codes-and-crosswalks

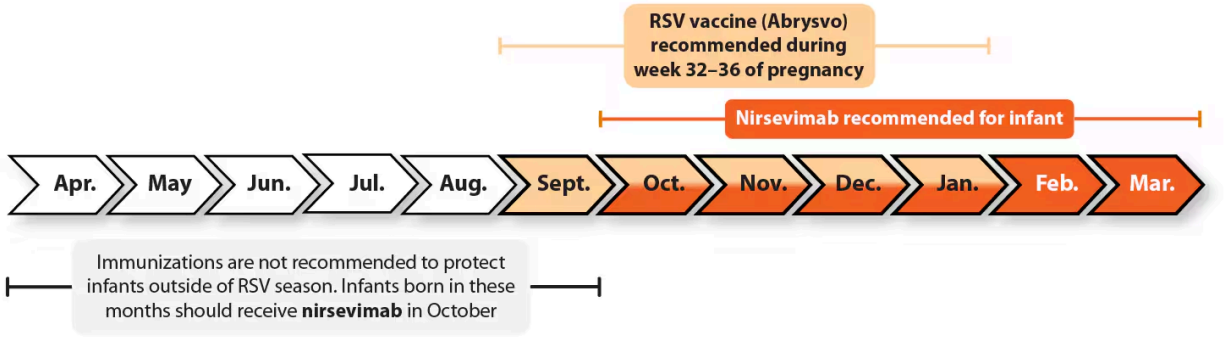
	reconstitution.	refrigerator, they must be used within 8 hours or discarded. • **Do not use nirsevimab beyond the expiration date printed on the label**.
Recommended Dosage	**0.5 mL** Currently recommended for administration as a single dose. It is not yet known whether additional doses might be needed in later pregnancies.	For infants < 8 months: • **Less than 5 kg:** 50 mg (0.5mL) • **5 kg and greater:** 100 mg (1mL) High risk children 8-19 months: 200 mg (administered as 2 IM injections).
How Administered	IM Injection	IM Injection
Coadministration	Can be administered without regard to timing of other routine immunizations, including simultaneous administration.	Can be administered without regard to timing of other routine immunizations, including simultaneous administration.
Gestation or Age of Immunization	32-36 weeks of pregnancy	• Patients less than 8 months • Patients Ages 8 through 19 months: If at increased risk for severe RSV disease
When to Administer (Seasonality)	Beginning of September through end of January in most of the continental United States. In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should follow state, local, or territorial guidance on timing of maternal RSV vaccination.	Beginning of October through end of March in most of the continental United States. In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.- affiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should

		follow state, local, or territorial guidance on timing of nirsevimab administration.
Contraindications (Product should NOT be administered)	History of severe allergic reaction (e.g., anaphylaxis) to any component of the maternal RSV vaccine.	History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of nirsevimab.
Precautions (Administration should be delayed)	The presence of a moderate or severe acute illness, with or without a fever.	The presence of a moderate or severe acute illness, with or without a fever.
Side Effects & Safety	• **Local and systemic reactions:** In clinical trials, the most common reactions after maternal RSV vaccine in pregnant people were pain at the injection site, headache, muscle pain, and nausea. • **Severe allergic reactions:** As with any medicine or vaccine, there is a remote chance of RSV vaccine causing a severe allergic reaction. • **Preterm birth:** In clinical trials, among people who were vaccinated in weeks 24 through 36 weeks of pregnancy, more preterm births were reported among maternal RSV vaccine recipients than among placebo recipients. This difference was not statistically different. Available data are insufficient to establish or exclude a causal relationship between preterm birth and maternal RSV vaccine. To reduce the potential risk of preterm birth when administering maternal RSV vaccine, FDA approved the vaccine for use during weeks 32 through 36 of pregnancy. The vaccine studies did not include people who already had a higher	• **Local and systemic reactions:** In clinical trials, the most common adverse events after nirsevimab were rash and injection-site reactions, each occurring in <1% of infants and young children. • **Severe allergic reactions**: As with any medicine or vaccine, there is a remote chance of nirsevimab causing a severe allergic reaction. • **Serious adverse event:** The incidence of serious adverse events was not increased in the nirsevimab arm compared with that in the placebo arm. No serious allergic reactions or immune complex disease were reported in the clinical trials.

	risk of preterm births. • **Hypertensive disorders of pregnancy:** Although not common, in clinical trials, hypertensive disorders of pregnancy (including pre-eclampsia) occurred in 1.8% of pregnant people who got the RSV vaccine compared to 1.4% of pregnant people who received a placebo.	

When to administer?

CDC recommends RSV immunizations during specific months to maximize protection during RSV season. RSV typically peaks between December and February.[11]



Best Practices for Vaccine Administration

Preventing vaccine administration errors

- A vaccine administration error is any preventable event that may cause or lead to inappropriate medication use or patient harm. While rare, during the 2023-2024 RSV season, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) received some reports[12] (CDC COCA) of the Pfizer (Abrysvo) or GSK (Arexvy) RSV vaccines being administered in error to young children.
- Vaccine administration errors may be due to causes such as distraction, insufficient staff training, misidentified products, and more. Take preventive actions to avoid vaccine administration errors and establish an environment

[11] https://www.cdc.gov/rsv/immunizations-protect-infants/
[12] https://emergency.cdc.gov/newsletters/coca/2024/012224.html

that values reporting and investigating errors as part of risk management and quality improvement.

Reporting vaccine administration errors

- Report any adverse events after RSV vaccination to VAERS regardless of which vaccine is used and even if it is not clear that the vaccine caused the adverse event. https://vaers.hhs.gov/index.html
- For Beyfortus, when not co-administered with other vaccines, report all suspected adverse reactions to MedWatch. https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

Vaccine Administration Resources

- ACIP General Best Practice Guidelines for Immunization | Center for Disease Control (CDC) [13]
- Preventing Vaccine Administration Errors | Center for Disease Control (CDC)
- CDC cautions against RSV immunization errors, offers guidance | American Academy of Pediatrics (AAP)
- Triple Checking COVID-19 Vaccine Administration | Maryland Department of Health (MDH)
- General Best Practice Guidelines for Immunization | Center for Disease Control (CDC)
- Vaccine Storage and Handling Toolkit | Center for Disease Control (CDC)

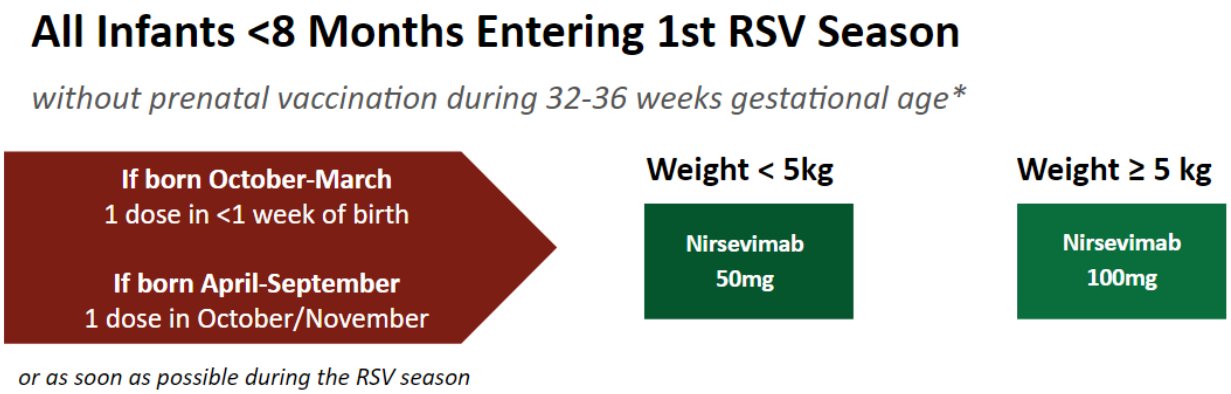
[13] https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Nirsevimab Background and Clinical Summary

Nirsevimab (Beyfortus™) is a long-acting monoclonal antibody product that provides passive immunization to protect infants against RSV. Nirsevimab was approved by the U.S. Food and Drug Administration (FDA) and recommended by CDC's Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) for the prevention of RSV lower respiratory tract disease in neonates and infants. Nirsevimab should be given just before and during RSV season, usually October-March. One dose of nirsevimab is expected to last at least 5 months. Nirsevimab co-administration with other immunizations, including the birth dose of Hepatitis B vaccine, is recommended. Additional guidance can be found from CDC.

[14]All infants from birth to 8 months born during or entering their **first RSV season** are recommended to receive one dose of nirsevimab (50 mg if <5 kg or 100 mg if ≥5 kg) if:

- The birth parent did not receive RSV vaccine during pregnancy.
- The birth parent's RSV vaccination status is unknown.
- The infant was born within 14 days of birth parent's RSV vaccination.

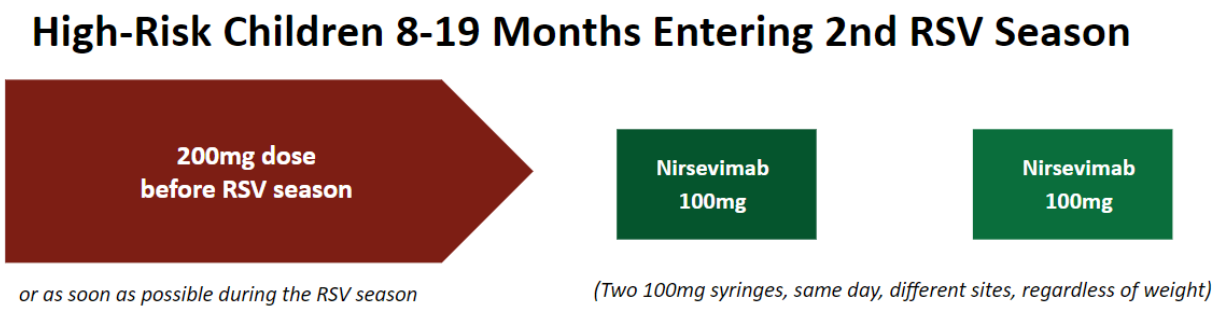


Young children aged 8 through 19 months entering their **second RSV season** are recommended to receive one dose of nirsevimab (200 mg) if they are at increased risk of severe RSV disease:

- Children with chronic lung disease of prematurity who required medical support at any time during the six-month period before the start of the second RSV season.
- Children with severe immunocompromise.
- Children with cystic fibrosis who have manifestations of severe lung disease

[14] https://www.cdc.gov/vaccines/vpd/rsv/hcp/child.html

(previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight-for-length <10th percentile.
- American Indian and Alaska Native children.



Nirsevimab Presentation, Administration, and Storage

Nirsevimab injection is a sterile, preservative-free, clear to opalescent, colorless to yellow solution supplied as follows:

Five 50 mg/0.5 mL single-dose pre-filled syringes in a carton: NDC 49281-575-15

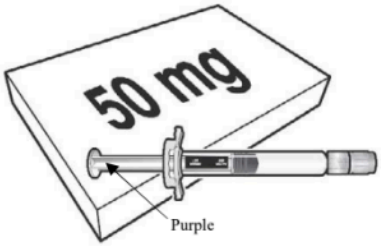
Five 100 mg/1 mL single-dose pre-filled syringes in a carton: NDC 49281-574-15

- Nirsevimab is stored in the refrigerator at 2-8°C (36.5 - 46.4°F). It may be kept at room temperature 68°F to 77°F (20°C to 25°C) for a maximum of 8 hours. After removal from the refrigerator, Beyfortus must be used within 8 hours or discarded. Do not freeze, shake, or expose to direct heat.
- Beyfortus is for intramuscular injection only, preferably in the anterolateral aspect of the thigh. The entire contents of the syringe should be administered intramuscularly.

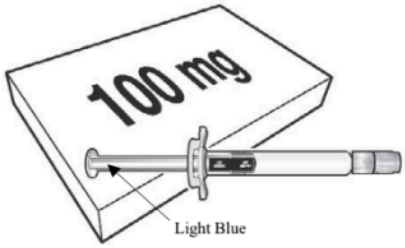
- Neither RSV vaccine (Pfizer Abrysvo, GSK Arexvy) is approved for use in infants or young children. Healthcare providers should take care to use the correct product for the correct population.
- Dosage and Administration
    - Step 1: Holding the Luer lock in one hand (avoid holding the plunger rod or syringe body), unscrew the syringe cap by twisting it counter-clockwise with the other hand.

Administration Instructions for Single-Dose Pre-filled Syringe

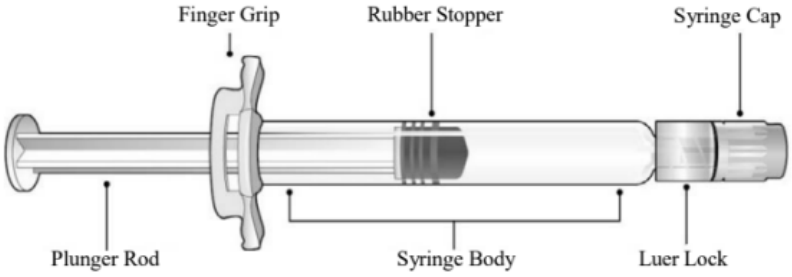
BEYFORTUS 50 mg (50 mg/0.5 mL) pre-filled syringe with a purple plunger rod.



BEYFORTUS 100 mg (100 mg/mL) pre-filled syringe with a light blue plunger rod.



Luer Lock Syringe Components



    - Step 2: Attach a Luer lock needle to the pre-filled syringe by gently twisting the needle clockwise onto the pre-filled syringe until slight resistance is felt.
    - Step 3: Hold the syringe body with one hand and carefully pull the needle cover straight off with the other hand. Do not hold the plunger rod while removing the needle cover or the rubber stopper may move. Do not touch the needle or let it touch any surface. Do not recap the needle or detach it from the syringe.
    - Step 4: Administer the entire contents of the BEYFORTUS pre-filled syringe as an IM injection, preferably in the anterolateral aspect of the

thigh. The gluteal muscle should not be used as an injection site because of the risk of damage to the sciatic nerve.
    - Step 5: Discard syringe into a sharps container. If two injections are required, repeat Steps 1-5 in a different injection site.

Other Helpful Resources

- Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children | Centers for Disease Control (CDC)
- AAP Recommendations for the Prevention of RSV Disease in Infants and Children |American Academy of Pediatrics (AAP)
- Nirsevimab Administration Visual Guide | American Academy of Pediatrics (AAP)
- Nirsevimab Immunization Information Sheet (IIS) | Immunize.org
- Healthcare Providers: RSV Prevention Information | Centers for Disease Control (CDC)
- Standing Orders for Administering Nirsevimab RSV Preventive Antibody (Beyfortus, by Sanofi) to Infants | Immunize.org

ABRYSVO Background and Clinical Summary

Pfizer's ABRYSVO™ is aRSVpreF (ABRYSVO, Pfizer) bivalent vaccine that consists of a recombinant RSV F protein antigen (based on both the RSV-A and RSV-B subtypes), stabilized in the prefusion conformation (preF).

ABRYSVO is indicated for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV). ABRYSVO is a vaccine indicated for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in people 60 years of age and older as well as for pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age. ABRYSVO is not approved for use in infants or young children.

The FDA approved ABRYSVO **for use in pregnant people during weeks 32 through 36 of gestation** for the prevention of RSV-associated lower respiratory tract disease in infants from birth through 6 months of age. The Advisory Committee on Immunization Practices (ACIP) recommends that all adults aged 75 years and older should receive a single dose of RSV vaccination. All adults aged 60 to 74 years with certain chronic medical conditions or other risk factors for severe RSV disease should receive a single dose of RSV vaccination.

ABRYSVO is the first and only vaccine given between 32 through 36 weeks of pregnancy to prevent RSV in babies from birth through 6 months of age. Maternal RSV vaccination is expected to resume in September (through Jan 2025 for most of the U.S.) with no anticipated supply/demand mismatch.

Epidemiologic evidence indicates that all adults ages 75 or older and adults ages 60-74 with certain risk factors are at increased risk of severe RSV. The following conditions increase the risk of severe RSV:

- Cardiovascular disease (e.g., heart failure; coronary artery disease; congenital heart disease, excluding isolated hypertension),
- Lung disease (e.g., chronic obstructive pulmonary disease [COPD], emphysema, asthma, interstitial lung disease, cystic fibrosis),
- Advanced chronic kidney disease (e.g., stages 4–5, dependence on hemodialysis or other renal replacement therapy),
- Diabetes mellitus with end-organ damage (e.g., diabetic nephropathy, neuropathy, retinopathy, or cardiovascular disease),
- Severe obesity (body mass index ≥40 kg/m2),
- Liver disorders (e.g., cirrhosis),
- Neurologic or neuromuscular conditions (e.g., neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness, excluding

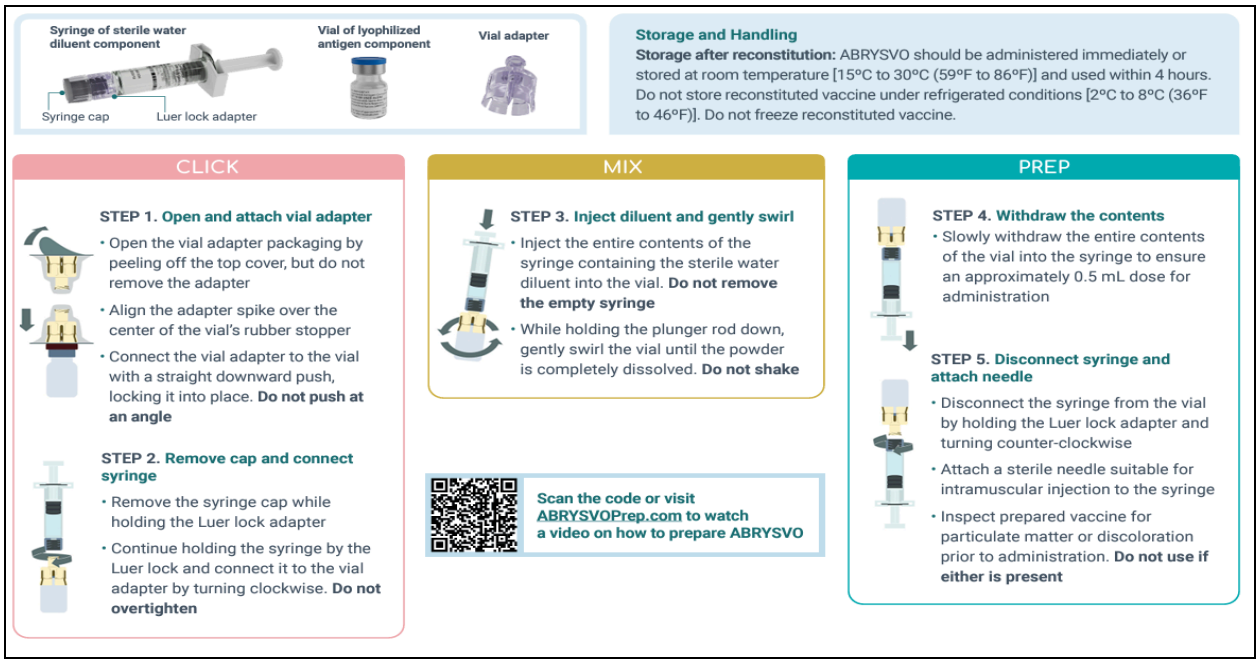
history of stroke without impaired airway clearance),
- Hematologic disorders (e.g., sickle cell disease, thalassemia), and
- Moderate or severe immune compromise (either attributable to a medical condition or receipt of immunosuppressive medications or treatment);

As well as:

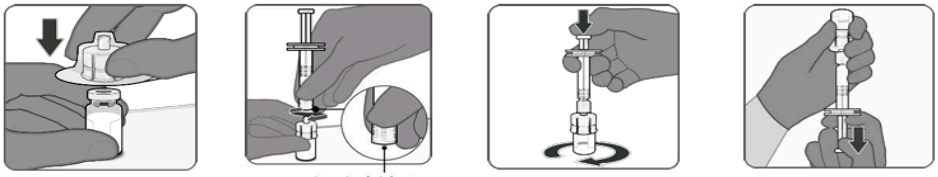
- People who are frail*;
- People who reside in nursing homes or other long-term care facilities providing assistance with activities of daily living;† and
- People with other chronic medical conditions or risk factors that a healthcare provider determines might increase the risk of severe disease due to respiratory infection.

ABRYSVO Presentation, Administration, and Storage

- Before reconstitution, store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F). Store these components in their original package and keep them together in the refrigerator to optimize organization.
- After reconstitution, a single dose of ABRYSVO is either approximately 0.5 mL (vial and prefilled syringe presentation) or 0.5 mL (vial and vial presentation). For the vial and prefilled syringe presentation, a single dose after reconstitution is approximately 0.5mL. For the vial and vial presentation, a single dose after reconstitution is 0.5 mL. Administer ABRYSVO immediately or store at room temperature [15°C to 30°C (59°F to 86°F)] and use within 4 hours. Discard reconstituted vaccine if not used within 4 hours.
- Administer RSVpreF vaccine (ABRYSVO, Pfizer) intramuscularly. The preferred site of administration is the deltoid region of the upper arm. Do not administer RSV vaccine intravenously, intradermally, or subcutaneously.
- Pregnant people can receive RSV, Tdap, COVID-19, and influenza vaccines during the same clinic visit.

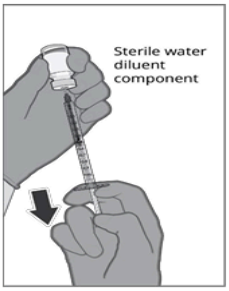


Reconstitution Instructions for Vial and Prefilled Syringe Presentation



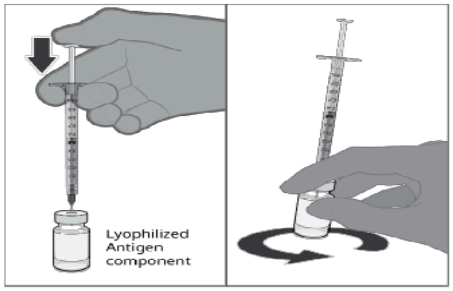
Step 1. Attachment of the vial adapter to the vial	Step 2. Connection of the syringe to the vial adapter	Step 3. Reconstitution of the Lyophilized Antigen Component with the Sterile Water Diluent Component to form ABRYSVO	Step 4. Withdrawal of ABRYSVO
Remove the flip top cap from the vial of Lyophilized Antigen Component. Peel off the top cover from the vial adapter packaging. While keeping the vial adapter in its packaging, center the adapter over the vial's stopper and attach to the vial with a straight downward push. Remove the packaging.	Hold the syringe of Sterile Water Diluent Component by the Luer lock adapter. Twist to remove the syringe cap. Connect the syringe to the vial adapter by turning the Luer lock.	Inject the entire contents of the syringe into the vial. Hold the plunger rod down and gently swirl the vial until the powder is completely dissolved (less than 1 minute). Do not shake.	Invert the vial completely and slowly withdraw the entire contents into the syringe for an approximately 0.5 mL dose of ABRYSVO. Twist to disconnect the syringe from the vial adapter. Attach a sterile needle suitable for intramuscular injection.

Reconstitution Instructions for the Vial and Vial Presentation



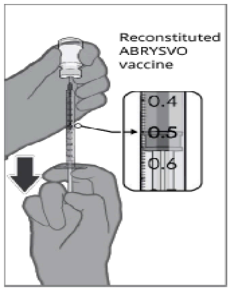
Step 1. Withdrawal of the Sterile Water Diluent

Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the Sterile Water Diluent Component.



Step 2. Reconstitution of the Lyophilized Antigen Component with the Sterile Water Diluent Component to form ABRYSVO

Inject the entire contents into the vial containing the Lyophilized Antigen Component (white powder). Gently swirl the vial in a circular motion until the powder is completely dissolved. Do not shake.



Step 3. Withdrawal of ABRYSVO

Withdraw 0.5 mL from the vial containing the reconstituted vaccine.

Other Helpful Resources

- ACIP Evidence to Recommendations for Use of Pfizer Bivalent RSVpreF Vaccine (ABRSYVO) in Older Adults|Centers for Disease Control (CDC)
- ACIP Evidence to Recommendations for Use of Pfizer RSVpreF in Pregnant People |Centers for Disease Control (CDC)
- ABRYSVO Package Insert |Food and Drug Administration (FDA)
- Respiratory Syncytial Virus (RSV) Vaccine VIS |Centers for Disease Control (CDC)
- CDC RSV Recommendations |Centers for Disease Control (CDC)
- ABRYSVO- Maternal |Pfizer
- ABRYSVO- Older Adult |Pfizer
- Standing Orders for Administering Pfizer RSV Vaccine (Abrysvo) during Pregnancy | Immunize.org

Appendix

I. Maryland Vaccines for Children

Vaccines for Children (VFC) is a federally funded entitlement program, administered by the Maryland Department of Health and the Centers for Disease Control and Prevention (CDC) that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay.

A. Maryland VFC's Website: www.MarylandVFC.org
B. Contact Maryland VFC: MDH.IZInfo@maryland.gov

II. ImmuNet

The Centers for Disease Control and Prevention (CDC) defines Immunization information systems (IIS) as systems to "help providers, families, and public health officials by consolidating immunization information into one reliable source. The information can then be used to guide patient care, improve vaccination rates, and ultimately reduce vaccine-preventable disease." ImmuNet is Maryland's IIS, a confidential and secure database that is HIPAA compliant. It stores an individual's vaccination records, and is a web-based tool for healthcare providers and schools to keep their patients/students vaccinated on time and avoid being under or over vaccinated.

A. Maryland's ImmuNet Website: www.mdimmunet.org
B. ImmuNet Support: health.maryland.gov/phpa/OIDEOR/IMMUN/Pages/immunet-support.aspx
C. Contact ImmuNet at mdh.mdimmunet@maryland.gov

III. Vaccine Manufacturers for Infant RSV Prevention (2024)

A. Sanofi (Nirsevimab)
    1. Information for Healthcare Providers: https://pro.campus.sanofi/us/products/beyfortus
    2. Information for Patients: https://www.beyfortus.com/
B. Pfizer (Abrysvo)
    1. Information for Healthcare Providers: https://abrysvoadult.pfizerpro.com/
    2. Information for Patients: https://www.abrysvo.com/pregnant-women
    3. Find vaccine near you: https://www.abrysvo.com/find-a-vaccine