

# Respiratory Syncytial Virus (RSV) Immunization Recommendations to Protect Infants and Children

**Slide Deck**

**Audience: Healthcare Professionals  
who Provide Care to Pregnant Patients**



# RSV is a leading cause of hospitalization in US infants

- 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 highest in **infants aged <3 months** and then decreases with increasing age
- **Preterm infants** experience higher hospitalization and ICU rates



# FDA approved and CDC recommends two ways to protect infants from severe RSV disease



**RSV vaccine  
given during  
pregnancy**



**RSV  
antibody  
given to  
the infant**



## Abrysvo (Pfizer) is the **ONLY** RSV vaccine approved for pregnant people

- CDC recommends **maternal RSV vaccination during 32 weeks + 0 days through 36 weeks + 6 days gestation**, with seasonal administration
  - During **September through January** in most of the continental United States
  - According to **local guidance** in jurisdictions where seasonality differs from most of the continental US
- Abrysvo (Pfizer) RSV vaccine can be **simultaneously administered** with other indicated vaccinations

# Maternal Abrysvo (Pfizer) RSV vaccine is efficacious against severe RSV disease in infants up to 6 months

- Abrysvo (Pfizer) RSV vaccine: Phase 2b and 3 trials (included >7500 people)
  - Full trial dosing interval included administration 24–36 weeks gestation
  - Additional analyses conducted during approved dosing interval (32–36 weeks)

## Vaccine efficacy estimates (through 180 days of life):



Severe medically attended RSV-associated lower respiratory tract infections (LTRI):

**69.4%** (97.58% CI = 44.3%–84.1%) when vaccinated during full trial dosing interval (24-36 weeks) NEJM.



Hospitalization for RSV-associated LTRI:

**56.8%** (99.17% CI = 10.1%–80.7%) when vaccinated during full trial dosing interval (24-36 weeks)

# Benefits of maternal vaccination with Abrysvo (Pfizer) RSV vaccine outweigh potential risks

- Most common side effects: pain at injection site, headache, myalgia, nausea

## What did clinical trial data show about risks during pregnancy?

More preterm births and reports of hypertension during pregnancy were observed among those who received vaccine during weeks 24-36 gestation versus placebo. The imbalance was not statistically significant.

## How do we interpret this?

- Available data are insufficient** to establish or exclude a causal relationship between these outcomes and Abrysvo.
- To reduce the potential risk of preterm birth, **vaccine was approved for use during weeks 32 through 36 of pregnancy.**

# Monitoring safety and effectiveness of maternal RSV vaccine will continue

- **Pfizer's pregnancy registry:** Individuals who received Abrysvo during pregnancy are encouraged to contact, or have their healthcare provider contact, 1-800-616-3791 to enroll in or get information about the registry.
- **Vaccine Adverse Event Reporting System (VAERS):** Advise vaccine recipient to report any adverse events to their healthcare provider or to the VAERS at 1-800-822-7967 and [www.vaers.hhs.gov](http://www.vaers.hhs.gov).
- **V-safe:** Encourage pregnant individuals to register for [v-safe](#), a digital platform that conducts health check-ins following RSV vaccination.

# Promote V-safe – we need your help!

Materials are available to share information about V-safe

- Information sheets
- Social media posts
- Communications to vaccine recipients

Materials and more information available at:

<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/v-safe/index.html>

## What is V-safe?

V-safe is an innovative vaccine safety monitoring system that allows you or your dependent to quickly and easily share how you feel after getting a vaccine. It takes just a few minutes to enroll, and then you will receive V-safe notifications through text messages or emails to complete **short, confidential health check-ins**. Your participation in V-safe makes a difference—it helps others know what to expect in the days following vaccination, and it helps CDC monitor the safety of vaccines for everyone.

### V-safe features:

- Receive health check-ins via text or email after vaccination.
- Enroll your dependents and complete check-ins on their behalf.
- Share how you feel after getting a vaccine dose.

### How can I enroll, and how does it work?

V-safe is available for several vaccines. Go to [vsafe.cdc.gov](https://www.cdc.gov/vsafe) to find out if you are eligible to enroll. If you are eligible, follow the prompts to register for V-safe health check-ins. During the first week after vaccination, V-safe will send you a text message or email notification each day to ask how you are feeling. Then you will get check-in messages once a week for up to 5 weeks. Depending on your answers, V-safe may send you a link to submit a report in the Vaccine Adverse Event Reporting System (VAERS).

You can opt out at any time by texting "STOP" when V-safe sends you a text message or by clicking "unsubscribe" when V-safe sends you an email. You can also opt back in by changing your preferred method of contact, found in your user profile. **Your personal information in V-safe is protected so that it stays confidential and private.**

### How can I enroll my dependent?

To enroll a dependent in V-safe, **add them to your existing account**, or create a new account if you don't have one yet. Enrolling a dependent does not require you to enter your own vaccination information or complete health check-ins for yourself.

Need step-by-step instructions? Go to: [www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)

V-safe gathers data employing strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws including the Privacy Act of 1974, standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Federal Information Security Management Act, and the Freedom of Information Act.



Sign up with your smartphone, tablet, or computer at [vsafe.cdc.gov](https://vsafe.cdc.gov)

OR

Aim your smartphone's camera at this code



Need help with V-safe?

Call  
1-833-748-1979

Email  
[CARS.HelpDesk@cdc.gov](mailto:CARS.HelpDesk@cdc.gov)

Visit  
[www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)



CS24195-V 10/05/2023



# Nirsevimab (Sanofi and AstraZeneca) is recommended for infants this season and young children at increased risk

- For **infants born October 2023 through March 2024**, immunize within 1 week of birth
  - Immunize infants with prolonged birth hospitalizations shortly before or promptly after discharge
- For **all other infants younger than 8 months this season**, administer as soon as nirsevimab is available assuming sufficient availability
- For **children 8–19 months and at increased risk for severe disease**, administer as soon as nirsevimab is available assuming sufficient availability



# Nirsevimab (Sanofi and AstraZeneca) is efficacious against severe RSV among infants entering their first RSV season

Two placebo-controlled, randomized trials including pre-term and term infants

**Vaccine efficacy estimates (through 150 days after injection):**



**Medically attended RSV-associated lower respiratory tract infections (LRTI):**

**79.0% (95% CI = 68.5%–86.1%)**



**Hospitalization for RSV-associated LRTI:**

**80.6% (95% CI = 62.3%–90.1%)**

Griffin MP, Yuan Y, Takas T, et al. <https://doi.org/10.1056/NEJMoa1913556>

Muller WJ, Madhi SA, Seoane Nuñez B, et al. <https://doi.org/10.1056/NEJMc2214773>

Jones JM, Fleming-Dutra KE, Prill MM, et al. <https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm>

# Benefits of nirsevimab administration outweigh potential risks

- Most common side effects: injection site reactions, rash

## What did clinical trial data show about safety of nirsevimab?

- The incidence of serious adverse events was not increased in those who received nirsevimab compared with those who received placebo

## How do we interpret this?

- We anticipate side effects to be mild or moderate and like those experienced after routine vaccinations

# Limited supply of nirsevimab is a challenge this season

## Limited Availability of Nirsevimab in the United States —Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023– 2024 Respiratory Virus Season

[Print](#)




Distributed via the CDC Health Alert Network

October 23, 2023, 3:30 PM ET

CDCHAN-00499

### Summary

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to provide options for clinicians to protect infants from respiratory syncytial virus (RSV) in the context of a [limited supply of nirsevimab](#) , a long-acting monoclonal antibody immunization product recommended for preventing RSV-associated lower respiratory tract disease in infants.

<https://emergency.cdc.gov/han/2023/han00499.asp>

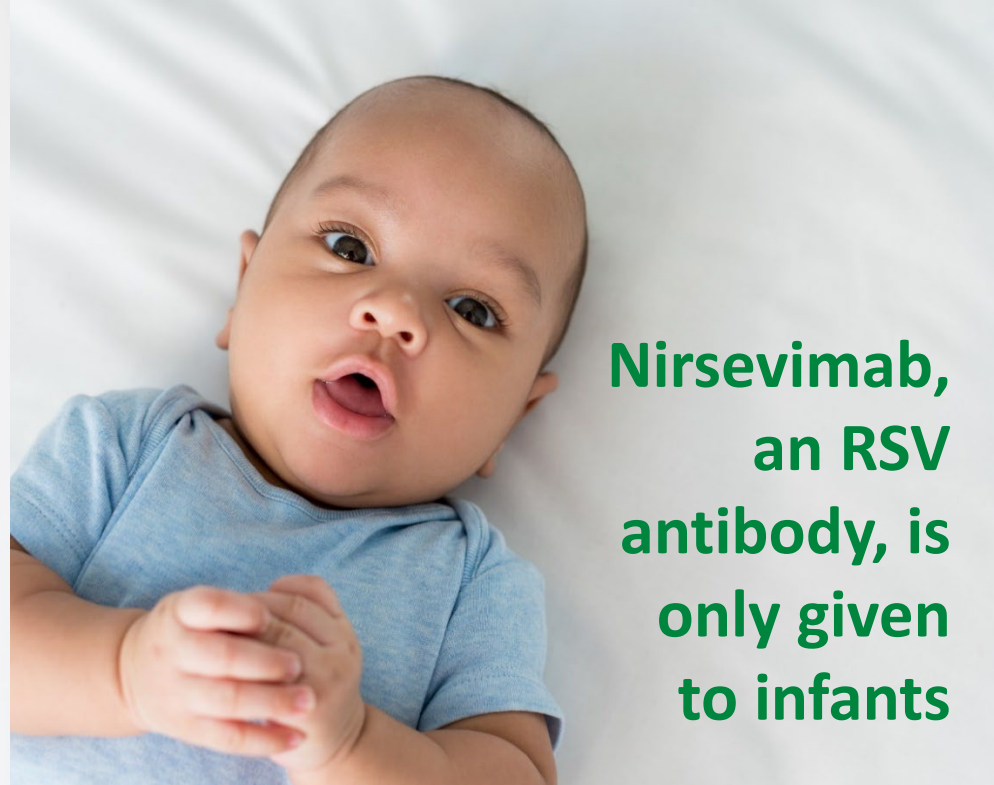
## Other barriers may exist this season

- Your clinic or hospital may or may not have these products available.
- Your local pharmacy may or may not have these products available.
- Pharmacies may require a prescription.
- Insurers have a year to cover newly approved products.
- Out-of-pocket costs are expensive to individuals (e.g., \$295 for Abrysvo; \$495 for nirsevimab).
- Lack of documentation of maternal vaccination might be a barrier to informed decision making for young infants.

## Summary: Two ways to protect infants from severe RSV disease



**Abrysvo  
(Pfizer) is the  
only RSV  
vaccine for use  
during  
pregnancy**



**Nirsevimab,  
an RSV  
antibody, is  
only given  
to infants**

**Counseling pregnant patients this season**



**YOU** are patients' most trusted source of information on vaccines.



# Consider raising these key points during shared decision-making conversations with pregnant patients

- Risk of severe RSV for young infants
- Known benefits of the approved products to help prevent severe RSV
- Relative advantages and disadvantages of each product
- Patient preferences
- Local availability of nirsevimab



## Sample script to counsel patients

At this point in your pregnancy, you are eligible to get the RSV vaccine to protect your baby from a severe respiratory illness called RSV. RSV is a common seasonal viral infection that can cause babies to get very sick. It 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. 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.

## Sample script to counsel patient continued

The other option called nirsevimab can be given to your baby after birth and works similarly to protect your baby from RSV illness after delivery.

**One or the other is recommended, but both are not needed for most babies. Keep in mind though that there may be limited availability of nirsevimab this season once your baby is born.**





# Advantages and disadvantages of Abrysvo (Pfizer) during pregnancy


- Advantages
  - Immediate protection after birth
  - Might be more resistant to potential changes in the virus, or variants
- Disadvantages
  - Potentially reduced protection in some situations (e.g., if birth of baby happens within 14 days of vaccination)
  - Potential risk for preterm birth and hypertensive disorders of pregnancy



# Advantages and disadvantages of nirsevimab for young infants

- Advantages
  - Protection might last longer than protection from maternal RSV vaccine
  - Assures direct receipt of antibodies
  - No potential risk for adverse pregnancy outcomes
- Disadvantages
  - Potentially limited availability during 2023-24 RSV season
  - Requires infant injection

## Common questions



**Which product is better – nirsevimab or maternal RSV vaccine?** Does one work better than the other? Is one safer than the other?

- No studies have directly compared the two products.
- However, both products have been shown to provide significant protection against severe RSV in young babies.
- Let's talk about which option might be best for you and your family.

# Common questions: What is it?

## 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.
- These antibodies will transfer across your placenta to your baby while you are 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.



## Common questions: Coadministration



Can the RSV vaccine be given at the same time as other maternal vaccines?

- Yes, you can receive RSV vaccine at the same time as other routine vaccinations, like Tdap, COVID-19, and flu.



## Common questions: Receiving both products

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.



# Common questions: Prior infection

Should I get the RSV vaccine if I've already had RSV before?



- Even if you had RSV infection in the past, 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.

# Common questions: Insurance coverage

Are these both 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, but companies have one year to comply with new recommendations
- Nirsevimab is covered
  - By the VFC program
  - By most private insurance plans, but companies have one year to comply with new recommendations



# As a provider, you can facilitate implementation

- Document receipt of maternal RSV vaccination (e.g., via immunization information system, electronic health records, written documentation)
- Routinely 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 – Abrysvo (Pfizer).
- Get familiar with your local access
  - Call local pharmacies to assess availability of RSV-prevention products
  - Ask local hospital about prioritization and availability of nirsevimab
  - If your practice does not carry these products or has insufficient supply, refer patients to local resources

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

