



## Suggested Topline Messages on the Nirsevimab Shortage

- Respiratory syncytial (sin-SISH-uhl) virus, or RSV, is a common respiratory virus that usually causes mild, cold-like symptoms. Most people recover in a week or two, but RSV can be serious. Infants and older adults are more likely to develop severe RSV and need hospitalization. Vaccines are available to protect older adults from severe RSV. Preventive options are available to protect infants and young children from severe RSV.
- There are now two ways to protect infants. The first, nirsevimab, is a long-acting monoclonal antibody immunization product recommended to protect infants from severe RSV disease. The second, Abrysvo™ (Pfizer), is a prenatal RSV vaccine which passes antibody protection from the pregnant person to the baby. As there are now limited opportunities to protect infants with nirsevimab, there is an immediate need for prenatal vaccination against RSV.
- To help protect infants from RSV, the American College of Obstetricians and Gynecologists, Centers for Disease Control and Prevention (CDC), and the Society for Maternal-Fetal Medicine recommend prenatal vaccination from September 2023 through January 2024 of all pregnant patients between 32 weeks and 36 weeks and 6 days of gestation with a single dose of RSV vaccine (Abrysvo, Pfizer).
- We encourage all prenatal care providers to provide RSV vaccine to their pregnant patients. If directly providing RSV vaccine is not immediately possible, a [strong referral](#) should be made to an in-network pharmacy where patients can be vaccinated. We encourage all pharmacists to vaccinate pregnant people who seek this protection for their babies. RSV vaccine can be co-administered with other recommended prenatal vaccines, including Tdap, COVID-19 and influenza vaccines.
- Clinicians are urged to clearly document receipt of RSV vaccination in the medical record and their jurisdiction's Immunization Information System (IIS). Documentation of this vaccine is especially critical because most infants will not need to be immunized with nirsevimab if they are already protected by prenatal vaccination at least 14 days before delivery.
- The limited availability of nirsevimab may be frustrating to parents and health care providers. However, the good news is that we can protect more infants than ever before with either nirsevimab or prenatal RSV vaccination.
- Regardless of vaccination status, all people can take steps to reduce their risk of infections, including frequent hand washing, covering coughs, masking when in crowded spaces, and staying home when sick.
- RSV is also an important cause of respiratory illness and hospitalization in older adults. Two vaccines (Abrysvo, Pfizer and Arexvy, GSK) are available to prevent RSV infection in persons 60 years of age and older. Speak to your medical provider to see if you should receive this vaccine.

## Potential Q&As

### Why are there limited supplies of nirsevimab?

In short, because demand has exceeded the available supply. We direct you to the statement by Sanofi [here](#) and refer further questions to them.

### How are providers deciding who should get the available product?

On October 23, the CDC issued guidance that suggests prioritizing available nirsevimab 100mg doses for infants at the highest risk for severe RSV disease: young infants (age <6 months) and infants with underlying conditions that place them at highest risk for severe RSV disease, including American Indian/Alaska Native infants, in the context of limited nirsevimab availability during the 2023-2024 RSV season. The full guidance is available [here](#). [Jurisdictions may want to add how these have been communicated to providers in the jurisdiction and if adaptations or additions have been made.]

### Why do some sites have doses while others have none?

Initially, orders for the Vaccines for Children Program were filled on a first-come, first-served basis. Shortly after the product became available, CDC was notified of limited supplies and responded with an allocation strategy to spread limited doses equitably across jurisdictions. There are not enough available doses to provide product to every site. Fortunately, vaccination of pregnant people between 32 and 36 weeks and 6 days gestation with RSV vaccine (Abrysvo, Pfizer) can also help protect infants from serious RSV disease.

### What is the message to anxious parents?

We understand and share the frustration. Ideally, there would be widespread availability of long-awaited tools to help prevent serious RSV infections, but unfortunately nirsevimab is in short supply for this season. We again stress the importance of vaccinating pregnant people against RSV, administering palivizumab for infants who meet the eligibility criteria, and taking precautions to limit the risk of infection.

More Information and resources:

- [ACOG, SFMP and AAP Statement on Nirsevimab Shortage](#) (ACOG)
- [Maternal Respiratory Syncytial Virus Vaccination](#) (ACOG)
- [Should I get the RSV vaccine During Pregnancy?](#) (ACOG)
- [Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations](#) (CDC)
- [Nirsevimab Frequently Asked Questions](#) (AAP)
- [\[Consider adding additional resources specific to your jurisdiction.\]](#)

### Background on RSV

- Respiratory syncytial virus, or RSV, is a common virus that affects the lungs.<sup>1</sup>
- RSV season starts in the fall and peaks in the winter in most regions of the U.S.<sup>1</sup>
- Almost all children will have had an RSV infection by their second birthday.<sup>2</sup>

- Antiviral medication is not routinely recommended to fight infection. Most RSV infections go away on their own in a week or two. However, RSV can cause severe illness in some people.<sup>2</sup>
- In very young infants with RSV, the only symptoms may be irritability, decreased activity, and breathing difficulties.<sup>2</sup>
- Infants, young children, and older adults are at increased risk of severe RSV.<sup>2</sup>
- RSV is the leading cause of infant hospitalization in the U.S.<sup>1</sup>

1. <https://www.cdc.gov/rsv/downloads/RSV-in-Infants-and-Young-Children.pdf>

2. <https://www.cdc.gov/rsv/about/symptoms.html>

### **Guidance on Borrowing**

On October 24, the CDC issued the following clarifications concerning borrowing VFC nirsevimab stock to immunize commercially insured children while there are nirsevimab supply constraints:

- The nirsevimab supply shortage continues to evolve and is not expected to resolve soon.
- The CDC Health Alert Network (HAN) notice recommended limiting nirsevimab use to infants ages 6 months and younger (formerly 8 months and younger) and infants with certain high risk medical conditions. However, this age restriction is unlikely to alleviate the supply shortage.
- The goal of the Vaccines for Children (VFC) program is to vaccinate VFC eligible children, and our first obligation is to those children. A VFC dose cannot be provided to a commercially insured child at the expense of vaccinating a VFC eligible child.
- Although the 2023-2024 VFC Operations Guide and the recently released nirsevimab addendum reiterated previous and long-standing policy for bidirectional borrowing between VFC and commercially purchased stock, it is likely not practical and not feasible for awardees to allow borrowing during times of supply constraints.
- While there are supply constraints for nirsevimab, VFC supply stock should remain prioritized for VFC eligible children.
- We strongly recommend that awardees take into consideration the supply in their jurisdictions and use the borrowing provisions for nirsevimab with caution, prioritizing supply for VFC eligible children while supply constraints exist.