

Health Advisory: Nirsevimab for RSV Prevention - Supply Issues

Minnesota Department of Health, Tuesday, October 24, 13:00 CDT 2023

Action Steps

Local and tribal health department: Please forward to hospitals, clinics, urgent care centers, emergency departments, and convenience clinics in your jurisdiction.

Hospitals, clinics and other facilities: Please forward to infection preventionists, primary care clinicians, infectious disease doctors, obstetric doctors, and all health care providers that care for infants and pregnant persons.

Health care providers:

- Prioritize the use of nirsevimab according to guidance below.
- Encourage RSVpreF vaccine (Abrysvo, Pfizer) when counseling pregnant people as another effective option for RSV prevention in infants.
- Use palivizumab for eligible children age 8 – 19 months per [AAP Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection](https://publications.aap.org/pediatrics/article/152/1/e2023061803/192153/Palivizumab-Prophylaxis-in-Infants-and-Young?autologincheck=redirected) (<https://publications.aap.org/pediatrics/article/152/1/e2023061803/192153/Palivizumab-Prophylaxis-in-Infants-and-Young?autologincheck=redirected>).
- Continue to advise patients to take measures to prevent the spread of respiratory illnesses.

CDC HAN

This is a follow-up to [CDC Health Alert Network \(HAN\) - 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](https://emergency.cdc.gov/han/2023/han00499.asp) (<https://emergency.cdc.gov/han/2023/han00499.asp>), released Monday, October 22, 2023.

These interim recommendations apply to healthcare settings with limited nirsevimab availability during the 2023–2024 RSV season. Interim recommendations are subject to change as new evidence becomes available.

Prioritization of Nirsevimab Administration

1. For infants weighing <5 kg, ACIP recommendations are unchanged. For infants born before October 2023, administer a 50mg dose of nirsevimab now. For infants born during October 2023 and throughout the RSV season, administer a 50mg dose of nirsevimab in the first week of life.
2. For infants weighing ≥ 5 kg, prioritize using 100mg nirsevimab doses in infants at highest risk of severe RSV disease:
 - Young infants aged <6 months.
 - American Indian and Alaska Native infants aged <8 months.
 - Infants aged 6 to <8 months with conditions that place them at high risk of severe RSV disease: premature birth at <29 weeks' gestation, chronic lung disease of prematurity, hemodynamically significant congenital heart disease, severe immunocompromise, severe cystic fibrosis (either manifestations of severe lung disease or weight-for-length less than 10th percentile), neuromuscular disease or congenital pulmonary abnormalities that impair the ability to clear secretions.
3. In palivizumab-eligible children aged 8–19 months, suspend using nirsevimab for the 2023–2024 RSV season. These children should receive palivizumab per [AAP Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection](https://publications.aap.org/pediatrics/article/152/1/e2023061803/192153/Palivizumab-Prophylaxis-in-Infants-and-Young?autologincheck=redirected) (<https://publications.aap.org/pediatrics/article/152/1/e2023061803/192153/Palivizumab-Prophylaxis-in-Infants-and-Young?autologincheck=redirected>).
4. Continue offering nirsevimab to American Indian and Alaska Native children aged 8–19 months who are not palivizumab-eligible and who live in remote regions, where transporting children with severe RSV for

escalation of medical care may be challenging, or in communities with known high rates of severe RSV among older infants and toddlers.

5. Follow [AAP Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection](https://publications.aap.org/pediatrics/article/152/1/e2023061803/192153/Palivizumab-Prophylaxis-in-Infants-and-Young?autologincheck=redirected) (<https://publications.aap.org/pediatrics/article/152/1/e2023061803/192153/Palivizumab-Prophylaxis-in-Infants-and-Young?autologincheck=redirected>) for palivizumab-eligible infants aged <8 months when the appropriate dose of nirsevimab is not available.
6. Avoid using two 50mg doses for infants weighing ≥ 5 kg (≥ 11 lbs), because 50mg doses should be reserved only for infants weighing <5 kg (<11 lbs), for example those born during the season who will be at increased risk for severe RSV illness because of their young age. Furthermore, providers should be aware that some insurers may not cover the cost of two 50mg doses for an individual infant.

Vaccination of Pregnant Persons with RSVpreF Vaccine

To alleviate strain on the supply of nirsevimab, providers should encourage pregnant people to receive RSVpreF vaccine (**Abrysvo**, Pfizer) during 32 weeks' gestation through 36 weeks and 6 days' gestation to prevent RSV-associated lower respiratory tract disease in infants. Only the Pfizer RSVpreF vaccine (**Abrysvo**) is approved and recommended for use in pregnant people. The GSK RSVpreF3 vaccine (**Arexvy**) should **not** be used in pregnant people.

Either RSVpreF vaccination or nirsevimab immunization for infants is recommended to prevent RSV-associated lower respiratory tract disease in infants, but administration of both products is not needed for most infants.

Preventative Measures for Patients

Families should be aware of everyday preventive measures to limit the spread of RSV respiratory illnesses, including washing hands, covering coughs and sneezes, cleaning frequently touched surfaces, wearing a well-fitting mask, and staying home when sick.

Background

RSV is a common cause of respiratory infection in U.S. infants, most of whom are infected with RSV during their first year of life. RSV is the leading cause of hospitalization among U.S. infants. The highest incidence of RSV-associated hospitalization occurs in infants aged <3 months and then decreases with increasing age. Because of the high incidence of severe RSV disease in the first months of life, RSV prevention products focus on passive immunization of young infants through maternal immunization or immunoprophylaxis with monoclonal antibodies.

In July 2023, the Food and Drug Administration (FDA) approved nirsevimab ([BeyfortusTM Prescribing Information](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf), Sanofi and AstraZeneca), a long-acting monoclonal antibody, for passive immunization to prevent RSV-associated lower respiratory tract disease among infants and young children. On August 3, 2023, CDC's Advisory Committee on Immunization Practices (ACIP) recommended nirsevimab for all infants aged <8 months who are born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk for severe RSV disease and are entering their second RSV season [[CDC MMWR Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices](https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7234a4-H.pdf) (<https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7234a4-H.pdf>)]. The recommended dosing of nirsevimab for infants weighing <5 kg (<11 lb) is 50mg. For infants aged <8 months weighing ≥ 5 kg (≥ 11 lb), the recommended dose is 100mg. For infants aged 8–19 months at increased risk of severe RSV disease entering their second season, the recommended dose is 200mg. Nirsevimab is supplied in single-dose prefilled

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syringes of either 50mg or 100mg. Cost of a nirsevimab prefilled syringe is the same for a 50mg dose or a 100mg dose.

Current reports to the National Respiratory and Enteric Virus Surveillance System (NREVSS), a national laboratory-based surveillance network, indicate RSV [[CDC Respiratory Syncytial Virus \(RSV\) Surveillance \(https://www.cdc.gov/surveillance/nrevss/rsv/index.html\)](https://www.cdc.gov/surveillance/nrevss/rsv/index.html)] transmission has increased to seasonal epidemic levels in the Southern regions of the United States and is expected to continue to increase in the rest of the country within the next 1–2 months.

For the 2023–2024 RSV season, [Sanofi Beyfortus \(https://www.news.sanofi.us/Sanofi-Beyfortus-Statement\)](https://www.news.sanofi.us/Sanofi-Beyfortus-Statement) reports a limited supply of nirsevimab, particularly the 100mg dose prefilled syringes used for infants weighing ≥ 5 kg. Based on manufacturing capacity and currently available stock, there are not sufficient 100mg dose prefilled syringes of nirsevimab to protect all eligible infants weighing ≥ 5 kg during the current RSV season. Additionally, supply of the 50mg dose prefilled syringes may be limited during the current RSV season. CDC continues to work with the manufacturer to understand how it may accelerate nirsevimab supply.

For More Information

- [CDC Respiratory Syncytial Virus \(RSV\) For Health Providers \(https://www.cdc.gov/rsv/clinical/index.html\)](https://www.cdc.gov/rsv/clinical/index.html)
- [CDC RSV Vaccination for Pregnant People \(https://www.cdc.gov/vaccines/vpd/rsv/hcp/pregnant-people.html\)](https://www.cdc.gov/vaccines/vpd/rsv/hcp/pregnant-people.html)
- [CDC RSV Prevention Information \(https://www.cdc.gov/vaccines/vpd/rsv/hcp/child.html\)](https://www.cdc.gov/vaccines/vpd/rsv/hcp/child.html)
- [ACIP and AAP Recommendations for Nirsevimab \(https://publications.aap.org/redbook/resources/25379/\)](https://publications.aap.org/redbook/resources/25379/)
- [CDC Options for Infant RSV Prevention At-a-Glance \(https://www.cdc.gov/vaccines/vpd/rsv/downloads/Infant-RSV-Prevention-At-A-Glance.pdf\)](https://www.cdc.gov/vaccines/vpd/rsv/downloads/Infant-RSV-Prevention-At-A-Glance.pdf)
- [AAP: Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection \(https://publications.aap.org/pediatrics/article/134/2/415/33013/Updated-Guidance-for-Palivizumab-Prophylaxis-Among\)](https://publications.aap.org/pediatrics/article/134/2/415/33013/Updated-Guidance-for-Palivizumab-Prophylaxis-Among)
- [MDH MnVFC Announcement: Nirsevimab \(Beyfortus\) Supply Constraints \(https://www.health.state.mn.us/people/immunize/hcp/mnvfc/ma23oct23.pdf\)](https://www.health.state.mn.us/people/immunize/hcp/mnvfc/ma23oct23.pdf)
- [MDH MnVFC Nirsevimab \(Beyfortus\) Supply and Ordering \(https://www.health.state.mn.us/people/immunize/hcp/mnvfc/ma16oct23.pdf\)](https://www.health.state.mn.us/people/immunize/hcp/mnvfc/ma16oct23.pdf)

A copy of this HAN is available at: [MDH Health Alert Network \(http://www.health.state.mn.us/han\)](http://www.health.state.mn.us/han)

The content of this message is intended for public health and health care personnel and response partners who have a need to know the information to perform their duties.