COLORADO
Department of Public Health & Environment

HEALTH ALERT NETWORK BROADCAST
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FROM: CO-CDPHE
SUBJECT: HAN Update – Limited availability of nirsevimab and prioritization recommendations
RECIPIENTS: Local Public Health Agencies / IPs / Clinical Labs / EDs / ID Physicians / Pediatric care providers
RECIPIENT INSTRUCTIONS: Local Public Health Agencies – please forward to healthcare providers

HEALTH UPDATE | Limited availability of nirsevimab and prioritization recommendations | October 27, 2023

Health care providers: Please distribute widely in your office

This information is for the public health and health care community. Do not post this document on a public web or social media site.

Key points

- Due to limited supply of nirsevimab (trade name Beyfortus) in the United States, on October 23, 2023, Centers for Disease Control and Prevention sent the following health advisory outlining interim recommendations for use of nirsevimab: 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. See the accompanying CDC HAN message or visit the link above for complete information.
- There is currently not sufficient available stock of 100mg prefilled syringes of nirsevmab to protect all eligible infants weighing 5kg or more during the current RSV season. Supply of 50mg prefilled syringes for infants weighing less than 5kg may also be limited during the current RSV season.
- Nirsevimab 100mg dose should be prioritized for infants at the highest risk for severe disease including young infants <6 months of age, infants aged 6 to <8 months with conditions that place them at high risk of severe RSV disease, and American Indian and Alaska Native infants aged <8 months.
- Recommendations for use of nirsevimab 50mg doses for infants weighing <5kg are unchanged at this time. **Avoid using two 50mg doses for infants weighing ≥5 kilograms to preserve supply for infants weighing <5 kilograms.**
- Nirsevimab use should be suspended for palivizumab-eligible children aged 8-19 months for the 2023-2024 RSV season. These children should receive palivizumab according to American Academy of Pediatrics (AAP) recommendations.
- Nirsevimab should be offered to American Indian and Alaska Native children aged 8-19 months who are not palivizumab-eligible and live in remote regions.

- RSVpreF vaccine (Abrysvo, Pfizer) is also recommended for use in pregnancy for prevention of respiratory syncytial virus-associated lower respiratory tract disease in infants. Prenatal care providers should discuss potential nirsevimab supply concerns when counseling those who are pregnant about RSVpreF vaccine (Abrysvo, Pfizer). Maternal vaccination is effective and will reduce the number of infants requiring nirsevimab during the RSV season.
- Effective October 16, 2023, the Colorado Department of Regulatory Agencies Division of Insurance adopted Emergency Regulation 23-E-08 requiring coverage of the product cost of the RSV immunizations and administration for applicable carriers, without cost sharing to the patient.
- Nirsevimab was recently added to the federal Vaccines for Children (VFC) program to ensure equitable access for all eligible infants and young children. The VFC program provides immunizations at no cost to children who might not otherwise be vaccinated because of inability to pay.
- To enroll as a Vaccines for Children (VFC) provider with the Colorado Department of Public Health and Environment, review the minimum qualifications and complete the provider interest form to start the VFC enrollment process.

Background information

In July 2023, the Food and Drug Administration (FDA) approved nirsevimab (trade name Beyfortus), a long-acting monoclonal antibody, to prevent lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants and young children. On August 3, 2023 Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommended nirsevimab for all infants <8 months old born during or entering their first RSV season and infants and children 8-19 months who remain at elevated risk for severe RSV disease entering a second RSV season. Nirsevimab is available in 50mg and 100mg prefilled syringe presentations. A 50mg dose of nirsevimab is recommended for infants weighing <5kg. A100mg dose is recommended for infants <8 months who weigh ≥5kg. A 200mg dose of nirsevimab is recommended for infants 8-19 months who are entering their second RSV season.
The manufacturer of nirsevimab is currently reporting limited quantities of the 100mg dose formulation such that there is not sufficient supply to protect all eligible infants ≥5kg during the 2023-2024 RSV season. This supply constraint applies to both commercial and publicly funded distribution channels. Given these constraints, CDC released interim recommendations for prioritized use of nirsevimab in healthcare settings where supply is limited.

CDC recommendations for health care providers

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:
    1. Young infants aged <6 months.
    2. American Indian and Alaska Native infants aged <8 months.
    3. 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 according to American Academy of Pediatrics (AAP) recommendations.
4. Continue offering nirsevimab to American Indian and Alaska Native children aged 8–19 months who are not palivizumab-eligible and 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 recommendations 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 kilograms (≥11 pounds), because 50mg doses should be reserved only for infants weighing <5 kilograms (<11 pounds). 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.
7. Providers should encourage those who are pregnant 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 their infants. Only the Pfizer RSVpreF vaccine (Abrysvo) is approved and recommended for use in those who are pregnant. The GSK RSVpreF3 vaccine (Arexvy) should not be used in those who are pregnant.
8. 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.

Population	Recommendation	Dose
Infants weighing < 5kg*	• 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. • Follow AAP recommendations for palivizumab-eligible infants aged <8 months when the appropriate dose of nirsevimab is not available.	50mg dose

Infants weighing ≥5 kg*	• Prioritize 100mg nirsevimab doses in infants at highest risk
	  ○ 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**
	• Follow AAP recommendations for palivizumab-eligible infants aged <8 months when the appropriate dose of nirsevimab is not available.
		100mg dose
		
		Avoid using two 50mg doses for infants weighing ≥5 kg.

Children aged 8-19 months*	• **Suspend using nirsevimab for palivizumab-eligible infants. These children should receive palivizumab.** • **Offer nirsevimab to American Indian and Alaska Native children who are not palivizumab-eligible and live in remote regions or communities with known high rates of severe RSV among older infants and toddlers.**	200mg dose (two 100mg injections given at the same time at different injection sites).
Those who are pregnant*	• Providers should encourage those who are pregnant 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 their infants. • The GSK RSVpreF3 vaccine (Arexvy) should not be used in those who are pregnant.	Single 0.5mL dose

* 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.

** Conditions that place infants age 6 to <8 months at high risk of severe RSV disease include: 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), and neuromuscular disease or congenital pulmonary abnormalities that impair the ability to clear secretions.

Links in order of appearance

- CDC Health Advisory #499 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

- AAP palivizumab prophylaxis guidance: https://publications.aap.org/pediatrics/article/152/1/e2023061803/192153/Palivizumab-Prophylaxis-in-Infants-and-Young?autologincheck=redirected
- RSVpreF vaccine recommendations: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm?s_cid=mm7241e1_w
- Colorado DORA DOI Emergency Regulation 23-E-08: https://drive.google.com/file/d/1GeY0m6D37hD6spbjwdLk0EsLeT2JNH4K/view
- VFC Requirements at a Glance: https://drive.google.com/file/d/1q2m0lhKtZ_iY0eECr_n8bXGyl9WZcWbA/view?usp=sharing
- VFC Provider Interest Form: https://fs9.formsite.com/ColoradoIMMprogram/VFC-Interest-Form/index

More information

- CDC COCA Call Oct. 26. 2023 "Protecting Infants from Respiratory Syncytial Virus (RSV)" [recording available]: https://emergency.cdc.gov/coca/calls/2023/callinfo_102623.asp
- ACOG, SMFM, and AAP Statement on Nirsevimab Shortage: https://www.acog.org/news/news-releases/2023/10/acog-smfm-aap-statement-on-nirsevimab-shortage
- CDC RSV Webpage for Healthcare Professionals: https://www.cdc.gov/rsv/clinical/index.html
- CDC RSV-NET Data Dashboard: https://www.cdc.gov/rsv/research/rsv-net/dashboard.html
- Colorado Viral Respiratory Diseases Data Dashboard: https://cdphe.colorado.gov/viral-respiratory-diseases-report

CDPHE Disease Reporting Line: 303-692-2700 or 303-370-9395 (after hours)