



## Department of Health

Heidi Hedberg, Commissioner  
Anne Zink, MD, Chief Medical Officer3601 C Street, Suite 540  
Anchorage, Alaska 99503

## Division of Public Health

Lindsey Kato, MPH, Director

<https://health.alaska.gov/dph/Epi>  
24 Hour Emergency (800) 478-0084  
Local (907) 269-8000

## Editors:

Joe McLaughlin, MD, MPH  
Louisa Castrodale, DVM, MPHBulletin No. 14  
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## Update on Nirsevimab for RSV Prevention During the 2023–24 RSV Season

## Background

Respiratory syncytial virus (RSV) is the leading cause of hospitalization among infants in the United States.<sup>1</sup> Hospitalization rates are higher for premature infants and infants with chronic lung disease or congenital heart disease.<sup>1</sup> Rural Alaska Native children have had up to 7-fold higher RSV hospitalization rates compared to other US children.<sup>2</sup>

During 2009–2023, the Statewide RSV Seasonality Workgroup published annual state-specific recommendations for Palivizumab (Synagis®), a monoclonal antibody administered monthly for 5 months to certain high-risk infants and children to reduce the risk of RSV hospitalization.<sup>3</sup> The AAP *Redbook* has recognized Alaska's unique RSV seasonality and higher hospitalization rates among Alaska Native infants and supports Alaska-specific prophylaxis criteria.<sup>1</sup>

Nirsevimab (Beyfortus™) is a long-acting monoclonal antibody for RSV prevention in newborns and infants that was approved by the US Food and Drug Administration (FDA) in July 2023.<sup>4</sup> Clinical trial data demonstrated that nirsevimab is highly efficacious among infants aged <8 months, preventing an estimated 79% of medically attended RSV-associated lower respiratory tract infections (LRTI) and 80.6% of RSV-associated LRTI with hospitalization compared to placebo through 150 days post-dose.<sup>5</sup> In August 2023, the Advisory Committee on Immunization Practices (ACIP) unanimously voted in favor of recommending nirsevimab for use as described below. The ACIP also voted for the inclusion of nirsevimab in the federal Vaccines for Children (VFC) program.<sup>4</sup>

## National Nirsevimab Administration Guidance

ACIP recommends 1 dose of nirsevimab for all infants aged <8 months born during or entering their first RSV season (50 mg for infants weighing <5 kg [ $<11$  lb] and 100 mg for infants weighing  $\geq 5$  kg [ $\geq 11$  lb]).<sup>5</sup> ACIP recommends 1 dose of nirsevimab (200 mg, administered as two 100 mg injections given at the same time at different injection sites) for infants and children aged 8–19 months who are at increased risk for severe RSV disease (Box) and entering their second RSV season.<sup>5</sup>

## Box. High-risk Criteria for Infants/Children Aged 8–19 Months

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season;
- Children with severe immunocompromise;
- Cystic fibrosis patients who have either 1) manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or 2)  $<10^{\text{th}}$  percentile weight-for-length; and
- American Indian and Alaska Native children (AI/AN).<sup>4</sup>

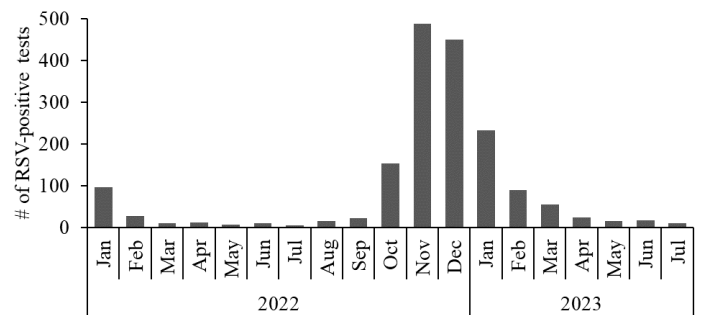
Nirsevimab should be administered shortly before the start of the RSV season (typically October through March in the Lower 48); however, it may be administered to age-eligible infants/children who have not yet received a dose at any time during the RSV season. Newborns should receive nirsevimab within 1 week of birth during the RSV season; administration can occur during the birth hospitalization. Children who have received nirsevimab should not receive palivizumab during the same RSV season.<sup>4</sup>

Nirsevimab is not expected to interfere with the immune response to other routine childhood immunizations; in accordance with general best practices for immunization, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended.<sup>5</sup>

## RSV Seasonality and Nirsevimab Availability in Alaska

During 2012–2018, the RSV season in Alaska occurred later than in the Lower 48 (starting in December/January and ending by May); as such, palivizumab was administered in Alaska from late November through May 15 annually. The COVID-19 pandemic altered RSV seasonality such that the 2021–22 and 2022–23 seasons started earlier than prior seasons.<sup>3</sup> Alaska's 2022–23 season started in October and declined by the end of March (Figure); however, RSV circulation continued in some parts of Alaska through summer 2023.

Figure. RSV-Positive Tests Reported to the Section of Epidemiology, by Month — Alaska, January 2022–July 2023



Provided national supply chains allow, nirsevimab will be available to Alaska providers through the Alaska Immunization Program from October 1, 2023, through March 31, 2024. If RSV activity warrants consideration for extension of this window beyond March 31, the Statewide RSV Seasonality Workgroup will convene a meeting to discuss updated guidance. The Section of Epidemiology (SOE) plans to produce a RSV, influenza, and COVID-19 surveillance snapshot that provides trend data starting in October; the snapshot will be updated weekly through the respiratory season under the “Spotlight” column of the [SOE homepage](#).

## Discussion

On August 3, 2023, the ACIP recommended nirsevimab for all infants aged <8 months born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk of severe RSV disease entering their second RSV season.<sup>5</sup> The ACIP high-risk criteria include AI/AN children aged 8–19 months.<sup>4</sup> This is because some AI/AN children have been found to be at much higher risk for RSV-associated hospitalization compared to similar-aged children in the United States.<sup>5</sup> The high rates of RSV-associated hospitalization in Alaska appear to be due in large part to socioeconomic disparities (e.g., multigenerational housing, hauled or collected water, and wood stove heating source) present in certain rural Alaska communities.<sup>2</sup> Because these disparities are not present in all Alaska communities, clinicians should be prepared to discuss the risks and benefits of nirsevimab administration when counseling parents/guardians about the need for their 8–19-month-old child to receive prophylaxis based solely on their Alaska Native race.

## References

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