

Interim Guidance for Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the Current Atypical Interseasonal RSV Spread
American Academy of Pediatrics Interim Clinical Guidance
August 10, 2021

Respiratory syncytial virus (RSV) causes annual epidemics of acute respiratory illnesses in children, ranging from mild upper respiratory tract infections to severe lower respiratory tract disease including bronchiolitis or pneumonia. Severe RSV disease occurs primarily in infants younger than 6 months during their first fall and winter season of life.

RSV activity in the United States usually begins in the fall and extends through spring; peak activity typically occurs in early February, although there can be regional variation.¹ Following the institution of nonpharmacologic interventions (eg, masking, social distancing) for the prevention of COVID-19 in March of 2020, the number of RSV infections in the United States decreased rapidly and dramatically.² Interactions between SARS-CoV-2 and other respiratory viruses may have also altered RSV epidemiology. RSV activity in the United States remained very low through the traditional 2020-2021 fall-winter season but began to increase in the spring of 2021.³ This interseasonal increase in activity is a marked deviation from the typical RSV epidemiology and is believed to be the result of the relaxation of nonpharmacologic interventions that were previously implemented to prevent the spread of SARS-CoV-2. Consequently, RSV activity is on the rise in certain regions of the United States, with corresponding increases in emergency department visits and hospitalizations of infants and children. It is unknown whether the current circulation of RSV in the United States will spread equally to all regions and increase to typically seen fall-winter levels of activity. It is also unclear how long this activity will persist.⁴

Although most RSV hospitalizations occur in previously healthy term infants, there is an increased risk of severe RSV disease in certain groups of infants and children, including preterm infants, especially those born at less than 29 weeks' gestation, infants with chronic lung disease of prematurity, infants with certain types of hemodynamically significant congenital heart disease, infants and young children with certain immunodeficiency states, and infants with pulmonary abnormalities or neurological and neuromuscular conditions that impair ability to clear secretions from the upper airway.⁵

The American Academy of Pediatrics (AAP) policy adopted in 2014 states that palivizumab, a humanized monoclonal antibody directed against the fusion protein of RSV, may be considered for use to decrease the risk of hospitalization in selected infants at significantly increased risk of severe RSV disease during the typical season.⁶ Up to 5 monthly doses are recommended to provide serum levels associated with protection for the approximately 6 months that comprise the typical RSV season. Given the current atypical interseasonal change in RSV epidemiology, which may represent a delayed onset of the 2020-2021 season, the AAP strongly supports consideration for use of palivizumab in patients who would be candidates per current eligibility recommendations.⁷ This recommendation applies to regions experiencing high rates of RSV circulation, consistent with a typical fall-winter season. The Centers for Disease Control and Prevention (CDC) monitors RSV activity in the United States in collaboration with state and county health departments and commercial and clinical laboratories.⁸ Guidelines for determining seasonal activity depend on the type of testing used for RSV.^{9,10}

The AAP recognizes the importance of maintaining flexible approaches including early initiation of palivizumab administration during this atypical interseasonal change in RSV epidemiology in 2021. Pediatric health care leaders will be key leaders to inform ongoing need in communities warranting specialized consideration. The need for palivizumab administration to eligible infants during this atypical interseason should be supported where activity approaches fall-winter season and should be reassessed at least monthly. This guidance document is not meant to supplant typical seasonal palivizumab administration guidance.

Interim Guidance Disclaimer: The COVID-19 clinical interim guidance provided [here](#) has been updated based on current evidence and information available at the time of publishing. Guidance will be regularly reviewed with regards to the evolving nature of the pandemic and emerging evidence. All interim guidance will be presumed to expire September 30, 2021, unless otherwise specified.

¹ Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory syncytial virus seasonality—United States, 2014–2017. *MMWR Morb Mortal Wkly Rep*. 2018;67(2):71-76. DOI: <https://doi.org/10.15585/mmwr.mm6702a4>

² Centers for Health Control and Prevention. Increased Interseasonal Respiratory Syncytial Virus (RSV) Activity in Parts of the Southern United States. CDC Health Advisory. June 10, 2021. Available at: <https://emergency.cdc.gov/han/2021/han00443.asp>

³ Centers for Disease Control and Prevention, The National Respiratory and Enteric Virus Surveillance System. Respiratory Syncytial Virus (RSV) Surveillance. Trends in the U.S. Available at: <https://www.cdc.gov/surveillance/nrevss/rsv/index.html>

⁴ Centers for Disease Control and Prevention. Changes in Influenza and Other Respiratory Virus Activity During the COVID-19 Pandemic — United States, 2020–2021. *MMWR Morb Mortal Wkly Rep*. 2021;70(29):1013-1019. DOI: <http://dx.doi.org/10.15585/mmwr.mm7029a1>

⁵ American Academy of Pediatrics, Committee on Infectious Diseases. Respiratory syncytial virus. In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. *Red Book: 2021 Report of the Committee on Infectious Diseases*. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021:628-636. Available at: <https://redbook.solutions.aap.org/chapter.aspx?sectionId=247326907&bookId=2591&resultClick=1>

⁶ American Academy of Pediatrics, Committee on Infectious Diseases. Respiratory syncytial virus. In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. *Red Book: 2021 Report of the Committee on Infectious Diseases*. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021:628-636. Available at: <https://redbook.solutions.aap.org/chapter.aspx?sectionId=247326907&bookId=2591&resultClick=1>

⁷ American Academy of Pediatrics, Committee on Infectious Diseases. Policy statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*. 2014;134(2):415-420. Reaffirmed February 2019. DOI: <https://doi.org/10.1542/peds.2014-1665>

⁸ Centers for Disease Control and Prevention, The National Respiratory and Enteric Virus Surveillance System. Respiratory Syncytial Virus (RSV) Surveillance. Trends in the U.S. Available at: <https://www.cdc.gov/surveillance/nrevss/rsv/index.html>

⁹ Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory syncytial virus seasonality—United States, 2014–2017. *MMWR Morb Mortal Wkly Rep*. 2018;67(2):71-76. DOI: <https://doi.org/10.15585/mmwr.mm6702a4>

¹⁰ Midgley CM, Haynes AK, Baumgardner JL, et al. Determining the seasonality of respiratory syncytial virus in the United States: the impact of increased molecular testing. *J Infect Dis*. 2017;216(3):345-355. DOI: <https://doi.org/10.1093/infdis/jix275>