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## Palivizumab Prophylaxis Guidance during Interseasonal RSV Activity, September 2021

### Background

Respiratory syncytial virus (RSV) is an important cause of hospitalization for 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 5-fold higher RSV hospitalization rates compared to other U.S. children.<sup>2</sup>

Palivizumab (Synagis®) is a monoclonal antibody that reduces the risk of RSV hospitalization in certain high-risk children.<sup>1,3</sup> In 2014, the American Academy of Pediatrics (AAP) revised the eligibility criteria for palivizumab prophylaxis to restrict availability to those children at highest risk.<sup>1,4,5</sup> In the US, RSV activity usually starts in late fall and peaks in February. The AAP recommends a maximum of 5 palivizumab doses to cover the season, which typically lasts 4–5 months.<sup>1,4</sup> The AAP *Redbook* recognizes Alaska’s unique RSV seasonality and increased RSV hospitalizations among Alaska Native infants and supports Alaska-specific prophylaxis criteria.<sup>4</sup>

### 2021 Interseasonal RSV Activity

In March 2020, following the institution of masking and social distancing for the prevention of coronavirus disease-19 (COVID-19), the number of Alaska and US. RSV infections decreased rapidly and dramatically.<sup>6,7</sup> RSV activity in the US remained very low through the traditional 2020–21 RSV season but began to increase in the spring of 2021.<sup>3,6,7</sup> This interseasonal increase in RSV activity is a marked deviation from the typical RSV epidemiology and is believed to be due to the relaxation of interventions to prevent the spread of SARS-CoV-2. Consequently, RSV activity and hospitalizations are on the rise in certain regions of the US. It is unknown whether the current circulation of RSV will increase to that typically seen for fall-winter levels or how long this activity will persist. Given the current atypical interseasonal change in RSV epidemiology, which may represent a delayed onset of the 2020–21 season, the AAP strongly supports consideration of the use of palivizumab for high-risk infants in regions experiencing elevated rates of RSV activity.<sup>7</sup> Per the AAP guidance, palivizumab administration should be supported where activity approaches fall-winter season and should be reassessed at least monthly.

### Alaska Interseasonal RSV Activity and Recommendations

Laboratory data from the Alaska State Public Health Laboratory (ASPHL) and other clinical laboratories are used to track trends. On August 25, 2021, the Statewide RSV Workgroup reviewed available RSV laboratory and hospitalization data. RSV activity waned in late March 2020 after social distancing mandates for the COVID-19 pandemic and stayed low through the rest of 2020 and into early 2021. RSV activity resumed in June 2021 and RSV hospitalizations increased in August, signifying a 2021 interseasonal RSV period. As of August 27, 47 RSV+ cases and 11 RSV hospitalizations were reported by ASPHL and health care providers; three facilities reported RSV in >10% of specimens.

Season onset can be determined in real time by identifying the first 2 consecutive weeks when RSV RT-PCR test positivity is ≥3% or antigen detection positivity is ≥10%.<sup>4</sup> Alaska’s Statewide RSV Workgroup recommends initiation of interseasonal palivizumab starting September 3, 2021. In keeping with the Interim Guidance from the AAP,<sup>7</sup> the Workgroup will reassess RSV activity monthly and send updated guidance when RSV activity declines. Clinicians are encouraged to test for RSV in children hospitalized with

respiratory infections. The Workgroup will give future guidance for the regular 2021–22 RSV season.

### Alaska Medicaid Palivizumab Reimbursement Criteria

During the 2021 interseason, defined as the period inclusive of September 3 through November 30, 2021, based on Statewide RSV Workgroup recommendations, Alaska Medicaid will authorize up to 3 monthly palivizumab doses starting on September 3, 2021. Coverage guidance for the regular 2021–22 season will be updated this fall. The clinical eligibility criteria for palivizumab for the 2021 interseasonal period will remain the same as during the 2020–21 season and will continue to reflect the 2009 AAP criteria (Table).<sup>6,7</sup>

**Table. Alaska Medicaid Palivizumab Coverage for the 2021 Interseason<sup>8</sup>**

Date of Birth	Gestational Age (Wks)	Risk Factors	# of Doses 9/3/21-11/30/21
Born on or after June 5, 2021 (<3 months)	32 to <35	At least one: • daycare attendance • sibling aged <5 years • home without running water • ≥3 people in child’s bedroom or ≥7 in child’s household	≤3, until 90 days of age
Born after March 3, 2021 (<6 months)	29 to <32		≤3
Born after Sep 3, 2020 (<12 months)	<29		≤3
Born after Sep 3, 2020 (<12 months)	Any	• congenital airway anomaly • neuromuscular disease	≤3
Born on or after Sep 3, 2019 with CHD; or born after Sep 3, 2019 with CLD	Any	• congenital heart disease (CHD) • chronic lung disease (CLD)	≤3

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