



April 10, 2017

Karen Remley, MD, MBA, MPH, FAAP
CEO, American Academy of Pediatrics
141 NW Point Boulevard
Elk Grove Village, IL 60007

Dear Dr. Remley:

I am writing on behalf of the National Coalition for Infant Health (NCfIH), a group of more than 150 professional, clinical, community health, and family support organizations. NCfIH advocates for access to approved clinical therapies demonstrated to improve the lives of premature infants and their families. The coalition has particular concern about the lack of access to preventive treatment for Respiratory Syncytial Virus (RSV), a restriction faced by the majority of premature infants.

In 2014, the AAP's Committee on Infectious Diseases (COID) revised its policy for palivizumab (Synagis) administration, which has been proven to prevent and/or lessen the severity of RSV disease. Previous COID guidelines aligned with the U.S. Food and Drug Administration label and reflected published clinical trial results in high-risk infants. However, the 2014 COID policy which was promptly adopted by state Medicaid plans and private payers, limits access for a significant portion of premature infants who are at risk for RSV disease and related complications. These guidelines subject an extremely vulnerable infant population to sub-optimal care by denying immunoprophylaxis. They also negate providers' ability to individually assess patients for cumulative risk and provide therapy when indicated.

Over 70 percent of premature infants are born between 30 and 35 weeks gestation, beyond the cut-off gestational age in the 2014 policy. These are vulnerable infants, whose premature lungs and fragile immune systems heighten their risk to contract RSV. Worse, these eligibility guidelines disproportionately affect African American and low-income families, whose babies are more likely to be born prematurely and suffer from other disparities.

National Coalition for Infant Health
1275 Pennsylvania Ave NW Suite 1100A
Washington, D.C. 20004
www.infanthealth.org

Several key research studies have been published since the revised policies were adopted in 2014. Data from the SENTINEL 1 study demonstrates the increased burden of RSV disease from the access restrictions. During the 2015-2016 season of the study, 678 preterm infants were hospitalized for RSV. Of these infants, 48 percent were admitted to the ICU and 19 percent required intubation and mechanical ventilation. These babies would have qualified for prophylaxis according to the FDA label, as validated in the IMPACT trial (1996).

Another study, analyzing claims data from both Medicaid and commercial payers for 2.2 million infants revealed that prophylaxis treatment in the 2014-2015 RSV season was down between 45-94 percent for commercially insured patients and 65-95 percent for Medicaid populations. During the same time span, RSV-related hospitalizations increased for these patient groups by 170 percent and 40 percent respectively.

The AAP/COID policy guidance has been adopted to determine as eligibility and payment criteria for therapy for commercial payers and Medicaid. The National Perinatal Association and the National Medical Association have convened consensus panels in the past, both of which produced consensus papers outlining a comprehensive, scientific evidence-based approach to RSV disease, utilizing the current, peer-reviewed published data. In a January 2013 press release, National Medical Association President Rahn Baily, MD, explained, "We cannot continue to experiment with our infants or support 'off-label' treatment via decreasing the length of treatment and dosing."

Given new, peer-reviewed data demonstrating the negative impact on premature infants and their families, the National Coalition for Infant Health respectfully requests the opportunity to discuss this issue with you and your staff in person. I will be contacting you within the next two weeks to schedule our discussion, or please feel free to contact me via phone at 972-989-1991 or email at drbabynp@gmail.com to make arrangements.

Sincerely,



Suzanne Staebler, DNP, APRN, NNP-BC, FAANP, FAAN
Health Policy Consultant, National Coalition for Infant Health

Allergy & Asthma Network

Council of International Neonatal Nurses

Hand to Hold

National Association of Neonatal Nurses

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National Association of Neonatal Nurse Practitioners

National Association of Perinatal Social Workers

National Medical Association, Section on Pediatrics

National Perinatal Association

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