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Committee on Infectious Diseases

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AMERICAN ACADEMY OF PEDIATRICS

POLICY STATEMENT

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

Recommendations for the Prevention of Respiratory Syncytial Virus Disease in Infants and Children: Policy Statement

Committee on Infectious Diseases

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All authors contributed substantially to the conception and design; review and interpretation of relevant literature; drafting and revisions; and final approval of the published version.

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ABSTRACT. This policy statement updates recommendations of the American Academy of Pediatrics (AAP) for the use of respiratory syncytial virus (RSV) immunization for the prevention of lower respiratory tract infection (LRTI) caused by RSV in infants and children. The AAP recommends RSV immunization for all infants under 8 months of age born during or entering their first RSV season, unless the infant has documented protection from vaccination of their pregnant parent; and for infants and

children 8 through 19 months of age who are at high risk of severe RSV disease and entering their second RSV season. A review of evidence supports expanding the high-risk criteria for administration of RSV immunization in infants and children 8 through 19 months of age entering their second RSV season. A discussion of the evidence supporting the AAP recommendations and additional details on infants and children included in the expanded recommendations are in the accompanying technical report (https://doi.org/10.1542/peds.2026-079049).

ABBREVIATIONS: AAP, American Academy of Pediatrics; COID, Committee on Infectious Diseases; LRTI, lower respiratory tract infection; RSV, respiratory syncytial virus.

INTRODUCTION

This policy statement updates recommendations of the American Academy of Pediatrics (AAP) for the use of respiratory syncytial virus (RSV) immunization for the prevention of lower respiratory tract infection (LRTI) caused by RSV in infants and children and an accompanying technical report provides further detail.[1] Of note, the products discussed in the AAP policy statement for the prevention of RSV are monoclonal antibodies, and the terms RSV immunization and RSV antibody are used interchangeably.

METHODOLOGY

The AAP Committee on Infectious Diseases (COID) developed recommendations for RSV immunization through an evidence-based process informed by scientific literature, public health data, and expert review. The COID convened a subgroup of COID members and external experts with relevant expertise. The subgroup worked in collaboration with strategic partners

including the Vaccine Integrity Project, and professional societies such as the American Medical Association and the Council on Medical Specialty Societies to access salient data sources. The subgroup identified clinical questions and reviewed available data on disease epidemiology; morbidity; mortality; and immunization safety, efficacy, and uptake, considering relevant domains of the Evidence to Recommendations framework.[2] Conflict of interest disclosures were collected from all participants, and members with relevant conflicts recused themselves from the COID evidence review and recommendations meeting as well as voting, as required. Proposed recommendations were presented to the full COID for discussion and vote by eligible members. Approved recommendations were incorporated into this policy statement and the accompanying technical report. Additional information about the 2026-2027 AAP immunization recommendation development process can be found at: https://www.aap.org/en/patient-care/immunizations/aap-immunization-recommendations-process-2026/.

UPDATES TO RECOMMENDATIONS

Starting in the 2026–2027 season, criteria for administration of RSV immunization in infants and children 8 through 19 months of age entering their second RSV season have been expanded to include clinical conditions conferring higher risk of significant illness:

- Children born preterm, at <32 weeks, 0 days' gestation, regardless of the need for medication or other support
- Children with hemodynamically significant congenital heart disease (ie, a defect that can result in symptoms and/or cardiac chamber dilation)[3]
- Children with anatomic pulmonary abnormalities or neuromuscular disorders that put them at risk for severe RSV disease

- Children with Down syndrome or other chromosomal differences placing them at higher risk of severe RSV disease

RECOMMENDATIONS

The AAP recommends RSV immunization[4] for:

- Infants <8 months of age born during or entering their first RSV season if:
    - the birthing parent did not receive RSVpreF vaccine during this pregnancy, per the American College of Obstetricians and Gynecologists' guidance[5]
    - the birthing parent's RSVpreF vaccination status is unknown, or
    - the infant was born <14 days after RSVpreF vaccination of the pregnant parent
- Infants and children 8 through 19 months of age at high risk of severe RSV disease and entering their second RSV season, regardless of the RSV vaccination status of the pregnant parent or the child's prior receipt of nirsevimab or clesrovimab when <8 months of age in their first RSV season

Note that all ages refer to chronologic age, not corrected age for infants born preterm.

High Risk Groups in Pediatrics

High-risk criteria for administration of RSV immunization in infants and children 8 through 19 months of age entering their second RSV season include the following:

- Children born preterm, at <32 weeks, 0 days' gestation, regardless of the need for medication or other support
- Children with chronic lung disease attributable to prematurity or to other significant neonatal conditions (eg, meconium aspiration or congenital diaphragmatic hernia) who required medical support (ie, chronic corticosteroid therapy, diuretic therapy, or

supplemental oxygen) at any time during the 6-month period before the start of the second RSV season

- Children with hemodynamically significant congenital heart disease (ie, a defect that can result in symptoms and/or cardiac chamber dilation)[3]
- Children with anatomic pulmonary abnormalities or neuromuscular disorders that put them at risk for severe RSV disease
- Children with severe immunocompromise
- Children with Down syndrome or other chromosomal differences placing them at higher risk of severe RSV disease
- Children with cystic fibrosis who have either:
    - manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year after birth or abnormalities on chest imaging that persist when stable), or
    - weight-for-length that is less than the 10th percentile

- American Indian or Alaska Native children[6,7]

Conditions associated with the high-risk criteria for administration of RSV immunization in infants and children 8 through 19 months of age entering their second RSV season, as well as evidence regarding risk for RSV disease in these populations, are described in the technical report.[1]

Equity Considerations

American Indian and Alaska Native children are included in the high-risk category because they experience significantly higher rates of severe RSV disease and hospitalization, with children living in rural and reservation communities most impacted. Evidence supports that

this increased risk in American Indian and Alaska Native children is associated with social drivers of health, including limited access to health services and transportation, lack of running water in the home in some communities, and high household occupancy and indoor air pollution.[6,7] Although social drivers of health may contribute to RSV-associated hospitalization risk in other groups, there are constraints in translating current evidence to implementable recommendations at a population level on the basis of these social risk factors. Limitations in the evidence include specificity regarding social factors that confer risk for poor outcomes related to RSV. Implementation constraints include the absence of available information regarding specific social risk factors at the point of care.

Approved Products

Two monoclonal antibody products, nirsevimab[8] and clesrovimab,[9] are recommended for prevention of RSV LRTI in infants younger than 8 months in the United States. Both products are administered as a single dose for infants younger than 8 months. The AAP recommends any licensed RSV immunization product appropriate for age and health status and does not prefer one product over another.

Only children 8 through 19 months who meet high-risk criteria should receive RSV immunization in their second RSV season. Nirsevimab is currently the only product indicated for prevention of RSV in children who remain vulnerable to RSV in their second RSV season.

Timing of Administration

RSV monoclonal antibody should be administered October 1 through March 31 in most of the continental United States. In tropical climates—including Florida, Guam, Hawaii, Puerto Rico, the US-affiliated Pacific Islands, and the US Virgin Islands—RSV seasonality may differ from most of the continental United States or may be unpredictable.[10] In Alaska, RSV

seasonality is also less predictable, and RSV activity often lasts longer than the national average.[11] Because the timing of RSV activity varies geographically in the United States, public health authorities may elect to provide revised guidance regarding the timing of RSV antibody administration based on local or regional surveillance data and feasibility of implementation (ie, extending or shortening the recommended administration period of October–March). Pediatricians, regional medical centers, and health systems should consult with state, tribal, local, or territorial health departments before systematically modifying the recommended months for RSV antibody administration for their eligible patient populations.[9] Under special circumstances (eg, travel to areas of increased RSV activity, concern of failure to return for administration), health care providers may use clinical judgment in determining when to administer RSV antibody outside the months of October through March to individual patients. When health care providers do so, consultation with state or territorial health care providers is not required.[9]

Infants born shortly before and during the RSV season should receive RSV immunization within the first week after birth, ideally during the birth hospitalization. If a birth hospital is unable to implement administration of nirsevimab or clesrovimab, the infant should receive RSV immunization in an ambulatory setting as soon as available.

Eligible infants who are <8 months of age and born outside of RSV season should receive RSV immunization shortly before RSV season or as early as feasible during the season. Administration can occur during any visit to a health care setting, including well-child visits.

Administration to Hospitalized Infants

Eligible infants with prolonged birth hospitalizations because of prematurity or other causes who are discharged during RSV season should receive RSV immunization shortly before or promptly after discharge from the hospital. Health care-associated RSV disease occurs;

however, the incidence is unknown. Safety data for use of RSV antibody in infants with a postmenstrual age (gestational age at birth plus chronologic age) of <32 weeks are limited. To prevent health care-associated RSV disease, providers may consider administering RSV immunization to eligible hospitalized infants during their hospitalization. This decision should be based on clinical judgment, considering the potential risks and benefits as well as local RSV activity.[12]

Coadministration With Routine Childhood Vaccines

In accordance with AAP's general best practices for immunizations, (https://publications.aap.org/redbook) simultaneous administration of RSV immunization with age-appropriate vaccines is recommended.[13] In clinical trials, when RSV immunization was administered concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the concomitantly administered regimen was similar to that of the childhood vaccines administered alone.[14] When concomitantly administered, RSV immunization is not expected to interfere with the immune response to other vaccines.[15]

Prior RSV Infection

Nirsevimab or clesrovimab should be administered as recommended regardless of whether the infant has already had an RSV infection at any time previously, including during the current season. Reinfection with RSV, even during the same season, can occur. Children who are moderately or severely ill with or without fever, including those who have known current RSV infection, should defer nirsevimab or clesrovimab until recovery from the acute illness and when clinical symptoms have improved.

Repeat Dose

A repeat dose of nirsevimab or clesrovimab is recommended for children who have previously received the immunization or whose birthing parent received RSVpreF vaccine during that pregnancy and subsequently undergo antibody-depleting treatments or procedures, such as plasmapheresis, cardiopulmonary bypass, or extracorporeal membrane oxygenation (ECMO), that may result in the loss of RSV-specific antibodies. See the package inserts for dosing guidance (www.fda.gov/drugsatfda).

Maternal RSV Vaccination[4,9]

Immunization is not needed for most infants <8 months of age whose birthing parent received RSVpreF vaccine during that pregnancy and ≥14 days before giving birth. Guidance for the use RSV vaccine during pregnancy for the prevention of severe RSV disease in young infants is available from the American College of Obstetricians and Gynecologists (https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/09/maternal-respiratory-syncytial-virus-vaccination). RSV immunization may be considered for infants whose birthing parent received RSVpreF vaccine during that pregnancy in rare circumstances when, on the basis of clinical judgment of the health care provider, the potential incremental benefit of administration is warranted. These situations include, but are not limited to:

- Infants whose birthing parent may not have mounted an adequate immune response to RSV vaccination (eg, pregnant people with immunocompromising conditions)
- Infants whose birthing parent has a medical condition associated with reduced transplacental antibody transfer (eg, pregnant people living with HIV infection)
- Infants who have undergone antibody-depleting treatments or procedures such as plasmapheresis, cardiopulmonary bypass (see FDA package inserts at

www.fda.gov/drugsatfda), or ECMO or exchange transfusion, leading to loss of maternal antibodies

- Infants with substantial increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease, intensive care admission with a requirement of oxygen at discharge)

Contraindications and Adverse Event Reporting

Both nirsevimab and clesrovimab are contraindicated in infants and children with a history of severe allergic reactions (eg, anaphylaxis) to any components or excipients in the product. See FDA package inserts at www.fda.gov/drugsatfda. If an adverse reaction occurs after administration of nirsevimab or clesrovimab, it should be reported to MedWatch (www.fda.gov/medwatch). Adverse reactions that occur after the coadministration of nirsevimab or clesrovimab with a vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS), with reports specifying that the patient received nirsevimab or clesrovimab on the VAERS form (https://vaers.hhs.gov). When adverse reactions that occur after the coadministration of nirsevimab or clesrovimab with a vaccine are reported to VAERS, additional reporting of the same adverse reactions to MedWatch is not necessary.

ADDITIONAL AAP RESOURCES

- **RSV Immunization Administration Visual Guide** (https://www.aap.org/rsv)
- **RSV Immunization Frequently Asked Questions** (https://www.aap.org/rsv)
- *Red Book* Chapter on Respiratory Syncytial Virus (**https://publications.aap.org/redbook**)

- **RSV Immunization Fact Sheet** (https://www.aap.org/en/patient-care/immunizations/vaccination-info-sheets/)

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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