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Respiratory Syncytial Virus (RSV) Prevention Update

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In September 2024, this publication featured a comprehensive review of available immunizations for respiratory syncytial virus (RSV) . Since that time, the landscape has shifted considerably. This update summarizes current immunization recommendations from the Advisory Committee on Immunization Practices and available products as shown in **Table 1**.

Background

RSV causes infections of the lungs and respiratory tract. RSV is endemic in the United States (U.S.), with most children being infected before their second birthday. In adults and healthy older children, RSV presents like other upper respiratory infections, with runny nose, coughing and congestion. In very young infants it can present as irritability, decreased activity and breathing difficulties. It can be difficult to distinguish from other common viral infections such as influenza and COVID-19. RSV demonstrates significant seasonality. The Centers for Disease Control and Prevention (CDC) has traditionally described RSV season onset as the first of two consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥10% or the mean percentage of specimens testing positive by polymerase chain reaction (PCR) ≥3%, whichever occurs first. Offset is the week before PCR testing falls to below 3%.

RSV tends to appear first in the Southeastern U.S. during the late summer or early fall, then moves to the West Coast later in the season.[1] In 2024, Oregon met RSV season onset criteria Dec. 21, and the season lasted until April 26, 2025. Oregon provides publicly available surveillance data at https://public.tableau.com/app/profile/oregon.public.health.division.acute.and.communicable.disease.pre/viz/OregonsRespiratoryVirusData/TestPositivity, and providers can register to receive Oregon Health Authority's (OHA) weekly RSV Surveillance Report at https://public.govdelivery.com/accounts/ORHA/signup/38395. Given Oregon's atypical seasonality, the Oregon Health Authority (OHA) recommends using local epidemiology to guide RSV immunizations and sends alerts to local health care providers when administration of RSV products is recommended to begin and end.

Severity of RSV is influenced by many factors. Infants younger than 12 months, particularly premature infants, adults over age 65, people with chronic heart or lung disease, and those with weakened immune systems are at greatest risk of severe disease.[2] OHA conducts year round population-based surveillance for laboratory-confirmed hospitalizations associated with RSV in Clackamas, Multnomah, and Washington Counties. In the 2024-2025 season, there were 466 hospitalizations, of which 158 occurred in children under 5 years of age and 162 were in adults 65 years of age or older. The cumulative hospitalization rate for last season is 25.7 per 100,000 people.[3]

To protect newborns, either maternal vaccination or infant immunization are recommended by the CDC, American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. Because these products provide comparable protection, most infants do not require both.

FDA Approved Products for RSV

Maternal vaccination with ABRYSVO[4], a recombinant vaccine containing RSV preF A and RSV preF B proteins, is available and is recommended to be administered between 32 and 36 weeks gestation during September through January or based on local epidemiology. Vaccination is recommended at the beginning of the 3rd trimester since it takes about 2 weeks for an immunized person to develop antibodies. Vaccination during pregnancy results in passive immunization of infants through transplacental antibody transfer, with protection lasting about 6 months.[5]

Monoclonal Antibodies

Infants whose mothers were not vaccinated during pregnancy or whose mothers were vaccinated fewer than 14 days before giving birth can receive one of two available monoclonal antibody (mAb) products—nirsevimab (BEYFORTUS)[6] or clesrovimab (ENFLONSIA)[7]. Both nirsevimab and clesrovimab are F protein-directed fusion inhibitors indicated for RSV prevention.

Dosing differs by product; nirsevimab dosing is weight-based, while clesrovimab is a single, fixed dose regardless of infant weight. Nirsevimab is also recommended for children ages 8-19 months at increased risk for severe RSV disease entering their second RSV season, including infants with chronic lung disease or prematurity who required medical support during the six months preceding the RSV season; severe immunocompromise; cystic fibrosis with manifestations of

severe lung disease or weight-for-length < 10th percentile; and all American Indian and Alaska Native children.
Palivizumab (SYNAGIS) has been voluntarily withdrawn by the manufacturer in favor of the newer single dose products and will no longer be available after December 31, 2025.

Current CDC recommendations are to administer RSV mAb products during October through March or based on local epidemiology. Clinicians should immunize infants within one week of birth for infants born during the RSV season. Monoclonal antibody products should not be administered to infants with a history of serious hypersensitivity reactions to the product or its excipients. Clesrovimab and Nirsevimab are generally well tolerated, with up to 4% of immunized infants experiencing local redness or swelling at the injection site and up to 3% experiencing a rash within 14 days of administration.

In clinical trials, Clesrovimab reduced medically-attended lower respiratory tract infections by 60% in the first 150 days. Efficacy against hospitalization was 90%.[7]

Vaccines

For adults, three different RSV vaccines (ABRYSVO[4], AREXVY[8], and mRESVIA[9]) are available and are recommended for all adults ages 75 and older, as well as adults ages 50-74 at increased risk for severe RSV, including those with chronic cardiovascular disease, chronic lung disease, end-stage renal disease, diabetes mellitus with complications, neurologic and neuromuscular conditions, chronic liver disease, chronic hematologic conditions, severe obesity, and moderate to severe immune compromise.[10] Clinical trial data show that each vaccine provides meaningful protection for two RSV seasons, with protection falling in the second year. Currently, there is no recommendation for revaccination and there is no preference for one brand over another. Additional surveillance and evaluation activities are ongoing to determine whether adults might benefit from receiving additional RSV vaccine doses in the future.[10]

Table 1. FDA-Approved Products for RSV

Drug	FDA-approved populations	Recommended populations	Dosing
Nirsevimab[6]* (Beyfortus)	Infants born during or entering their first RSV season; children < 2 years of age at increased risk for severe RSV disease	All infants < age 8 months born during or entering their first RSV season; children ages 8-19 months at increased risk for severe RSV disease	50 mg/0.5 mL for infants < 5 kg, 100 mg/1.0 mL for infants ≥ 5 kg, IM; 200 mg (2 x 100 mg injections) for children ages 8-19 months, IM
Clesrovimab[7]* (Enflonsia)	Infants born during or entering their first RSV season	All infants < age 8 months born during or entering their first RSV season	105 mg/0.7 mL regardless of weight, IM
Palivizumab (Synagis)	Discontinued effective 12/31/2025		
Abrysvo (bivalent, recombinant vaccine)	Pregnant individuals at 32-36 weeks gestational age; all people ≥ age 60; ages 18-59 at increased risk for severe RSV disease	Pregnant individuals at 32-36 weeks gestational age; all people ≥ age 75; ages 50-74 years at increased risk for severe RSV disease	0.5 mL, IM
Arexvy (adjuvanted, recombinant vaccine)	All people ≥ age 60; ages 50-59 at increased risk for severe RSV disease	All people ≥ age 75; ages 50-74 years at increased risk for severe RSV disease	0.5 mL, IM
mResvia (mRNA vaccine)	All people ≥ age 60; ages 18-59 at increased risk for severe RSV disease	All people ≥ age 75; ages 50-74 at increased risk for severe RSV disease	0.5 mL, IM

Abbreviations: IM = intramuscular; mL = milliliter; RSV = respiratory syncytial virus.
Key: * Monoclonal antibody

Contraindications, Precautions, and Adverse Events

Clesrovimab and nirsevimab are contraindicated in infants and children with a history of serious hypersensitivity reactions to a previous dose or any product excipients. The most common side effects include rash and injection site erythema and swelling. In clinical trials, adverse events were similar in recipients and controls.[6,7]

RSV vaccination is contraindicated in individuals with a history of severe hypersensitivity reactions to any component or excipient present in the product.

Pre-licensure clinical trials identified a small number of Guillain-Barre syndrome (GBS) in older participants that received ABRYSVO and AREXVY. Post licensure safety data evaluated risk in the 42 days after vaccination with a control period (days 43-90 postvaccination). Initial analysis did not demonstrate an increased risk of GBS associated with RSV vaccination but an elevated GBS risk could not be ruled out. Additional analyses will be conducted that includes review of medical records.[10]

Coverage of RSV Products

Both Clesrovimab and Nirsevimab are available to enrolled clinics through the Vaccines for Children program for eligible children. Children who are on the Oregon Health Plan, who are uninsured, or who are of Native American or Alaskan Native descent may receive the product at no cost. A vaccine administration fee not to exceed $21.96 per dose may be billed.

Insurance plans subject to the provisions of the Affordable Care Act should provide first dollar coverage for both monoclonal antibodies and RSV vaccines for eligible populations.

Medicare provides vaccine coverage through Medicare Advantage plans or through part D.

Conclusion

With multiple effective products available, many severe RSV infections are now preventable. Infants should receive protection, either through maternal immunization with ABRYSVO vaccine, or with a dose of mAb given at the beginning of their first RSV season. Children who continue to be at high risk may also receive a dose of nirsevimab at the beginning of their second RSV season.

High-risk adults over 50 years of age may receive a single dose of any of the three FDA-approved RSV vaccines. However, since coverage wanes over time and additional doses are not currently recommended, individual risk should be discussed with the patient when determining vaccination timing.

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