

Department of Health and Human Services Maine Center for Disease Control and Prevention 286 Water Street 11 State House Station Augusta, Maine 04333-0011 Tel: (207) 287-8016; Fax (207) 287-9058 TTY Users: Dial 711 (Maine Relay)

# Maine Health Alert Network (HAN) System

# **PUBLIC HEALTH ADVISORY**

То:	Health Care Providers
From:	Dr. Isaac Benowitz, State Epidemiologist
Subject:	U.S. CDC: Increased Respiratory Syncytial Virus (RSV) Activity in Parts of the Southeastern United States: New Prevention Tools Available to Protect Patients
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Please review this information from U.S. CDC on respiratory syncytial virus activity in the southeast, which typically precedes activity in other parts of the U.S. This advisory includes an overview of newly available RSV vaccines and other prevention options.

RSV trends in Maine can be found at U.S. CDC's *RSV State Trends* website, available at <u>https://www.cdc.gov/surveillance/nrevss/rsv/state.html#ME</u>.

Maine CDC will host an educational lunch and learn on Wednesday 9/27 at 12 PM. The webinar will include presentations on the three new RSV vaccine products: Beyfortus (nirsevimab), Abrysvo, and Arexvy. It will cover product availability, patient eligibility, specific vaccine recommendations, the impact on respiratory virus season, and more. Maine CDC staff will be joined by the manufacturers of all three RSV vaccine products.

Maine CDC webinar: Newly Available RSV Products (Sep 27, 2023, at 12 PM ET) <u>https://mainestate.zoom.us/j/84489870195?pwd=QkNoME9sL2Z6djVOTGVKYjZaMDNLZz09</u> Meeting ID: 844 8987 0195 / Passcode: 50265015

Maine CDC anticipates having nirsevimab available this fall for all VFC-eligible infants and young children. RSV vaccination for adults 60 years and older is also anticipated to be available by this fall-winter for enrolled 317 Adult Vaccine Program providers for administration to uninsured adults.

# U.S. CDC: Increased Respiratory Syncytial Virus (RSV) Activity in Parts of the Southeastern United States: New Prevention Tools Available to Protect Patients

## Summary

The Centers for Disease Control and Prevention (U.S. CDC) is issuing this Health Alert Network (HAN) Health Advisory to notify clinicians and caregivers about increases in respiratory syncytial virus (RSV) activity across some parts of the Southeastern United States in recent weeks, suggesting a continued shift toward seasonal RSV trends observed prior to the COVID-19 pandemic. Historically, such regional increases have predicted the beginning of RSV season nationally, with increased RSV activity spreading north and west over the following 2–3 months. RSV can cause severe disease in infants, young children, and older adults.

In anticipation of the onset of the 2023-2024 RSV season, U.S. CDC encourages clinicians to prepare to implement new RSV prevention options. Monoclonal antibody products, including a new, long-acting product, **nirsevimab (Beyfortus™, Sanofi and AstraZeneca)**, are available to protect infants and some <u>young children at higher risk</u> for severe RSV disease. For all infants ages <8 months, and infants and children ages 8–19 months who are at <u>increased risk</u> of severe RSV, clinicians should start to offer nirsevimab when it becomes available (expected by early October).

Also, two new vaccines are available to protect older adults from severe RSV disease. For adults ages 60 years and older, clinicians should offer a single dose of an RSV vaccine, either **RSVPreF3** (Arexvy, GSK) or **RSVpreF (Abrysvo™, Pfizer)**, based on shared clinical decision-making between the healthcare provider and the patient. Clinicians should also talk to their patients about other vaccines available this fall to help prevent respiratory infections. Clinicians should consider testing symptomatic patients with high-risk conditions for COVID-19, influenza, and RSV to inform treatment decisions. Healthcare personnel, childcare providers, and staff at long-term care facilities should stay home and not go to work when they have fever or symptoms of respiratory infection to reduce the spread of respiratory infections including RSV.

## Background

RSV is an RNA virus, and transmission occurs primarily via respiratory droplets when a person coughs or sneezes, or through direct contact with a contaminated surface. Infants, young children, and older adults, especially those with chronic medical conditions, are at increased risk of severe disease from RSV infection. U.S. CDC estimates that every year RSV causes approximately 58,000–80,000 hospitalizations (1,2) and 100–300 deaths (3,4) in children ages <5 years, as well as 60,000–160,000 hospitalizations (5,6) and 6,000–10,000 deaths (3,4,7) among adults ages 65 years and older.

In the United States, the annual RSV season has historically started in the fall and peaked in winter. However, this pattern was disrupted during the COVID-19 pandemic, likely due to public health measures to reduce the spread of COVID-19 that also reduced the spread of RSV. RSV activity was limited between May 2020 and March 2021, followed by an atypical season with onset in May 2021 that peaked in July and August and continued through the end of 2021 (8). In 2022, RSV activity began in the summer, peaking across the United States in October and November, and rapidly declining by winter. Despite the disruptions in timing, RSV activity continued its geographic pattern of starting in Florida and the southeast before spreading to northern and western parts of the continental United States in 2021 and 2022.

In recent weeks, U.S. CDC has observed an increase in RSV activity in parts of the Southeastern United States. Nationally, the weekly percentage of positive detections reported to the <u>National</u> <u>Respiratory and Enteric Virus Surveillance System</u> (NREVSS), a national laboratory-based

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surveillance network, has remained below the season onset threshold of polymerase chain reaction (PCR) test positivity of 3.0% for 2 consecutive weeks. However, NREVSS data show increases in weekly PCR positivity above 3.0% in Florida beginning in the week ending July 22, 2023, and the 3-week moving average of PCR positivity has been greater than 5.0% for the past 4 weeks. More robust data are available through Florida's <u>sentinel surveillance</u>, which also shows PCR positivity just under 5.0% for the most recent week. In Georgia, U.S. CDC has also observed an increase in rates of RSV-associated hospitalizations reported to <u>RSV-NET</u>, a population-based surveillance system. Among children ages <4 years, RSV-associated hospitalization rates increased from 2.0 hospitalizations per 100,000 population for the week ending August 5, 2023, to 7.0 hospitalizations per 100,000 population for the week ending August 5, 2023, to 7.0 hospitalizations ages <1 year. Due to reporting delays, surveillance data may be less complete in the 2 most recent weeks.

In 2023, new prevention tools for RSV have become available.

- Nirsevimab is a long-acting monoclonal antibody approved by the Food and Drug Administration (FDA) to protect infants and some young children at increased risk for severe RSV disease. Nirsevimab is safe and efficacious. In clinical trials, one dose of nirsevimab administered as an intramuscular injection protected infants for at least 5 months (the length of an average RSV season) and reduced the risk of severe RSV disease by about 80% (9). The incidence of serious adverse events was not increased among nirsevimab recipients compared with placebo recipients in the clinical trials (9).
- RSVPreF3 and RSVpreF are recombinant protein vaccines that are both approved by FDA for use in adults ages 60 years and older to prevent RSV-associated lower respiratory tract disease. During the first RSV season after vaccination, each vaccine was more than 80% efficacious in preventing RSV-associated lower respiratory tract disease (10). A small number of participants in clinical trials (6 of 38,177 total participants aged ≥60 years who received either vaccine) developed inflammatory neurologic events within 6 weeks after RSV vaccination, but it was unclear whether these events were related to RSV vaccination (10).

On August 21, 2023, FDA approved the RSVpreF vaccine (Abrysvo<sup>™</sup>, Pfizer) for use in pregnant people during weeks 32 through 36 of gestation for the prevention of RSV-associated lower respiratory tract disease in infants from birth through 6 months of age. U.S. CDC's Advisory Committee on Immunization Practices (ACIP) will consider the evidence for a policy recommendation about RSV vaccination in this population in the future. U.S. CDC and FDA will continue to monitor the safety and effectiveness of RSV vaccines and nirsevimab, review data as collected, keep the public informed of findings, and use data to make recommendations – consistent with standard practices for all immunization products.

# **Recommendations for Clinicians**

A clinician's recommendation is one of the most important factors in whether patients choose to accept a prevention product or vaccine. As we head into respiratory virus season this fall, it's important to understand new prevention tools, recommend them to patients who could benefit, and use them effectively to prevent severe RSV disease.

 Monoclonal antibodies for infants and young children: Clinicians should start to offer nirsevimab when it becomes available (expected by early October) for all infants ages <8 months, and for infants and for children ages 8–19 months who are at increased risk for severe RSV disease (see specific recommendations below). Nirsevimab may not be readily available in all birthing hospitals or primary care settings this RSV season. RSV seasonality in tropical climates and Alaska may be less predictable and clinicians in these areas should consult state, local, or territorial guidance on timing of nirsevimab administration.

U.S. CDC recommends nirsevimab for the following groups:

• All infants ages <8 months born during or entering their first RSV season should

receive 1 dose of nirsevimab.

- Infants born shortly before or during the RSV season should receive nirsevimab within their first week of life.
- Infants not born shortly before or during this RSV season should receive nirsevimab shortly before the start of their first RSV season or as early as feasible during the season.
- Infants and children ages 8–19 months <u>who are at increased risk</u> for severe RSV disease, such as those who are severely immunocompromised, should receive 1 dose of nirsevimab shortly before entering or during their second RSV season.

# Dosage of nirsevimab:

All infants ages <8 months:

- 50 mg dose administered as a single injection for infants weighing <5 kg [<11 lb]
- 100 mg dose administered as a single injection for infants weighing  $\geq$ 5 kg [ $\geq$  11 lb] Infants and children ages 8–19 months who are at increased risk for severe RSV disease:
- 200 mg dose administered as two 100 mg injections

Another prevention product, palivizumab (Synagis®, Sobi<sup>TM</sup>), is available for children <24 months of age <u>with certain conditions</u> that place them at increased risk for severe RSV disease. Where nirsevimab is not available during this RSV season, the <u>American Academy</u> <u>of Pediatrics (AAP)</u> recommends that eligible infants and older babies should continue to receive palivizumab until nirsevimab becomes available.

- 2. RSV vaccines for older adults: U.S. CDC recommends that adults ages 60 years and older may receive a single dose of RSV vaccine (either product) using <u>shared clinical decision-making</u> to prevent RSV-associated lower respiratory tract disease. Clinicians should discuss RSV vaccination with adults ages 60 years and older. Vaccination should be prioritized in adults ages 60 years and older who are most likely to benefit, including those with certain chronic medical conditions associated with increased risk of severe RSV disease, such as heart disease (e.g., heart failure, coronary artery disease), lung disease (e.g., chronic obstructive pulmonary disease [COPD], asthma), and immunocompromising conditions. Adults with advanced age and those living in nursing homes or other long-term care facilities are also at increased risk of severe RSV disease and may benefit from RSV vaccination.
- 3. Healthcare providers should also talk to their patients about other vaccines (e.g., COVID-19, influenza) available this fall to help prevent respiratory illness.
- 4. Healthcare providers can co-administer the vaccines for which a patient is eligible in the same visit, including RSV, COVID-19, and influenza vaccines. When deciding whether to co-administer other vaccines with RSV vaccine at the same visit, providers can consider whether the patient is up to date with currently recommended vaccines, the feasibility of their returning for additional vaccine doses, their risk of acquiring vaccine-preventable disease, the vaccine reactogenicity profiles, and patient preferences.
- 5. Clinicians should consider testing patients with symptoms of acute respiratory illness and high- risk conditions for respiratory pathogens to inform patient management. Although treatment for RSV is supportive, diagnostic testing can help identify patients who might benefit from medications to treat other respiratory pathogens, such as COVID-19 and influenza. Real-time reverse transcription-polymerase chain reaction (rRT-PCR) is the preferred method for testing for respiratory viruses.
- 6. Healthcare personnel, childcare providers, and staff of long-term care facilities should stay home and not go to work when they have fever or symptoms of respiratory infection.

# **Recommendations for the Public**

- Expectant parents, parents of infants under the age of 8 months, and parents with older babies (through age 19 months) at increased risk of severe RSV disease should talk with their healthcare providers about using monoclonal (preventive) antibodies to protect against RSV this season. Infants under the age of 8 months should receive preventive antibodies to protect against RSV this season.
- 2. Adults ages 60 years and older should talk to their healthcare provider about whether RSV vaccination is appropriate for them.
- 3. Stay home and away from others when you are sick. If you are at increased risk of severe illness, contact your healthcare provider to see if you would benefit from early diagnostic testing. Treatments for influenza and COVID-19 are available that, if given within days of symptoms starting, can reduce your risk of hospitalization and death.

## For More Information

- U.S. CDC RSV Information for Healthcare Providers
- <u>U.S. CDC RSV National Trends NREVSS</u>
- U.S. CDC RSV Surveillance and Research
- U.S. CDC RSV Symptoms and Care
- U.S. CDC Preventing RSV (Respiratory Syncytial Virus)
- RSV Vaccination: What Older Adults 60 Years of Age and Over Should Know | U.S. CDC
- Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over | U.S. CDC
- Shared clinical decision-making: RSV Vaccination for Adults 60 Years and Older
- Frequently Asked Questions About RSV Vaccine for Adults | U.S. CDC

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