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TECHNICAL BULLETIN

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TOPIC: FDA Approves Use of Respiratory Syncytial Virus (RSV) Immunization for Infants and Children

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TO: All Health Care Providers and Facilities; Pharmacists; Local Health Authorities

BACKGROUND

In July 2023, the U.S. Food and Drug Administration (FDA) approved Beyfortus (nirsevimab), a long-acting monoclonal antibody, for the prevention of severe respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in neonates and infants. This RSV immunization provides a critical tool to protect against RSV, which is the leading cause of hospitalization among infants in the United States., according to the Centers for Disease Control and Prevention (CDC). With the evidence presented at the August 3, 2023, Advisory Committee on Immunization Practices (ACIP) meeting, the committee also voted to include Beyfortus (nirsevimab) in the Vaccines for Children (VFC) program, which provides recommended vaccines and immunizations at no cost to about half of the Nation's children. This technical bulletin summarizes the CDC's most recent neonate and infant RSV immunization recommendations, including eligibility and schedule.

In most parts of the United States., RSV circulation is seasonal and typically starts during the fall and peaks in the winter and is transmitted from person to person through close contact with someone infected. According to the CDC, administering Beyfortus (nirsevimab) to neonates and infants born during or entering their first RSV season and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season has been shown to reduce the risk of both hospitalizations and healthcare visits for RSV by about 80 percent. In addition, research suggests that some American Indian or Alaska Native (AI/AN) children experience high rates of severe RSV disease. A recent study found that the incidence of RSV-associated hospitalization among some AI/AN children aged 12–23 months was four to 10 times that of similar-aged children across seven sites in the United States. These studies have been limited to specific populations and might not broadly represent a risk in all AI/AN children. Given the available evidence, ACIP also recommends nirsevimab for AI/AN children entering their second RSV season.[1] Data on coadministration of Beyfortus (nirsevimab) with other routine childhood vaccines is limited; however, based on the limited data from clinical trials, coadministration of Beyfortus (nirsevimab) with routine childhood vaccines resulted in a similar rate of adverse events compared with administration of the immunization alone.[2]

Infants born shortly before or during the RSV season should receive nirsevimab within one week of birth. Nirsevimab administration can occur during the birth hospitalization or in the outpatient setting. The optimal timing for nirsevimab administration is shortly before the RSV season begins; however,

nirsevimab may be administered to age-eligible infants and children who have not yet received a dose at any time during the season. Only a single dose of nirsevimab is recommended for an RSV season, and based on clinical data, the duration of protection offered by a single dose of Beyfortus extends through five months. Infants with prolonged birth hospitalizations related to prematurity or other causes should receive nirsevimab shortly before or promptly after hospital discharge.[3]

Those eligible to receive a single dose of Beyfortus (nirsevimab), include:

Neonates and infants aged < 8 months, born during or entering their first RSV season	Infants and children aged 8-19 months, who are at risk for severe RSV disease, and entering their second RSV season[4]
Weight-based dose amount: Neonates and infants entering their first RSV season, who weigh <5kg: 50 mg single dose, to be administered intramuscularly. Neonates and infants entering their first RSV season, who weigh ≥5kg: 100 mg single dose, to be administered intramuscularly.	Dose amount: 200 mg single dose (administered as two 100 mg injections given at the same time at different injection sites), to be administered intramuscularly.

Storage and handling: Store refrigerated between 2°C and 8°C (36°F and 46°F). Beyfortus may be kept at room temperature between 20°C and 25°C (68°F and 77°F) for a maximum of 8 hours. After removal from the refrigerator, Beyfortus must be used within 8 hours or discarded. Store Beyfortus in its original carton to protect from light until time of use. Do not freeze, shake, or expose Beyfortus to heat.

Note: Beyfortus is available in a 50 mg and a 100 mg pre-filled syringe. Please refer to Beyfortus' prescribing information for full details.

Precautions and contraindications for Beyfortus (nirsevimab) include, but are not limited to, the following:

- When administering Beyfortus (nirsevimab) to children with increased risk for bleeding, providers should follow ACIP's general best practice guidelines for immunization.
- Beyfortus (nirsevimab) is contraindicated in persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a product component.
- Adverse reactions might occur after administration of Beyfortus (nirsevimab) alone.
- Possible side effects of Beyfortus (nirsevimab) include rash and injection site reactions and should not be given to infants and children with a history of serious hypersensitivity reactions to Beyfortus' active ingredients or any of its excipients. Beyfortus (nirsevimab) comes with warnings and precautions about serious hypersensitivity reactions, including anaphylaxis, which have been observed with other human IgG1 monoclonal antibodies. Beyfortus (nirsevimab) should be given with caution to infants and children with clinically significant bleeding disorders.[5]
- Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS) or by calling 1-800-822-7967. Reports should specify that the patient received nirsevimab on the VAERS form. Health care providers will usually file this report, or individuals may complete the form. VAERS is only for reporting reactions. VAERS staff members do not give medical advice.

For more information and/or additional resources, CDC has updated their RSV in Infants and Young Children and RSV for Healthcare Providers web pages.

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Questions

For updated guidance, review the Division of Public and Behavioral Health Technical Bulletin web page regularly. Email nviz@health.nv.gov for other questions regarding RSV.

[1] Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

[2] Coadministration with Routine Childhood Vaccines: Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

[3] Timing of Nirsevimab Administration: Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

[4] BOX. Infants and children aged 8–19 months with increased risk for severe disease who are recommended to receive nirsevimab when entering their second respiratory syncytial virus season

[5] FDA Approves New Drug to Prevent RSV in Babies and Toddlers | FDA

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