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TO: Healthcare Providers, Hospitals, Clinical Laboratories, and Local Health Departments (LHDs)

From: New York State Department of Health (NYSDOH), Bureau of Immunization

HEALTH ADVISORY: Respiratory Syncytial Virus Pediatric Immunization: Nirsevimab (Beyfortus)

For Healthcare Providers, Hospitals, Local Health Departments, Newborn Nurseries, Newborn Intensive Care Units, Pediatrics, Emergency Medicine, Pediatric Intensive Care Units, Obstetrics, Infectious Disease, Nursing, Pharmacy, Internal Medicine, and Family Medicine

Summary

The purpose of this advisory is to provide information about nirsevimab (Beyfortus), a long-acting monoclonal antibody for passive immunization to prevent lower respiratory tract infection caused by respiratory syncytial virus (RSV) among infants and young children. It is given intramuscularly (IM).

- Nirsevimab is recommended for infants less than 8 months of age during their first RSV season and for infants 8-19 months of age during their second RSV season.
- On Aug. 3, 2023, the Advisory Committee on Immunization Practices (ACIP) voted in favor of the inclusion of nirsevimab on the Centers for Disease Control and Prevention's (CDC's) Child and Adolescent Immunization Schedule and in the Vaccines for Children Program.
- Nirsevimab will be available for ordering by providers enrolled in the Vaccines for Children Program in October 2023.
- ACIP recommendations for the use of nirsevimab were published in the Morbidity and Mortality Weekly Report (MMWR) on August 25th, 2023. MMWR
- An RSV vaccine (ABRYSVO) was recently approved by the U.S. Food and Drug Administration and recommended by ACIP for administration to pregnant women/people between 32 and 36 weeks gestation before and during the RSV season. Pregnant women/people should receive information on both maternal vaccine and nirsevimab and work with their health care provider to determine whether to vaccinate the pregnant patient or rely on administration of nirsevimab to the infant after birth.

Background

Respiratory syncytial virus (RSV) is a highly contagious virus that usually causes mild, cold-like symptoms; however, RSV infection can be serious, especially in infants and older adults. RSV has long been recognized as a significant cause of severe respiratory disease in infants

worldwide. Approximately two-thirds of infants will be infected with RSV in their first year of life, and while most infants only develop an upper respiratory tract infection, many will go on to develop a lower respiratory tract infection. In fact, RSV is the leading cause of infant hospitalization each year. An estimated 75% of infants hospitalized with RSV have no underlying medical conditions.

Although not currently reportable, limited available data currently show low levels of RSV activity. Recent RSV seasons have been atypical in timing or intensity, likely related to pandemic effects. However, analyses suggest that RSV activity is returning to the typical seasonal pattern observed in pre-pandemic seasons when cases increased in the fall and peaked during the winter.

Recommendations

All infants aged <8 months born during or entering their first RSV season are recommended to receive one dose of nirsevimab (50 mg IM for infants <5 kg and 100 mg IM for infants ≥5 kg). The RSV season starts in the fall and peaks in the winter, but the timing and severity in a given community can vary from year to year. Providers should use their best judgement in determining when the RSV season is occurring.

Providers should target administration:

- During the birth hospitalization, as seasonally appropriate, as this would be the ideal time to give nirsevimab. Infants with prolonged birth hospitalizations should receive nirsevimab shortly before or promptly after hospital discharge.
- If not given during the birth hospitalization, then shortly after discharge by one week of age in an outpatient setting.
- During a scheduled well child visit before the start of the RSV season.

Children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab (200 mg, administered as two 100 mg IM injections given at the same time at different injection sites). Providers should target administration just before the start of the RSV season.

Children at high risk include:

- Children with chronic lung disease of prematurity who required medical support any time during the 6-month period before the start of the second RSV season
- Children who are severely immunocompromised
- Children with cystic fibrosis who have 1) manifestations of severe lung disease, or 2) weight-for-length <10th percentile
- American Indian or Alaska Native children

Storage and handling

Nirsevimab is a sterile, preservative-free, clear to opalescent, colorless to yellow solution. Each nirsevimab pre-filled syringe is for single use only. Store nirsevimab refrigerated between 36°F to 46°F (2°C to 8°C). It may be kept at room temperature 68°F to 77°F (20°C to 25°C) for a maximum of 8 hours. After removal from the refrigerator, it must be used within 8 hours or discarded. Store nirsevimab in its original carton to protect from light until time of use. Do not freeze, shake, or expose to heat.

Other Considerations

On Aug. 15, 2023, the American Academy of Pediatrics (AAP) released "ACIP and AAP Recommendations for Nirsevimab" for the 2023-24 season and "Nirsevimab Frequently Asked Questions." See the link below. Some clarifications include:

- A single dose of nirsevimab may be administered to age-eligible infants and children who have not yet received a dose at any time during the season.
- Based on pre-pandemic patterns, nirsevimab could be administered in most of the continental US from October through the end of March. Providers in jurisdictions with altered seasonality should consult state, local, or territorial guidance on timing of nirsevimab administration.

Coadministration with Routine Childhood Vaccines

Nirsevimab is not expected to interfere with the immune response to other routine childhood immunizations. In accordance with general best practices for immunization, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended.

Precautions and Contraindications

- When administering nirsevimab to children with increased risk for bleeding, providers should follow ACIP's general best practice guidelines for immunization.
- 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 nirsevimab alone; these reactions may be reported to MedWatch online (https://www.fda.gov/medwatch) by fax, by mail, or by contacting FDA at 1-800-FDA-1088. Adverse reactions might occur after the coadministration of nirsevimab with a vaccine; these reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS), and reports should specify that the patient received nirsevimab on the VAERS form. Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (https://vaers.hhs.gov).
- When adverse reactions that occur after the coadministration of nirsevimab with a vaccine are reported to VAERS, additional reporting of the same adverse reactions to MedWatch is not necessary.

Resources

- MMWR: 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
- American Academy of Pediatrics: ACIP and AAP Recommendations for Nirsevimab and Frequently Asked Questions about Nirsevimab
- Sanofi site with prescribing information, safety information and information for healthcare professionals
- AstraZeneca site: Link
- CDC's RSV General Information Page
- European Medical Association: https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf