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AAP releases nirsevimab guidance, calls for continued access to palivizumab

by **Melissa Jenco** • News Content Editor

The AAP is recommending all infants under 8 months receive the new monoclonal antibody nirsevimab to protect them from respiratory syncytial virus (RSV), while also providing guidance for continued use of palivizumab in the 2023-'24 season.

"Pediatricians are sadly familiar with the dangers of RSV and its devastating consequences for some families," AAP President Sandy L. Chung, M.D., FAAP, said in a press release. "We are eager to offer all infants this protection and urge federal officials to see that it is made available and affordable in all communities."

RSV causes about 58,000 to 80,000 hospitalizations and 100 to 300 deaths per year in children under 5 years, according to data from the Centers for Disease Control and Prevention (CDC).

Nirsevimab (Beyfortus) is a long-acting monoclonal antibody given as an intramuscular injection that is intended to protect children against lower respiratory tract disease caused by RSV. It was approved by the Food and Drug Administration in mid-July and the CDC in early August. It is expected to be available this fall, although some children may not have immediate access.

Eligible children

Nirsevimab is recommended for all infants under 8 months born during or entering their first RSV season.

It also should be given to children 8 months through 19 months who are at increased risk of severe RSV disease and entering their second RSV season. This high-risk group includes children with chronic lung disease of prematurity who require medical support during the six months before the start of the second RSV season, children who are

severely immunocompromised, children with cystic fibrosis who have manifestations of severe lung disease or weight-for-length below the 10th percentile, American Indian children and Alaska Native children.

Timing

For most of the continental U.S., the typical RSV season is October through March. Infants born shortly before or during the RSV season should receive nirsevimab in their first week of life either in the hospital or an outpatient setting. Newborns with a prolonged hospital stay should get it shortly before or after discharge.

For other infants and eligible toddlers, nirsevimab should be administered shortly before the start of the RSV season. Age-eligible infants and toddlers who did not receive a dose at the start of the season can receive a dose at any time during the season. Only eligible high-risk children should get a dose in both their first and second seasons, even if they are younger than 8 months entering their second season. However, a healthy infant born at the end of the season who did not receive nirsevimab and is less than 8 months entering their second RSV season may receive nirsevimab.

Providers can adjust administration timing based on local RSV activity if needed. In tropical climates and Alaska, providers should consult state, local or territorial guidance on the timing.

Nirsevimab and palivizumab

Nirsevimab may not be available or feasible to administer in some settings this season. In these cases, eligible high-risk infants and children in their first or second year or life should receive the monoclonal antibody palivizumab, which includes a series of monthly doses.

Children who receive fewer than five doses of palivizumab in the 2023-’24 season can receive one dose of nirsevimab, but then should not receive any additional doses of palivizumab. Any children who receive nirsevimab should not receive palivizumab later that season.

High-risk children who received palivizumab in their first RSV season should receive nirsevimab in their second season, if it is available and they remain eligible. If it is unavailable, they should receive palivizumab.

Co-administration with routine childhood vaccines

The AAP recommends nirsevimab be given at the same time as age-appropriate vaccines. Nirsevimab is not expected to interfere with the immune response.

Logistical issues

Nirsevimab’s cost of $495 and its classification as a drug have caused concern about its implementation. Logistical hurdles include large up-front cost to providers, inadequate payment, few hospitals participating in the Vaccines for Children (VFC) program and

inclusion in immunization information systems. The AAP is engaged in conversations on these issues.

Dr. Chung recently sent a letter to the leaders of the CDC and Centers for Medicare & Medicaid Services outlining these concerns. She urged a comprehensive strategy to ensure equitable access to the product in hospitals, birthing centers and ambulatory practice settings as well as flexibilities in the VFC program to address these hurdles.

In its new guidance, the AAP said, “Equity in access to nirsevimab is of the highest priority to nirsevimab is of the highest priority to the AAP.”