The American Academy of Pediatrics (AAP) Committee on Infectious Diseases has updated its guidance on the use of palivizumab (Synagis) prophylaxis in infants and children at increased risk of respiratory syncytial virus (RSV) infection. Because the palivizumab package labeling does not include a definition of high-risk children, the AAP aims to provide health care professionals with specific guidance on who should receive prophylaxis. Use of palivizumab should be restricted to the populations addressed in this guideline.

**Key Points for Practice**
- Palivizumab may be administered to infants born before 29 weeks’ gestation who are younger than 12 months at the beginning of RSV season.
- Palivizumab prophylaxis may be given during RSV season during the first year of life in preterm infants with chronic lung disease of prematurity who are born before 32 weeks’ gestation.
- Infants 12 months or younger who have hemodynamically significant CHD may benefit from palivizumab prophylaxis, especially those with acyanotic heart disease.

From the AFP Editors

The American Academy of Pediatrics (AAP) Committee on Infectious Diseases has updated its guidance on the use of palivizumab (Synagis) prophylaxis in infants and children at increased risk of respiratory syncytial virus (RSV) infection. Because the palivizumab package labeling does not include a definition of high-risk children, the AAP aims to provide health care professionals with specific guidance on who should receive prophylaxis. Use of palivizumab should be restricted to the populations addressed in this guideline.

**Preterm Infants Without Chronic Lung Disease of Prematurity or CHD**

In preterm infants without chronic lung disease of prematurity or congenital heart disease (CHD), palivizumab may be administered to those born before 29 weeks’ gestation who are younger than 12 months at the beginning of RSV season. In infants born in the midst of RSV season, fewer than five doses of palivizumab are needed. Data are unclear on the benefits of prophylaxis in infants born at 29 weeks’ gestation or later; these infants may receive prophylaxis if they have CHD, chronic lung disease, or another condition. Once infants reach the second year of life, palivizumab is not recommended solely on the basis of prematurity. Despite this guidance, some experts have stated that prophylaxis is not warranted even in infants born before 29 weeks’ gestation because of data showing only a small increase in the risk of hospitalization.

**Preterm Infants with Chronic Lung Disease of Prematurity**

In preterm infants with chronic lung disease of prematurity (those born before 32 weeks’ gestation who require greater than 21% oxygen for at least the first 28 days after birth), palivizumab prophylaxis may be considered during RSV season during the first year of life. If the infant continues to require medical support (maintenance corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the six months before the start of his or her second RSV season, prophylaxis may be considered. Otherwise, prophylaxis is not recommended in the second year of life.

**Infants with Hemodynamically Significant CHD**

Infants 12 months or younger who have hemodynamically significant CHD may benefit from palivizumab prophylaxis. Those most likely to benefit include infants with acyanotic heart disease who are receiving medication to control congestive heart failure and who will require cardiac surgery, and infants with moderate to severe pulmonary hypertension. These recommendations apply to infants in the first year of life who are born within 12 months of the beginning of RSV season. Those who are not at increased risk of RSV infection and therefore should not receive prophylaxis include: infants and children with hemodynamically insignificant heart disease, infants with lesions corrected by surgery (unless continued medication for heart failure is needed), infants with mild cardiomyopathy not receiving medical therapy, and children in the second year of life.
**Other Recommendations**

Infants with neuromuscular disease or congenital anomaly that impairs ability to clear secretions from the upper airway because of ineffective cough are at risk of prolonged hospitalization from lower respiratory tract infection; therefore, prophylaxis may be considered in the first year of life. Prophylaxis may also be considered in children younger than 24 months who are profoundly immunocompromised during RSV season. There are insufficient data to recommend routine palivizumab prophylaxis in children with Down syndrome or cystic fibrosis. In Alaska Native and American Indian populations, infants may be eligible for prophylaxis depending on the burden of RSV disease.

Monthly prophylaxis should be discontinued in infants who have a breakthrough RSV hospitalization. The likelihood of a second RSV hospitalization in the same season is extremely low. Palivizumab prophylaxis is not recommended for the prevention of health care–associated RSV disease. Infants in a neonatal unit who qualify for prophylaxis because of prematurity, chronic lung disease, or CHD may receive a first dose of palivizumab 48 to 72 hours before discharge or promptly following discharge.

**Dosing**

A maximum of five monthly doses of palivizumab (15 mg per kg per dose) may be administered during the RSV season to qualifying infants. Administering more than this is not recommended within the continental United States. Five monthly doses will provide more than six months of serum palivizumab concentrations above the desired level for most children. A dose beginning in November and continuing for a total of five doses provides protection through April. Infants born during RSV season may require fewer doses.

**Guideline source:** American Academy of Pediatrics

**Evidence rating system used?** No

**Literature search described?** No

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MARA LAMBERT, AFP Senior Associate Editor

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