RSV is a leading cause of hospitalization for babies <1 year[1]

What is RSV and when does it occur?

RSV is a common virus, easily spread, and usually causes cold-like symptoms[2,3]

It is a seasonal virus contracted by nearly all children by the age of 2[2,4]

RSV typically occurs from **late fall through spring**, but the season can vary by geography and from year to year[4]

In many babies, the virus leads to a mild respiratory infection with symptoms similar to the common cold or flu, but in some babies, it can develop into **a much more serious infection**[3]

Hospitalization rates for RSV are **~16 times higher** than those for influenza in children <1 year of age[5]

Who is at high-risk for RSV?[6]

Prematurity

<29 wGA and <12 months of age*
with no other qualifying conditions

29 to 35 wGA
with other qualifying conditions

*6 to <12 months of age is outside the approved SYNAGIS Indication.

Special populations

BPD/CLDP

<32 wGA
and requiring >21% oxygen for at least the first 28 days after birth

- **<12 months of age** at the start of RSV season
- **12-24 months of age** at the start of RSV season, with required medical support in the past 6 months

HS-CHD

<12 months of age
at the start of RSV season

The 2014 AAP guidance was based on a systematic review by the AAP Committee on Infectious Diseases (COID) and the Subcommittee on Bronchiolitis of all recent and older peer-reviewed literature.[6]

The guidance does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

BPD=bronchopulmonary dysplasia; CA=chronological age; CLDP=chronic lung disease of prematurity; HS-CHD=hemodynamically significant congenital heart disease; RSV=respiratory syncytial virus; RSVH=respiratory syncytial virus hospitalization; wGA=weeks gestational age.

INDICATION

SYNAGIS, 50 mg and 100 mg for injection, is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:

- with a history of premature birth (≤35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

LIMITATIONS OF USE

The safety and efficacy of SYNAGIS have not been established for treatment of RSV disease.

IMPORTANT SAFETY INFORMATION

- SYNAGIS is contraindicated in children who have had a previous significant hypersensitivity reaction to SYNAGIS

Please see additional Important Safety Information on page 2.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

DISCUSSION GUIDE FOR NURSE COORDINATORS

SYNAGIS: Preventive Therapy for Infants at High-Risk for RSV*

What is SYNAGIS?

- SYNAGIS is the only FDA-approved monoclonal antibody shown to help protect certain high-risk babies from RSV-related hospitalization[7]
- SYNAGIS has been shown to significantly reduce hospitalizations caused by RSV[7]

How does it work?

- SYNAGIS provides RSV-fighting antibodies to defend against RSV, it is not a vaccine[7]
- Through monthly injections, SYNAGIS provides enough antibodies to protect a baby's lungs from severe infection caused by RSV for 28-30 days[7]

How often is SYNAGIS dosed?

- SYNAGIS does not induce endogenous anti-RSV antibodies, so it must be administered every 28-30 days[7]
- It's important that high-risk infants receive monthly doses of SYNAGIS throughout the RSV season, which typically runs for 6 months from late fall through spring[4,7]

Babies should receive their first dose before RSV season starts to build up their protection[7]

Babies with certain types of lung or heart disease remain at high risk for severe RSV disease up to 24 months of age at RSV season start and may need SYNAGIS in both their first and second RSV seasons[7,8]

Parents/caregivers of eligible patients can pay as little as $0 per dose with the SYNAGIS Copay Program

Learn more about access & support at SYNAGISHCP.com

*SYNAGIS is indicated for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients.

IMPORTANT SAFETY INFORMATION (continued)

- Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to SYNAGIS. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to SYNAGIS. The relationship between these reactions and the development of antibodies to SYNAGIS is unknown. If a significant hypersensitivity reaction occurs with SYNAGIS, its use should be permanently discontinued. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of SYNAGIS
- As with any intramuscular injection, SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder
- Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays
- Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count <50,000/microliter) and injection site reactions have been reported

DOSING

The recommended dose of SYNAGIS is 15 mg/kg of body weight given monthly by intramuscular injection. The first dose of SYNAGIS should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season.

The efficacy of SYNAGIS at doses less than 15 mg/kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

Please click here for full Prescribing Information for SYNAGIS, including Patient Information.

References: 1. Leader S, Kohlhase K. Respiratory syncytial virus-coded pediatric hospitalizations, 1997 to 1999. *Pediatr Infect Dis J*. 2002;21(7):629-632. **2.** Glezen WP, Taber LH, Frank AL, Kasel JA. Risk of primary infection and reinfection with respiratory syncytial virus. *Am J Dis Child*. 1986;140:543-546. **3.** Centers for Disease Control and Prevention. Symptoms and care. Last reviewed June 26, 2018. Accessed June 5, 2020. https://www.cdc.gov/rsv/about/symptoms.html **4.** Centers for Disease Control and Prevention. RSV transmission. Last reviewed June 26, 2018. Accessed June 5, 2020. https://www.cdc.gov/rsv/about/transmission.html **5.** Zhou H, Thompson WW, Viboud CG, et al. Hospitalizations associated with influenza and respiratory syncytial virus in the United States, 1993-2008. *Clin Infect Dis*. 2012;54(10):1427-1436. **6.** American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*. 2014;134(2):415-420. **7.** SYNAGIS [package insert]. Waltham, MA: Sobi, Inc. **8.** Centers for Disease Control and Prevention. Respiratory syncytial virus infection (RSV). Last reviewed June 26, 2018. Accessed June 5, 2020. https://www.cdc.gov/rsv/clinical/index.html

FDA=Food and Drug Administration; RSV=respiratory syncytial virus.

Colorado prescriber, please click here for additional information.

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