ID ANY OF 3

IDENTIFY high-risk patients eligible for SYNAGIS

Patients who meet the following criteria

Premature birth (≤35 weeks gestational age [wGA] and ≤6 months of age at start of the upcoming RSV season)

- Early-preterm infants **born <29 wGA**
- Preterm infants born 29-32 wGA
- Late-preterm infants born 33-34 wGA and <3 months CA with risk factors (eg, increased number of people in household, passive smoke exposure, day care attendance)[1]

Bronchopulmonary dysplasia/chronic lung disease of prematurity (BPD/CLDP)

- ≤24 months of age at the start of the upcoming RSV season
- Within the last 6 months, receiving medical treatments for BPD/CLDP that may include any of the following:
  - — Supplemental oxygen
  - — Bronchodilator
  - — Diuretic
  - — Corticosteroid therapy

Hemodynamically significant congenital heart disease (HS-CHD)

- ≤24 months of age at the start of the upcoming RSV season
- HS-CHD, which may include any of the following:
  - — Is receiving medication to control congestive heart failure
  - — Has moderate to severe pulmonary hypertension
  - — Has acyanotic or cyanotic heart disease

CA=chronological 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
- 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

Please see additional Important Safety Information on back and accompanying full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS®
PALIVIZUMAB

Clinical associations support RSV immunoprophylaxis for high-risk patients

	FDA-approved Label[2]	2014 AAP Guidance[3]	2018 NPA Guidelines[4]
Prematurity	***≤35 wGA and ≤6 months of age*** at the start of RSV season	***<29 wGA and <12 months of age**** with no other qualifying conditions	***<28 0/7 wGA and <12 months of age**** at the start of RSV season
		29 to 35 wGA with other qualifying conditions	***28 0/7 to 32 0/7 wGA and <6 months of age*** at the start of RSV season
			32 1/7 to 35 6/7 wGA and <6 months of age at the start of RSV season, with significant provider-identified risk factors
BPD/CLDP	***≤24 months of age*** at the start of RSV season, and with medical treatment required for BPD/CLDP within the previous 6 months	***<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	***<24 months of age*** at the start of RSV season, and with medical management required within 6 months
HS-CHD	***≤24 months of age*** at the start of RSV season	***<12 months of age*** at the start of the RSV season	***<24 months of age*** at the start of RSV season, unless cardiology waiver obtained

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

Consider the guidelines when identifying high-risk patients.

Learn about Access & Affordability at **SYNAGISCONNECT.com**

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.

IMPORTANT SAFETY INFORMATION (continued)

- 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 see accompanying full Prescribing Information for SYNAGIS, including Patient Information.

CA=chronological age; AAP=American Academy of Pediatrics; NPA=National Perinatal Association; RSV=respiratory syncytial virus.

References: 1. The Impact-RSV Study Group. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. *Pediatrics*. 1998;102(3):531-537. **2.** SYNAGIS [package insert]. Gaithersburg, MD: MedImmune. **3.** 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. **4.** Goldstein M, Phillips R, DeVincenzo JP, et al. National Perinatal Association respiratory syncytial virus (RSV) prevention clinical practice guideline: an evidence-based interdisciplinary collaboration. *Neonatology Today*. 2017;12(10):1-11.

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