ALL INFANTS ARE NOT THE SAME

IDENTIFY your highest-risk infants who may benefit from SYNAGIS®

The highest-risk infants require year-round identification

PATIENTS WHO MAY BENEFIT FROM SYNAGIS[1]:

Premature

Premature infants
(≤35 wGA and ≤6 months of age at the 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

Risk factors for RSV incidence and severity include[2-4]:

- YOUNG CHRONOLOGICAL AGE (<3 MONTHS)
- CROWDED LIVING CONDITIONS
- PRESCHOOL-AGED SIBLINGS
- PASSIVE SMOKE EXPOSURE
- DAYCARE ATTENDANCE

BPD/CLDP

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, required medical treatment* for BPD/CLDP

***Medical treatment may include any of the following[2]:**

- SUPPLEMENTAL OXYGEN
- BRONCHODILATOR AND/OR CORTICOSTEROID THERAPY
- DIURETIC

HS-CHD

Hemodynamically significant congenital heart disease (HS-CHD)

- ≤24 months of age at the start of the upcoming RSV season

Children with HS-CHD who may benefit from SYNAGIS include those who[5,6]:

- ARE RECEIVING MEDICATION TO CONTROL CONGESTIVE HEART FAILURE
- HAVE MODERATE TO SEVERE PULMONARY HYPERTENSION
- HAVE ACYANOTIC OR CYANOTIC HEART DISEASE

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.

CONTRAINDICATIONS

Previous significant hypersensitivity reaction to SYNAGIS.

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions: Anaphylaxis and anaphylactic shock (including fatal cases) and other severe acute hypersensitivity reactions have been reported. Permanently discontinue SYNAGIS and administer appropriate medication if such reactions occur.

RSV=respiratory syncytial virus; wGA=weeks gestational age.

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

SYNAGIS®
PALIVIZUMAB

25+ YEARS OF CLINICAL EXPERIENCE
PROTECTING THE HIGHEST RISK INFANTS FROM RSV

ALL INFANTS ARE NOT THE SAME

The AAP and NPA recommend SYNAGIS® for the following patients at the highest risk for severe RSV disease:

	SYNAGIS INDICATION[1]	2014 AAP GUIDANCE[6]	2024 NPA GUIDELINE[7]
Premature	≤35 wGA and ≤6 months of age at the start of RSV season	<29 wGA and <12 months of age* at the start of RSV season with no other qualifying conditions *6 to <12 months is outside the approved SYNAGIS Indication. 29 to 35 wGA with other qualifying conditions	<28 0/7 wGA and <12 months of age* at the start of RSV season *6 to <12 months is outside the approved SYNAGIS Indication. 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 RSV season	<24 months of age at the start of RSV season, unless cardiology waiver obtained

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.

USE THESE INTERACTIVE BIRTHDAY GUIDES TO HELP IDENTIFY PATIENTS DURING THE 2024-2025 RSV SEASON.

2014 American Academy of Pediatrics (AAP) Guidance
2024 National Perinatal Association (NPA) Guideline

RSV PROTECTION GUIDE

SCHEDULE A MEETING WITH A SOBI REP

IMPORTANT SAFETY INFORMATION (continued)

Coagulation Disorders: SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder.

RSV Diagnostic Test Interference: Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays.

Serious Adverse Reactions: The most common serious adverse reactions occurring with SYNAGIS are anaphylaxis and other acute hypersensitivity reactions.

Most Common Adverse Reactions: The most common adverse reactions are fever and rash.

Postmarketing Experience: Severe thrombocytopenia and injection site reactions have been identified during post approval use of SYNAGIS.

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

These are not all the possible risks associated with SYNAGIS.

Please see full Prescribing Information for SYNAGIS, including Patient Information.

To report suspected adverse reactions, contact Sobi North America at 1-866-773-5274 or the FDA at 1-800-FDA-1088.

All imagery is for illustrative purposes only.

AAP=American Academy of Pediatrics; BPD=bronchopulmonary dysplasia; CLDP=chronic lung disease of prematurity; HS-CHD=hemodynamically significant congenital heart disease; NPA=National Perinatal Association; RSV=respiratory syncytial virus; wGA=weeks gestational age.

References: 1. SYNAGIS (palivizumab) [prescribing information]. Waltham, MA: Sobi, Inc. 2021. **2.** 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. **3.** Ambrose CS, Anderson EJ, Simões EAF, et al. Respiratory syncytial virus disease in preterm infants in the US born at 32-35 weeks gestation not receiving immunoprophylaxis. *Pediatr Infect Dis J*. 2014;33(6):576-582. **4.** AAP Committee on Infectious Diseases. *Red Book (2012): Report of the Committee on Infectious Diseases*. 29th ed. American Academy of Pediatrics; 2012:609-618. **5.** Feltes TF, Cabalka AK, Meissner HC, et al; Cardiac Synagis Study Group. Palivizumab prophylaxis reduces hospitalization due to respiratory syncytial virus in young children with hemodynamically significant congenital heart disease. *J Pediatr*. 2003;143(4):532-540. **[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.** Goldstein M, Hopkins B, Kadri M, et al. National Perinatal Association 2024 respiratory syncytial virus (RSV) prevention clinical practice guideline: clinical presentation, prevention strategies, and social impacts in children: an evidence-based interdisciplinary collaboration. *Neonatology Today*. 2024;19(1):9-38.

For WAC pricing, visit synagishcp.com/wac-pricing.

sobi rare strength

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SYNAGIS® PALIVIZUMAB

25+ YEARS OF CLINICAL EXPERIENCE
PROTECTING THE HIGHEST RISK INFANTS FROM RSV

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