PATIENT ID KIT

IDENTIFY high-risk patients eligible for **SYNAGIS** THROUGHOUT THE YEAR

Preterm
≤35 wGA who are 6 months of age or younger at the beginning of RSV season

BPD/CLDP
≤24 months of age

Hemodynamically significant CHD
≤24 months of 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

BPD/CLDP=bronchopulmonary dysplasia/chronic lung disease of prematurity; wGA=weeks gestational age.

All imagery is for illustrative purposes only

Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

3 steps to identify and protect high-risk infants

IDENTIFY
1
Identify high-risk patients eligible for SYNAGIS

RECORD
2
Record identified patients for SYNAGIS for the upcoming RSV season

ENROLL
3
Enroll identified patients into SYNAGIS patient support programs

Protect your high-risk infants with **SYNAGIS**

SYNAGIS **provides antibodies to protect an infant's lungs** from severe infection caused by RSV—it is not a vaccine[1]

High-risk infants should receive continuous, **monthly doses (every 28-30 days)** throughout the RSV season[1-3]*

High-risk patients require year-round identification

FALL
- Identify patients in-season
- Initiate protection

WINTER
- Identify patients in-season
- Initiate protection or continue dosing

SPRING
- Identify patients for next season
- Continue dosing during late-season

SUMMER
- Identify patients for next season

GET THE LATEST RSV VIROLOGY TRENDS
cdc.gov/surveillance/nrevss/rsv/state.html

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

*RSV season can vary by geography and from year to year.[2]
RSV=respiratory syncytial virus.

Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

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The PATIENT ID KIT

Use these resources to help identify, record, and enroll your patients

IDENTIFY 1

Identify high-risk patients eligible for SYNAGIS

Eligibility Grid

Identify high-risk patients eligible for SYNAGIS.

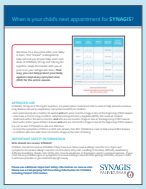
- SYNAGIS criteria
- Guidance from the American Academy of Pediatrics
- Guidelines from the National Perinatal Association

RECORD 2

Record identified patients for SYNAGIS for the upcoming RSV season

Patient ID Log

Identify and track patients who are eligible for SYNAGIS.



Dose Scheduling Card

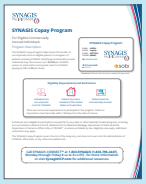
Remind parents/caregivers about SYNAGIS dosing and appointments.

ENROLL 3

Enroll identified patients into SYNAGIS patient support programs

SYNAGIS CONNECT™

Understand how SYNAGIS CONNECT™ can help provide access & support.



SYNAGIS Copay Program

Inform eligible parents/caregivers about a financial assistance program that may reduce their out-of-pocket costs.

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

RSV=respiratory syncytial virus.

Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

IDENTIFY 1

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)[4]

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

IMPORTANT SAFETY INFORMATION (continued)

- 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

CA=chronological age; RSV=respiratory syncytial virus.

Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

IDENTIFY 1

Clinical associations support RSV immunoprophylaxis for high-risk patients

	FDA-approved Label[1]	2014 AAP Guidance[3]	2018 NPA Guidelines[5]
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

Consider the recommendations when identifying high-risk patients.

Learn about Access & Support at SYNAGISHCP.com

IMPORTANT SAFETY INFORMATION (continued)

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.

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

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.

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

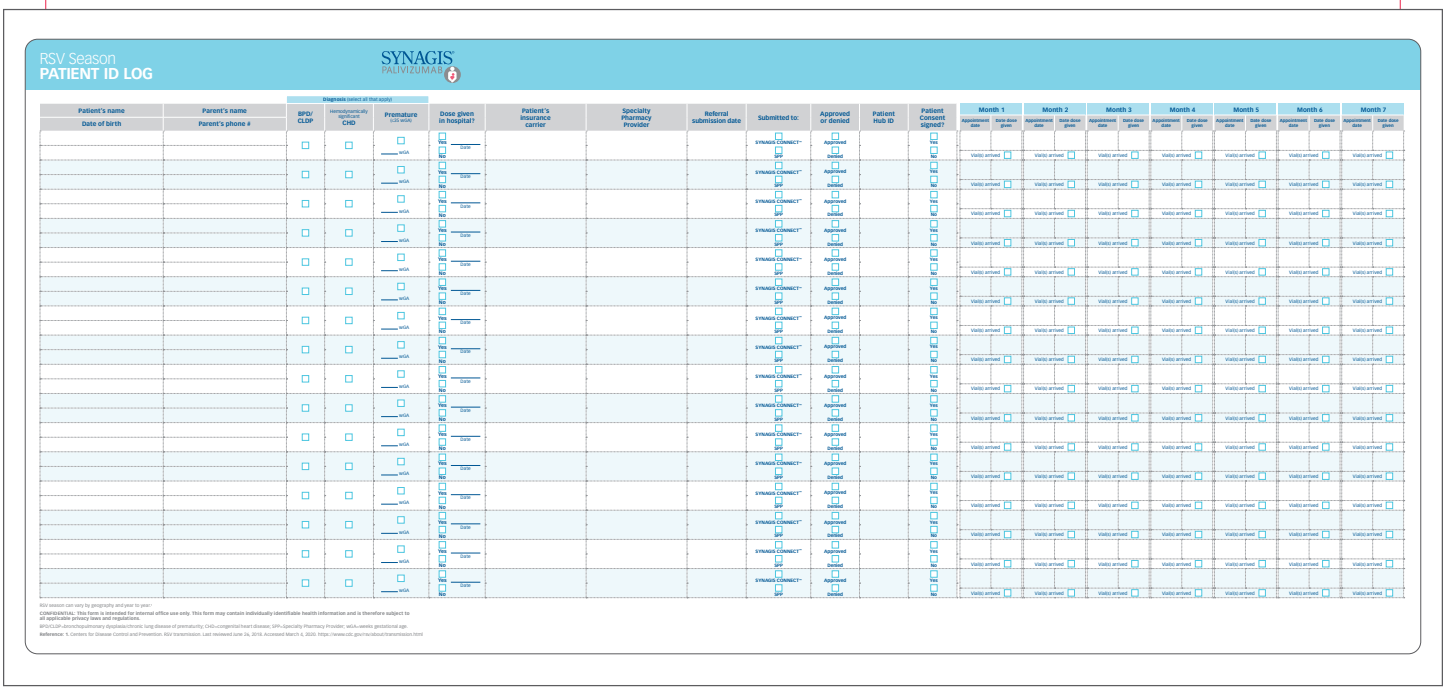
Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

RECORD 2

RSV season **PATIENT ID LOG**

This tool will help you track patients who are eligible for SYNAGIS during the upcoming RSV season. Details include important patient and insurance information, as well as columns to keep track of monthly doses and appointments.



RSV Season
PATIENT ID LOG

SYNAGIS® PALIVIZUMAB

Patient's name / Date of birth	Parent's name / Parent's phone #	Diagnosis (select all that apply): BPD/CLDP	Hemodynamically significant CHD	Premature (≤35 wGA)	Dose given in hospital?	Patient's insurance carrier	Specialty Pharmacy Provider	Referral submission date	Submitted to:	Approved or denied	Patient Hub ID	Patient Consent signed?	Month 1 (Appointment date / Date dose given / Visit(s) arrived)	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7
		☐	☐	☐ ___ wGA	☐ Yes ☐ No ___ Date				☐ SYNAGIS Connect™ ☐ SPP	☐ Approved ☐ Denied		☐ Yes ☐ No	☐	☐	☐	☐	☐	☐	☐

RSV season can vary by geography and year to year.

CONFIDENTIAL: This form is intended for internal office use only. This form may contain individually identifiable health information and is therefore subject to all applicable privacy laws and regulations.

BPD/CLDP=bronchopulmonary dysplasia/chronic lung disease of prematurity; CHD=congenital heart disease; SPP=Specialty Pharmacy Provider; wGA=weeks gestational age.

Reference: 1. Centers for Disease Control and Prevention. RSV transmission. Last reviewed June 24, 2018. Accessed March 4, 2020. https://www.cdc.gov/rsv/about/transmission.html

Contact your SYNAGIS representative for access to a printed copy of this tool.

Download an editable PDF of this Patient ID Log

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

RSV=respiratory syncytial virus.

Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

RECORD 2

RSV season **CONSUMER DOSE SCHEDULING CARD**

This tool will help parents and caregivers track their baby's next dose of SYNAGIS.

When is your child's next appointment for **SYNAGIS**?

We know it's a busy time after your baby is born. This "tracker" is designed to help remind you of your little one's next dose of SYNAGIS, 50 mg and 100 mg for injection. Keep this tracker with you or post it on your refrigerator door. **That way, you can help protect your baby against respiratory syncytial virus (RSV) for the entire season.**

Dose of SYNAGIS	Date Received	Given by (Initials)	Next Dose Needed In	Date for Next Dose of SYNAGIS
Dose 1	__/__/__		28-30 days	__/__/__
Dose 2	__/__/__		28-30 days	__/__/__
Dose 3	__/__/__		28-30 days	__/__/__
Dose 4	__/__/__		28-30 days	__/__/__
Dose 5	__/__/__		28-30 days	__/__/__

PHYSICIAN: Schedule this patient for dosing during the next season? ☐ Yes ☐ No

Be sure to ask your doctor:

"Should my baby be protected during the next season too?"

APPROVED USE

SYNAGIS, 50 mg and 100 mg for injection, is a prescription medication that is used to help prevent a serious lung disease caused by respiratory syncytial virus (RSV) in children:

- born prematurely (at or before 35 weeks) **and** who are 6 months of age or less at the beginning of RSV season
- who have a chronic lung condition called bronchopulmonary dysplasia (BPD), that needed medical treatment within the last 6 months, **and** who are 24 months of age or less at the beginning of RSV season
- born with certain types of heart disease **and** who are 24 months of age or less at the beginning of RSV season

It is not known if SYNAGIS is safe and effective:

- to *treat* the symptoms of RSV in a child who already has RSV. SYNAGIS is used to help *prevent* RSV disease
- in children who are older than 24 months of age at the start of dosing

IMPORTANT SAFETY INFORMATION

Who should not receive SYNAGIS?

Children should not receive SYNAGIS if they have ever had a severe allergic reaction to it. Signs and symptoms of a severe allergic reaction could include itchy rash; swelling of the face; difficulty swallowing; difficulty breathing; bluish color of the skin; muscle weakness or floppiness; and/or unresponsiveness. If your child has any of these signs or symptoms of a severe allergic reaction after getting SYNAGIS, call your child's healthcare provider or get medical help right away.

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

SYNAGIS® PALIVIZUMAB

Contact your SYNAGIS representative for access to printed copies of this tool.

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

RSV=respiratory syncytial virus.

Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

ENROLL 3

SYNAGIS CONNECT™

SYNAGIS CONNECT™ is a patient support program created by Sobi to provide individualized support to help appropriate patients get access to SYNAGIS® (palivizumab). SYNAGIS CONNECT™ can help parents and caregivers understand the treatment process and their financial options, support providers in navigating insurance and reimbursement questions, and assist in the coordination of care and the specialty pharmacy process.

In order for patients and their caregivers to take advantage of this program, consent/authorization must be obtained.

SYNAGIS CONNECT™ can assist with:

Parent/Caregiver

- Patient out-of-pocket costs*
- Identifying prescription coverage
- Patient Assistance Program*

Healthcare Professionals

- Reimbursement support services, including benefits investigations and prior authorization
- Claims and appeal process support
- Field reimbursement support through a single point of contact
- Transition of care and referral management
- Specialty pharmacy coordination

Access documents and resources on SYNAGIS.com. To begin patient enrollment, log in to www.covermymeds.com or fax completed forms to 1-800-201-4938.

For additional assistance, call 1-833-SYNAGIS (1-833-796-2447), Monday through Friday 8 AM to 8 PM EST

*For eligible patients.

Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

ENROLL 3

SYNAGIS® PALIVIZUMAB

SYNAGIS Copay Program

For Eligible Commercially

Program Description

The SYNAGIS Copay Program helps lessen the burden of out-of-pocket costs on eligible parents or caregivers of patients receiving SYNAGIS. Qualifying commercially insured individuals may have access up to **$6,000** per SYNAGIS season to assist with out-of-pocket costs for SYNAGIS (paying as little as **$0** per dose).

SYNAGIS Copay Program

RxBIN: **610524**
RxPCN: **Loyalty**
RxGRP: **50777916**
ISSUER: **(80840)**

ID: XXXXXXXXXX

SYNAGIS® PALIVIZUMAB

RxCrossroads By McKesson

sobi

Disclaimer: Patients will not receive a physical copay card.

Eligibility Requirements and Restrictions

- Individual has out-of-pocket costs for SYNAGIS
- Patient must be a resident of the United States or Puerto Rico
- Patient must be commercially insured

There are no income requirements to participate in the program. Claims or transactions must be made within 180 days from the date of service.

Individuals are ineligible if prescriptions are paid for by any state or other federally funded programs, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, Department of Defense (DoD), Department of Veterans Affairs (VA), or TRICARE®, or where prohibited by law. Eligibility rules apply. Additional restrictions may apply.

The SYNAGIS Copay Program covers the cost of the drug only, and does not cover costs for administration of SYNAGIS, office visits, or any other associated costs.

Call SYNAGIS CONNECT™ at 1-833-SYNAGIS (1-833-796-2447), Monday through Friday 8 AM to 8 PM EST, for more information or visit SynagisHCP.com for additional resources.

Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

ENROLL 3

SYNAGIS® PALIVIZUMAB

How the SYNAGIS Copay Program Works

- If you are told that you have an out-of-pocket cost for SYNAGIS and you meet the other program eligibility requirements, a SYNAGIS Copay Program account will be created for you
- Your prescriber's office, specialty pharmacy, or home health care will use this program to cover your out-of-pocket costs for SYNAGIS up to **$6000** per SYNAGIS season (7/1-6/30)

Terms of Use

This offer is not insurance. Use of this program may be prohibited under the terms of your health insurance plan or the program benefits may not count toward any plan deductible requirements. Consult with your insurer if you have questions about your plan requirements. Individual is responsible for applicable taxes, if any. Patient must be enrolled in the program before use. If you have any questions regarding this offer, please call SYNAGIS CONNECT™ at 1-866-285-8419. Other restrictions may apply.

This offer is non-transferable, limited to one per person, and cannot be combined with any other offer. Void where prohibited by law, taxed, or restricted. Parents or guardians, pharmacists, and prescribers cannot seek reimbursement from health insurance or any third party for any part of the benefit received by the patient through this offer. Sobi reserves the right to rescind, revoke, or amend this offer, its eligibility requirements, and terms of use at any time without notice. This offer is not conditioned on any past, present, or future purchase, including refills. Offer must be presented along with a valid prescription at time of purchase.

The program does not cover costs associated with patient visits, including prescriber, staff, or administrative charges associated with administering SYNAGIS.

Offer is invalid for claims or transactions more than 120 days from the date of service.

BY USING THIS PROGRAM, YOU UNDERSTAND AND AGREE TO COMPLY WITH THESE ELIGIBILITY REQUIREMENTS AND TERMS OF USE.

SYNAGIS CONNECT™

SYNAGIS CONNECT™ is an optional program provided by Sobi for patients and their parents, guardians, and providers that can help you understand your coverage and financial obligation for SYNAGIS and provide resources to help with treatment and payment for treatment.

SYNAGIS CONNECT™ representatives can answer questions related to

- Prescription coverage
- Out-of-pocket costs and pharmacy options
- Affordability programs (based on eligibility)
- Claims and appeal process support

Please see additional Important Safety Information on pages 1-11.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

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

RSV=respiratory syncytial virus.

References: 1. [SYNAGIS [package insert]. Gaithersburg, MD: MedImmune]. **2.** Centers for Disease Control and Prevention. RSV transmission. Last reviewed June 26, 2018. Accessed March 8, 2020. https://www.cdc.gov/rsv/about/transmission.html **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.** 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. **5.** 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.

Learn more about us at SOBI.com

SYNAGIS® PALIVIZUMAB