RSV READY KIT

Resource to help you identify, protect, and support your most vulnerable patients

- ***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

All imagery is for illustrative purposes only.

Please see additional Important Safety Information on pages 1-58. Click here for full Prescribing Information for SYNAGIS, including Patient Information.

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To download the complete kit,
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COMPLETE KIT

—OR—

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WELCOME!

The RSV READY KIT includes resources to help you identify, protect, and support high-risk infants from RSV

IDENTIFY 1
Identify high-risk patients who are eligible for SYNAGIS

EDUCATE 2
Discuss RSV and SYNAGIS treatment with parents/caregivers

ACCESS & SUPPORT 3
Help patients get started and continue with SYNAGIS treatment

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 **monthly doses (every 28-30 days)** throughout the RSV season[1-3]*

INDICATION
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For patient identification resources or educational information, contact your SYNAGIS Clinical Account Manager or Institutional Director

For access and support information, contact your SYNAGIS Field Reimbursement Senior Manager

IMPORTANT SAFETY INFORMATION (continued)

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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.

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*RSV season can vary by geography and from year to year.[1]

RSV=respiratory syncytial virus.

References: 1. [SYNAGIS [package insert]. Waltham, MA: Sobi, Inc.] **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.

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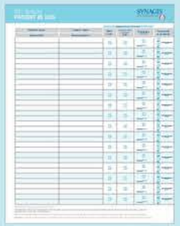
The RSV READY KIT

IDENTIFY 1

Eligibility Grid

Identify high-risk patients eligible for SYNAGIS

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



Patient ID Log

Identify and track patients who are eligible for SYNAGIS

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IMPORTANT SAFETY INFORMATION (continued)

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RSV=respiratory syncytial virus.

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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.

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Please see additional Important Safety Information on page 2.
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1 IDENTIFY
2 EDUCATE
3 ACCESS & SUPPORT

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 more about access & support at SYNAGISHCP.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.
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Please click here for 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]. Waltham, MA: Sobi, Inc. **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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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.

INDICATION

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1 IDENTIFY
2 EDUCATE
3 ACCESS & SUPPORT

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The RSV READY KIT

EDUCATE 2

Discussion Guide

Help educate parents/caregivers about RSV and SYNAGIS

- Explanation of RSV and seasonality
- Patients who are eligible for SYNAGIS
- Facts about SYNAGIS treatment

SYNAGIS is NOT a Vaccine

Provide information about SYNAGIS as a monoclonal antibody used to help protect high-risk infants against severe RSV

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DISCUSSION GUIDE FOR NURSE COORDINATORS

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**[5]

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

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.[1]

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.

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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[1]
- SYNAGIS has been shown to significantly reduce hospitalizations caused by RSV[1]

How does it work?

- SYNAGIS provides RSV-fighting antibodies to defend against RSV, it is not a vaccine[1]
- Through monthly injections, SYNAGIS provides enough antibodies to protect a baby's lungs from severe infection caused by RSV for 28-30 days[1]

How often is SYNAGIS dosed?

- SYNAGIS does not induce endogenous anti-RSV antibodies, so it must be administered every 28-30 days[1]
- 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[1]

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[1,8]

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)

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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, Kaselj A. 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.

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SYNAGIS is NOT a vaccine

SYNAGIS is the only FDA-approved monoclonal antibody to help protect high-risk infants against RSV[1]

- SYNAGIS delivers antibodies that are immediately available to fight RSV[1,2]
- Unlike vaccines, antibodies do not provide long-lasting immunity.[2] SYNAGIS needs to be given each month (every 28-30 days) throughout the RSV season to provide continuous protection against RSV[1,3-5]
  - Noncompliance puts infants at increased risk for RSV-related hospitalizations[3]

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SYNAGIS® PALIVIZUMAB

Protect your high-risk infants
Dose with SYNAGIS

- **SYNAGIS** does not induce endogenous anti-RSV antibodies and must be administered every 28-30 days[1]
- High-risk infants should receive **monthly doses** of SYNAGIS throughout the RSV season, which typically runs from late fall through spring[1,4,5]*

Get patients STARTED ON SYNAGIS

SYNAGIS CONNECT™

SYNAGIS CONNECT® is a patient support program created by Sobi to provide individualized support to help appropriate patients get access to SYNAGIS.

For more information, call 1-833-SYNAGIS (1-833-796-2447) or visit SYNAGISHCP.com

Commercially eligible patients may get up to $6000 per SYNAGIS season to assist with out-of-pocket costs for SYNAGIS (paying as little as $0 per dose)

Disclaimer: Patients will not receive a physical copay card. Eligibility requirements apply.†

†Patient must be a resident of the US or Puerto Rico. Patient must be commercially insured. There are no income requirements to participate in the program. Patient must not be insured by any government, state, or federally funded prescription program, including Medicare, Medicaid, Medigap, VA, DOD, or TRICARE.

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.

RSV=respiratory syncytial virus.

*RSV season can vary by geography and from year to year.[4]

References: 1. SYNAGIS [package insert]. Waltham, MA: Sobi, Inc. **2.** Delves PJ, et al. Vaccines. In: *Roitt's Essential Immunology*. 11th ed. Malden, MA: Blackwell Publishing; 2006:287-311. **3.** Makari D, Checchia PA, DeVincenzo J. Rationale for full-season dosing for passive antibody prophylaxis of respiratory syncytial virus. *Hum Vaccin Immunother*. 2014;10(3):607-614. **4.** Centers for Disease Control and Prevention. RSV transmission. Last reviewed June 26, 2018. Accessed March 6, 2020. https://www.cdc.gov/rsv/about/transmission.html **5.** 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.

Colorado prescriber, please click here for additional information.

Learn more about us at SOBI.com

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SYNAGIS® PALIVIZUMAB

The RSV READY KIT

ACCESS & SUPPORT 3

HEALTHCARE PROFESSIONALS

Getting Started With SYNAGIS
Determine the appropriate pathway to get patients started on SYNAGIS

SYNAGIS CONNECT® Overview
Understand how SYNAGIS CONNECT® can help provide access & support

SYNAGIS CONNECT® Process Flow
Follow these steps to navigate the patient access & support process with SYNAGIS CONNECT®

Universal Enrollment and Prescription Form
Complete and provide patient information to SYNAGIS CONNECT® or a specialty pharmacy to prescribe SYNAGIS for your patients

Information to Help Complete the Universal Enrollment and Prescription Form
Information for completing the Universal Enrollment and Prescription Form

Limited Distribution Specialty Pharmacy Network Grid
Identify the select specialty pharmacies from which you can obtain SYNAGIS

Coding Resource
Review useful codes for the billing and reimbursement of SYNAGIS and identification of high-risk babies

PARENTS/CAREGIVERS

SYNAGIS Parent/Caregiver Consent Form
Help parents/caregivers provide their authorization to enroll in SYNAGIS CONNECT®

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

DOSING-SPECIFIC RESOURCES

Dose Scheduling Card
Remind parents/caregivers about SYNAGIS dosing and appointments

Dosing Calendar
Schedule patient dosing appointments

Dosing Guide
Review information on SYNAGIS storage, preparation, and administration

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 pages 1-58. Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS CONNECT™ SYNAGIS® PALIVIZUMAB

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 see additional Important Safety Information on pages 1-58.
Click here for full Prescribing Information for SYNAGIS, including Patient Information.

RSV=respiratory syncytial virus.

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SYNAGIS CONNECT™ SYNAGIS® PALIVIZUMAB

SYNAGIS® PALIVIZUMAB Getting Started With SYNAGIS

When an appropriate patient is identified for SYNAGIS prophylaxis, follow these steps to initiate treatment.

STEP 1 – Complete the Referral Process

HUB REFERRAL
- Complete a Universal Enrollment and Prescription Form
- Fax to SYNAGIS CONNECT™, or complete the Hub Enroll process through the CoverMyMeds® portal

DIRECT REFERRAL TO PAYER OR SPECIALTY PHARMACY (SP)
- SYNAGIS CONNECT™ will not support the prior authorization (PA) and prescription process unless requested by the office
- To ensure you follow the correct process, contact the plan and/or SP directly

BUY-AND-BILL
- Follow the appropriate PA process according to the payer
- Follow your office protocol for ordering through the appropriate specialty distributor

Helpful resources: Refer to the SYNAGIS CONNECT™ Process Flow for Healthcare Provider Offices flashcard, Limited Distribution Specialty Pharmacy Network flashcard, Specialty Distribution Model flashcard, or the Payer Grid for more details.

SYNAGIS CONNECT™ can assist with the PA process and benefits verification.

STEP 2 – Approval or Denial

- Communicate approval or denial to parent/caregiver
- If you have not received either an approval or denial within 7 business days, please contact SYNAGIS CONNECT™, the payer, or the appropriate SP

APPROVAL
- The SP will call the parent/caregiver and provider prior to shipment.*
- The parent/caregiver should answer/return the call from the SP and inform the patient's provider if the SP makes any changes

DENIAL
- Review the denial letter from the patient's insurance plan to determine the reason and next steps
- Follow the protocol to which your office adheres to appeal the denial

SYNAGIS CONNECT™ can assist with information needed for the Denials and Appeals process.†

STEP 3 – Continuum of Care

SYNAGIS CONNECT™ OR DIRECT REFERRAL PATHWAYS*
- Coordinate delivery of product with the SP and parent/caregiver monthly
- Confirm information with the SP, including location, dose, and date
- Ensure adherence to monthly dosing in season through ongoing discussions with parent/caregiver and ongoing coordination with the SP

BUY-AND-BILL PATHWAY
- Follow payer-specific PA requirements for each dose
- Coordinate with parent/caregiver to schedule administration
- Ensure adherence to monthly dosing in season through ongoing discussions with parent/caregiver

Review and update information on forms (e.g., changes in patient weight) per PA requirements prior to each dose.

SYNAGIS CONNECT™ | If you have questions, you can contact SYNAGIS CONNECT™ at 1-833-SYNAGIS (1-833-796-2447) or your Field Reimbursement Senior Manager.‡ The Parent/Caregiver Consent Form can be found on SYNAGISHCP.com.

*In some cases, the office may need to notify the SP of approval prior to each dose.
†Only if parent/caregiver consent is obtained.
‡Field Reimbursement Senior Managers will be able to support on specific cases if parent/caregiver consent is obtained.
Sobi, Inc. and SYNAGIS CONNECT™ do not guarantee coverage or reimbursement for SYNAGIS. Coverage and reimbursement decisions are made by insurance companies following the receipt of claims.

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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	Healthcare Professionals	
Patient out-of-pocket costs*	Reimbursement support services, including benefits investigations and prior authorization	Transition of care and referral management
Identifying prescription coverage	Claims and appeal process support	Specialty pharmacy coordination
Patient Assistance Program*	Field reimbursement support through a single point of contact	

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.

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SYNAGIS® PALIVIZUMAB

SYNAGIS CONNECT™ Process Flow for Healthcare Provider (HCP) Offices

When an appropriate patient is identified for SYNAGIS prophylaxis, either in the neonatal intensive care unit (NICU) or in your office, follow these steps to utilize SYNAGIS CONNECT™.

Look for this icon if your office uses paper forms

Look for this icon if your office uses the CoverMyMeds® (CMM) portal

This icon denotes the role of SYNAGIS CONNECT™

	HCP OFFICE	SYNAGIS CONNECT™
STEP 1	• Complete the Universal Enrollment and Prescription Form • Fax the completed form to SYNAGIS CONNECT™ • Submit Parent/Caregiver consent	• Click the Hub Enroll button in the CMM portal • Complete the Universal Enrollment and Prescription Form • Submit Parent/Caregiver consent	• Completes BV • Accesses the appropriate PA information • Explores financial assistance options for eligible patients*
STEP 2	• Receive results of the BV and appropriate PA form from SYNAGIS CONNECT™ • Complete PA form and submit it directly to the payer	• Receive results of the BV • Complete the required PA form† in the CMM portal • If PA submission through a payer-specific portal is required, complete the PA process directly through the payer's portal	• Follows up with the payer and your office as needed
STEP 3	• If the PA is obtained outside of CMM, provide the approval information to SYNAGIS CONNECT™	• If the PA is approved through the CMM portal, SYNAGIS CONNECT™ is automatically informed	• Sends the prescription to the appropriate SP via CMM
STEP 4	• The SP will communicate directly with the HCP office and the patient's parent/caregiver to coordinate delivery • If copay assistance has not been obtained, the SP will verify and enroll the parent/caregiver as appropriate		

For patients identified in the NICU

- NICU submits Authorization for the Transition of Care and Parent/Caregiver Consent form to SYNAGIS CONNECT™
- SYNAGIS CONNECT™ notifies HCP office via fax or through the CMM portal to initiate a Universal Enrollment and Prescription Form

SYNAGIS CONNECT™ **SYNAGIS CONNECT™** is powered by CoverMyMeds. Enroll patients today through your CoverMyMeds account—or create an account at no charge to get started.

BV=benefits verification; CMM=CoverMyMeds®; PA=prior authorization; SP=specialty pharmacy.
*If parent/caregiver consent is obtained.
†Some fields may be prepopulated. Check for accuracy and complete all other required information.
Sobi, Inc. and SYNAGIS CONNECT™ do not guarantee coverage or reimbursement for SYNAGIS. Coverage and reimbursement decisions are made by insurance companies following the receipt of claims.

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SYNAGIS CONNECT®

Universal Enrollment and Prescription Form

SYNAGIS® PALIVIZUMAB

• Enroll online at www.CoverMyMeds.com. • Fax to SYNAGIS CONNECT® at 1.800.201.4938.

○ Buy-and-Bill Benefit ○ Preferred Specialty Pharmacy _____

PATIENT INFORMATION ○ Please indicate if multiple births.

Last Name:_____ First Name:_____ Middle Initial:_____

Date of Birth*:_____/_____/_____ Sex: ○ Male ○ Female *Patient weight information is collected in the prescription section.

PARENT/CAREGIVER INFORMATION

Last Name:_____ First Name:_____ Middle Initial:_____

Street:_____ Unit:_____ City:_____ State:_____ ZIP Code:_____

Home Phone #:_____ Mobile Phone #:_____

Email:_____ Preferred Contact Method: ○ Phone ○ Text ○ Email

Best Time to Call: ○ Morning ○ Afternoon ○ Evening Preferred Language:_____

○ Enroll me in the SYNAGIS Copy Program. Eligibility requirements apply.

○ I authorize SYNAGIS CONNECT® to send text messages when appropriate and hereby agree to receive this type of communication. Standard data and message rates may apply.

○ I authorize SYNAGIS CONNECT® to leave a detailed message, including the name of my child's prescription, SYNAGIS.

INSURANCE INFORMATION Please provide a copy of all insurance cards (front and back). ○ No Insurance

Policyholder Full Name:_____ Policyholder Date of Birth:_____/_____/_____

Primary Medical Insurance:_____

Insurance Phone #:_____ Group #:_____ ID #:_____

Secondary Medical Insurance:_____

Insurance Phone #:_____ Group #:_____ ID #:_____

Prescription Insurance:_____ RxGroup:_____ RxBIN:_____ RxPCN:_____

▼ FOR HEALTHCARE PROVIDER USE ONLY ▼

PRESCRIBER INFORMATION

Last Name:_____ First Name:_____ Office/Institution Name:_____

Street:_____ Suite:_____ City:_____ State:_____ ZIP Code:_____

NPI #:_____ DEA #:_____ Tax ID #:_____

Medicaid Provider ID #:_____

Office Contact Name:_____ Phone #:_____

Fax #:_____ Email:_____

PRESCRIBER AUTHORIZATION: My signature certifies that the person named on this form is my patient, that the information provided, to the best of my knowledge, is complete and accurate, and that therapy with SYNAGIS is medically necessary. I certify that I have obtained the written authorization of my patient's parent or caregiver in accordance with all applicable state and federal laws to release the individually identifiable health information indicated on this form to Scio, and SYNAGIS CONNECT® patient support program and I understand that the information that I provide on this form will be used by the program for purposes of verifying my patient's insurance coverage and eligibility, coordinating the dispensing of my patient's prescription medicine, and introducing SYNAGIS CONNECT® support services to my patient, including contacting my patient's parent/caregiver by telephone or mail for these purposes. I authorize SYNAGIS CONNECT® to transmit the above prescription to the appropriate specialty pharmacy for my patient. I understand that I am under no obligation to prescribe any Scio products and that I have no restriction will I receive any benefit from Scio for doing so. I will not seek reimbursement from any third-party payer, or government entity for any product provided free of charge by SYNAGIS CONNECT®.

Special Note: Prescribers in all states must follow applicable laws for a valid prescription. For prescribers in states with official prescription form requirements, please submit an actual prescription along with this enrollment form.

SIGN HERE **Prescriber Signature**_____ **Date**_____

CLINICAL INFORMATION Attach any required clinical notes.

○ Prematurity: _____ weeks/days' GA (eg, 32.3)

ICD-10:_____

Birth Weight:_____kg

Current Weight:_____kg

Date of Weight:_____/_____/_____

○ Bronchopulmonary dysplasia/chronic lung disease

○ Age <12 months ○ Age 12 months to <24 months

Supplemental oxygen (dates)_____

Chronic corticosteroids (drugs/dates):_____

Diuretic therapy (drug/dates):_____

Bronchodilators (drugs/dates):_____

ICD-10:_____

○ Hemodynamically significant congenital heart disease

○ Age <12 months ○ Age 12 months to <24 months

ICD-10:_____

○ Other conditions:

Description:_____

Diagnosis:_____

ICD-10:_____

NICU/Hospital dose administered: ○ No ○ Yes Date(s):_____ Needs by date:_____ Expected date of first/next injection:_____

Current medications:_____ Known allergies:_____

Deliver to: ○ Office/Clinic ○ Patient's Home ○ Other_____

Home Health Agency Services Requested for Injection Administration ○ No ○ Yes **Preferred Home Health Agency**_____

MEDICATION	STRENGTH	DOSE & DIRECTION	QUANTITY & REFILLS
SYNAGIS® (palivizumab)	50 mg and/or 100 mg vials	Inject 15 mg/kg IM one time per 28-30 days	Quantity: QS to achieve 15 mg/kg dose ; Refills: _____
○ OPTIONAL: Epinephrine	1:1000 amp	Inject 0.01 mg/kg SC as directed for anaphylaxis	Quantity: _____ Refills: _____

○ Ancillary supplies

Stamp Signature Not Allowed

SIGN HERE **Prescriber Signature**_____ **Date**_____

Dispense as Written

OR

Prescriber Signature_____ **Date**_____

Substitution Permitted

PARENT/CAREGIVER CONSENT CONTINUED ON NEXT PAGE

Not Required for Submission

1 of 3

SYNAGIS CONNECT®

SYNAGIS® PALIVIZUMAB

Patient Last Name:_____ First Name:_____ Date of Birth:_____

AUTHORIZATION TO SHARE HEALTH INFORMATION:

By signing below, I authorize my child's healthcare providers and staff, pharmacies, and health insurers to use and to disclose to Sobi, Inc., and its affiliates, business partners, vendors, and other agents (collectively, "Sobi") health information about my child related to my child's medical condition and treatment, health insurance and coverage claims, and prescription (including fill/refill information) for SYNAGIS ("Information") to (1) enroll my child in and provide services under the SYNAGIS CONNECT® patient support program (the "Program"); (2) obtain information on my child's insurance coverage; (3) coordinate prescription fulfillment as indicated by my child's physician; (4) provide me with adherence reminders and support; and (5) contact me to conduct market research and to arrange for my receipt of educational, promotional, and/or marketing materials about Sobi support programs or Sobi products. Once my child's Information has been disclosed to Sobi, I understand that federal privacy laws may no longer protect it from further disclosure. However, I also understand that Sobi will protect my child's Information by using and disclosing it only for the purposes allowed by me in this Authorization or as otherwise required by law.

I understand and agree that the pharmacy that dispenses SYNAGIS may receive payment from Sobi in exchange for disclosing my child's Information to Sobi and providing Program services.

I understand that I do not have to sign this Authorization. A decision by me not to sign this Authorization will not affect my child's ability to obtain medical treatment from healthcare providers, payment for treatment or eligibility for health insurance benefits, or access to Sobi medications. However, if I do not sign this Authorization, I understand my child will not be able to participate in the Program.

I understand that this Authorization expires (2) two years from the date signed below, or earlier if required by state or local law, unless and until I cancel (take back) this Authorization before then. I may change my mind and cancel this Authorization at any time by calling 1-833-SYNAGIS (1-833-796-2447) or by notifying Sobi in writing at SYNAGIS CONNECT, PO Box 29076, Phoenix, AZ 85038-9076. Cancellation of this Authorization will end further uses and disclosures of my child's Information by my child's healthcare provider and staff, pharmacies, and health insurers based on this Authorization, and my child's participation in the Program when they receive notice of my cancellation, but will not affect any uses or disclosure of my child's Information made by my child's healthcare providers and staff, pharmacies, and health insurers based on this Authorization before receipt of the cancellation.

CONSENT FOR ENROLLMENT IN SYNAGIS CONNECT®

By signing below, I am enrolling in SYNAGIS CONNECT® (the "Program"). I authorize Sobi, Inc., and its affiliates, business partners, vendors, and other agents (collectively, "business partners" and together with Sobi, Inc., "Sobi") to provide me and my child with services for which we are eligible under the Program. Such services may include medication and adherence communications and support, medication dispensing support, insurance coverage and financial assistance support, disease and medication education, and other support services offered now or in the future. As part of the Program offerings, I agree to enrollment in the copay assistance program if I am eligible.

- ○ I consent to receive autodialed and prerecorded marketing calls and text messages from Sobi, and companies working with Sobi, at the telephone number(s) that I provide. I understand that my consent is not required as a condition of purchasing or receiving any goods or services from Sobi. I understand that I may revoke this Authorization and choose not to receive automated marketing calls and text messages from Sobi at any time by calling 1-833-SYNAGIS (1-833-796-2447) or by notifying Sobi in writing at PO Box 29076, Phoenix, AZ 85038-9076.
- ○ I understand and consent to SYNAGIS CONNECT® contacting me via email or cell phone using the contact information provided in this form to provide me with dosing reminders. SYNAGIS CONNECT® may also use my information for market research or to evaluate and improve the company's services and programs. I understand that I may stop SYNAGIS CONNECT® from contacting me at any time by clicking the "Unsubscribe" link at the bottom of the emails I receive from SYNAGIS CONNECT®. I may also opt out at any time by replying "STOP" to the text messages I receive. I understand that SYNAGIS CONNECT® and companies providing services to SYNAGIS CONNECT® will not sell or rent my personally identifiable information. For more information about Sobi Terms and Conditions, including privacy practices, please read our Terms and Conditions by visiting https://sobi-northamerica.com/terms-and-conditions. Please review our Privacy Policy on the next page.

CONSENT FOR AUTHORIZATION TO SHARE HEALTH INFORMATION:

Full name (printed) of parent/caregiver: _____

SIGN HERE **Signature of Parent/Caregiver** _____ **Date** _____

CONSENT FOR ENROLLMENT SYNAGIS CONNECT®:

Full name (printed) of parent/caregiver: _____

SIGN HERE **Signature of Parent/Caregiver** _____ **Date** _____

SYNAGIS CONNECT®

SYNAGIS® PALIVIZUMAB

Patient Last Name:_____ First Name:_____ Date of Birth:_____

SOBI, INC., PRIVACY POLICY

GENERAL

Sobi, Inc. respects the privacy of every individual who visits http://www.sobi-northamerica.com (the "Web Site"). This Privacy Policy outlines the information Sobi, Inc. will collect and how we will use that information.

PERSONALLY IDENTIFIABLE INFORMATION

There may be cases where Sobi, Inc. will ask you for personally-identifiable information such as your name, mailing address, and email address. For example, we may request personally-identifiable information when you participate in a survey, contest, or other service that requires registration or subscription. Sobi, Inc. will not collect any personally-identifiable information about you unless you provide it to us voluntarily.

When you view the website, we may store some information on your computer. This information will be in the form of a "cookie" or similar file and will help us to offer increased personalization and functionality. With most internet browsers, you can erase cookies from your computer hard drive, block all cookies, or receive a warning before a cookie is stored. Please refer to your browser instructions or help screen to learn more about these functions.

Except as stated in this Privacy Policy, or as otherwise stated at the time personally-identifiable information is gathered, we will not provide personally-identifiable information to third parties who are not under the direction and control of Sobi, Inc..

CHILDREN

The Web Site is not directed at individuals under thirteen years of age, and Sobi, Inc. does not intend to collect any personally-identifiable information from such individuals, unless otherwise stated at the time such information is collected.

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Sobi, Inc. may also automatically collect non-personally-identifiable information about your use of the Web Site, such as the domain from which you access the Internet (for example, aol.com, if you are connecting from an America Online account), the date and time you access the Web Site, and the Internet address of the website from which you linked directly to our Web Site. This information will not be linked to personally-identifiable information. Sobi, Inc. may use this information to analyze and enhance the Web Site and may aggregate this information and share such aggregated information with business partners, sponsors and other third parties.

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The Web Site may allow links to various other web sites. Sobi, Inc. assumes no responsibility for the information practices of sites you are able to access through the Web Site. These links to other sites do not imply affiliation or endorsement of a linked site.

SECURITY

The importance of security for all personally-identifiable information associated with visitors to the Web Site is of utmost concern to us. Unfortunately, no data transmission over the Internet can be guaranteed to be secure. As a result, Sobi, Inc. cannot ensure or warrant the security of any information you transmit to us, and you do so at your own risk. Once we receive your personally-identifiable information, we will take reasonable efforts to ensure its security on our systems.

YOUR ACCEPTANCE OF THESE TERMS

By using the Web Site, you signify your assent to the Sobi, Inc. Privacy Policy. If you do not agree to this Policy, please do not use the Web Site. Your continued use of the Web Site following the posting of changes to these terms will mean you accept those changes. Sobi, Inc. will, however, use personally-identifiable information only in accordance with the version of the Privacy Policy under which the information was collected.

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Not Required for Submission

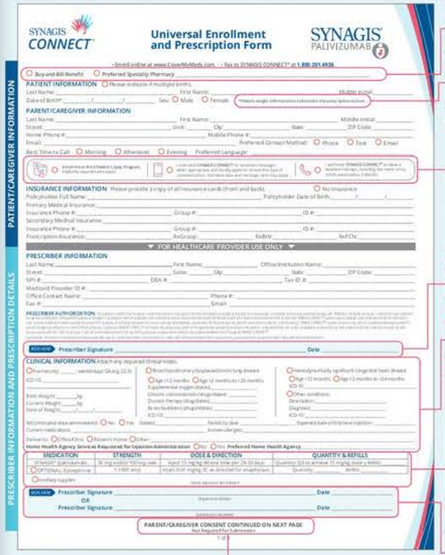
SYNAGIS® PALIVIZUMAB

Information to Help Complete the Universal Enrollment and Prescription Form

The Universal Enrollment and Prescription Form acts as both a prescription for SYNAGIS® (palivizumab) and consent to enroll in SYNAGIS CONNECT®, Sobi's patient support program. This can be completed as a paper form and faxed to SYNAGIS CONNECT® or to the preferred specialty pharmacy, or it can be completed electronically through the CoverMyMeds® portal.

If SYNAGIS CONNECT® has previously received an Authorization for the Transition of Care and Parent/Caregiver Consent form for your patient from the neonatal intensive care unit, your office will be provided a partially completed version of this form via fax or CoverMyMeds® if your office uses the CoverMyMeds® portal.

Make sure all fields are complete before sending the form back to SYNAGIS CONNECT® or to the preferred specialty pharmacy.


SYNAGIS CONNECT®

Universal Enrollment and Prescription Form

SYNAGIS® PALIVIZUMAB

PATIENT/CAREGIVER INFORMATION

PRESCRIBER INFORMATION AND PRESCRIPTION DETAILS

PATIENT INFORMATION

PARENT/CAREGIVER INFORMATION

INSURANCE INFORMATION

FOR HEALTHCARE PROVIDER USE ONLY

PRESCRIBER INFORMATION

PRESCRIBER AUTHORIZATION

CLINICAL INFORMATION

MEDICATION | STRENGTH | DOSE & DIRECTION | QUANTITY & REFILLS

PARENT/CAREGIVER CONSENT CONTINUED ON NEXT PAGE

Healthcare professionals can select Buy-and-Bill or Preferred Specialty Pharmacy.

Patient weight will be documented toward the bottom of this page for prescribed dosage under Clinical Information.

Parents/caregivers can choose to fill in the red circles to consent to

- Enroll in the Copay Program, if eligible
- Receive text messages from SYNAGIS CONNECT®
- Receive detailed voice messages from SYNAGIS CONNECT®

If any option is chosen, both signatures for consent are **required** on page 2.

A second signature from the prescriber is required to consent to the Prescriber Authorization.

The Clinical Information section includes details pertaining to diagnosis and a reminder to attach clinical documentation.

- The Prescription section covers either strength of SYNAGIS at QS to achieve the 15 mg/kg dose
- Prescription for epinephrine is optional
- The prescriber can choose to fill in the red circle to include ancillary supplies as needed for administration, such as syringes, with the prescription
- The prescriber can determine dosage strength based on the patient's weight

Prescriber signature required for **either** Dispense as Written **or** Substitution Permitted. Stamp signatures are not allowed.

All attempts should be made to obtain parent/caregiver consent on page 2. If the parent/caregiver cannot be reached, this page can be sent separately and SYNAGIS CONNECT® will reach out to the parent/caregiver to obtain consent.

SYNAGIS® PALIVIZUMAB

Information to Help Complete the Universal Enrollment and Prescription Form

The Authorization to Share Health Information and Consent for Enrollment in SYNAGIS CONNECT® must **each** be signed in order for SYNAGIS CONNECT® to provide services.

If necessary, this page can be omitted from initial submission if attempts to connect with the patient's parent/caregiver fail. If parent/caregiver is not available to sign, SYNAGIS CONNECT® will reach out to obtain parent/caregiver consent.

SYNAGIS CONNECT

SYNAGIS® PALIVIZUMAB

Patient Last Name: _____ First Name: _____ Date of Birth: _____

AUTHORIZATION TO SHARE HEALTH INFORMATION:

By signing below, I authorize my child's healthcare providers and staff, pharmacies, and health insurers to use and to disclose to Sobi, Inc., and its affiliates, business partners, vendors, and other agents (collectively, "Sobi") health information about my child related to my child's medical condition and treatment, health insurance and coverage claims, and prescription (including fill/refill information) for SYNAGIS ("Information") to: (1) enroll my child in and provide services under the SYNAGIS CONNECT® patient support program (the "Program"); (2) obtain information on my child's insurance coverage; (3) coordinate prescription fulfillment as indicated by my child's physician; (4) provide me with adherence reminders and support; and (5) contact me to conduct market research and to arrange for my receipt of educational, promotional, and/or marketing materials about Sobi support programs or Sobi products. Once my child's Information has been disclosed to Sobi, I understand that federal privacy laws may no longer protect it from further disclosure. However, I also understand that Sobi will protect my child's Information by using and disclosing it only for the purposes allowed by me in this Authorization or as otherwise required by law.

I understand and agree that the pharmacy that dispenses SYNAGIS may receive payment from Sobi in exchange for disclosing my child's Information to Sobi and providing Program services.

I understand that I do not have to sign this Authorization. A decision by me not to sign this Authorization will not affect my child's ability to obtain medical treatment from healthcare providers, payment for treatment or eligibility for health insurance benefits, or access to Sobi medications. However, if I do not sign this Authorization, I understand my child will not be able to participate in the Program.

I understand that this Authorization expires (2) two years from the date signed below, or earlier if required by state or local law, unless and until I cancel (take back) this Authorization before then. I may change my mind and cancel this Authorization at any time by calling 1-833-SYNAGIS (1-833-796-2447) or by notifying Sobi in writing at SYNAGIS CONNECT, PO Box 29079, Phoenix, AZ 85038-9079. Cancellation of this Authorization will end further uses and disclosures of my child's Information by my child's healthcare provider and staff, pharmacies and health insurers based on this Authorization, and my child's participation in the Program when they receive notice of my cancellation, but will not affect any uses or disclosures of my child's Information made by my child's healthcare providers and staff, pharmacies, and health insurers based on this Authorization before receipt of the cancellation.

CONSENT FOR ENROLLMENT IN SYNAGIS CONNECT®

By signing below, I am enrolling in SYNAGIS CONNECT® (the "Program"), a customer Sobi, Inc., and its affiliates, business partners, vendors, and other agents (collectively, "business partners" and together with Sobi, Inc., "Sobi") to provide me and my child with services for which we are eligible under the Program. Such services may include medication and adherence communications and support, medication dispensing support, insurance coverage and financial assistance support, disease and medication education, and other support services offered now or in the future. As part of the Program offerings, I agree to enrollment in the copay assistance program if I am eligible.

- ○ I consent to receive autodialed and prerecorded marketing calls and text messages from Sobi, and companies working with Sobi, at the telephone number(s) that I provide. I understand that my consent is not required as a condition of purchasing or receiving any goods or services from Sobi. I understand that I may revoke this Authorization and choose not to receive automated marketing calls and text messages from Sobi at any time by calling 1-833-SYNAGIS (1-833-796-2447) or by notifying Sobi in writing at PO Box 29079, Phoenix, AZ 85038-9079.
- ○ I understand and consent to SYNAGIS CONNECT® providing me via email or cell phone using the contact information provided in this form to provide me with dosing reminders. SYNAGIS CONNECT® may also use my information for market research or to evaluate and improve the company's services and programs. I understand that I may stop SYNAGIS CONNECT® from contacting me at any time by clicking the "Unsubscribe" link at the bottom of the emails I receive from SYNAGIS CONNECT®. I may also opt out at any time by replying "STOP" to the text messages I receive. I understand that SYNAGIS CONNECT® and companies providing services to SYNAGIS CONNECT® will not sell or rent my personally identifiable information. For more information about Sobi Terms and Conditions, including privacy practices, please read our Terms and Conditions by visiting https://sobi-northamerica.com/terms-and-conditions/. Please review our Privacy Policy on the next page.

CONSENT FOR AUTHORIZATION TO SHARE HEALTH INFORMATION:

Full name (printed) of parent/caregiver: _____

SIGN HERE Signature of Parent/Caregiver _____ Date _____

CONSENT FOR ENROLLMENT SYNAGIS CONNECT®:

Full name (printed) of parent/caregiver: _____

SIGN HERE Signature of Parent/Caregiver _____ Date _____

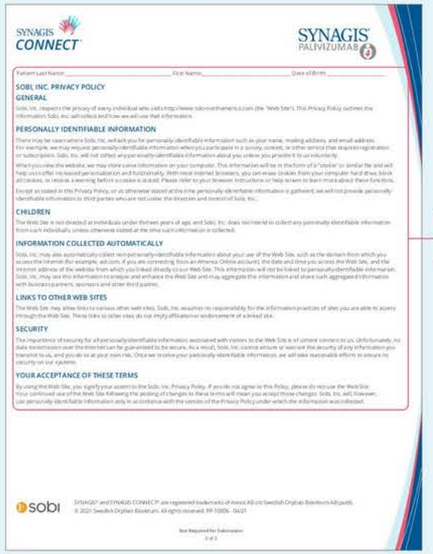
3 of 3

Patient name and date of birth must be on each page.

Parents/caregivers can choose to fill in the red circles to consent to receive marketing calls and text messages from SYNAGIS CONNECT®.

SYNAGIS® PALIVIZUMAB

Information to Help Complete the Universal Enrollment and Prescription Form



SYNAGIS CONNECT

SYNAGIS® PALIVIZUMAB

Patient Last Name: _____ First Name: _____ Date of Birth: _____

SOBI, INC. PRIVACY POLICY

GENERAL

Sobi, Inc. respects the privacy of every individual who visits http://www.sobi-northamerica.com (the "Web Site"). This Privacy Policy outlines the information Sobi, Inc. will collect and how we will use that information.

PERSONALLY IDENTIFIABLE INFORMATION

There may be cases where Sobi, Inc. will ask you for personally identifiable information such as your name, mailing address, and email address. For example, we may request personally identifiable information when you participate in a survey, contest, or other service that requires registration or subscription. Sobi, Inc. will not collect any personally identifiable information about you unless you provide it to us voluntarily.

While you view the website, we may store some information on your computer. This information will be in the form of a "cookie" or similar file and will help us to offer increased personalization and functionality. With most Internet browsers, you can erase cookies from your computer hard drive, block all cookies, or receive a warning before a cookie is stored. Please refer to your browser instructions or help screen to learn more about these functions.

Except as stated in this Privacy Policy, or as otherwise stated at the time personally identifiable information is gathered, we will not provide personally identifiable information to third parties who are not under the direction and control of Sobi, Inc..

CHILDREN

The Web Site is not directed at individuals under thirteen years of age, and Sobi, Inc. does not intend to collect any personally identifiable information from such individuals, unless otherwise stated at the time such information is collected.

INFORMATION COLLECTED AUTOMATICALLY

Sobi, Inc. may also automatically collect non-personally identifiable information about your use of the Web Site, such as the domain from which you access the Internet (for example, aol.com, if you are connecting from an America Online account), the date and time you access the Web Site, and the Internet address of the website from which you linked directly to our Web Site. This information will not be linked to personally identifiable information. Sobi, Inc. may use this information to analyze and enhance the Web Site and may aggregate the information and share such aggregated information with business partners, sponsors and other third parties.

LINKS TO OTHER WEB SITES

The Web Site may allow links to various other web sites. Sobi, Inc. assumes no responsibility for the information practices of sites you are able to access through the Web Site. These links to other sites do not imply affiliation or endorsement of a linked site.

SECURITY

The importance of security for all personally identifiable information associated with visitors to the Web Site is of utmost concern to us. Unfortunately, no data transmission over the Internet can be guaranteed to be secure. As a result, Sobi, Inc. cannot ensure or warrant the security of any information you transmit to us, and you do so at your own risk. Once we receive your personally identifiable information, we will take reasonable efforts to ensure its security on our systems.

YOUR ACCEPTANCE OF THESE TERMS

By using the Web Site, you signify your assent to the Sobi, Inc. Privacy Policy. If you do not agree to this Policy, please do not use the Web Site. Your continued use of the Web Site following the posting of changes to these terms will mean you accept those changes. Sobi, Inc. will, however, use personally identifiable information only in accordance with the version of the Privacy Policy under which the information was collected.

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Not Required for Submission

2 of 3

This page explains the Sobi, Inc., Privacy Policy. It is for your reference only and does not need to be returned to the prescriber or to SYNAGIS CONNECT®.

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SYNAGIS®
PALIVIZUMAB

SYNAGIS Limited Distribution Specialty Pharmacy Network

Order SYNAGIS by calling or faxing prescriptions to these specialty pharmacies.

AcariaHealth
1-855-422-2742
1-877-252-2444

Accredo
1-877-482-5927
1-877-369-3447

Advanced Pharmacy Solutions
1-800-464-7736 (option 3)
1-949-582-6111

AllianceRx Walgreens Prime
1-888-282-5166
1-855-569-2511

Amber Specialty Pharmacy
1-888-370-1724
1-402-896-3774

Avella Specialty Pharmacy
1-877-546-5779
1-877-546-5780

CVS Specialty Pharmacy
1-800-237-2767
1-800-323-2445

Diplomat Specialty Pharmacy
1-888-293-9309 (option 1)
1-866-391-1890

Duncan Specialty Pharmacy
1-270-247-3725
1-270-247-6033

Elixir Specialty Pharmacy
1-877-437-9012
1-877-309-0687

Exactus Pharmacy Solutions
1-866-458-9246
1-866-458-9245

Humana Specialty
1-800-486-2668
1-877-405-7940

Hy-Vee Pharmacy Solutions
1-877-794-9833
1-402-861-4941

Lumicera Health Services
1-855-847-3554
1-855-847-3558

Magellan Rx Pharmacy
1-866-554-2673
1-800-327-4561

Optum Specialty Pharmacy
1-888-293-9309 (option 1)
1-866-391-1890

PerformSpecialty
1-855-287-7888
1-844-489-9565

US Bioservices
1-877-842-4604
1-877-872-4606

Vital Care Rx
1-877-229-1724
1-877-229-1725

Walmart Specialty Pharmacy
1-877-453-4566
1-866-537-0877

In Puerto Rico

Optima Health
1-787-883-5959
1-787-883-6042

Special Care Pharmacy Services
1-787-781-4585
1-787-783-2951

SYNAGIS CONNECT™

SYNAGIS CONNECT™ can answer questions and provide support in understanding our specialty pharmacy network. Call **1-833-SYNAGIS (1-833-796-2447),** Monday through Friday 8 AM to 8 PM EST, to speak to a representative or visit **SYNAGISHCP.com** for additional resources.

For more information about SYNAGIS, including full Prescribing Information, please visit SYNAGIS.com.

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SYNAGIS® PALIVIZUMAB

Coding Resource

SYNAGIS® (palivizumab) is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.[1]

This resource lists codes that may be useful for billing and reimbursement for SYNAGIS. It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring that all coding is accurate and documented in the medical record based on the condition of the patient. The use of the following codes does not guarantee reimbursement.

National Drug Code (NDC)[1]

10-digit NDC

Dosage	Code
50-mg vial	66658-230-1
100-mg vial	66658-231-1

11-digit NDC

Dosage	Code
50-mg vial	66658-230-01
100-mg vial	66658-231-01

Current Procedural Terminology® (CPT)[2]

	Code	Description
Supply and administration of RSV immunoprophylaxis	90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each
	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

Healthcare Common Procedure Coding System (HCPCS)[3]

Code	Description
S9562	Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

INDICATION

SYNAGIS® (palivizumab), 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 4 and accompanying full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

Diagnosis Codes[1,4-6]

● Label Guidance ● AAP Guidance ● NPA Guidelines

PREMATURITY (≤35 WEEKS GA)

ICD-10-CM	Description	ICD-10-CM	Description
P07.21	Extreme immaturity of newborn, GA <23 completed weeks	P07.32	Preterm newborn, GA 29 completed weeks
P07.22	Extreme immaturity of newborn, GA 23 completed weeks	P07.33	Preterm newborn, GA 30 completed weeks
P07.23	Extreme immaturity of newborn, GA 24 completed weeks	P07.34	Preterm newborn, GA 31 completed weeks
P07.24	Extreme immaturity of newborn, GA 25 completed weeks	P07.35	Preterm newborn, GA 32 completed weeks
P07.25	Extreme immaturity of newborn, GA 26 completed weeks	P07.36	Preterm newborn, GA 33 completed weeks*
P07.26	Extreme immaturity of newborn, GA 27 completed weeks	P07.37	Preterm newborn, GA 34 completed weeks*
P07.31	Preterm newborn, GA 28 completed weeks	P07.38	Preterm newborn, GA 35 completed weeks*

BRONCHOPULMONARY DYSPLASIA/CHRONIC LUNG DISEASE OF PREMATURITY

ICD-10-CM	Description
P27.1	Bronchopulmonary dysplasia originating in the perinatal period
P27.8	Other chronic respiratory diseases originating in the perinatal period
P27.9	Unspecified chronic respiratory disease originating in the perinatal period

HEMODYNAMICALLY SIGNIFICANT CONGENITAL HEART DISEASE

ICD-10-CM	Description	ICD-10-CM	Description
I42.9	Cardiomyopathy, unspecified	Q20.8	Other congenital malformations of cardiac chambers and connections
I50.9	Heart failure, unspecified	Q20.9	Congenital malformation of cardiac chambers and connections, unspecified
P29.30	Pulmonary hypertension of newborn	Q21.0	Ventricular septal defect
Q20.0	Common arterial trunk	Q21.1	Atrial septal defect
Q20.1	Double outlet right ventricle	Q21.2	Atrioventricular septal defect
Q20.2	Double outlet left ventricle	Q21.3	Tetralogy of Fallot
Q20.3	Discordant ventriculoarterial connection	Q21.4	Aortopulmonary septal defect
Q20.4	Double inlet ventricle	Q21.8	Other congenital malformations of cardiac septa
Q20.5	Discordant atrioventricular connection	Q21.9	Congenital malformation of cardiac septum, unspecified
Q20.6	Isomerism of atrial appendages	Q22.0	Pulmonary valve atresia

AAP=American Academy of Pediatrics; GA=gestational age; ICD-10-CM=*International Classification of Diseases, 10th Revision, Clinical Modification*; NPA=National Perinatal Association.

*NPA guidelines recommend SYNAGIS for patients with additional provider-identified risk factors.

Please see Important Safety Information on pages 1 and 4 and accompanying full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

Diagnosis Codes (cont'd)

● Label Guidance ● AAP Guidance ● NPA Guidelines

HEMODYNAMICALLY SIGNIFICANT CONGENITAL HEART DISEASE (cont'd)[1,4-6]

ICD-10-CM	Description	ICD-10-CM	Description
Q22.1	Congenital pulmonary valve stenosis	Q25.3	Supravalvular aortic stenosis
Q22.2	Congenital pulmonary valve insufficiency	Q25.40	Congenital malformation of aorta unspecified
Q22.3	Other congenital malformations of pulmonary valve	Q25.41	Absence and aplasia of aorta
Q22.4	Congenital tricuspid stenosis	Q25.42	Hypoplasia of aorta
Q22.5	Ebstein's anomaly	Q25.43	Congenital aneurysm of aorta
Q22.6	Hypoplastic right heart syndrome	Q25.44	Congenital dilation of aorta
Q22.8	Other congenital malformations of tricuspid valve	Q25.45	Double aortic arch
Q22.9	Congenital malformation of tricuspid valve, unspecified	Q25.46	Tortuous aortic arch
Q23.0	Congenital stenosis of aortic valve	Q25.47	Right aortic arch
Q23.1	Congenital insufficiency of aortic valve	Q25.48	Anomalous origin of subclavian artery
Q23.2	Congenital mitral stenosis	Q25.49	Other congenital malformations of aorta
Q23.3	Congenital mitral insufficiency	Q25.5	Atresia of pulmonary artery
Q23.4	Hypoplastic left heart syndrome	Q25.6	Stenosis of pulmonary artery
Q23.8	Other congenital malformations of aortic and mitral valves	Q25.71	Coarctation of pulmonary artery
Q24.1	Levocardia	Q25.72	Congenital pulmonary arteriovenous malformation
Q24.2	Cor triatriatum	Q25.79	Other congenital malformations of pulmonary artery
Q24.3	Pulmonary infundibular stenosis	Q25.8	Other congenital malformations of other great arteries
Q24.4	Congenital subaortic stenosis	Q25.9	Congenital malformation of great arteries, unspecified
Q24.5	Malformation of coronary vessels	Q26.0	Congenital stenosis of vena cava
Q24.6	Congenital heart block	Q26.1	Persistent left superior vena cava
Q24.8	Other specified congenital malformations of heart	Q26.2	Total anomalous pulmonary venous connection
Q25.0	Patent ductus arteriosus	Q26.3	Partial anomalous pulmonary venous connection
Q25.1	Coarctation of aorta	Q26.4	Anomalous pulmonary venous connection, unspecified
Q25.21	Interruption of aortic arch	Q26.8	Other congenital malformations of great veins
Q25.29	Other atresia of aorta	Q26.9	Congenital malformation of great vein, unspecified

PATIENT HISTORY[4]

ICD-10-CM	Description
Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)

Please see Important Safety Information on pages 1 and 4 and accompanying full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

IMPORTANT SAFETY INFORMATION (cont'd)

- 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 see additional Important Safety Information on page 1 and accompanying full Prescribing Information for SYNAGIS, including Patient Information.

You are encouraged to report suspected adverse reactions to the FDA by visiting www.FDA.gov/medwatch or calling 1-800-FDA-1088.

SYNAGIS CONNECT®

For more information, call **SYNAGIS CONNECT®** at **1-833-SYNAGIS (1-833-796-2447)**, Monday through Friday 8 AM to 8 PM EST, or visit **SYNAGISHCP.com** for additional resources.

References: 1. SYNAGIS [prescribing information]. Waltham, MA: Sobi, Inc. **2.** American Medical Association. *CPT® 2020 Professional Edition*. Chicago, IL: American Medical Association; 2020. **3.** Alpha-numeric HCPCS. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS. Accessed May 28, 2020. **4.** 2020 ICD-10-CM. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM. Accessed May 28, 2020. **5.** 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. **6.** Goldstein M, Phillips R, DeVincenzo JP, et al. National Perinatal Association 2018 Respiratory Syncytial Virus (RSV) Prevention Clinical Practice Guideline: an evidence-based interdisciplinary collaboration. *Neonatology Today*. 2017;12(10):1-14.

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SYNAGIS® PALIVIZUMAB

SYNAGIS Parent/Caregiver Consent Form

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 the patient and their caregiver to take advantage of this program, consent/authorization must be obtained.

Parent/caregiver should complete this form legibly and sign it. All completed forms should be faxed to 1-800-201-4938.

PATIENT INFORMATION

Last Name:_____ First Name:_____ Middle Initial:_____

Date of Birth:_____ SYNAGIS CONNECT® Hub ID (if known):_____

PARENT/CAREGIVER INFORMATION

Last Name:_____ First Name:_____ Middle Initial:_____

Street:_____ Unit:_____ City:_____ State:_____ ZIP Code:_____

Home Phone #:_____ Mobile Phone #:_____

Email:_____ Preferred Contact Method: ○ Phone ○ Text ○ Email

Best Time to Call: ○ Morning ○ Afternoon ○ Evening Preferred Language:_____

○ **Enroll me in the SYNAGIS Copay Program.** Eligibility requirements apply.

○ I authorize **SYNAGIS CONNECT®** to send text messages when appropriate and hereby agree to receive this type of communication. Standard data and message rates may apply.

○ I authorize **SYNAGIS CONNECT®** to leave a detailed message, including the name of my child's prescription, SYNAGIS.

PRESCRIBER INFORMATION

Primary Care Provider/Specialist Name:_____

Street:_____ Suite:_____ City:_____ State:_____ ZIP Code:_____

Phone #:_____ Fax #:_____

AUTHORIZATION TO SHARE HEALTH INFORMATION:

By signing below, I authorize my child's healthcare providers and staff, pharmacies, and health insurers to use and to disclose to Sobi, Inc., and its affiliates, business partners, vendors, and other agents (collectively, "Sobi") health information about my child related to my child's medical condition and treatment, health insurance and coverage claims, and prescription (including fill/refill information) for SYNAGIS ("Information") to (1) enroll my child in and provide services under the SYNAGIS CONNECT® patient support program (the "Program"); (2) obtain information on my child's insurance coverage; (3) coordinate prescription fulfillment as indicated by my child's physician; (4) provide me with adherence reminders and support; and (5) contact me to conduct market research and to arrange for my receipt of educational, promotional, and/or marketing materials about Sobi support programs or Sobi products. Once my child's Information has been disclosed to Sobi, I understand that federal privacy laws may no longer protect it from further disclosure. However, I also understand that Sobi will protect my child's Information by using and disclosing it only for the purposes allowed by me in this Authorization or as otherwise required by law.

I understand and agree that the pharmacy that dispenses SYNAGIS may receive payment from Sobi in exchange for disclosing my child's Information to Sobi and providing Program services.

I understand that I do not have to sign this Authorization. A decision by me not to sign this Authorization will not affect my child's ability to obtain medical treatment from healthcare providers, payment for treatment or eligibility for health insurance benefits, or access to Sobi medications. However, if I do not sign this Authorization, I understand my child will not be able to participate in the Program.

I understand that this Authorization expires (2) two years from the date signed below, or earlier if required by state or local law, unless and until I cancel (take back) this Authorization before then. I may change my mind and cancel this Authorization at any time by calling 1-833-SYNAGIS (1-833-796-2447) or by notifying Sobi in writing at SYNAGIS CONNECT, PO Box 29076, Phoenix, AZ 850 38-9076. Cancellation of this Authorization will end further uses and disclosures of my child's Information by my child's healthcare provider and staff, pharmacies, and health insurers based on this Authorization, and my child's participation in the Program when they receive notice of my cancellation, but will not affect any uses or disclosure of my child's Information made by my child's healthcare providers and staff, pharmacies, and health insurers based on this Authorization before receipt of the cancellation.

Full name (printed) of parent/caregiver _____

SIGN HERE **Signature of Parent/Caregiver** _____ **Date** _____

1 of 2

SYNAGIS® PALIVIZUMAB

Consent for Enrollment in SYNAGIS CONNECT®

SYNAGIS CONNECT®

Patient Last Name: _____ First Name: _____ Date of Birth: _____

CONSENT FOR ENROLLMENT IN SYNAGIS CONNECT®:

By signing below, I am enrolling in SYNAGIS CONNECT® (the "Program"). I authorize Sobi, Inc., and its affiliates, business partners, vendors, and other agents (collectively, "business partners" and together with Sobi, Inc., "Sobi") to provide me and my child with services for which we are eligible under the Program. Such services may include medication and adherence communications and support, medication dispensing support, insurance coverage and financial-assistance support, disease and medication education, and other support services offered now or in the future. As part of the Program offerings, I agree to enrollment in the copay assistance program if I am eligible.

- ○ I consent to receive autodialed and prerecorded marketing calls and text messages from Sobi, and companies working with Sobi, at the telephone number(s) that I provide. I understand that my consent is not required as a condition of purchasing or receiving any goods or services from Sobi. I understand that I may revoke this Authorization and choose not to receive automated marketing calls and text messages from Sobi at any time by calling 1-833-SYNAGIS (1-833-796-2447) or by notifying Sobi in writing at: PO Box 29076, Phoenix, AZ 85038-9076.
- ○ I understand and consent to SYNAGIS CONNECT® contacting me via email or cell phone using the contact information provided in this form to provide me with dosing reminders. SYNAGIS CONNECT® may also use my information for market research or to evaluate and improve the company's services and programs. I understand that I may stop SYNAGIS CONNECT® from contacting me at any time by clicking the "Unsubscribe" link at the bottom of the emails I receive from SYNAGIS CONNECT®. I may also opt out at any time by replying "STOP" to the text messages I receive. I understand that SYNAGIS CONNECT® and companies providing services to SYNAGIS CONNECT® will not sell or rent my personally-identifiable information. For more information about Sobi Terms and Conditions, please visit https://sobi-northamerica.com/terms-and-conditions. Please review our Privacy Policy below.

Full name (printed) of parent/caregiver _____

SIGN HERE Signature of Parent/Caregiver _____ Date _____

SOBI, INC., SITE PRIVACY POLICY

GENERAL

Sobi, Inc. respects the privacy of every individual who visits http://www.sobi-northamerica.com (the "Web Site"). This Privacy Policy outlines the information Sobi, Inc. will collect and how we will use that information.

PERSONALLY IDENTIFIABLE INFORMATION

There may be cases where Sobi, Inc. will ask you for personally-identifiable information such as your name, mailing address, and email address. For example, we may request personally-identifiable information when you participate in a survey, contest, or other service that requires registration or subscription. Sobi, Inc. will not collect any personally-identifiable information about you unless you provide it to us voluntarily.

When you view the website, we may store some information on your computer. This information will be in the form of a "cookie" or similar file and will help us to offer increased personalization and functionality. With most internet browsers, you can erase cookies from your computer hard drive, block all cookies, or receive a warning before a cookie is stored. Please refer to your browser instructions or help screen to learn more about these functions.

Except as stated in this Privacy Policy, or as otherwise stated at the time personally-identifiable information is gathered, we will not provide personally-identifiable information to third parties who are not under the direction and control of Sobi, Inc..

CHILDREN

The Web Site is not directed at individuals under thirteen years of age, and Sobi, Inc. does not intend to collect any personally-identifiable information from such individuals, unless otherwise stated at the time such information is collected.

INFORMATION COLLECTED AUTOMATICALLY

Sobi, Inc. may also automatically collect non-personally-identifiable information about your use of the Web Site, such as the domain from which you access the Internet (for example, aol.com, if you are connecting from an America Online account), the date and time you access the Web Site, and the Internet address of the website from which you linked directly to our Web Site. This information will not be linked to personally-identifiable information. Sobi, Inc. may use this information to analyze and enhance the Web Site and may aggregate this information and share such aggregated information with business partners, sponsors and other third parties.

LINKS TO OTHER WEB SITES

The Web Site may allow links to various other web sites. Sobi, Inc. assumes no responsibility for the information practices of sites you are able to access through the Web Site. These links to other sites do not imply affiliation or endorsement of a linked site.

SECURITY

The importance of security for all personally-identifiable information associated with visitors to the Web Site is of utmost concern to us. Unfortunately, no data transmission over the Internet can be guaranteed to be secure. As a result, Sobi, Inc. cannot ensure or warrant the security of any information you transmit to us, and you do so at your own risk. Once we receive your personally-identifiable information, we will take reasonable efforts to ensure its security on our systems.

YOUR ACCEPTANCE OF THESE TERMS

By using the Web Site, you signify your assent to the Sobi, Inc. Privacy Policy. If you do not agree to this Policy, please do not use the Web Site. Your continued use of the Web Site following the posting of changes to these terms will mean you accept those changes. Sobi, Inc. will use personally-identifiable information only in accordance with the version of the Privacy Policy under which the information was collected.

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SYNAGIS® PALIVIZUMAB

SYNAGIS Copay Program

For Eligible Commercially Insured Individuals

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

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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.

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How the SYNAGIS Copay Program Works

- If you have an out-of-pocket cost for SYNAGIS and you meet the other program eligibility requirements, follow the steps below to enroll in the SYNAGIS Copay Program

Sign up for the Copay Program on SynagisHCP.com

Enroll in the Copay Program through www.CoverMyMeds.com

Talk to someone at your specialty pharmacy who can enroll you in the Copay Program

- Your prescriber's office, specialty pharmacy, or home healthcare will use this program to cover your out-of-pocket costs for SYNAGIS up to **$6,000** per SYNAGIS season (7/1-6/30)

Terms of Use

Limitations apply. Valid only for those with private insurance. The program includes the copay card or payment card (if applicable) with a combined annual limit of $6,000. Patient is responsible for any costs once the dollar limit is reached during the program term (July-June) calendar year. Program is not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, or (iii) where the patient's insurance plan reimburses the entire cost of the drug. The value of the program is exclusively for the benefit of patients and is not intended to be credited toward patient out-of-pocket obligations and maximums, including applicable copayments, coinsurance and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or healthcare savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the program. Valid only in the United States and Puerto Rico. This program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Sobi, Inc., reserves the right to rescind, revoke, or amend the program and discontinue support at any time without notice.

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

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 the patient and their caregiver to take advantage of this program, consent/authorization must be obtained.

SYNAGIS CONNECT™ representatives can answer questions related to
- Identifying prescription coverage
- Out-of-pocket costs
- Patient Assistance Program (for eligible patients)

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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

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.

How is SYNAGIS given?

SYNAGIS is given as a monthly injection, usually in the thigh (leg) muscle, by your child's healthcare provider. If your child has a problem with bleeding or bruises easily, an injection could cause a problem. Your child should receive their first injection of SYNAGIS before the RSV season starts, to help protect them before RSV becomes active. RSV season is usually fall through spring, but it may begin earlier or last longer in certain areas. When RSV is most active, your child will need to receive injections of SYNAGIS every 28-30 days to help protect them from severe RSV disease for about a month. Your child should continue to receive monthly injections of SYNAGIS until the end of RSV season. Your child may still get severe RSV disease after receiving SYNAGIS. If your child has an RSV infection, they should continue to get their monthly injections throughout the RSV season to help prevent severe disease from new RSV infections.

The effectiveness of injections of SYNAGIS given less than monthly throughout the RSV season has not been established.

What are the possible side effects of SYNAGIS?

Serious side effects include severe allergic reactions, which may happen after any injection of SYNAGIS and may be life-threatening or cause death. Call your child's healthcare provider or get medical help right away if your child has any of the signs or symptoms of a serious allergic reaction. See "Who should not receive SYNAGIS?" for more information.

Common side effects of SYNAGIS include fever and rash.

These are not all the possible side effects of SYNAGIS.

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

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

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SYNAGIS® PALIVIZUMAB

SYNAGIS® PALIVIZUMAB

2021-2022 Dosing Calendar | Every 28 Days[1,*]

Use this calendar to help schedule dosing and office appointments for your patients.

How to use 28-day dosing:

- Locate initial dosing date on calendar
- Move 1 box ***down*** (This will be 28 days later)
- Continue scheduling by moving ***down*** the same column

Key:

- Federal Holidays in 2021-2022
- Weekends in 2021-2022

TH	F	S	SU	M	T	W	TH	F	S	SU	M	T	W	TH	F	S	SU	M	T	W	TH	F	S	SU	M	T	W
1 JUL	2 JUL	3 JUL	4 JUL	5 JUL	6 JUL	7 JUL	8 JUL	9 JUL	10 JUL	11 JUL	12 JUL	13 JUL	14 JUL	15 JUL	16 JUL	17 JUL	18 JUL	19 JUL	20 JUL	21 JUL	22 JUL	23 JUL	24 JUL	25 JUL	26 JUL	27 JUL	28 JUL
29 JUL	30 JUL	31 JUL	1 AUG	2 AUG	3 AUG	4 AUG	5 AUG	6 AUG	7 AUG	8 AUG	9 AUG	10 AUG	11 AUG	12 AUG	13 AUG	14 AUG	15 AUG	16 AUG	17 AUG	18 AUG	19 AUG	20 AUG	21 AUG	22 AUG	23 AUG	24 AUG	25 AUG
26 AUG	27 AUG	28 AUG	29 AUG	30 AUG	31 AUG	1 SEP	2 SEP	3 SEP	4 SEP	5 SEP	6 SEP	7 SEP	8 SEP	9 SEP	10 SEP	11 SEP	12 SEP	13 SEP	14 SEP	15 SEP	16 SEP	17 SEP	18 SEP	19 SEP	20 SEP	21 SEP	22 SEP
23 SEP	24 SEP	25 SEP	26 SEP	27 SEP	28 SEP	29 SEP	30 SEP	1 OCT	2 OCT	3 OCT	4 OCT	5 OCT	6 OCT	7 OCT	8 OCT	9 OCT	10 OCT	11 OCT	12 OCT	13 OCT	14 OCT	15 OCT	16 OCT	17 OCT	18 OCT	19 OCT	20 OCT
21 OCT	22 OCT	23 OCT	24 OCT	25 OCT	26 OCT	27 OCT	28 OCT	29 OCT	30 OCT	31 OCT	1 NOV	2 NOV	3 NOV	4 NOV	5 NOV	6 NOV	7 NOV	8 NOV	9 NOV	10 NOV	11 NOV	12 NOV	13 NOV	14 NOV	15 NOV	16 NOV	17 NOV
18 NOV	19 NOV	20 NOV	21 NOV	22 NOV	23 NOV	24 NOV	25 NOV	26 NOV	27 NOV	28 NOV	29 NOV	30 NOV	1 DEC	2 DEC	3 DEC	4 DEC	5 DEC	6 DEC	7 DEC	8 DEC	9 DEC	10 DEC	11 DEC	12 DEC	13 DEC	14 DEC	15 DEC
16 DEC	17 DEC	18 DEC	19 DEC	20 DEC	21 DEC	22 DEC	23 DEC	24 DEC	25 DEC	26 DEC	27 DEC	28 DEC	29 DEC	30 DEC	31 DEC	1 JAN	2 JAN	3 JAN	4 JAN	5 JAN	6 JAN	7 JAN	8 JAN	9 JAN	10 JAN	11 JAN	12 JAN
13 JAN	14 JAN	15 JAN	16 JAN	17 JAN	18 JAN	19 JAN	20 JAN	21 JAN	22 JAN	23 JAN	24 JAN	25 JAN	26 JAN	27 JAN	28 JAN	29 JAN	30 JAN	31 JAN	1 FEB	2 FEB	3 FEB	4 FEB	5 FEB	6 FEB	7 FEB	8 FEB	9 FEB
10 FEB	11 FEB	12 FEB	13 FEB	14 FEB	15 FEB	16 FEB	17 FEB	18 FEB	19 FEB	20 FEB	21 FEB	22 FEB	23 FEB	24 FEB	25 FEB	26 FEB	27 FEB	28 FEB	1 MAR	2 MAR	3 MAR	4 MAR	5 MAR	6 MAR	7 MAR	8 MAR	9 MAR
10 MAR	11 MAR	12 MAR	13 MAR	14 MAR	15 MAR	16 MAR	17 MAR	18 MAR	19 MAR	20 MAR	21 MAR	22 MAR	23 MAR	24 MAR	25 MAR	26 MAR	27 MAR	28 MAR	29 MAR	30 MAR	31 MAR	1 APR	2 APR	3 APR	4 APR	5 APR	6 APR
7 APR	8 APR	9 APR	10 APR	11 APR	12 APR	13 APR	14 APR	15 APR	16 APR	17 APR	18 APR	19 APR	20 APR	21 APR	22 APR	23 APR	24 APR	25 APR	26 APR	27 APR	28 APR	29 APR	30 APR	1 MAY	2 MAY	3 MAY	4 MAY
5 MAY	6 MAY	7 MAY	8 MAY	9 MAY	10 MAY	11 MAY	12 MAY	13 MAY	14 MAY	15 MAY	16 MAY	17 MAY	18 MAY	19 MAY	20 MAY	21 MAY	22 MAY	23 MAY	24 MAY	25 MAY	26 MAY	27 MAY	28 MAY	29 MAY	30 MAY	31 MAY	1 JUN
2 JUN	3 JUN	4 JUN	5 JUN	6 JUN	7 JUN	8 JUN	9 JUN	10 JUN	11 JUN	12 JUN	13 JUN	14 JUN	15 JUN	16 JUN	17 JUN	18 JUN	19 JUN	20 JUN	21 JUN	22 JUN	23 JUN	24 JUN	25 JUN	26 JUN	27 JUN	28 JUN	29 JUN
30 JUN	1 JUL	2 JUL	3 JUL	4 JUL	5 JUL	6 JUL	7 JUL	8 JUL	9 JUL	10 JUL	11 JUL	12 JUL	13 JUL	14 JUL	15 JUL	16 JUL	17 JUL	18 JUL	19 JUL	20 JUL	21 JUL	22 JUL	23 JUL	24 JUL	25 JUL	26 JUL	27 JUL

*Patients should receive SYNAGIS® (palivizumab) every 28 to 30 days throughout the RSV season. This calendar has been provided as a guide only and is not intended to be a substitute for or an influence on the independent medical judgment of the healthcare professional.

INDICATION

SYNAGIS® (palivizumab), 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 throughout. Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

Dosing Calendar | Every 30 Days[1,*]

Use this calendar to help schedule dosing and office appointments for your patients.

How to use 30-day dosing:

- Locate initial dosing date on calendar
- Move 1 box ***down*** and 2 boxes to the ***right*** (This will be 30 days later)
- Continue scheduling by moving 1 box ***down*** and 2 boxes to the ***right***

Key:

- Federal Holidays in 2021-2022
- Weekends in 2021-2022

TH	F	S	SU	M	T	W	TH	F	S	SU	M	T	W	TH	F	S	SU	M	T	W	TH	F	S	SU	M	T	W
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29 JUL	30 JUL	31 JUL	1 AUG	2 AUG	3 AUG	4 AUG	5 AUG	6 AUG	7 AUG	8 AUG	9 AUG	10 AUG	11 AUG	12 AUG	13 AUG	14 AUG	15 AUG	16 AUG	17 AUG	18 AUG	19 AUG	20 AUG	21 AUG	22 AUG	23 AUG	24 AUG	25 AUG
26 AUG	27 AUG	28 AUG	29 AUG	30 AUG	31 AUG	1 SEP	2 SEP	3 SEP	4 SEP	5 SEP	6 SEP	7 SEP	8 SEP	9 SEP	10 SEP	11 SEP	12 SEP	13 SEP	14 SEP	15 SEP	16 SEP	17 SEP	18 SEP	19 SEP	20 SEP	21 SEP	22 SEP
23 SEP	24 SEP	25 SEP	26 SEP	27 SEP	28 SEP	29 SEP	30 SEP	1 OCT	2 OCT	3 OCT	4 OCT	5 OCT	6 OCT	7 OCT	8 OCT	9 OCT	10 OCT	11 OCT	12 OCT	13 OCT	14 OCT	15 OCT	16 OCT	17 OCT	18 OCT	19 OCT	20 OCT
21 OCT	22 OCT	23 OCT	24 OCT	25 OCT	26 OCT	27 OCT	28 OCT	29 OCT	30 OCT	31 OCT	1 NOV	2 NOV	3 NOV	4 NOV	5 NOV	6 NOV	7 NOV	8 NOV	9 NOV	10 NOV	11 NOV	12 NOV	13 NOV	14 NOV	15 NOV	16 NOV	17 NOV
18 NOV	19 NOV	20 NOV	21 NOV	22 NOV	23 NOV	24 NOV	25 NOV	26 NOV	27 NOV	28 NOV	29 NOV	30 NOV	1 DEC	2 DEC	3 DEC	4 DEC	5 DEC	6 DEC	7 DEC	8 DEC	9 DEC	10 DEC	11 DEC	12 DEC	13 DEC	14 DEC	15 DEC
16 DEC	17 DEC	18 DEC	19 DEC	20 DEC	21 DEC	22 DEC	23 DEC	24 DEC	25 DEC	26 DEC	27 DEC	28 DEC	29 DEC	30 DEC	31 DEC	1 JAN	2 JAN	3 JAN	4 JAN	5 JAN	6 JAN	7 JAN	8 JAN	9 JAN	10 JAN	11 JAN	12 JAN
13 JAN	14 JAN	15 JAN	16 JAN	17 JAN	18 JAN	19 JAN	20 JAN	21 JAN	22 JAN	23 JAN	24 JAN	25 JAN	26 JAN	27 JAN	28 JAN	29 JAN	30 JAN	31 JAN	1 FEB	2 FEB	3 FEB	4 FEB	5 FEB	6 FEB	7 FEB	8 FEB	9 FEB
10 FEB	11 FEB	12 FEB	13 FEB	14 FEB	15 FEB	16 FEB	17 FEB	18 FEB	19 FEB	20 FEB	21 FEB	22 FEB	23 FEB	24 FEB	25 FEB	26 FEB	27 FEB	28 FEB	1 MAR	2 MAR	3 MAR	4 MAR	5 MAR	6 MAR	7 MAR	8 MAR	9 MAR
10 MAR	11 MAR	12 MAR	13 MAR	14 MAR	15 MAR	16 MAR	17 MAR	18 MAR	19 MAR	20 MAR	21 MAR	22 MAR	23 MAR	24 MAR	25 MAR	26 MAR	27 MAR	28 MAR	29 MAR	30 MAR	31 MAR	1 APR	2 APR	3 APR	4 APR	5 APR	6 APR
7 APR	8 APR	9 APR	10 APR	11 APR	12 APR	13 APR	14 APR	15 APR	16 APR	17 APR	18 APR	19 APR	20 APR	21 APR	22 APR	23 APR	24 APR	25 APR	26 APR	27 APR	28 APR	29 APR	30 APR	1 MAY	2 MAY	3 MAY	4 MAY
5 MAY	6 MAY	7 MAY	8 MAY	9 MAY	10 MAY	11 MAY	12 MAY	13 MAY	14 MAY	15 MAY	16 MAY	17 MAY	18 MAY	19 MAY	20 MAY	21 MAY	22 MAY	23 MAY	24 MAY	25 MAY	26 MAY	27 MAY	28 MAY	29 MAY	30 MAY	31 MAY	1 JUN
2 JUN	3 JUN	4 JUN	5 JUN	6 JUN	7 JUN	8 JUN	9 JUN	10 JUN	11 JUN	12 JUN	13 JUN	14 JUN	15 JUN	16 JUN	17 JUN	18 JUN	19 JUN	20 JUN	21 JUN	22 JUN	23 JUN	24 JUN	25 JUN	26 JUN	27 JUN	28 JUN	29 JUN
30 JUN	1 JUL	2 JUL	3 JUL	4 JUL	5 JUL	6 JUL	7 JUL	8 JUL	9 JUL	10 JUL	11 JUL	12 JUL	13 JUL	14 JUL	15 JUL	16 JUL	17 JUL	18 JUL	19 JUL	20 JUL	21 JUL	22 JUL	23 JUL	24 JUL	25 JUL	26 JUL	27 JUL

*Patients should receive SYNAGIS® (palivizumab) every 28 to 30 days throughout the RSV season. This calendar has been provided as a guide only and is not intended to be a substitute for or an influence on the independent medical judgment of the healthcare professional.

IMPORTANT SAFETY INFORMATION (Cont'd)

- 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 additional Important Safety Information on the reverse side. Click here for full Prescribing Information for SYNAGIS, including Patient Information.

Reference: 1. SYNAGIS [prescribing information]. Waltham, MA: Sobi, Inc.

Colorado prescriber, please click here for more information.

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SYNAGIS® PALIVIZUMAB

Dosing Guide

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

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 3. Click here for full Prescribing Information for SYNAGIS, including Patient Information.

How Supplied

SYNAGIS® (palivizumab) is supplied as a liquid formulation for intramuscular (IM) injection.[1]

- Single-use vials
- Preservative-free
- Sterile solution
- 50-mg/0.5-mL box and vial have pink stripe
- 100-mg/1-mL box and vial have blue stripe

Storage[1]

Upon receipt and until use, SYNAGIS should be stored between 2°C and 8°C (36°F and 46°F) in its original container. DO NOT freeze. DO NOT use beyond the expiration date.

Preparation[1]

- Using aseptic techniques, attach a sterile needle to a sterile syringe
- Remove the flip top from the vial and clean the rubber stopper with 70% isopropyl alcohol or equivalent
- **DO NOT dilute the product**
- **DO NOT shake vial**
- Using the needle, withdraw the appropriate volume of SYNAGIS for your patient
- SYNAGIS does not contain a preservative and should be administered immediately after withdrawal from vial
- SYNAGIS is supplied in single-use vials. DO NOT re-enter the vial. Discard any unused portion

For additional information and a helpful dosing calculator, visit SYNAGIS.com.

Please see Important Safety Information on pages 1 and 3. Click here for full Prescribing Information for SYNAGIS, including Patient Information.

Administration[1]

SYNAGIS® (palivizumab) should be administered in a dose of 15 mg/kg via IM injection using aseptic technique, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve.

Preferred location for injection

Once administered, notify the specialty pharmacy to initiate refill process for next dose, if needed.

IMPORTANT SAFETY INFORMATION

- 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

LIMITATIONS OF USE

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

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

Dosing[1]

The recommended dose of SYNAGIS® (palivizumab) is 15 mg/kg of body weight given monthly by IM 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.

Dosing Table[1,*]

To calculate the dose per month, multiply the patient weight (in kg) by 15 mg/kg and divide by 100 mg/mL (1.0 kg=2.20462262 lb). Injection volume over 1 mL should be given as a divided dose.

(Patient weight (kg) x 15 mg/kg) ÷ 100 mg/mL

Patient weight	Dose per month	Patient weight	Dose per month
1.2 kg (2 lb, 10 oz)	0.18 mL	5.8 kg (12 lb, 13 oz)	0.87 mL
1.4 kg (3 lb, 1 oz)	0.21 mL	6.0 kg (13 lb, 4 oz)	0.90 mL
1.6 kg (3 lb, 8 oz)	0.24 mL	6.2 kg (13 lb, 11 oz)	0.93 mL
1.8 kg (3 lb, 15 oz)	0.27 mL	6.4 kg (14 lb, 2 oz)	0.96 mL
2.0 kg (4 lb, 7 oz)	0.30 mL	6.6 kg (14 lb, 9 oz)	0.99 mL
2.2 kg (4 lb, 14 oz)	0.33 mL	6.8 kg (15 lb, 0 oz)	1.02 mL
2.4 kg (5 lb, 5 oz)	0.36 mL	7.0 kg (15 lb, 7 oz)	1.05 mL
2.6 kg (5 lb, 12 oz)	0.39 mL	7.2 kg (15 lb, 14 oz)	1.08 mL
2.8 kg (6 lb, 3 oz)	0.42 mL	7.4 kg (16 lb, 5 oz)	1.11 mL
3.0 kg (6 lb, 10 oz)	0.45 mL	7.6 kg (16 lb, 12 oz)	1.14 mL
3.2 kg (7 lb, 1 oz)	0.48 mL	7.8 kg (17 lb, 3 oz)	1.17 mL
3.4 kg (7 lb, 8 oz)	0.51 mL	8.0 kg (17 lb, 10 oz)	1.20 mL
3.6 kg (7 lb, 15 oz)	0.54 mL	8.2 kg (18 lb, 1 oz)	1.23 mL
3.8 kg (8 lb, 6 oz)	0.57 mL	8.4 kg (18 lb, 8 oz)	1.26 mL
4.0 kg (8 lb, 13 oz)	0.60 mL	8.6 kg (18 lb, 15 oz)	1.29 mL
4.2 kg (9 lb, 4 oz)	0.63 mL	8.8 kg (19 lb, 6 oz)	1.32 mL
4.4 kg (9 lb, 11 oz)	0.66 mL	9.0 kg (19 lb, 13 oz)	1.35 mL
4.6 kg (10 lb, 2 oz)	0.69 mL	9.2 kg (20 lb, 5 oz)	1.38 mL
4.8 kg (10 lb, 9 oz)	0.72 mL	9.4 kg (20 lb, 12 oz)	1.41 mL
5.0 kg (11 lb, 0 oz)	0.75 mL	9.6 kg (21 lb, 3 oz)	1.44 mL
5.2 kg (11 lb, 7 oz)	0.78 mL	9.8 kg (21 lb, 10 oz)	1.47 mL
5.4 kg (11 lb, 14 oz)	0.81 mL	10.0 kg (22 lb, 1 oz)	1.50 mL
5.6 kg (12 lb, 6 oz)	0.84 mL	10.2 kg (22 lb, 8 oz)	1.53 mL

*Information here has been provided as a guide only and is not intended to be a substitute for or an influence on the independent judgment of the healthcare professional.

Please see Important Safety Information on pages 1 and 3. Click here for full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS® PALIVIZUMAB

SYNAGIS CONNECT®

SYNAGIS CONNECT® is a free program created by Sobi to provide individualized support to help 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 the patient and their caregiver to take advantage of this program, consent/authorization must be obtained.

SYNAGIS CONNECT® representatives can answer questions related to

- Insurance verification
- Identifying prescription coverage
- Claims and appeal process support
- Patient out-of-pocket costs
- Affordability programs (based on eligibility)

SYNAGIS CONNECT®

Call SYNAGIS CONNECT® at 1-833-SYNAGIS (1-833-796-2447) for more information or visit SYNAGIS.com for additional resources.

Please see Important Safety Information on pages 1 and 3. Click here for full Prescribing Information for SYNAGIS, including Patient Information.

Reference: 1. SYNAGIS [prescribing information]. Waltham, MA: Sobi, Inc.

Colorado prescriber, please click here for more information.

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PP-8593

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SYNAGIS safely and effectively. See full prescribing information for SYNAGIS.

SYNAGIS® (palivizumab) injection , for intramuscular use
Initial U.S. Approval: 1998

----------INDICATIONS AND USAGE----------

Synagis is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody 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 (less than or equal to 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. (1)

----------DOSAGE AND ADMINISTRATION----------

15 mg per kg of body weight, administered intramuscularly prior to commencement of the RSV season and remaining doses administered monthly throughout the RSV season. (2.1)

Children undergoing cardio-pulmonary bypass should receive an additional dose of Synagis as soon as possible after the cardio-pulmonary bypass procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled. (2.1, 12.3)

----------DOSAGE FORMS AND STRENGTHS----------

Single-dose liquid solution vials: 50 mg per 0.5 mL and 100 mg per 1 mL. (3)

----------CONTRAINDICATIONS----------

Previous significant hypersensitivity reaction to Synagis. (4)

----------WARNINGS AND PRECAUTIONS----------

- Anaphylaxis and anaphylactic shock (including fatal cases), and other severe acute hypersensitivity reactions have been reported. Permanently discontinue Synagis and administer appropriate medications if such reactions occur. (5.1)
- As with any intramuscular injection, Synagis should be given with caution to children with thrombocytopenia or any coagulation disorder. (5.2)
- Palivizumab may interfere with immunological-based RSV diagnostic tests such as some antigen detection-based assays. (5.3, 12.4)

----------ADVERSE REACTIONS----------

Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact 1866-773-5274 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------USE IN SPECIFIC POPULATIONS----------

Safety and effectiveness in children older than 24 months of age at the start of dosing have not been established. (8.4)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 11/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Synagis 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 (less than or equal to 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 *[see Clinical Studies (14)]*.

Limitations of Use:

The safety and efficacy of Synagis have not been established for treatment of RSV disease *[see Warnings and Precautions (5.4)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Information

The recommended dose of Synagis is 15 mg per 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. In the northern hemisphere, the RSV season typically commences in November and lasts through April, but it may begin earlier or persist later in certain communities.

Synagis serum levels are decreased after cardio-pulmonary bypass *[see Clinical Pharmacology (12.3)]*. Children undergoing cardio-pulmonary bypass should receive an additional dose of Synagis as soon as possible after the cardio-pulmonary bypass procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled.

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

2.2 Administration Instructions

- **DO NOT DILUTE THE PRODUCT.**
- **DO NOT SHAKE OR VIGOROUSLY AGITATE THE VIAL.**
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use any vials exhibiting particulate matter or discoloration.
- Using aseptic techniques, attach a sterile needle to a sterile syringe. Remove the flip top from the Synagis vial and wipe the rubber stopper with a disinfectant (e.g., 70% isopropyl alcohol). Insert the needle into the vial and withdraw into the syringe an appropriate volume of solution. Administer immediately after drawing the dose into the syringe.

- Synagis should be administered in a dose of 15 mg per kg intramuscularly using aseptic technique, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve. The dose (volume of injection in mL) per month = patient weight (kg) x 15 mg per kg ÷ 100 mg per mL of Synagis. Injection volumes over 1 mL should be given as a divided dose.
- Synagis is supplied as a single-dose vial and does not contain preservatives. Do not re-enter the vial after withdrawal of drug; discard unused portion. Only administer one dose per vial.
- Use sterile disposable syringes and needles. To prevent the transmission of hepatitis viruses or other infectious agents from one person to another, DO NOT reuse syringes and needles.

3 DOSAGE FORMS AND STRENGTHS

Single-dose liquid solution vials: 50 mg per 0.5 mL and 100 mg per 1 mL.

4 CONTRAINDICATIONS

Synagis is contraindicated in children who have had a previous significant hypersensitivity reaction to Synagis *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

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. Signs and symptoms may include urticaria, pruritus, angioedema, dyspnea, respiratory failure, cyanosis, hypotonia, hypotension, and unresponsiveness. 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 anaphylaxis or other significant hypersensitivity reaction occurs, administer appropriate medications (e.g., epinephrine) and provide supportive care as required. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of Synagis.

5.2 Coagulation Disorders

Synagis is for intramuscular use only. As with any intramuscular injection, Synagis should be given with caution to children with thrombocytopenia or any coagulation disorder.

5.3 RSV Diagnostic Test Interference

Palivizumab may interfere with immunological-based RSV diagnostic tests such as some antigen detection-based assays. In addition, palivizumab inhibits virus replication in cell culture, and therefore may also interfere with viral culture assays. Palivizumab does not interfere with reverse transcriptase-polymerase chain reaction based assays. Assay interference could lead to false-negative RSV diagnostic test results. Therefore, diagnostic test results, when obtained, should be used in conjunction with clinical findings to guide medical decisions *[see Microbiology (12.4)]*.

5.4 Treatment of RSV Disease

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

5.5 Proper Administration

The single-dose vial of Synagis does not contain a preservative. Administration of Synagis should occur immediately after dose withdrawal from the vial. The vial should not be re-entered. Discard any unused portion.

6 ADVERSE REACTIONS

The most serious adverse reactions occurring with Synagis are anaphylaxis and other acute hypersensitivity reactions *[see Warnings and Precautions (5.1)]*.

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to Synagis (n=1639) compared with placebo (n=1143) in children 3 days to 24.1 months of age at high risk of RSV-related hospitalization in two clinical trials. Trial 1 was conducted during a single RSV season and studied a total of 1502 children less than or equal to 24 months of age with BPD or infants with premature birth (less than or equal to 35 weeks gestation) who were less than or equal to 6 months of age at study entry. Trial 2 was conducted over four consecutive seasons among a total of 1287 children less than or equal to 24 months of age with hemodynamically significant congenital heart disease.

In Trials 1 and 2 combined, fever and rash were each reported more frequently among Synagis than placebo recipients, 27% versus 25%, and 12% versus 10%, respectively. Adverse reactions observed in the 153-patient crossover study comparing the liquid and lyophilized formulations were comparable for the two formulations, and were similar to those observed with Synagis in Trials 1 and 2.

Immunogenicity

In Trial 1, the incidence of anti-palivizumab antibody following the fourth injection was 1.1% in the placebo group and 0.7% in the Synagis group. In children receiving Synagis for a second season, one of the fifty-six children had transient, low titer reactivity. This reactivity was not associated with adverse events or alteration in serum concentrations. Immunogenicity was not assessed in Trial 2.

A trial of high-risk preterm children less than or equal to 24 months of age was conducted to evaluate the immunogenicity of the lyophilized formulation of Synagis (used in Trials 1 and 2 above) and the liquid formulation of Synagis. Three hundred seventy-nine children contributed to the 4 to 6 months post-final dose analysis. The rate of anti-palivizumab antibodies at this time point was low in both formulation groups (anti-palivizumab antibodies were not detected in any subject in the liquid formulation group and were detected in one subject in the lyophilized group (0.5%), with an overall rate of 0.3% for both treatment groups combined).

These data reflect the percentage of children whose test results were considered positive for antibodies to palivizumab in an enzyme-linked immunosorbent assay (ELISA) and are highly dependent on the sensitivity and specificity of the assay.

The ELISA has substantial limitations in detecting anti-palivizumab antibodies in the presence of palivizumab. Immunogenicity samples tested with the ELISA assay likely contained palivizumab at levels that may interfere with the detection of anti-palivizumab antibodies.

An electrochemical luminescence (ECL) based immunogenicity assay, with a higher tolerance for palivizumab presence compared to the ELISA, was used to evaluate the presence of anti-palivizumab antibodies in subject samples from two additional clinical trials. The rates of anti-palivizumab antibody positive results in these trials were 1.1% and 1.5%.

6.2 Postmarketing Experience

The following adverse 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.

Blood and Lymphatic System Disorders: severe thrombocytopenia (platelet count less than 50,000 per microliter)

General Disorders and Administration Site Conditions: injection site reactions

Limited information from post-marketing reports suggests that, within a single RSV season, adverse events after a sixth or greater dose of Synagis are similar in character and frequency to those after the initial five doses.

7 DRUG INTERACTIONS

No formal drug-drug interaction studies were conducted. In Trial 1, the proportions of children in the placebo and Synagis groups who received routine childhood vaccines, influenza vaccine, bronchodilators, or corticosteroids were similar and no incremental increase in adverse reactions was observed among children receiving these agents.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Synagis is not indicated for use in females of reproductive potential.

8.2 Lactation

Risk Summary

Synagis is not indicated for use in females of reproductive potential.

8.4 Pediatric Use

The safety and effectiveness of Synagis in children older than 24 months of age at the start of dosing have not been established *[see Clinical Studies (14)]*.

10 OVERDOSAGE

Overdoses with doses up to 85 mg per kg have been reported in clinical studies and post-marketing experience with Synagis, and in some cases, adverse reactions were reported. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment instituted.

11 DESCRIPTION

Palivizumab is a humanized monoclonal antibody ($IgG1\kappa$) produced by recombinant DNA technology, directed to an epitope in the A antigenic site of the F protein of RSV. Palivizumab is a composite of human (95%) and murine (5%) antibody sequences. The human heavy chain sequence was derived from the constant domains of human IgG1 and the variable framework regions of the V_H genes Cor and Cess. The human light chain sequence was derived from the constant domain of C_K and the variable framework regions of the V_L gene K104 with J_K -4. The murine sequences were derived from a murine monoclonal antibody, Mab 1129, in a process that involved the grafting of the murine complementarity determining regions into the human antibody frameworks. Palivizumab is composed of two heavy chains and two light chains and has a molecular weight of approximately 148,000 Daltons.

Synagis is supplied as a sterile, preservative-free liquid solution at 100 mg per mL to be administered by intramuscular injection. Thimerosal or other mercury-containing salts are not used in the production of Synagis. The solution has a pH of 6.0 and should appear clear or slightly opalescent.

Each 100 mg single-dose vial of Synagis liquid solution contains 100 mg of palivizumab and also contains chloride (0.5 mg), glycine (0.1 mg), and histidine (3.9 mg), in a volume of 1 mL.

Each 50 mg single-dose vial of Synagis liquid solution contains 50 mg of palivizumab and also contains chloride (0.2 mg), glycine (0.06 mg), and histidine (1.9 mg), in a volume of 0.5 mL.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Palivizumab is a recombinant humanized monoclonal antibody with anti-RSV activity *[see Microbiology (12.4)]*.

12.3 Pharmacokinetics

In children less than or equal to 24 months of age without congenital heart disease (CHD), the mean half-life of palivizumab was 20 days and monthly intramuscular doses of 15 mg per kg achieved mean ± SD 30 day trough serum drug concentrations of 37 ± 21 mcg per mL after the first injection, 57 ± 41 mcg per mL after the second injection, 68 ± 51 mcg per mL after the third injection, and 72 ± 50 mcg per mL after the fourth injection. Trough concentrations following the first and fourth Synagis dose were similar in children with CHD and in non-cardiac patients. In children given Synagis for a second season, the mean ± SD serum concentrations following the first and fourth injections were 61 ± 17 mcg per mL and 86 ± 31 mcg per mL, respectively.

In 139 children less than or equal to 24 months of age with hemodynamically significant CHD who received Synagis and underwent cardio-pulmonary bypass for open-heart surgery, the mean ± SD serum palivizumab concentration was 98 ± 52 mcg per mL before bypass and declined to 41 ± 33 mcg per mL after bypass, a reduction of 58% *[see Dosage and Administration (2.1)]*. The clinical significance of this reduction is unknown.

Specific studies were not conducted to evaluate the effects of demographic parameters on palivizumab systemic exposure. However, no effects of gender, age, body weight, or race on palivizumab serum trough concentrations were observed in a clinical study with 639 children with CHD (less than or equal to 24 months of age) receiving five monthly intramuscular injections of 15 mg per kg of Synagis.

The pharmacokinetics and safety of Synagis liquid solution and Synagis lyophilized formulation administered via intramuscular injection at 15 mg per kg were studied in a cross-over trial of 153 infants less than or equal to 6 months of age with a history of prematurity. The results of this trial indicated that the trough serum concentrations of palivizumab were comparable between the liquid solution and the lyophilized formulation, which was the formulation used in the clinical studies.

A population pharmacokinetic analysis was performed across 22 studies in 1800 patients (1684 pediatric and 116 adult patients) to characterize palivizumab pharmacokinetics and inter-subject variability in serum concentrations. Palivizumab pharmacokinetics was described by a two-compartment linear model with an elimination half-life of 24.5 days in pediatric patients. Clearance of palivizumab in a typical pediatric patient (body weight 4.5 kg) less than or equal to 24 months of age without CHD was estimated to be 11 mL per day with a bioavailability of 70% following intramuscular administration. The inter-patient variability in drug clearance was 48.7% (CV%). Covariate analysis did not identify any factors that could account for the inter-patient variability in order to predict serum concentrations a priori in an individual patient.

12.4 Microbiology

Mechanism of Action

Palivizumab, a recombinant humanized monoclonal antibody which provides passive immunity against RSV, acts by binding the RSV envelope fusion protein (RSV F) on the surface of the virus and blocking a critical step in the membrane fusion process. Palivizumab also prevents cell-to-cell fusion of RSV-infected cells.

Antiviral Activity

The antiviral activity of palivizumab was assessed in a microneutralization assay in which increasing concentrations of antibody were incubated with RSV prior to addition of the human epithelial cells HEp-2. After incubation for 4-5 days, RSV antigen was measured in an ELISA assay. The neutralization titer (50% effective concentration [EC_{50}]) is expressed as the antibody concentration required to reduce detection of RSV antigen by 50% compared with untreated virus-infected cells. Palivizumab exhibited median EC_{50} values of 0.65 mcg per mL (mean 0.75 ± 0.53 mcg per mL; n=69, range 0.07-2.89 mcg per mL) and 0.28 mcg per mL (mean 0.35 ± 0.23 mcg per mL; n=35, range 0.03-0.88 mcg per mL) against clinical RSV A and RSV B isolates, respectively. The majority of clinical RSV isolates tested (n=96) were collected from subjects across the United States (CA, CO, CT, IL, MA, NC, NY, PA, RI, TN, TX, VA), with the remainder from Japan (n=1), Australia (n=5) and Israel (n=2). These isolates encoded the most common RSV F sequence polymorphisms found among clinical isolates worldwide.

Palivizumab serum concentrations of greater than or equal to 40 mcg per mL have been shown to reduce pulmonary RSV replication in the cotton rat model of RSV infection by 100-fold.

Resistance

Palivizumab binds a highly conserved region on the extracellular domain of mature RSV F, referred to as antigenic site II or site A, which encompasses amino acids 262 to 275. All RSV mutants that exhibit resistance to palivizumab have been shown to contain amino acid changes in this region on the F protein.

F protein sequence variations within antigenic site A: Amino acid substitutions in antigenic site A selected either in cell culture, in animal models, or in human subjects that resulted in palivizumab resistance were N262D, N268I, K272E/M/N/Q/T, and S275F/L. RSV variants expressing the K272N substitution in F protein showed a 5164 ± 1731-fold decrease in susceptibility (i.e., fold increase in EC_{50} value) when compared to the wild-type RSV, while variants containing the N262D, S275F/L, or K272E/M/Q/T substitutions showed a greater than 25,000-fold decrease in susceptibility to palivizumab. The N268I substitution conferred partial resistance to palivizumab; however, fold changes in susceptibility were not quantified for this mutant. Studies carried out to investigate the mechanism of virus escape from palivizumab showed a correlation between antibody binding and virus neutralization. RSV with substitutions in antigenic site A that were resistant to neutralization by palivizumab did not bind to palivizumab.

At least one of the palivizumab resistance-associated substitutions, N262D, K272E/Q, or S275F/L was identified in 8 of 126 clinical RSV (59 RSV A and 67 RSV B) isolates from subjects who failed immunoprophylaxis, resulting in a combined resistance-associated mutation frequency of 6.3%. A review of clinical findings revealed no association between antigenic A site sequence changes and RSV disease severity among children receiving palivizumab immunoprophylaxis who develop RSV lower respiratory tract disease.

Analysis of 254 clinical RSV isolates (145 RSV A and 109 RSV B) collected from immunoprophylaxis-naive subjects revealed palivizumab resistance-associated substitutions in 2 (1 with N262D and 1 with S275F), resulting in a resistance-associated mutation frequency of 0.79%.

F protein sequence variations outside antigenic site A: In addition to the sequence variations in antigenic site A known to confer palivizumab resistance, F protein substitutions T100A, G139S, N165D/H/Q/I, T326A, V450A in RSV A, and T74I, A147V, I206L, S285G, V450I, T455I in RSV B were identified in viruses isolated from failures of immunoprophylaxis. These substitutions were not identified in RSV F sequences derived from 254 clinical isolates from immunoprophylaxis-naïve subjects and thus are considered treatment-associated and non-polymorphic. Recombinant RSV B encoding the S285G substitution exhibited palivizumab sensitivity (EC_{50} value = 0.39 ± 0.02 mcg per mL) similar to recombinant wild-type RSV B (EC_{50} value = 0.17 ± 0.02 mcg per mL).

Palivizumab susceptibility of RSV encoding common F protein sequence polymorphisms located proximal to antigenic site A was evaluated. Recombinant RSV A encoding N276S (EC_{50} value = 0.72 ± 0.07 mcg per mL), and recombinant RSV B with S276N (EC_{50} value = 0.42 ± 0.04 mcg per mL), exhibited sensitivities comparable to the corresponding recombinant wild-type RSV A (EC_{50} value = 0.63 ± 0.22 mcg per mL) and RSV B (EC_{50} value = 0.23 ± 0.07 mcg per mL). Likewise, RSV B clinical isolates containing the polymorphic variation V276A were at least as sensitive to neutralization by palivizumab (EC_{50} range 0.08-0.45 mcg per mL) as laboratory strains of wild-type RSV B (EC_{50} value = 0.54 ± 0.08 mcg per mL). No known polymorphic or non-polymorphic sequence variations outside the antigenic site A on RSV F have been demonstrated to render RSV resistant to neutralization by palivizumab.

Interference of RSV Diagnostic Assays by Palivizumab

Interference with immunologically-based RSV diagnostic assays by palivizumab has been observed in laboratory studies. Rapid chromatographic/enzyme immunoassays (CIA/EIA), immunofluorescence assays (IFA), and direct immunofluorescence assays (DFA) using monoclonal antibodies targeting RSV F protein may be inhibited. Therefore, caution should be used in interpreting negative immunological assay results when clinical observations are consistent with RSV infection. A reverse transcriptase-polymerase chain reaction (RT-PCR) assay, which is not inhibited by palivizumab, may prove useful for laboratory confirmation of RSV infection *[see Warnings and Precautions (5.3)]*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis, mutagenesis, and reproductive toxicity studies have not been performed.

14 CLINICAL STUDIES

The safety and efficacy of Synagis were assessed in two randomized, double-blind, placebo-controlled trials of prophylaxis against RSV infection in children at high risk of an RSV-related hospitalization. Trial 1 was conducted during a single RSV season and studied a total of 1502 children less than or equal to 24 months of age with BPD or infants with premature birth (less than or equal to 35 weeks gestation) who were less than or equal to 6 months of age at study entry. Trial 2 was conducted over four consecutive seasons among a total of 1287 children less than or equal to 24 months of age with hemodynamically significant congenital heart disease. In both trials participants received 15 mg per kg Synagis or an equivalent volume of placebo via intramuscular injection monthly for five injections and were followed for 150 days from randomization. In Trial 1, 99% of all subjects completed the study and 93% completed all five injections. In Trial 2, 96% of all subjects completed the study and 92% completed all five injections. The incidence of RSV hospitalization is shown in Table 1. The results were shown to be statistically significant using Fisher's exact test.

Table 1: Incidence of RSV Hospitalization by Treatment Group

Trial		Placebo	Synagis	Difference Between Groups	Relative Reduction
Trial 1 Impact-RSV	N	500	1002		
	Hospitalization	53 (10.6%)	48 (4.8%)	5.8%	55%
Trial 2 CHD	N	648	639		
	Hospitalization	63 (9.7%)	34 (5.3%)	4.4%	45%

In Trial 1, the reduction of RSV hospitalization was observed both in children with BPD (34/266 [12.8%] placebo versus 39/496 [7.9%] Synagis) and in premature infants without BPD (19/234 [8.1%] placebo versus 9/506 [1.8%] Synagis). In Trial 2, reductions were observed in acyanotic (36/205 [11.8%] placebo versus 15/300 [5.0%] Synagis) and cyanotic children (27/343 [7.9%] placebo versus 19/339 [5.6%] Synagis).

The clinical studies do not suggest that RSV infection was less severe among children hospitalized with RSV infection who received Synagis for RSV prophylaxis compared to those who received placebo.

16 HOW SUPPLIED/STORAGE AND HANDLING

Synagis is supplied in single-dose vials as a preservative-free, sterile liquid solution at 100 mg per mL for intramuscular injection.

50 mg vial NDC 66658-230-01
The 50 mg vial contains 50 mg Synagis in 0.5 mL.

100 mg vial NDC 66658-231-01
The 100 mg vial contains 100 mg Synagis in 1 mL.

The rubber stopper used for sealing vials of Synagis is not made with natural rubber latex.

Storage

Upon receipt and until use, Synagis should be stored between 2°C and 8°C (36°F and 46°F) in its original container. DO NOT freeze. DO NOT use beyond the expiration date.

17 PATIENT COUNSELING INFORMATION

Advise the patient's caregiver to read the FDA-approved patient labeling (Patient Information)

Hypersensitivity Reactions

Inform the patient's caregiver of the signs and symptoms of potential hypersensitivity reactions, and advise the caregiver to seek medical attention immediately if the child experiences a severe hypersensitivity reaction to Synagis *[see Contraindications (4) and Warnings and Precautions (5.1)]*.

Administration

Advise the patient's caregiver that Synagis should be administered by a healthcare provider once a month during the RSV season by intramuscular injection and the importance of compliance with the full course of therapy *[see Dosage and Administration (2)]*.

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Swedish Orphan Biovitrum AB (publ)
Stockholm, Sweden

Distributed by:
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PATIENT INFORMATION
SYNAGIS® (Si-na-jis)
(palivizumab)
injection

What is SYNAGIS?

SYNAGIS 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.

SYNAGIS contains man-made, disease-fighting proteins called antibodies.

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.

It is not known if SYNAGIS is safe and effective in children who are older than 24 months of age at the start of dosing.

Who should not receive SYNAGIS?

Your child should not receive SYNAGIS if they have ever had a severe allergic reaction to it. See the end of this leaflet for a complete list of ingredients in SYNAGIS. Signs and symptoms of a severe allergic reaction could include:

- severe rash, hives, or itching skin
- swelling of the lips, tongue, or face
- swelling of the throat, difficulty swallowing
- difficult, rapid, or irregular breathing
- bluish color of skin, lips, or under fingernails
- muscle weakness or floppiness
- unresponsiveness

Before your child receives SYNAGIS, tell your healthcare provider about all of your child's medical conditions, including if your child:

- has ever had a reaction to SYNAGIS.
- has bleeding or bruising problems. SYNAGIS is given by injection. If your child has a problem with bleeding or bruises easily, an injection could cause a problem.

Tell your child's healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How is SYNAGIS given?

- SYNAGIS is given as a monthly injection, usually in the thigh (leg) muscle, by your child's healthcare provider.
- Your child's healthcare provider will give you detailed instructions on when SYNAGIS will be given.
  - "RSV season" is the time of year when RSV infections most commonly happen, usually fall through spring, but it may begin earlier or last longer in certain areas. During this time, when RSV is most active, your child will need to receive SYNAGIS injections. Your healthcare provider can tell you when the RSV season starts in your area.
  - **Your child should receive the first SYNAGIS injection before the RSV season starts** to help prevent RSV infection. If the season has already started, your child should receive their first SYNAGIS injection as soon as possible to help protect them when exposure to the virus is more likely.
  - **SYNAGIS is needed every 28-30 days during the RSV season**. Each injection of SYNAGIS helps protect your child from severe RSV disease for about 1 month. **Keep all of your child's appointments with your healthcare provider.**
- **If your child misses an injection, talk to your healthcare provider and schedule another injection as soon as possible.**
- **Your child may still get severe RSV disease after receiving SYNAGIS.** Talk to your healthcare provider about what symptoms to look for. If your child gets a RSV infection, they should continue to receive their scheduled SYNAGIS injections to help prevent severe disease from new RSV infections.
- If your child has certain types of heart disease and has corrective surgery, your healthcare provider may need to give your child an additional SYNAGIS injection soon after surgery.

What are the possible side effects of SYNAGIS?

SYNAGIS may cause serious side effects including:

- **Severe allergic reactions.** Severe allergic reactions may happen after **any injection** of SYNAGIS, and may be life-threatening or cause death. Call your healthcare provider or get medical help right away if your child has any of the signs or symptoms of a serious allergic reaction. **See "Who should not receive SYNAGIS?".**

The most common side effects of SYNAGIS include fever and rash.

These are not all the possible side effects of SYNAGIS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects at 1866-773-5274.

General information about the safe and effective use of SYNAGIS.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. You can ask your pharmacist or healthcare provider for information about SYNAGIS that is written for health professionals.

What are the ingredients in SYNAGIS?

Active ingredient: palivizumab

Inactive ingredients: chloride, glycine, and histidine

Manufactured by: Swedish Orphan Biovitrum AB (publ) , Stockholm, Sweden

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For more information, go to www.synagis.com or call 1866-773-5274.

This Patient Information has been approved by the U.S. Food and Drug Administration
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Although RSV typically occurs from late fall through spring, high-risk patients require year-round monitoring[1-4]*

FALL
- Initiate protection
- Identify patients in season

WINTER
- Continue protection
- Identify patients in season

SPRING
- Provide late-season protection
- Identify patients for next season

SUMMER
- Identify patients for next season

- SYNAGIS **provides antibodies to protect a baby's lungs** from severe infection caused by RSV—it is not a vaccine[4]
- High-risk infants should receive **monthly doses (every 28-30 days)** throughout the RSV season[4-6]

*RSV season can vary by geography and from year to year. Year-round RSV activity has been reported in Florida and Puerto Rico.[2,3]

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.

RSV=respiratory syncytial virus.

References: 1. Centers for Disease Control and Prevention. Brief report: respiratory syncytial virus activity—United States, July 2012–June 2014. *MMWR Morb Mortal Wkly Rep.* 2014;63:1133-1136. **2.** Mullins JA, Lamonte AC, Bresee JS, Anderson LJ. Substantial variability in community respiratory syncytial virus season timing. *Pediatr Infect Dis J.* 2003;22:857-862. **3.** Molinari Such M, Garcia I, Garcia L, et al. Respiratory syncytial virus-related bronchiolitis in Puerto Rico. *P R Health Sci J.* 2005;24(2):137-140. **4.** [SYNAGIS [package insert]. Waltham, MA: Sobi, Inc.] **5.** 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 **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.

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

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