

BEFORE YOU DO ANYTHING ELSE THIS RSV SEASON, IDENTIFY YOUR HIGHEST-RISK INFANTS FIRST

Steps to help protect the highest-risk infants from severe RSV disease

Please see additional Important Safety Information throughout and on page 10. Please see full Prescribing Information for SYNAGIS, including Patient Information.

INDICATION

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

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

LIMITATIONS OF USE

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

CONTRAINDICATIONS

Previous significant hypersensitivity reaction to SYNAGIS.

IMPORTANT SAFETY INFORMATION

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

RSV=respiratory syncytial virus.



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



IDENTIFY **PATIENTS**

TRACK PATIENTS
AND MONITOR
SEASON START

GET PATIENTS
STARTED EARLY

ORDER **SYNAGIS**

HELP PATIENTS STAY ON SYNAGIS IMPORTANT SAFETY INFORMATION



TRACK PATIENTS

AND MONITOR

GET PATIENTS STARTED EARLY

ORDER **SYNAGIS**

HELP PATIENTS STAY ON SYNAGIS

IMPORTANT SAFETY **INFORMATION**



THE AAP AND NPA RECOMMEND SYNAGIS FOR THE FOLLOWING PATIENTS AT THE HIGHEST RISK FOR SEVERE RSV DISEASE:

SYNAGIS INDICATION¹

2014 AAP Guidance^{2*}

2024 NPA Guidelines³

Premature

≤35 wGA and ≤6 months of age at the start of RSV season

<29 wGA and <12 months of age[†]

at the start of RSV season with no other qualifying conditions

[†]6 to <12 months is outside the approved SYNAGIS Indication.

29 to 35 wGA

with other qualifying conditions

<28 0/7 wGA and <12 months of age[†]

at the start of RSV season

[†]6 to <12 months is outside the approved SYNAGIS Indication.

28 0/7 to 32 0/7 wGA and

< 6 months of age at the start of RSV season

32 1/7 to 35 6/7 wGA and

<6 months of age at the start of RSV season, with significant provider-identified risk factors



≤24 months of age

at the start of RSV season. and with medical treatment required for BPD within the previous 6 months

≤24 months of age

at the start of RSV season

<32 wGA

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

- <12 months of age</p> 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

<12 months of age

at the start of RSV season

<24 months of age

at the start of RSV season, and with medical management required within 6 months



VIEW ELIGIBILITY GRID

<24 months of age

at the start of RSV season, unless cardiology waiver obtained

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

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.

AAP=American Academy of Pediatrics; EHR=electronic health record; BPD=bronchopulmonary dysplasia; HS-CHD=hemodynamically significant congenital heart disease; RSV=respiratory syncytial virus; wGA=weeks gestational age.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

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

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

> LEARN MORE ABOUT THE **HIGHEST-RISK RSV PATIENTS**

Please see additional Important Safety Information throughout and on page 10. Please see full Prescribing Information for SYNAGIS, including Patient Information.

REFERENCES

USE THESE INTERACTIVE BIRTHDAY GUIDES TO HELP IDENTIFY PATIENTS

at the highest risk for severe RSV disease during the 2024-2025 season

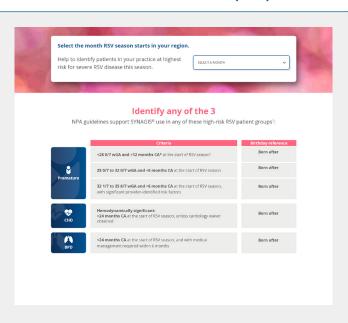
START HERE

2014 American Academy of Pediatrics (AAP) Guidance

Select the m	onth RSV season starts in your region.	
Holp to ident	ify patients in your practice at highest	
	re RSV disease this season.	~
TISK TOT SCYCT	C NOV disease dill's season.	
	Identify any of the 3	
AAP σι	idance supports SYNAGIS® use in any of these high-risk RSV pa	atient groups1.
7 4 11 8	touries supports strivious assembly of these night isk list pe	atterne Broups :
	Criteria	Birthday reference
8	Citeria	
Premature	≤28 weeks, 6 days gestational age	Born after
Premature		
	Hemodynamically significant: (Either of these)	
	 Has acyanotic* congenital heart disease and is receiving medication to 	
V		
₩	control congestive heart failure and will require cardiac surgery * Has moderate to severe pulmonary hypertension	Born after
CHD	control congestive heart failure and will require cardiac surgery	Born after
CHD	control congestive heart failure and will require cardiac surgery * Has moderate to severe pulmonary hypertension	Born after
CHD	control congestive heart failure and will require cardac surgery * Mas moderate to severe pulmonary hypertension *Chemister spering adminishably preplets in information younget beard-effects in the first year of life may be made in consultation with a pediatric cardiologics.	
сно	control congestive heart failure and will require cardiac surgery Has moderate to severe pulmonary hypertension Decisions regarding paliviumab prophylasis for infants with cyanotic heart defects in the first	Born after Born after
СНО	control congestive heart failure and will require cardiac surgery *Has moderate to severe pulmonary hypertension *Bession reprincipativiumsic prophysis for brinkins in greate heart deletion in the first your of the may be made in consultation with a postance cardisages. *22 wGA and requiring >21% oxygen for at least the first 28 days	
СНД	control congestive heart failure and will require cardiac surgery. **His moderate is severe pulmonary hypertension. **Conson repaired prolineate prophylish to inflor will operate heart shelf in the first year of the may be made inconditions will a pediatric care designs. **22 wGA and requiring **21% oxygen for at least the first 28 days after birth. **22 wGA and requiring **21% oxygen for at least the first 28 days. **22 wGA and requiring **21% oxygen for at least the first 28 days. **23 wGA and requiring **21% oxygen for at least the first 28 days. **23 wGA and requiring **21% oxygen for at least the first 28 days. **24 wGA and requiring **21% oxygen for at least the first 28 days. **25 wGA and requiring **21% oxygen for at least the first 28 days. **25 wGA and requiring **21% oxygen for at least the first 28 days. **25 wGA and requiring **21% oxygen for at least the first 28 days. **25 wGA and requiring **21% oxygen for at least the first 28 days. **26 wGA and requiring **21% oxygen for at least the first 28 days. **27 wGA and requiring **21% oxygen for at least the first 28 days. **27 wGA and requiring **21% oxygen for at least the first 28 days. **28 wGA and requiring **21% oxygen for at least the first 28 days. **28 wGA and requiring **21% oxygen for at least the first 28 days. **29 wGA and requiring **21% oxygen for at least the first 28 days. **29 wGA and requiring **21% oxygen for at least the first 28 days. **29 wGA and requiring **21% oxygen for at least the first 28 days. **29 wGA and requiring **21% oxygen for at least the first 28 days. **20 wGA and requiring **21% oxygen for at least the first 28 days. **20 wGA and requiring **21% oxygen for at least the first 28 days. **20 wGA and **20 wGA	
сно	control congestion heart failure and will require cardials surgery. *Na moderal et as ower pulmonary hyperterisation *Cecisions repering poleonanch prophysia for inform win genetic least deficts in the first year of the major least in introduction with a poleonic cardiologis. *22 wGA and requiring >21% oxygen for at least the first 28 days after a letch.	
CHD A BPD	control congestive heart failure and will require cardiac surgery. **His moderate to severe pulmonary hypertension. **Censors repaired, and vision and production and operation has referred to the first year of the may be made in consistance with a pediatric cardisages. **23 wide, and requiring >21% oxygen for at least the first 28 days nature sizion. **23 wide, and requiring >21% oxygen for at least the first 28 days nature before the consistance of the first 28 days nature before the consistency of the first 28 days nature before the consistency of the first 28 days nature before the consistency of the first 28 days nature before the consistency of the first 28 days nature before the consistency of the first 28 days nature before the first 28 days nature before the first 28 days nature first 30 days nature first 30 days not seen to see the first 28 days nature first 30 days	Born after
	control congestive heart failure and will require cardiac surgery. **Namoderate to severe pulmonary hypertension **Canons reprint generation and problems for them are greated heart shades in the first year of the may be made in consistent with a pediate clear design. **-32 w GA and requiring **21% oxygen for at least the first 28 days after birth **-42 w GA and requiring **21% oxygen for at least the first 28 days after birth control of the start of the second RSV season!* (Any 1 of these) **- Supplemental oxygen **- Discrete: **	
	control congestive heart failure and will require cardiac surgery. *Naminoders to severe pullmanus hyperterisoris *Consistent regarding advisionable problems for inform som guestic heart derive in the fixet year of the may be made in consistent with a podarec cardisages. *32 wGA and requiring >21% oxygen for at least the first 28 days after before \$4.23 wGA and requiring >21% oxygen for at least the first 28 days after before the consistent problems of the problems of t	Born after
	control congestive heart failure and will require cardiac surgery. **Namoderate to severe pulmonary hypertension **Canons reprint generation and problems for them are greated heart shades in the first year of the may be made in consistent with a pediate clear design. **-32 w GA and requiring **21% oxygen for at least the first 28 days after birth **-42 w GA and requiring **21% oxygen for at least the first 28 days after birth control of the start of the second RSV season!* (Any 1 of these) **- Supplemental oxygen **- Discrete: **	Born after

START HERE

2024 National Perinatal Association (NPA) Guidelines



EHR=electronic health record; RSV=respiratory syncytial virus.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Most Common Adverse Reactions: The most common adverse reactions are fever and rash. Postmarketing Experience: Severe thrombocytopenia and injection site reactions have been identified during post approval use of SYNAGIS.

> LEARN MORE ABOUT THE **HIGHEST-RISK RSV PATIENTS**

Please see additional Important Safety Information throughout and on page 10. Please see full Prescribing Information for SYNAGIS, including Patient Information.

















REDUCE THE RISK OF MISSING PATIENTS WHO MAY BENEFIT FROM SYNAGIS®

• Build automated EHR patient list reports based on ICD-10 codes



RUN PATIENT LIST REPORTS MONTHLY TO HELP WITH YEAR-**ROUND PATIENT IDENTIFICATION**

- Stay vigilant when RSV activity does not follow typical patterns
- Track babies born in spring or summer ("out of RSV season") who may otherwise be missed



USE YOUR EHR IN HEALTHCARE **SYSTEMS WITH NICUs THAT ALSO** HAVE OUTPATIENT **SETTINGS**

• Send reports to each affiliate so they can continue to run reports monthly



ADVOCATE TO ESTABLISH A PATIENT LIST REPORT PROCEDURE

• Bridge gaps in care or tracking



VIEW EHR

EHR=electronic health record; ICD-10=International Classification of Diseases, Tenth Revision; NICU=neonatal intensive care unit; RSV=respiratory syncytial virus.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

These are not all the possible risks associated with SYNAGIS.

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

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

> LEARN MORE ABOUT THE **HIGHEST-RISK RSV PATIENTS**

LEARN HOW YOUR EHR CAN HELP YOU IDENTIFY

the highest-risk infants who may benefit from SYNAGIS

Please see additional Important Safety Information throughout and on page 10. Please see full Prescribing Information for SYNAGIS, including Patient Information.



IDENTIFY **PATIENTS** TRACK PATIENTS AND MONITOR SEASON START

GET PATIENTS STARTED EARLY

ORDER **SYNAGIS**

HELP PATIENTS STAY ON SYNAGIS

IMPORTANT SAFETY INFORMATION



MONITOR RSV ACTVITY AND FOLLOW UP WITH YOUR HIGHEST-RISK INFANTS



ALL INFANTS ARE NOT THE SAM

USE TOOLS TO TRACK PATIENTS

- Automated EHR reports can ensure that patients receive all SYNAGIS® doses
- Manual patient ID logs can help record and track potential patients



REVIEW LAST SEASON'S PATIENTS

 Find and track potential secondseason patients



REVIEW TRANSITIONOF-CARE FORMS

FOR PATIENTS REFERRED FROM THE NICU

• Not always provided by the NICU



DETERMINE RSV SEASON ONSET

 Defined by local RSV virology



ASK THE PRESCRIBER TO REVIEW LIST OF PATIENTS IDENTIFIED PRIOR TO SUBMITTING REFERRALS



VIEW RSV VIROLOGY



VIEW PATIENT ID LOG $\label{eq:energy} \mbox{EHR=electronic health record; NICU=neonatal intensive care unit; RSV=respiratory syncytial virus.}$

INDICATION

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

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

LIMITATIONS OF USE

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

CONTRAINDICATIONS

Previous significant hypersensitivity reaction to SYNAGIS.

Please see additional Important Safety Information throughout and on page 10. Please see full <u>Prescribing Information</u> for SYNAGIS, including Patient Information.





GET ELIGIBLE PATIENTS STARTED ON SYNAGIS® AS EARLY AS POSSIBLE



ALL INFANTS ARE NOT THE SAME

COLLECT ALL PRESCRIPTION

AND MEDICAL BENEFIT INSURANCE INFORMATION



SOME PATIENTS
MAY HAVE
COVERAGE
UNDER BOTH
BENEFITS OR ONLY
THE MEDICAL OR
PHARMACY BENEFIT:

1 card for both the pharmacy and medical benefits

OR

2 cards: 1 for pharmacy and 1 for medical benefits



COMPLETE A BENEFITS INVESTIGATION

TO VERIFY COVERAGE FOR SYNAGIS

Review PA requirements and Specialty Pharmacy network options.



COMPLETE AND SUBMIT THE PA REQUEST, IF NEEDED

 If the patient has primary and secondary insurance, complete the PA process for both



FOLLOW UP
WITH HEALTH
PLAN OR PAYER
ON PA OUTCOME,

IF NEEDED



VIEW
TIPS FOR BENEFITS
INVESTIGATION



VIEW
PRIOR AUTHORIZATION
REFERENCE GUIDE

PA=prior authorization.

IMPORTANT SAFETY INFORMATION

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

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

Please see additional Important Safety Information throughout and on page 10. Please see full <u>Prescribing Information</u> for SYNAGIS, including Patient Information.





NAVIGATING THE SPECIALTY PHARMACY



ALL INFANTS ARE NOT THE SAM

ORDER SYNAGIS BY SUBMITTING THE COMPLETED SPECIALTY PHARMACY FORM

The completed Specialty Pharmacy form serves as the prescription. If required by the payer, it may also be necessary to submit a payer-approved PA form.



REMIND CAREGIVERS THAT THEIR APPROVAL IS NEEDED*

 The Specialty Pharmacy will call to confirm shipment and collect payment

HELPFUL HINT: This call will most likely come from an 800 number. If parents miss the call, remind them to listen to the voicemail and call the phone number provided.



SCHEDULE SYNAGIS DELIVERY A FEW DAYS PRIOR TO ADMINISTRATION APPOINTMENT



PROVIDE SPECIALTY
PHARMACY WITH
PATIENT'S UPDATED
WEIGHT AHEAD OF
TIME TO ENSURE
APPROPRIATE DOSE
IS SHIPPED



VIEW SPECIALTY PHARMACY NETWORK ENROLLMENT FORMS



VIEW SPECIALTY
PHARMACY CONTACT

*Remind parents/caregivers that the Specialty Pharmacy is chosen by their insurance plan or selected by their infant's healthcare provider. Inform them that a Specialty Pharmacy provides medications used to treat rare or complex conditions. Many times, these medications require a physician to administer the medication, have special delivery/shipment requirements, and require specific instructions from a pharmacist.

PA=prior authorization.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

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

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

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

Please see additional Important Safety Information throughout and on page 10. Please see full <u>Prescribing Information</u> for SYNAGIS, including Patient Information.





REFERENCES

REMINDERS FOR PARENTS/CAREGIVERS

IT'S IMPORTANT TO SCHEDULE ALL DOSING APPOINTMENTS (every 28 to 30 days) IN ADVANCE



PATIENT CONSENT FORM

Complete to receive Sobi field reimbursement support.



VIEW PATIENT CONSENT FORM



SYNAGIS DOSING **CALENDAR**

Use when scheduling patient dosing appointments with parents/caregivers.



VIEW SYNAGIS DOSING CALENDAR



DOSE **SCHEDULING CARD**

Help parents/caregivers remember each dosing appointment.



Contact your SYNAGIS representative for this resource.



SYNAGIS BROCHURE

Helpful information for parents/caregivers.



BROCHURE



COPAY ASSISTANCE PROGRAM

Help eligible patients with commercial insurance manage out-of-pocket costs.



VIEW COPAY



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

These are not all the possible risks associated with SYNAGIS.

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

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

FOR MORE RESOURCES,

VISIT SYNAGISHCP.COM

Please see additional Important Safety Information throughout and on page 10. Please see full Prescribing Information for SYNAGIS, including Patient Information.







ALL INFANTS ARE NOT THE SAME

References:

- 1. SYNAGIS (palivizumab) [prescribing information]. Waltham, MA: Sobi, Inc. 2021.
- **2.** 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.
- **3.** Goldstein M, Hopkins B, Kadri M, et al. National Perinatal Association 2024 respiratory syncytial virus (RSV) prevention clinical practice guideline: clinical presentation, prevention strategies, and social impacts in children: an evidence-based interdisciplinary collaboration. *Neonatology Today*. 2024;19(1):9-38.

Please see additional Important Safety Information throughout and on page 10. Please see full Prescribing Information for SYNAGIS, including Patient Information.

















INDICATION

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

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

LIMITATIONS OF USE

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

CONTRAINDICATIONS

Previous significant hypersensitivity reaction to SYNAGIS.

IMPORTANT SAFETY INFORMATION

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

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

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

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

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

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

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

These are not all the possible risks associated with SYNAGIS.

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

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

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

All imagery is for illustrative purposes only.

Additional resources at SYNAGISHCP.com



Learn more about us at SOBI.com

SYNAGIS is a registered trademark of Arexis AB c/o Swedish Orphan Biovitrum AB (publ) ©2024 Swedish Orphan Biovitrum. All rights reserved. PP-21713 01/24





IDENTIFY PATIENTS TRACK PATIENTS AND MONITOR **SEASON START**

GET PATIENTS STARTED EARLY

ORDER **SYNAGIS**

HELP PATIENTS STAY ON SYNAGIS

IMPORTANT SAFETY INFORMATION

