



## MODULE 2

# HOW TO EDUCATE PARENTS ON RSV AND SYNAGIS<sup>®</sup> (PALIVIZUMAB)

Coordinator Corner has developed this summary to assist your learning and help you fully understand the information featured in this video

## Video breakdown by topic

### Topic: Explaining RSV to parents: A respiratory virus that can infect the lungs | Time: 0:46

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- Because of the seriousness of severe RSV disease, it's very important to be thorough when educating parents about RSV and therapy with SYNAGIS
  - Coordinator quick tip: Use the comprehensive patient brochure on SYNAGIS and RSV as a visual aid for parent discussions and point out key information that may be most relevant
    - Offer it to the parents to take home for further review (available in English and Spanish)
- Help parents understand RSV by explaining that it:
  - Is a common respiratory virus that can infect the lungs
  - Can easily spread, and nearly all children will catch it at least once by the time they reach 2 years of age
  - Is like the flu. RSV is a seasonal virus, making risk of infection higher during peak times of the year
  - Has a season. RSV season usually starts in the fall and runs into the spring, but varies by climate and geography
    - It may run longer in tropical climates, such as Florida and Puerto Rico
  - Usually causes mild-to-moderate cold-like symptoms, but they should be aware that some babies are at increased risk for developing severe RSV disease

### INDICATION AND IMPORTANT SAFETY INFORMATION

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 ( $\leq 35$  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

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.**



## 2 Topic: Explaining RSV to parents: Severe RSV disease can have serious consequences on a baby's health | Time: 1:34

- Once parents have a basic understanding of RSV, explain that severe RSV disease can have serious consequences on a baby's health
  - Severe RSV disease is the #1 cause of hospitalization in all children younger than 12 months in the United States. Complications include:
    - Bronchiolitis (swelling of the lower airways of the lungs)
    - Pneumonia
    - Life-threatening breathing problems

## 3 Topic: Explaining RSV to parents: Certain babies are at high risk | Time: 1:57

- It's important to tell parents that certain babies are at high risk for severe RSV disease, and that these are the babies who may be eligible for SYNAGIS
- Explain that their child may be at high risk if he or she was born at the beginning of RSV season:
  - Prematurely at  $\leq 35$  weeks GA and who are 6 months of age or younger
  - With certain types of bronchopulmonary dysplasia or chronic lung disease of prematurity that required medical treatment within the previous 6 months and who are 24 months of age or younger
  - With certain types of heart disease and who are 24 months of age or younger
- These high-risk babies have a reduced ability to fight off lung infections, raising their risk for severe RSV disease

## 4 Topic: Explaining SYNAGIS to parents | Time: 2:34

- What you have just explained to parents about severe RSV disease may sound intimidating, so inform them that there is one FDA-approved medication that has been shown to help protect certain high-risk babies from RSV-related hospitalization: SYNAGIS<sup>1</sup>
  - Tell parents that SYNAGIS:
    - Is NOT a vaccine, but a medication<sup>1</sup>
    - Is given as an intramuscular injection, usually in the thigh
    - Provides RSV-fighting antibodies with each dose<sup>1</sup>
      - Coordinator quick tip: Define antibodies for parents:
        - Antibodies are proteins your body makes to fight infection and are a crucial part of the immune system<sup>2</sup>
    - Make sure parents understand that SYNAGIS does not treat RSV disease, but rather provides antibodies that may significantly reduce RSV-related hospitalizations<sup>1,3</sup>
  - Coordinator quick tip: When babies fall into high-risk groups, talk to parents about SYNAGIS during their first appointment. Let them know that their child has special health considerations, and that SYNAGIS can help protect him or her from this potentially serious virus.<sup>1</sup> Also discuss the potential side effects of SYNAGIS

### IMPORTANT SAFETY INFORMATION

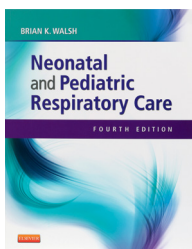
Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count  $< 50,000$ /microliter) and injection site reactions have been reported.

**Please see additional Important Safety Information on page 4, and accompanying full Prescribing Information for SYNAGIS, including Patient Information.**



**5 Topic: Explaining the importance of proper dosing | Time: 4:29**

- *Note: Even though you've already clarified that SYNAGIS® (palivizumab) is not a vaccine, some parents may still believe it works like one*
  - Explain that SYNAGIS does not make babies immune to RSV disease. SYNAGIS provides enough RSV-fighting antibodies in each dose to help protect babies for about a month during RSV season
- Key point: Babies should receive their first dose of SYNAGIS before RSV season starts<sup>1</sup>
  - Their baby's first dose of SYNAGIS is given before RSV season starts to build protection before RSV activity increases
- Key point: SYNAGIS needs to be given every 28 to 30 days throughout the RSV season<sup>1</sup>
  - This ensures that the levels of antibodies remain high enough to help keep babies protected
    - If a baby misses a dose or receives it late, antibody levels drop and the risk for severe RSV disease rises
- Parents of babies with certain types of lung or heart disease need to keep one additional point in mind<sup>1</sup>:
  - Their babies remain at high risk for severe RSV disease up to 24 months of age at RSV season start
    - These babies may need to receive SYNAGIS in both their first and second RSV seasons
- Coordinator quick tip: Proactively schedule all appointments for SYNAGIS to keep on a 28 to 30 day dosing schedule
  - Even though these developing babies may begin to look stronger and healthier through RSV season, they may still be at high risk for severe RSV disease
    - It is essential to stress the importance of continued and timely dosing for SYNAGIS through the full dosing schedule
    - When parents arrive for their first appointment, ask them to schedule all appointments for SYNAGIS before they leave
      - This keeps everyone ahead of scheduling and even adds a few days of flexibility in case an appointment needs to be pushed back a day or two



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If you want to become an official certified SYNAGIS Coordinator, Coordinator Corner will help you every step of the way. All you have to do is view all the modules and take all the checkpoints to become certified and eligible to receive an educational textbook, or you can make a charitable donation.

You must be registered to be eligible for certification—**so register today.**

**IMPORTANT SAFETY INFORMATION**

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 4, and accompanying full Prescribing Information for SYNAGIS, including Patient Information.**

## 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
- 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

## INDICATION

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 ( $\leq 35$  weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
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- 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.

## DOSING

The recommended dose of SYNAGIS is 15 mg/kg of body weight given monthly by intramuscular injection. The first dose of SYNAGIS should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season.

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

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

**References:** **1.** SYNAGIS [package insert]. Gaithersburg, MD: MedImmune. **2.** Yeung CY, Hobbs JR. Serum- $\gamma$ G-globulin levels in normal premature, postmature, and "small-for-dates" newborn babies. *Lancet*. 1968;1(7553):1167-1170. **3.** 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.



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