MODULE 5

APPROVAL OR DENIAL

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

1 Topic: What to do when a referral is approved | Time: 0:15

Once you have been successful in getting a patient referral approved for SYNAGIS® (palivizumab, there is still work to be done. After receiving notification of an approved referral:

- Promptly coordinate with parents to schedule the high-risk baby's first, or next, dose of SYNAGIS
  - If a home care agency or other clinic will be responsible for dosing, make sure to communicate with them to ensure a dosing schedule is set
  - To begin scheduling dosing:
    - Confirm if the baby already received his or her first dose of SYNAGIS while in the NICU or the nursery
      - If he or she hasn't, and if RSV season hasn't started yet, find out when dosing can start in your area by checking with a MedImmune representative or the RSVAlert® website
    - If RSV season is already in full swing and the baby has not received the first dose, schedule it as soon as possible
    - If the baby has already received the first dose, schedule the next one 28 to 30 days later

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 (≤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

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.

2 Topic: Setting expectations with parents and caregivers | Time: 1:14

- After the first dose has been scheduled, parents and caregivers may not know what to expect next. Here's how you can help them:
  - Explain that they should schedule all remaining appointments for SYNAGIS® (palivizumab) at once, each between 28 and 30 days apart, so future scheduling won't get overlooked
  - Make sure to reinforce the importance of timely dosing
  - Clarify that SYNAGIS is NOT a vaccine, but a medication that provides enough antibodies to help protect their baby against severe RSV disease for 1 month
- Talk to parents about the following:
  - Insurance coverage for SYNAGIS and any potential out-of-pocket costs for which they may be responsible
  - Access 360™, a support program for SYNAGIS, which may be able to provide financial assistance
    - Eligible parents can submit a claim to be reimbursed for the cost of SYNAGIS and/or administration, by filling out an Access 360 claim form
  - Potential consent-to-ship phone calls from the Specialty Pharmacy Provider (SPP), so these calls do not come as a surprise
  - Potential scheduling calls from a home health nurse (if SYNAGIS will be administered by a home health agency)
- Coordinate with SPP for medication supply
  - Confirm how you will be receiving communication from the SPP (e.g., fax, email)
  - Communicate often with the SPP to ensure SYNAGIS is delivered on time and in proper dosage
  - Periodically verify patient's information with the SPP
    - *Note: Access 360 can also follow up with the SPP*

3 Topic: What to do when a referral is denied | Time: 3:04

- When a referral is denied, remember that there are still options available to appeal the insurance company's decision. Upon receiving denial letter from the payer:
  - Identify the exact reason for denial
    - Clinical (e.g., patient not being within payer policy)
    - Administrative (e.g., a missing signature or ICD-9 or ICD-10 code)
  - Request a written denial and keep a record of the name and contact information of the person who handles your request
    - You will also want to pinpoint the necessary steps for appealing the denial, which can usually be found in the denial letter
      - Take care to follow the appeals process exactly as outlined. If the letter does not state these steps, contact the payer directly to find out what they are
  - Discuss referral denial with parents/caregivers
    - Parents may feel discouraged and unsure of what to do next; you'll want to be reassuring and keep them informed about possibilities and next steps
    - Encourage them to be proactive by contacting their insurance provider and/or their employer to find out what options they may have
    - Educate parents on how they may counteract the denial by appealing it

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

4 Topic: Appealing the denial | Time: 4:32

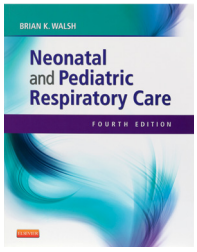
- The earlier you file the appeal, the better chance you have of preventing unnecessary holdups
  - If you have multiple appeals in your queue, group them together to streamline the process
  - Contact payer within 24 hours
  - Keep parents informed throughout the appeals process
- Preparing an appeal letter
  - List all of the risk factors and clinically relevant information that puts the patient at high risk for severe RSV disease. This may include:
    - Local RSV virology data (RSVAlert.com) if you are filing the appeal during the RSV season
    - Letter from a medical specialist, such as a pulmonologist, cardiologist, or neonatologist

5 Topic: When an appeal does not overturn a denial | Time: 5:42

- When an appeal doesn't result in an overturned denial, you still have a few options for disputing the denial
  - Request a peer-to-peer review with a medical director
  - Request a third-party review
    - The insurance company will consult with an external specialist, such as a cardiologist or pulmonologist
  - In peer-to-peer and third-party reviews, the medical professionals may be able to identify potential errors in the reasons given for the denial, as well as provide further support for the medical necessity of SYNAGIS® (palivizumab)

6 Topic: Access 360 appeal support | Time: 6:20

- Access 360 cannot actually submit an appeal on your behalf, but it CAN provide you with:
  - Payer-specific forms, instructions, and contact information
  - Follow up communications with the payer on the outcome of the appeal
  - *Note: The AstraZeneca Medical Information team can also provide you with additional clinical supporting documentation*
- If your appeal is unsuccessful, Access 360 offers reimbursement assistance options to parents through its various support programs
  - Contact your MedImmune field reimbursement manager (FRM) for denial-specific support if there is a signed Patient Authorization Form (PAF) on file



PREEMIES TODAY®

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

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.

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 (≤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.

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.

AstraZeneca

Gaithersburg, MD 20878 US-12533 7/17
Customer Support Network: 1-877-633-4411 (Option 6)

SYNAGIS® PALIVIZUMAB