SYNAGIS®
PALIVIZUMAB

SYNAGIS Prior Authorization Reference 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

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 Important Safety Information throughout and full Prescribing Information for SYNAGIS, including Patient Information.

SYNAGIS Prior Authorization Reference Guide

A prior authorization (PA) is a request for approval of coverage for SYNAGIS® (palivizumab) from a health plan before it can be administered. PAs allow health plans to monitor costs and to ensure that medications are necessary and appropriate for the patients to whom they are prescribed.

Respiratory syncytial virus (RSV) reminders

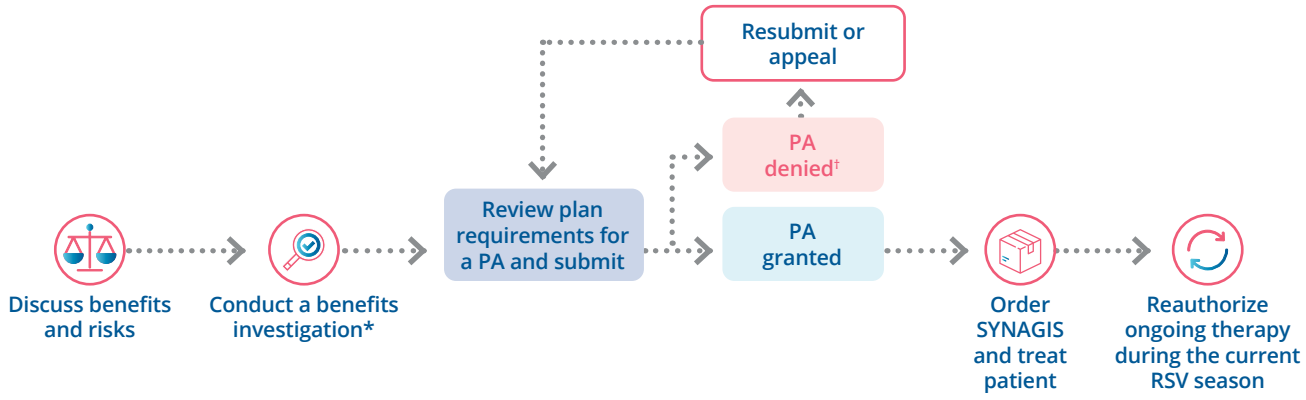
RSV is a contagious disease that affects nearly all children by the age of 2 years[1]

In most of the United States, RSV season starts in the fall and lasts through the spring[2]

Local RSV testing data are monitored through the National Respiratory and Enteric Virus Surveillance System (NREVSS) to help determine RSV seasonal patterns[3]

It is important to begin the PA process for SYNAGIS prior to the start of RSV season in your geographic area to ensure timely initiation of treatment for high risk patients.

PA Process Overview



*If SYNAGIS is not on formulary, a medical exception (ME) may be requested.

†If a PA is denied, an ME request may be submitted in support.

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).

If parent/caregiver consent is on file, SYNAGIS CONNECT™ can provide you with the appropriate PA forms and follow up on the submission status.

The healthcare provider office must complete and submit the PA request, but SYNAGIS CONNECT™ can provide support at every step in the process.

For more information, call **1-833-SYNAGIS (1-833-796-2447)**, Monday through Friday, 8 AM to 8 PM EST.

IMPORTANT SAFETY INFORMATION

- As with any intramuscular injection, SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder

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How to Complete a PA for SYNAGIS

STEP 1

Complete a benefits investigation

A benefits investigation helps verify SYNAGIS® (palivizumab) health plan restrictions and patient cost-sharing responsibilities

If the results determine SYNAGIS is not covered, an ME may be submitted. SYNAGIS may be covered under either the medical benefit or the pharmacy benefit.

STEP 2

Complete the PA request

Accurate, complete forms and documentation ensure an efficient and timely approval process

- Check the health plan's website to determine submission details
- Options for submitting the PA request may include
  - Faxing a paper form
  - Completing an electronic form on the CoverMyMeds® portal or a proprietary health plan portal
  - Speaking with someone at the plan by phone
- Because PAs can be denied if an incorrect or incomplete form is submitted, make sure to follow the directions to accurately complete the appropriate form

Examples of supplemental documentation that can help increase PA approval chances

- Peer-reviewed literature
- Relevant patient medical history and detailed clinical notes to inform the treatment recommendation
- Product Prescribing Information
- Letter of medical necessity

Including these documents can help get patients started on treatment as soon as possible.

STEP 3

Track the status of the PA request and follow up as needed

- Keep a copy of everything submitted to the health plan and a log of PA submissions and denials for each patient, including reference numbers
- Keep track of dates and methods of correspondence with the health plan
- Record the names of contacts and reviewers with whom you speak and summarize your conversations

Depending on the plan, you may need to complete multiple PA forms to ensure your patients continue to receive monthly doses of SYNAGIS throughout the RSV season. Since the season may span more than 1 calendar year (eg, from October to March), a second benefits investigation may also need to be completed.

IMPORTANT SAFETY INFORMATION

- Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays

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SYNAGIS® PALIVIZUMAB

When a Medical Exception Might Be Needed

If SYNAGIS® (palivizumab) is not covered by a health plan or for a certain patient, you may need to request an ME instead of completing a PA or in support of a PA. An ME communicates a physician's request to use a medication that is nonpreferred or not covered by the health plan based on a patient's individual circumstances.

An ME request usually requires specific documentation, including a letter of medical necessity, and more information about a patient's medical history.

To assist in your development of an ME request for infants and children at high risk for RSV, you may consider including clinical data and information from evidence-based RSV prevention guidelines, such as those from the National Perinatal Association and the American Academy of Pediatrics.

Make sure to follow up with the health plan to confirm receipt of the ME request and to check the decision status.

Refer to the Sample Letter of Medical Necessity to help you explain why SYNAGIS is appropriate for your patient.

What to Do if a PA Is Denied

For more information about what to do in the event of a PA denial, please see the SYNAGIS Denial and Appeals Reference Guide.

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

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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.

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 full Prescribing Information for SYNAGIS, including Patient Information.

References: 1. Protect against respiratory syncytial virus. Centers for Disease Control and Prevention website. https://www.cdc.gov/features/rsv/index.html. Accessed August 26, 2020. **2.** Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory syncytial virus seasonality – United States, 2014-2017. *MMWR Morb Mortal Wkly Rep*. 2018;67(2):71-76. **3.** The National Respiratory and Enteric Virus Surveillance System (NREVSS). Centers for Disease Control and Prevention website. https://www.cdc.gov/surveillance/nrevss/index.html. Accessed August 26, 2020.

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