SYNAGIS®
PALIVIZUMAB

SYNAGIS Denial and Appeals 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.

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Why a Request Might Be Denied by a Health Plan

A prior authorization (PA) or medical exception (ME) may be denied for many reasons. Incomplete and/or inaccurate information on the submitted form and clinical issues are the 2 most common reasons for denial.

Types of Denials

Administrative denial

Denied due to incorrect form, incomplete information, or inaccurate information

- Ensure that you are using the correct PA form
- Carefully review the request to verify that the information is complete and correct
- If the reason for the denial is not provided, call the health plan for more information
- Resubmit the request if necessary
- Keep a copy of the denial letter

Clinical denial

Denied due to clinical reasons

- Can occur if the medical condition of the patient does not fall within recommended guidelines; payer policies, including seasonality; or the product label for SYNAGIS® (palivizumab)
- It may be helpful to submit documentation showing medical need

Levels of Appeal

In the event that a health plan denies a PA or an ME, the parent or caregiver of the patient has the right to appeal the decision and you may be asked to submit the appeal to the health plan. **Because of the seasonal nature of respiratory syncytial virus and recommended SYNAGIS dosing, there is a sense of urgency behind the appeals process.**[1,2]

*Each level may involve multiple instances of communication.

First-level appeal: Letter of appeal or peer-to-peer discussion
A letter of medical necessity may be submitted to the health plan to overturn a denial. In order to expedite the appeal, you may consider contacting the health plan and arranging for the prescribing physician to have a peer-to-peer discussion with a clinical representative or medical director at the plan.

Second-level appeal: Medical review
The appeal is reviewed by a medical director at the health plan who has not been involved with the claim decision.

Third-level appeal: External review
The external review is conducted by an independent, third-party reviewer working with a board-certified physician in the same field as the patient's physician.

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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Steps of the Appeal Process

STEP 1

Review the denial notification

Review the denial notification to understand the reason for denial and the circumstances that need to be addressed and explained in the appeal. Make sure to follow any appeal instructions included in the denial letter. Call the payer, if necessary, to clarify the reason for denial.

STEP 2

Submit a letter of medical necessity or initiate a peer-to-peer discussion that addresses the grounds for disputing the denial

Refer to the Sample Letter of Medical Necessity for an example of what the letter may look like

Arrange to speak with a clinical representative or medical director at the health plan for a peer-to-peer discussion

You may choose to include the following information in your appeal:

- A description of the patient's medical history
- Recent hospital discharge or surgery notes
- A statement that explains why the patient needs the prescribed medication
- Details about the clinical efficacy and safety of the medication, and relevant recommendations for treatment from evidence-based guidelines
- Contact information for you and the patient's parent/caregiver

STEP 3

Follow up on the status of the appeal, and complete a second appeal if needed

If neither you nor the patient's parent/caregiver has received a decision within a timely manner, it may be best to follow up with the health plan.

Confirm that the letter of medical necessity was received and ask about its status → **If the coverage denial is upheld, you can submit another appeal with new information or ask for a supervisor or manager for further assistance** → **If the denial is upheld again, ask for a one-time exception or consider filing a complaint with the state's Insurance Commissioner**

- When speaking with health plans, be sure to keep track of dates and methods of correspondence and ask for reference numbers. Record the names of insurance contacts and reviewers with whom you speak and summarize your conversations with them

STEP 4

External appeal

- If the insurer continues to deny the claim, the patient's parent/caregiver may request an external appeal
- The process varies by state, but typically involves an independent third party who will review the claim and make a final, binding decision
- At this time, SYNAGIS CONNECT™ will go over affordability options with you and your patient's parent/caregiver

IMPORTANT SAFETY INFORMATION

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

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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).

If parent/caregiver consent is on file, SYNAGIS CONNECT™ is able to provide you with resources to help with the appeals process.

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

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- 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 full Prescribing Information for SYNAGIS, including Patient Information.

References: 1. Synagis [package insert]. Gaithersburg, MD: MedImmune; 2017. **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.

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