SYNAGIS CONNECT®

SYNAGIS® (palivizumab) Denial and Appeals Reference Guide

This resource is offered for informational purposes only and is not intended to provide reimbursement or legal advice. The practice, pharmacy, or healthcare provider is responsible for reviewing and understanding the patient's payer coverage and any plan requirements. SYNAGIS CONNECT® and Sobi, Inc. do not guarantee third-party coverage, payment, or reimbursement.

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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.

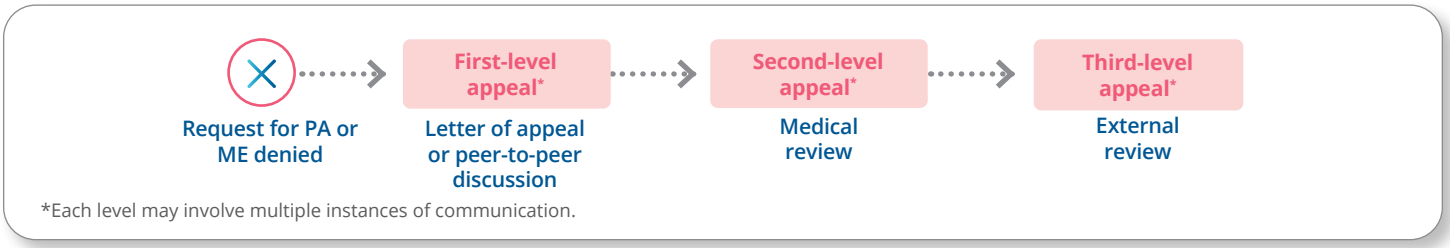
Clinical denial

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.
- 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 recommended monthly dosing for SYNAGIS, there is a sense of urgency behind the appeals process.**[1]



*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.

SYNAGIS CONNECT® 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.

SYNAGIS CONNECT®

SYNAGIS CONNECT® offers access and reimbursement support to help patients access SYNAGIS® (palivizumab). SYNAGIS CONNECT provides information regarding patient healthcare coverage options and financial assistance information that may be available to help patients with financial needs.

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 ET.

Reference: 1. SYNAGIS (palivizumab) [prescribing information]. Waltham, MA: Sobi, Inc; 2021.

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