

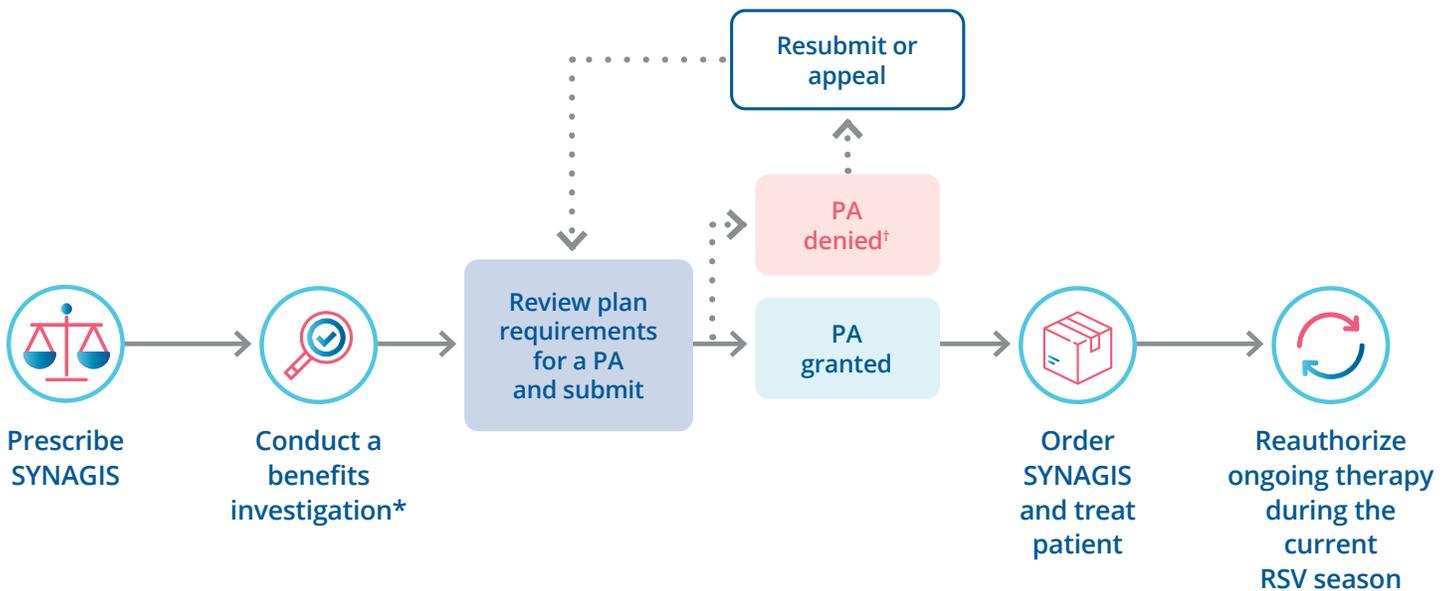


SYNAGIS[®] (palivizumab) Prior Authorization Reference Guide

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.

PA Process Overview

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



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

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

SYNAGIS CONNECT[®] offers access and reimbursement support to help patients access SYNAGIS. 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 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 ET.

How to Complete a PA for SYNAGIS® (palivizumab)



STEP 1

COMPLETE A BENEFITS INVESTIGATION

A benefits investigation identifies if a patient's health plan covers SYNAGIS and if there are any additional requirements, such as a PA

If the results of the benefits investigation determine that SYNAGIS is not covered, it may be necessary to submit an ME. SYNAGIS may be covered under either the medical benefit or the pharmacy benefit. For step-by-step instructions for completing a Benefits Investigation, please see [Tips for Completing a Benefits Investigation](#).



STEP 2

COMPLETE THE PA REQUEST

When a health plan requires a PA, it is important to identify, complete, and submit the appropriate PA form

- Call the health plan or check its website to **determine PA submission requirements**. Remember, different payers within a geographic area may have different criteria for the same drug.
- Determine whether the plan is **fully insured** or **self-insured**.
 - *Fully insured plans* provide a standard package of benefits. *Self-insured plans* provide a customized package of benefits that are specific to 1 employer and may carve out pharmacy benefits to a separate pharmacy benefit manager.^{1,2}
- When a patient is covered under a Blue Cross Blue Shield plan, it is important to identify if the plan is **local** or **out-of-state**. Out-of-state plans may have different PA processes and will use the locally contracted specialty pharmacy.
 - The PA process may differ if SYNAGIS is covered under the medical benefit and the plan is out-of-state.
- Additionally, determine whether the plan is **managed by a third-party administrator** who may require that a PA be completed in a specific way.
- Finally, be sure to identify the appropriate PA form and complete the form according to the payer's direction. Options for submitting the PA request may include



Completing the payer's SYNAGIS-specific PA form



Completing an electronic form through the CoverMyMeds® portal or through a proprietary health plan portal

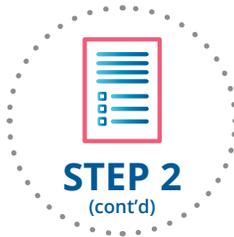


Speaking by phone with someone at the plan

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A PA can be denied due to inaccurate or incomplete information; be sure to follow the plan's instructions for accurately submitting the appropriate PA form.

How to Complete a PA for SYNAGIS[®] (palivizumab) (cont'd)



COMPLETE THE PA REQUEST (cont'd)

To obtain PA approval, you may need to submit



A copy of the patient's insurance card(s)



Relevant patient medical history, diagnosis, tests and lab results, and detailed clinical notes to inform the treatment recommendation



A letter of medical necessity (please see a sample letter on the next page)

Additional supplemental documentation which may help to improve the outcome of the PA review may include



Peer-reviewed literature



SYNAGIS Prescribing Information



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 patient's health plan, it may be necessary to complete multiple PA forms to ensure that your patient continues to receive monthly doses of SYNAGIS throughout the RSV season. Because the season may span more than 1 calendar year (eg, from October to March), a second benefits investigation may also need to be completed.

Sample Letter of Medical Necessity

If a payer requests a letter of medical necessity, be sure to include chart notes or a letter explaining why treatment with SYNAGIS® (palivizumab) is appropriate for your patient. Below is a sample letter of medical necessity that can be used as a template. Please note that some payers may require a specific letter of medical necessity form.

Sample Letter of Medical Necessity—SYNAGIS® (palivizumab)

[The following is a sample Letter of Medical Necessity. The text within pink brackets is templated and should be replaced with pertinent information for the individual patient on whose behalf you are submitting the letter. Italicized information within brackets is intended to provide additional guidance and should be omitted from the final letter.]

[Date]
[Payer Medical Director/Contact Name]
[Payer Organization Name]
[Payer Street Address]
[Payer City, State, ZIP Code]

RE: [Patient Name]
Date of birth: [Patient's Date of Birth]
Policy ID/Group number: [Policy ID/Group Number]
Policy holder: [Policy Holder's Name]

Dear [Payer Medical Director/Contact Name]:

I am [Physician Name, credentials, specialty, hospital/practice], and I am writing on behalf of my patient, [Patient Name], to document the medical necessity of SYNAGIS® (palivizumab), which is prescribed as prophylaxis for respiratory syncytial virus (RSV).

1. Patient-Specific Rationale for Treatment

In brief, it is my medical opinion that [initiating/continuing] treatment with SYNAGIS for [Patient Name] is medically appropriate and necessary, and its administration should be covered. Outlined below are [Patient Name]'s medical history and prognosis, and the rationale for treatment with SYNAGIS. The patient meets the following criteria for treatment: *[List specific criteria here]*.

[Note: The following section is to be completed by the physician based on the patient's medical history and prognosis.]

2. Summary of Patient's Medical History *[You may be required to include]*

- [Patient's diagnosis and current condition]
- [Relevant medical history]
- [Neonatal intensive care unit clinical notes]

3. SYNAGIS Dosing Information

[Note: Mention the starting dose and potential duration of therapy based on SYNAGIS dosing and administration. You may choose to include details from the Prescribing Information attached to the end of this sample letter and/or mention the current RSV trends and American Academy of Pediatrics Interim Guidance.]

Please call my office at [telephone number] if you require additional information. I look forward to receiving your timely response and approval of this authorization.

Sincerely,
[Physician Name]
[Title, Institution]
[Email/Phone Number]

[Note: Attach full Prescribing Information.]

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Access the Sample Letter of Medical Necessity [here](#) to help explain why SYNAGIS is appropriate for your patient.

When a Medical Exception (ME) May Be Needed

If SYNAGIS® (palivizumab) is not covered by a health plan or for a certain patient, you may need to request an ME. 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.

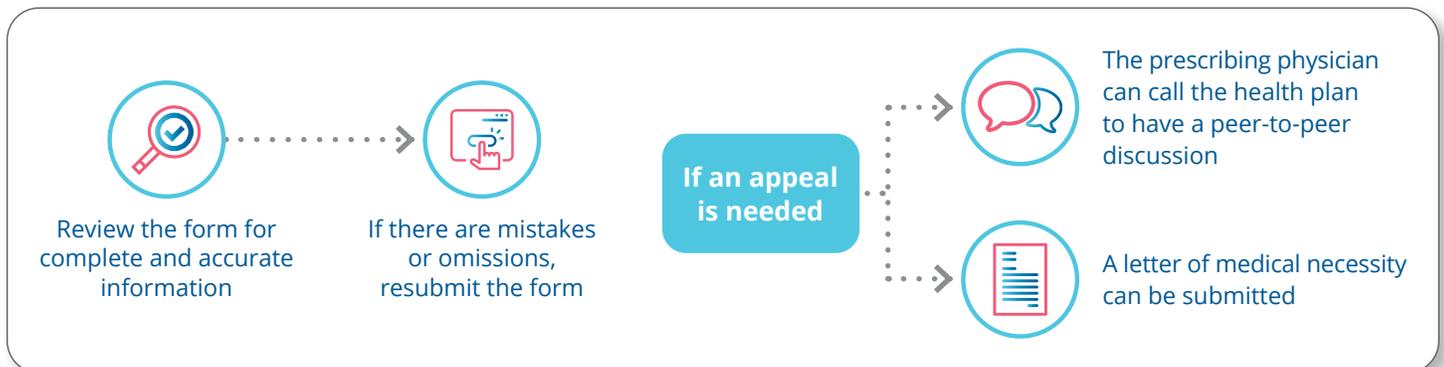


An ME request usually requires specific documentation, including a letter of medical necessity, and additional information about a patient's medical history.

When completing 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.

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

What to Do if a PA Is Denied



Remember, SYNAGIS CONNECT® can help with evaluating a patient's insurance coverage by performing a benefits investigation and can provide PA and appeal assistance.

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

References: 1. Walker E. Fully-insured vs. self-insured health plans. PeopleKeep website. Published September 2, 2022. Updated December 9, 2022. Accessed April 4, 2023. <https://www.peoplekeep.com/blog/fully-insured-vs-self-insured-health-plans> 2. Anderson BN, Reed A. PBM best practices series: carve-in vs carve-out programs. Milliman. Published December 2019. Accessed April 4, 2023. <https://fr.milliman.com/-/media/milliman/pdfs/articles/best-practices-pharmacy-benefits-carve-in-carve-out.ashx>