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
PA Process Overview

A prior authorization (PA) is a request for a health plan's approval for coverage of 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.

RSV REMINDERS

RSV is a contagious disease that affects nearly all children by the age of 2 years. In most of the United States, RSV season starts in the fall and lasts through the spring. Local RSV testing data are monitored through the National Respiratory and Enteric Virus Surveillance System to help determine RSV seasonal patterns.

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.

RSV=respiratory syncytial virus.

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.

Please see Important Safety Information throughout and full Prescribing Information for SYNAGIS, including Patient Information.
How to Complete a PA for SYNAGIS® (palivizumab)

**COMPLETE A BENEFITS INVESTIGATION**

A benefits investigation helps verify SYNAGIS health plan restrictions and patient cost-sharing responsibilities

If the results of the benefits investigation determine that SYNAGIS is not covered, an ME may be submitted. 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.

**COMPLETE THE PA REQUEST**

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

- 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.
- For patients who are covered under a Blue Cross Blue Shield plan, determine whether 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
- Determine whether the plan is managed by a third-party administrator who may require that a PA be completed in a specific way
- Submit the PA request according to the payer’s preferred method. 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

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.

**IMPORTANT SAFETY INFORMATION**

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

Please see Important Safety Information throughout and full Prescribing Information for SYNAGIS, including Patient Information.
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 to improve the outcome of the PA review may include

- Peer-reviewed literature
- SYNAGIS Prescribing Information

Including these documents with your PA request can help to start patients on treatment as soon as possible.

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 that your patients continue 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.

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 Important Safety Information throughout and full Prescribing Information for SYNAGIS, including Patient Information.
Sample Letter of Medical Necessity

A payer may request documentation of medical necessity, which may include chart notes or a letter explaining why treatment with SYNA GIS® (palivizumab) is appropriate for a patient. Below is a sample letter of medical necessity that can be used as a template when submitting a PA request. Please note that some payers may require a specific letter of medical necessity form.

[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], writing on behalf of my patient, [Patient Name], to document the medical necessity of SYNA GIS® (palivizumab), which is prescribed as prophylaxis for respiratory syncytial virus.

1. Patient-Specific Rationale for Treatment

In brief, based on the clinical data available to date, it is my medical opinion that initiating treatment with SYNA GIS for [Patient Name] is medically appropriate and necessary, and its administration should be covered. Below, this letter outlines [Patient Name]'s medical history and the rationale for treatment with SYNA GIS. 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 the following
• Patient’s diagnosis and current condition
• Relevant medical history
• Neonatal intensive care unit clinical notes]

3. SYNA GIS Dosing Information

[Note: Mention the starting dose and potential duration of therapy based on SYNA GIS dosing and administration and the respiratory syncytial virus season in your geographic region. You may choose to include details from the Prescribing Information attached to the end of this example letter.]

Please call my office at [telephone number] if I can provide you with any 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.]

Access the Sample Letter of Medical Necessity here to help explain why SYNA GIS is appropriate for your patient.

IMPORTANT SAFETY INFORMATION

• SYNA GIS is contraindicated in children who have had a previous significant hypersensitivity reaction to SYNA GIS

Please see Important Safety Information throughout and full Prescribing Information for SYNA GIS, including Patient Information.
When a Medical Exception 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 developing 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

Review the form for complete and accurate information

If there are mistakes or omissions, resubmit the form

If an appeal is needed

The prescribing physician can call the health plan to have a peer-to-peer discussion

A letter of medical necessity can be submitted

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

IMPORTANT SAFETY INFORMATION

• 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.
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
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- 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.
- 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.