



**BlueCross BlueShield
of Alabama**

Synagis® (palivizumab) Medical Policy Prior Authorization Program Summary

Precertification/Prior Authorization may be required under certain plans. Please verify each member's benefits.

OBJECTIVE

The intent of the Synagis® (palivizumab) Prior Authorization (PA) program is to ensure that patients prescribed therapy meet the selection requirements defined in product labeling and/or clinical guidelines and/or clinical studies. The PA defines appropriate use as the Food and Drug Administration (FDA) labeled indication for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV infection as defined by American Association of Pediatrics (AAP) 2014 guidelines. Length of approvals will be as recommended by the AAP guidelines.

AGENTS

Synagis® (palivizumab)

CRITERIA FOR APPROVAL

Synagis® (palivizumab) will be approved for patients who have not exceeded the maximum recommended doses of palivizumab for the current respiratory syncytial virus (RSV) season when the following criteria are met:

1. The patient has not received the maximum recommended doses of Synagis (palivizumab) for the current respiratory syncytial virus (RSV) season
AND
2. ONE of the following
 - a. Patient's chronological age at the start of the RSV season is less than 12 months **AND** ONE of the following:
 - i. Gestational age is <29 weeks 0 days
OR
 - ii. The patient was a preterm infant who developed chronic lung disease of prematurity defined as gestational age (birth at) <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth
OR
 - iii. The patient is profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency, solid organ/hematopoietic stem cell transplant, undergoing chemotherapy, or advanced acquired immunodeficiency)
OR
 - iv. The patient has either congenital abnormalities of the airway or a neuromuscular condition that impairs the ability to clear respiratory tract secretions because of an ineffective cough
OR
 - v. The patient has cystic fibrosis (CF) **AND** clinical evidence of chronic lung disease (CLD) and/or nutritional compromise
OR
 - vi. The patient has hemodynamically significant congenital heart disease and requires cardiac transplantation during the current RSV season
OR
 - vii. The patient has hemodynamically significant congenital heart disease **AND** ONE of the following

1. The patient has acyanotic heart disease and the patient is receiving medication to control congestive heart failure AND the patient will require a cardiac surgical procedure
OR
2. The patient has moderate to severe pulmonary hypertension
OR
- b. Patient's chronological age at the start of the RSV season is 12 months to 24 months AND ONE of the following:
 - i. The patient has hemodynamically significant congenital heart disease and requires cardiac transplantation during the current RSV season
OR
 - ii. The patient has chronic lung disease of prematurity (defined as gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth) AND continues to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the 2nd RSV season
OR
 - iii. The patient profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency, solid organ/hematopoietic stem cell transplant, undergoing chemotherapy, or advanced acquired immunodeficiency)
OR
 - iv. The patient has cystic fibrosis (CF) AND manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the 1st year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or has weight for length less than the 10th percentile

Length of approval: up to 5 doses until March 31 EXCEPT the following:

1. Patients who have hemodynamically significant congenital heart disease and who will undergo a surgical procedure involving cardiopulmonary bypass or extra-corporeal membrane oxygenation during the RSV season and who will continue to require prophylaxis after the surgical procedure may receive one extra dose of Synagis (palivizumab) after bypass or at the conclusion of the extra-corporeal membrane oxygenation (up to 6 doses per RSV season).

Length of approval:

Approvals will be for up to 5 doses until March 31 EXCEPT:

- Patients with CHD requiring surgery involving cardiopulmonary bypass during RSV prophylaxis therapy (approval for one extra dose)

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.

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