BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.20.004

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Biologicals	**Original Policy Date:**	June 9, 2011
Subject:	Synagis	**Page:**	1 of 5

Last Review Date: December 8, 2023

Synagis

Description

Synagis (palivizumab)

Background
Synagis (palivizumab) contains man-made, disease fighting proteins called antibodies to help prevent a serious lung disease caused by Respiratory Syncytial Virus (RSV) in children at high risk for lung disease from RSV. Children at high risk for severe RSV disease often do not have enough of their own antibodies. Synagis is used in certain groups of children to help prevent severe RSV disease by increasing protective RSV antibodies. This target population includes infants and children with chronic lung disease, bronchopulmonary dysplasia (CLD/BPD), a history of premature birth (29 weeks or less gestation), or with hemodynamically significant cyanotic or congenital heart disease (CHD). Synagis is not used to treat the symptoms of RSV disease once a child already has it. It is only used to prevent RSV disease (1-2).

RSV season is a term used to describe the time of year when RSV infections most commonly occur. RSV season generally lasts from November through April in most locations in the United States. The CDC website (CDC National Respiratory) may be used as a resource when the RSV season starts in a certain area (2-3).

Synagis is administered monthly each month during the RSV season. The child should receive the first dose before the RSV season starts, to help protect the child before RSV becomes active. If the season has already started, the child should receive their first dose as soon as possible. Thereafter, doses should be administered monthly as scheduled. Treatment may be maintained in patients with the most severe CLD who continue to require medical therapy and

children with hemodynamically significant congenital heart disease since studies show that patients may benefit from prophylaxis during a second RSV season (1).

Regulatory Status
FDA-approved indication: Synagis is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients (1).

Limitations of Use: The safety and efficacy of Synagis have not been established for the treatment of RSV disease (1).

The American Academy of Pediatrics has provided guidance for the use of Synagis. In the first year of life, Synagis prophylaxis is recommended for infants born before 29 weeks gestation who are younger than 12 months at the start of the RSV season. Synagis prophylaxis is also recommended for preterm infants with chronic lung disease (CLD) of prematurity, defined as birth at less than 32 weeks gestation and a requirement for greater than 21% oxygen for at least 28 days after birth (2).

During the second year of life (between 12 months and 24 months of age), consideration of palivizumab prophylaxis is recommended only for infants who satisfy this definition of CLD of prematurity and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season. For infants with CLD who do not continue to require medical support in the second year of life prophylaxis is not recommended (2).

Certain children who are 12 months or younger with hemodynamically significant CHD may benefit from palivizumab prophylaxis. Children with hemodynamically significant CHD who are most likely to benefit from immunoprophylaxis include infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension. Decisions regarding palivizumab prophylaxis for infants with cyanotic heart defects in the first year of life may be made in consultation with a pediatric cardiologist (2).

Synagis is for intramuscular use only. Synagis should be given with caution to children with thrombocytopenia or any coagulation disorder (1).

Clinicians may administer up to a maximum of 5 monthly doses of Synagis (15 mg/kg per dose) during the RSV season to infants who qualify for prophylaxis in the first year of life. Qualifying infants born during the RSV season may require fewer doses (2).

Safety and effectiveness in children older than 24 months of age at the start of dosing have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Synagis may be considered **medically necessary** if the conditions indicated below are met.

Synagis may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Prevention of infection caused by Respiratory Syncytial virus (RSV)

AND ONE of the following:

1. Less than 12 months old at the start of RSV season*
   AND ONE of the following:
   a. Hemodynamically significant congenital heart disease (e.g. congestive heart failure, or pulmonary hypertension)
   b. Congenital airway abnormality that impairs the ability to clear secretions
   c. Neuromuscular disorder that decreases the ability to manage airway secretions
   d. Chronic lung disease (CLD) in infants less than 32 weeks gestational age
   e. Preterm infants less than 29 weeks gestational age

2. Child in second year of life (between 12 months and less than 24 months of age) at

the start of RSV season*

AND ONE of the following:

a. Cardiac transplant or bypass patients
b. Severely immunocompromised
c. Chronic lung disease (CLD) in infants less than 32 weeks gestational age requiring continued medical support

*RSV season generally lasts from November through April in most locations in the United States. Consult the CDC National Respiratory and Enteric Virus Surveillance System (NREVSS) for RSV surveillance at https://www.cdc.gov/surveillance/nrevss/rsv/state.html.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months (PA may start 1 month prior to the RSV season*)
Each new RSV season is the initiation of therapy

Rationale

Summary

Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. The target population includes infants with bronchopulmonary dysplasia/chronic lung disease (BPD/CLD), infants with a history of premature birth (less than 29 weeks gestational age), severely immunocompromised children under the age of 2 years and children with hemodynamically significant congenital heart disease (CHD). The American Academy of Pediatrics has provided guidance for the use of Synagis. Synagis does not treat RSV infections nor prevent non-severe RSV infections and is therefore not indicated for the purpose (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Synagis while maintaining optimal therapeutic outcomes.

References

1. Synagis [package insert]. Waltham, MA: Sobi Inc; November 2021.

2. American Academy of Pediatrics. RSV Policy Statement — Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics*. August 2014; 134(2):415-420.
3. The National Respiratory and Enteric Virus Surveillance System (NREVSS) Website. https://www.cdc.gov/surveillance/nrevss/rsv/state.html

Policy History

Date	Action
September 2012	Annual editorial and reference update.
September 2013	Annual editorial review and reference update Removal of the AAP guidelines and aligned the criteria to the label.
December 2013	Annual editorial review and update
September 2014	Aligned with the AAP guidelines, separation of requirements between the first year of life and the second year of life.
December 2014	Annual editorial and reference update
June 2016	Annual review and reference update Policy code changed from 5.05.04 to 5.20.04
December 2017	Annual editorial review and reference update
November 2018	Annual editorial review and reference update
December 2019	Annual review
December 2020	Annual review
September 2021	Annual review and reference update. CDC link update.
September 2022	Annual review and reference update
June 2023	Annual review
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.