

Clinical Criteria

Subject: Synagis (palivizumab)

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Overview

This document addresses the use of Synagis (palivizumab), a monoclonal antibody approved by the Food and Drug Administration for prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) infection in select pediatric individuals.

Randomized placebo-controlled clinical trials have demonstrated the safety and efficacy of Synagis in reducing hospitalizations due to RSV infection and in reductions in other measures of RSV infection severity for a very specific group of infants and children. Epidemiologic data indicate that the risk of severe RSV infection most likely to require hospitalization is greater in the presence of risk factors.

In 2014, the American Academy of Pediatrics (AAP) issued updated guidelines regarding the use of immune prophylaxis for RSV. AAP reaffirmed this guidance in 2019. A summary of the AAP RSV guidance is as follows:

Preterm Infants without Chronic Lung Disease (CLD) of Prematurity or Congenital Heart Disease (CHD)

Infants born before 29 weeks, 0 days gestation in the first year of life

Preterm Infants with CLD

 Infants born before 32 weeks, 0 days gestation and a requirement for >21% oxygen for at least 28 days after birth in the first year of life

Infants with CHD

- Prophylaxis may be administered in first year of life to certain infants with hemodynamically significant heart disease
- Consultation with a cardiologist if recommended for patients with cyanotic heart disease for prophylaxis decisions

Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder

 Prophylaxis may be considered in first year of life to children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways

Immunocompromised Children

 Prophylaxis may be considered in children under 24 months who will be profoundly immunocompromised during the RSV season

Children with Down Syndrome

• Insufficient data available to routinely recommend prophylaxis

Children with Cystic Fibrosis

Insufficient data available to routinely recommend prophylaxis

Timing of Prophylaxis for Alaska Native and American Indian Infants

- Greater flexibility in use of prophylaxis as a result of potentially higher disease burden
- Use of government RSV surveillance data may be helpful in decision-making

Discontinuation of Prophylaxis Among Children who Experience Breakthrough RSV Hospitalization

Discontinue prophylaxis

Prophylaxis in the Second Year of Life

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• Recommended in children who require ≥28 days of supplemental oxygen after birth and continue to require medical intervention (supplemental oxygen, chronic systemic corticosteroid therapy, diuretics)

Number of Monthly Doses in Season

Maximum of 5

Other

- · Prophylaxis is not recommended for prevention of primary asthma or reduction of subsequent wheezing episodes
- Prophylaxis is not recommended for prevention of nosocomial disease
- Not recommended for use in RSV treatment

Because 5 monthly doses of Synagis will provide more than 6 months of adequate serum concentrations for most infants, administration should be limited to the peak RSV seasons in the continental United States, November to April. Qualifying infants born during RSV season will need fewer than 5 doses for protection until the season ends.

Specific information about national and regional RSV trends, especially pertaining to the peak variations in Florida and Alaska as well as atypical interseason RSV, is available from the National Respiratory and Enteric Virus Surveillance System (NREVSS) at: http://www.cdc.gov/surveillance/nrevss/rsv/index.html. The start of RSV season is signaled by surveillance data showing antigen positive test rates ≥10% OR PCR positive test rates ≥3%.*

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Synagis (palivizumab)

Requests for Synagis (palivizumab) may be approved if the following criteria are met:

- I. Request is submitted for one of the following:
 - RSV Season (typically November through March)

OR

Request is submitted for off-season (outside of November through March)

AND

RSV antigen test positivity rate of more than 10% for at least 2 consecutive weeks*

OR

PCR test positivity rate is more than 4% for at least 2 consecutive weeks*

*Arkansas RSV Antigen Test Positivity Rates and PCR Test Positivity Rates can be found here: https://www.cdc.gov/surveillance/nrevss/rsv/state.html#AR

- II. Provider must submit the following:
 - · Recipient's birth weight

AND

Recipient's current weight and the date measured

AND

Any relevant medical conditions or considerations

AND

III. Provider must include the diagnosis or reason for treatment

AND

IV. Provider must indicate if this request for palivizumab prophylaxis is for the first or second season.

AND

- V. Provider must indicate which of the following criteria the patient currently meets:
 - 1. Chronic lung disease (CLD) of prematurity AND < 2 years of age at start of RSV season. CLD of prematurity is defined as gestational of age < 32 weeks, 0 days and a requirement for > 21% oxygen for at least the first 28 days after birth. A second season of palivizumab prophylaxis is recommended only for infants with CLD of prematurity as defined above and who continue to require supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy during the 6-month period before the start of the second RSV season.

OR

2. Former premature (≤ 28 weeks, 6 days estimated gestational age [EGA]) **AND** < 12 months of age at the **start** of RSV season. For infants born during the RSV season, fewer than 5 monthly doses will be needed.

OR

- Infants ≤ 12 months of age at start of RSV season with hemodynamically significant congenital heart disease (CHD). Children that meet these criteria will be:
 - **a)** infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and
 - b) infants with moderate to severe pulmonary hypertension. Infants with cyanotic heart defects in the first year of life will be reviewed on a case-by-case basis.

OR

4. Infants < 12 months of age at start of RSV season with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough.

OR

Severe immunocompromised AND patient is < 2 years of age.

Quantity Limits

Synagis (palivizumab) Quantity Limit

Drug	Limit
Synagis (palivizumab) 50 mg, 100 mg vial	15 mg/kg once a month for up to 5 doses per RSV season

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

90378 Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each [Synagis]

HCPCS

Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care S9562

coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

ICD-10 Diagnosis

P07.21-P07.26 Extreme prematurity P07.31-P07.38 Preterm Newborn

P27.1 Bronchopulmonary dysplasia originating in the perinatal period Other chronic respiratory diseases originating in the perinatal period P27.8-P27.9

142.9 Cardiomyopathy, unspecified 150.9 Heart failure, unspecified

Congenital malformation of cardiac chambers and Q20.0-Q20.9

connections

Q21.0-Q21.8 Ventricular septal defects Q22.0 Pulmonary valve atresia

Document History

Revised: 10/25/2022 Document History:

- 10/25/2022 Custom Arkansas policy created.
- 12/20/2021 Minor wording change.
- 10/07/2021 Minor adjustments on seasonality.
- 8/20/2021 Annual Review: Add note providing direction on how to address the delayed 2021 RSV season and to refer to CDC website for RSV season by region. Add exclusion for more than two seasons of prophylaxis. Wording and formatting changes. Coding reviewed: Added ICD-10-CM P07.21-P07.26, P07.31-P07.38, P27.1, P27.8-P27.9, I42.9, I50.9, Q20.0-Q20.9, Q21.0-Q21.8, Q22.0
- 11/30/2020 Administrative update to add documentation requirements.
- 8/21/2020 Annual Review: No changes. Coding Reviewed: No changes.
- 09/23/2019 Administrative update to add drug specific quantity limit.
- 09/09/2019 Annual Review: Wording and formatting changes. Coding reviewed: No changes.
- 08/17/2018 Annual Review: Wording and formatting updates. Add in reference for criteria.

References

- American Academy of Pediatrics Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection: Policy Statement. Pediatrics. 2014; 134(2):415-420. Erratum in: Pediatrics. 2014; 134(6):1221. Available at: http://pediatrics.aappublications.org/content/134/2/415.full. Accessed: July 8, 2021.
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- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 8, 2021.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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