



<ul style="list-style-type: none"> <li>Recommended in children who require <math>\geq 28</math> days of supplemental oxygen after birth and continue to require medical intervention (supplemental oxygen, chronic systemic corticosteroid therapy, diuretics)</li> </ul>
<b>Number of Monthly Doses in Season</b>
<ul style="list-style-type: none"> <li>Maximum of 5</li> </ul>
<b>Other</b>
<ul style="list-style-type: none"> <li>Prophylaxis is not recommended for prevention of primary asthma or reduction of subsequent wheezing episodes</li> <li>Prophylaxis is not recommended for prevention of nosocomial disease</li> <li>Not recommended for use in RSV treatment</li> </ul>

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  $\geq 10\%$  OR PCR positive test rates  $\geq 3\%$ .\*

## 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 ( $\leq$  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**

3. Infants  $\leq$  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**

5. 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.

*CPT*

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

#### HCPCS

**S9562** Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

#### ICD-10 Diagnosis

<b>P07.21-P07.26</b>	Extreme prematurity
<b>P07.31-P07.38</b>	Preterm Newborn
<b>P27.1</b>	Bronchopulmonary dysplasia originating in the perinatal period
<b>P27.8-P27.9</b>	Other chronic respiratory diseases originating in the perinatal period
<b>I42.9</b>	Cardiomyopathy, unspecified
<b>I50.9</b>	Heart failure, unspecified
<b>Q20.0-Q20.9</b>	Congenital malformation of cardiac chambers and connections
<b>Q21.0-Q21.8</b>	Ventricular septal defects
<b>Q22.0</b>	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

1. 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.
2. 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: Technical Report. *Pediatrics*. 2014; 134(2):e620-e638. Available at: <http://pediatrics.aappublications.org/content/134/2/e620.full.pdf+html>. Accessed: July 8, 2021.
3. Arkansas Medicaid Prescription Drug Program Synagis Prior Authorization (PA) Request Form. [https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx\\_PA\\_Request\\_Form\\_Synagis.pdf](https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_PA_Request_Form_Synagis.pdf). Accessed: October 25, 2022.
4. 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.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only – American Medical Association