

palivizumab (Synagis)

Date of Origin: 01/2023

Last Review Date: 02/26/2025

Effective Date: 03/01/2025

Dates Reviewed: 02/2025

Developed By: Medical Necessity Criteria Committee

I. Length of Authorization

- Initial: Five months
- Renewal: N/A

II. Dosing Limits

Product Name	Dosage Form	Indication	Quantity Limit
palivizumab (Synagis)	100 mg/1mL	Respiratory syncytial virus (RSV) prophylaxis	15 mg/kg (1 dose) per 28 days
	50 mg/0.5mL		

III. Initial Approval Criteria CWQI HCS

- I. Palivizumab (Synagis) may be considered medically necessary when the following criteria below are met:
 - A. Therapy is given during the current RSV season, **AND**
 - B. Member is being managed by, or in consultation with, a pulmonologist or cardiologist; **AND**
 - C. A diagnosis of one of the following:
 1. **Preterm Infants WITHOUT congenital morbidities** (e.g. chronic lung disease of prematurity; or congenital heart disease); **AND**
 - i. Member was born before 29 weeks, 0 days of gestation; **AND**
 - ii. Member is less than 12 months of postnatal age; **OR**
 2. **Preterm Infants WITH Chronic Lung Disease (CLD)**; **AND**
 - i. Member was born before 32 weeks, 0 days of gestation; **AND**
 - ii. Member required respiratory support (supplement with greater than 21% oxygen) for at least the first 28 days after birth; **AND**
 - iii. Member is less than 12 months of age; **OR**
 - iv. Member is less than 24 months of age; **AND**
 - v. Continues to require medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of second RSV season; **OR**

3. **Infants and Children with Hemodynamically Significant Congenital Heart Disease (CHD); AND**
 - i. Member is less than 12 months of age; **AND**
 - ii. Member has moderate to severe pulmonary hypertension; **OR**
 - iii. Member has cyanotic heart disease; **OR**
 - iv. Member has acyanotic heart disease; **AND**
 - a. Member is receiving medication to control congestive heart failure; **AND**
 - b. Member will require cardiac surgical procedures; **OR**
4. **Children undergoing cardiac transplantation during RSV season; AND**
 - i. Member is less than 24 months of age; **OR**
5. **Infants with Anatomic Pulmonary Abnormalities or Neuromuscular disorder; AND**
 - i. Member is less than 12 months of age; **AND**
 - ii. Member has an impaired ability to clear secretions from the upper airway; **OR**
6. **Immunocompromised Children; AND**
 - i. Member is less than 24 months of age; **AND**
 - ii. Member is profoundly immunocompromised (e.g. undergoing chemotherapy, HIV, SCID, DiGeorge, IgA deficiency, Hypergammaglobulinemia etc.); **OR**
7. **Children with Cystic Fibrosis, Primary Ciliary Dyskinesia, or other rare lung disease; AND**
 - i. Member is less than 12 months of age; **AND**
 - a. Member has clinical evidence of chronic lung disease (CLD); **OR**
 - b. Member has clinical evidence of nutritional compromise; **OR**
 - ii. Member is less than 24 months of age; **AND**
 - a. Member had a hospitalization for pulmonary exacerbation in the first year of life; **OR**
 - b. Member has abnormalities on chest radiography/chest computed tomography that persist when stable; **OR**
 - c. Member has a weight for length less than the 10th percentile

- II. Palivizumab (Synagis) is considered **NOT medically necessary** when the criteria above are not met and/or when used for:
- A. Infants or children who were born after 32 weeks
 - B. Infants and children with hemodynamically insignificant heart disease such as:
 1. Secundum atrial septal defect
 2. Small ventricular septal defect
 3. Pulmonic stenosis
 4. Uncomplicated aortic stenosis
 5. Mild coarctation of the aorta
 6. Patent ductus arteriosus
 - C. Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
 - D. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
 - E. Children in the second year (≥ 24 months) of life
 - F. Children with Down syndrome without other comorbid conditions listed in the Initial Evaluation (section I) portion of this policy.

- III. Palivizumab (Synagis) is considered investigational when used for all other conditions, including but not limited to:
 - A. For the treatment of RSV

IV. Renewal Criteria

N/A

V. Investigational or Considered Not Medically Necessary

- I. The listed diagnoses are included in the AAP 2017 RSV Guidance as not medically necessary for immunoprophylaxis with palivizumab (Synagis)
 - A. Infants or children who were born after 32 weeks
 - B. Infants and children with hemodynamically insignificant heart disease such as:
 - i. Secundum atrial septal defect
 - ii. Small ventricular septal defect
 - iii. Pulmonic stenosis
 - iv. Uncomplicated aortic stenosis
 - v. Mild coarctation of the aorta
 - vi. Patent ductus arteriosus
 - C. Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
 - D. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
 - E. Children in the second year (≥ 24 months) of life
 - F. Children with Down syndrome without other comorbid conditions listed in the Initial Evaluation (section I) portion of this policy.
- II. Treatment of RSV
 - A. Safety and efficacy has not been established for the use of palivizumab (Synagis) for the treatment of RSV.

VI. CPT or HCPC codes covered

Codes	Description
90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each
S9562	Home injectable therapy, palivizumab injection (e.g., Synagis®); includes administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

VII. Annual Review History

Review Date	Revisions	Effective Date
01/2023	Policy adopted from Pharmacy Rx criteria	02/01/2023
02/2025	Review: Confirmed and added applicable codes	02/26/2025

VIII. References

1. Synagis [Prescribing Information]. Gaithersburg, MD: MedImmune, LLC. March 2014. Wegzyn C, Toh LK, Biguenet S, et al. Safety and Effectiveness of Palivizumab in Children at High Risk of Serious Disease Due to Respiratory Syncytial Virus Infection: A Systematic Review. *Infect Dis Ther.* 2014 Dec; 3(2): 133–158.
2. American Academy of Pediatrics: Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Available at: <https://pediatrics.aappublications.org/content/134/2/415>
3. American Academy of Pediatrics: RSV recommendations unchanged after review of new data. Available at: <https://www.aappublications.org/news/2017/10/19/RSV101917>
4. Policy Statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. *Pediatrics.* August 2014; 134(2): e415-20. doi: 10.1542/peds.2014-1665. Reaffirmed February 2019. Available online at <https://pediatrics.aappublications.org/content/134/2/415.full#sec-13>.
5. Goldstein M, Phillips R, DeVincenzo J, et al. The National Perinatal Association 2018 Respiratory Syncytial Virus (RSV) Prevention Clinical Practice Guideline: An Evidence-Based Interdisciplinary Collaboration. October 2017.
6. Center for Disease Control and Prevention: Respiratory Syncytial Virus Infection (RSV). Available at: <https://www.cdc.gov/rsv/clinical/index.html>
7. Red Book® 2018. Committee on Infectious Diseases; American Academy of Pediatrics; David W. Kimberlin, MD, FAAP; Michael T. Brady, MD, FAAP; Mary Anne Jackson, MD, FAAP; Sarah S. Long, MD, FAAP. Section 3: Respiratory Syncytial Virus. Available at <https://redbook.solutions.aap.org/Book.aspx?bookid=2205>. Accessed December 4th, 2020.

Appendix 1 – Covered Diagnosis Codes

Jurisdiction(s): 5, 8	NCD/LCD Document (s):

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be

found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35053&bc=gAAAAAAAAAAAAAA==	

NCD/LCD Document (s): A52701
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52701&bc=gAAAAAAAAAAAAAA==

Jurisdiction(s): 6,K	NCD/LCD Document (s): A52450
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52450&bc=gAAAAAAAAAAAAAA==	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corporation (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC