Subject to: ☐Site of Care
☐Medication Sourcing
☐Medicare Adv.
Enhanced Oncology Value

Synagis® (Palivizumab)
(Intramuscular)

Document Number: IC-0120

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I. Length of Authorization

- Initial: Prior authorization validity will be provided for a maximum of 5 monthly doses for use during the typical RSV season, unless otherwise specified.
  - **± Note:** In regions experiencing high rates of RSV circulation, consistent with a typical RSV season onset, prior authorization validity may be provided if surveillance data from the CDC indicate a high percent positivity rate for RSV testing in the area.
  - In infants and children < 24 months already eligible and on prophylaxis with palivizumab, 1 additional post-op dose can be approved after cardiopulmonary bypass or after extracorporeal membrane oxygenation (ECMO), followed by the remaining monthly doses for the season.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 5 billable units every 28 days

III. Initial Approval Criteria

> ***Note:** Please consult the current American Academy of Pediatrics (AAP) clinical practice guidelines for recommended agents for prevention of RSV disease in Infants and Children.*

Prior authorization validity is provided in the following conditions:

Prevention of serious lower respiratory tract disease caused by Respiratory Syncytial Virus (RSV) † ‡ [1-3,14,22,24]

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- Member has NOT had an RSV infection during the current RSV season; **AND**
- Member has NOT received nirsevimab for the current RSV season; **AND**
- Member does NOT have access to, or it is not feasible to administer nirsevimab; **AND**
    - Member is < 12 months of age entering their first RSV season; **AND**
        - One of the following apply regarding the pregnant parent's RSV vaccination status:
            - Member is ≥ 8 months of age, regardless of pregnant parent's RSV vaccination status; **OR**
            - The pregnant parent did not receive an RSV vaccine prior to birth; **OR**
            - The provider judges that the incremental benefit to administering palivizumab to the infant born to a vaccinated pregnant member is warranted due to one of the following:
                - Member was born < 14 days after the pregnant parent's RSV vaccination; **OR**
                - The pregnant parent did not mount an adequate immune response to vaccination or has a condition associated with reduced transplacental antibody transfer (e.g., persons with immunocompromising conditions); **OR**
                - The infant has experienced loss of transplacentally acquired antibodies (e.g., those who have undergone cardiopulmonary bypass or ECMO); **OR**
                - The infant has substantially increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease or intensive care admission requiring oxygen at hospital discharge); **AND**
        - Member meets one of the following risk factors:
            - Member gestational age (GA) < 29 weeks, 0 days; **OR**
            - Member has chronic lung disease (CLD) of prematurity (GA < 32 weeks, 0 days and the member required > 21% supplemental oxygen for at least the first 28 days after birth); **OR**
            - Member has hemodynamically significant congenital heart disease (CHD) with one of the following**:
                - Acyanotic heart disease on CHF medications and will require cardiac surgery; **OR**
                - Moderate to severe pulmonary hypertension; **OR**
                - Cyanotic heart defects and the prescriber is a pediatric cardiologist or has consulted a pediatric cardiologist; **OR**
                - Undergoing cardiac transplant during the RSV season; **OR**
                - Cardiac lesions have been adequately corrected by surgery, but continues to require medication for CHF; **OR**
                - Mild cardiomyopathy and receiving medical therapy for the condition; **OR**
            - Member has cystic fibrosis; **AND**

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- Member has clinical evidence of chronic lung disease (CLD) and/or nutritional compromise; **OR**
- Member has an impaired ability to clear upper airway secretions because of an ineffective cough due to congenital anomaly or a neuromuscular disease; **OR**
- Member is profoundly immunocompromised; **OR**

- Member is < 24 months of age entering their second RSV season; **AND**
  - Member meets one of the following risk factors:
    - Member has chronic lung disease (CLD) of prematurity (GA < 32 weeks, 0 days and the member required > 21% supplemental oxygen for at least the first 28 days after birth); **AND**
      - Member has required medical support (chronic steroids, diuretic therapy, or supplemental oxygen) within 6 months prior to the start of the second season; **OR**
    - Member has congenital heart disease (CHD) undergoing cardiac transplant during the RSV season**; **OR**
    - Member has cystic fibrosis; **AND**
      - Member has weight for length < 10th percentile; **OR**
      - Member has severe lung disease (i.e., previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography, or chest computed tomography that persist when stable); **OR**
    - Member is profoundly immunocompromised

±RSV SEASON [2,3,13,14,18,22,23]

- There is variability in the onset and offset of the **typical** RSV season each year. Generally, it begins in October, peaks in December or January and ends in April within the continental US.
- A **typical** RSV season onset is determined when **both** of the following are met*:
  - Timeframe: Fall season (generally October)
  - RSV is detected at high rates, defined by statewide or local positivity rates of either of the following:
    - ≥ 3% polymerase chain reaction (PCR) positivity rate average over 2 consecutive weeks
    - ≥ 10% antigen test positivity rate average over 2 consecutive weeks
- A typical RSV season offset generally occurs around April when there is decreased RSV activity to < 3% PCR positivity and/or < 10% antigen positivity for > 2 consecutive weeks.
- The AAP recommends a maximum of 5 doses of palivizumab during the **typical** RSV season, which provides at least 6 months of RSV prophylaxis. If prophylaxis is initiated later in the RSV season, the infant or child may receive less than 5 doses.
- For example, a total of 5 monthly doses beginning in November and the last dose given in March will provide protection for most infants through April and is recommended for most areas in the US. However, according to the AAP, if the first dose is given in October, the fifth and final dose should be given in February, which will provide protection through March. Similarly, if the first dose is given in December, the fifth and final dose should be administered in April, which will provide protection for most infants through May.

** The typical RSV season onset and offset may not be applicable for the reasons below:*

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±RSV SEASON [2,3,13,14,18,22,23]
• **RSV atypical interseasonal activity** – Interseasonal spikes in RSV activity may occur outside the usual timeframe for the typical RSV season when RSV is detected at high rates (via the same PCR or antigen positivity measures as noted above for a typical season). • **Native American Indian infants** – There is limited information about the burden of RSV infection among American Indian populations. Prophylaxis can be considered for Alaska Natives, Navajo, and White Mountain Apache infants in the first year of life. • **States with variable RSV seasons** – This includes Alaska and Florida. Due to the varied epidemiology of RSV infection in these states, clinicians can use guidance from public health authorities (e.g., CDC, state health departments, etc.) to determine the onset and offset of the local RSV season. Despite differences in onset and offset of RSV infection in some states or regions, only a maximum of 5 doses will be approved. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded *(refer to Section I).*

V. Dosage/Administration [1-3]

Indication	Dose
RSV Prevention	The recommended dose is 15 mg/kg administered intramuscularly once a month (28-30 days) for up to 5 doses** throughout the typical RSV season. **Note: – Infants and children already eligible and on prophylaxis with palivizumab who are undergoing surgical procedures involving cardiopulmonary bypass should receive an additional dose of palivizumab as soon as possible after the cardiopulmonary bypass or after extracorporeal membrane oxygenation (ECMO) (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled.

VI. Billing Code/Availability Information

HCPCS/CPT Code:

- 90378 – Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each; 1 billable unit = 50 mg
- S9562 – Home injectable therapy, palivizumab or other monoclonal antibody for rsv, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

NDC(s):

- 50 mg/0.5 mL solution for injection in a single-dose vial: 66658-0230-xx
- 100 mg/1 mL solution for injection in a single-dose vial: 66658-0231-xx

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
P07.21	Extreme immaturity of newborn, GA
P07.22	Extreme immaturity of newborn, GA 23 completed weeks
P07.23	Extreme immaturity of newborn, GA 24 completed weeks
P07.24	Extreme immaturity of newborn, GA 25 completed weeks
P07.25	Extreme immaturity of newborn, GA 26 completed weeks
P07.26	Extreme immaturity of newborn, GA 27 completed weeks
P07.31	Preterm newborn, GA 28 completed weeks
P07.32	Preterm newborn, GA 29 completed weeks
P07.33	Preterm newborn, GA 30 completed weeks
P07.34	Preterm newborn, GA 31 completed weeks
P07.35	Preterm newborn, GA 32 completed weeks
P07.36	Preterm newborn, GA 33 completed weeks
P07.37	Preterm newborn, GA 34 completed weeks
P07.38	Preterm newborn, GA 35 completed weeks
P27.1	Bronchopulmonary dysplasia originating in the perinatal period
P27.8	Other chronic respiratory diseases originating in the perinatal period
P27.9	Unspecified chronic respiratory disease originating in the perinatal period
I42.9	Cardiomyopathy, unspecified

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I50.9	Heart failure, unspecified
P29.30	Pulmonary hypertension of newborn
Q20.0	Common arterial trunk
Q20.1	Double outlet right ventricle
Q20.2	Double outlet left ventricle
Q20.3	Discordant ventriculoarterial connection
Q20.4	Double inlet ventricle
Q20.5	Discordant atrioventricular connection
Q20.6	Isomerism of atrial appendages
Q20.8	Other congenital malformations of cardiac chambers and connections
Q20.9	Congenital malformation of cardiac chambers and connections, unspecified
Q21.0	Ventricular septal defect
Q21.1	Atrial septal defect
Q21.2	Atrioventricular septal defect
Q21.3	Tetralogy of Fallot
Q21.4	Aortopulmonary septal defect
Q21.8	Other congenital malformations of cardiac septa
Q21.9	Congenital malformation of cardiac septum, unspecified
Q22.0	Pulmonary valve atresia
Q22.1	Congenital pulmonary valve stenosis
Q22.2	Congenital pulmonary valve insufficiency
Q22.3	Other congenital malformations of pulmonary valve
Q22.4	Congenital tricuspid stenosis
Q22.5	Ebstein's anomaly
Q22.6	Hypoplastic right heart syndrome
Q22.8	Other congenital malformations of tricuspid valve
Q22.9	Congenital malformation of tricuspid valve, unspecified
Q23.0	Congenital stenosis of aortic valve
Q23.1	Congenital insufficiency of aortic valve
Q23.2	Congenital mitral stenosis
Q23.3	Congenital mitral insufficiency
Q23.4	Hypoplastic left heart syndrome
Q23.8	Other congenital malformations of aortic and mitral valves
Q24.1	Levocardia
Q24.2	Cor triatriatum

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Q24.3	Pulmonary infundibular stenosis
Q24.4	Congenital subaortic stenosis
Q24.5	Malformation of coronary vessels
Q24.6	Congenital heart block
Q24.8	Other specified congenital malformations of heart
Q25.0	Patent ductus arteriosus
Q25.1	Coarctation of aorta
Q25.21	Interruption of aortic arch
Q25.29	Other atresia of aorta
Q25.3	Supravalvular aortic stenosis
Q25.40	Congenital malformation of aorta unspecified
Q25.41	Absence and aplasia of aorta
Q25.42	Hypoplasia of aorta
Q25.43	Congenital aneurysm of aorta
Q25.44	Congenital dilation of aorta
Q25.45	Double aortic arch
Q25.46	Tortuous aortic arch
Q25.47	Right aortic arch
Q25.48	Anomalous origin of subclavian artery
Q25.49	Other congenital malformations of aorta
Q25.5	Atresia of pulmonary artery
Q25.6	Stenosis of pulmonary artery
Q25.71	Coarctation of pulmonary artery
Q25.72	Congenital pulmonary arteriovenous malformation
Q25.79	Other congenital malformations of pulmonary artery
Q25.8	Other congenital malformations of other great arteries
Q25.9	Congenital malformation of great arteries, unspecified
Q26.0	Congenital stenosis of vena cava
Q26.1	Persistent left superior vena cava
Q26.2	Total anomalous pulmonary venous connection
Q26.3	Partial anomalous pulmonary venous connection
Q26.4	Anomalous pulmonary venous connection, unspecified
Q26.8	Other congenital malformations of great veins
Q26.9	Congenital malformation of great vein, unspecified

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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

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 Corp (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 Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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

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