Clinical Policy: Palivizumab (Synagis)

Reference Number: PA.CP.PHAR.16
Effective Date: 01/2018
Last Review Date: 04/2025

Description
Palivizumab (Synagis®) is a recombinant humanized monoclonal antibody with anti-respiratory syncytial virus (RSV).

FDA Approved Indication(s)
Synagis is indicated for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients:

- With a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season;
- With bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season;
- With hemodynamically significant congenital heart disease and who are 24 months of age or younger at the beginning of RSV season.

Limitation(s) of use: The safety and efficacy of Synagis have not been established for treatment of RSV disease.

Policy/Criteria
It is the policy of PA Health & Wellness that Synagis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Preterm Infant (must meet all)**:**

1. Diagnosis of preterm infant with gestational age < 29 weeks;
2. Age at onset of RSV season < 12 months;
3. Request is for RSV prophylaxis;
4. Member must use Beyfortus®, if available*, unless contraindicated or clinically significant adverse effects are experienced;
   ** Confirm supply constraints prior to bypassing this requirement (see Appendix D).*
5. Medical justification supports requests for RSV beyond September through May* (*see Appendix D*);
   **Requests for RSV prophylaxis outside of the typical season (e.g., September through May) by region may be considered. Traditionally RSV season onset was defined by consecutive weeks when RSV antigen-based tests exceeded 10% positivity. Due to the increased use of PCR testing, alternative statistical methods are used to determine seasonality in real time. Local and State health departments should be consulted to determine the real-time RSV season. Additional information on RSV trends by state can be found by visiting:* https://www.cdc.gov/nrevss/php/dashboard/index.html.
6. Member has not been hospitalized with RSV disease during the current RSV season;
7. For the current RSV season, member has not previously received Beyfortus or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination (*see Appendix F for exceptions)*;
8. Dose does not exceed 15 mg/kg once a month by intramuscular (IM) administration (*see Appendix E for dose rounding guidelines*).

Approval duration: up to 5 doses per RSV season
** Overlap of two seasons due to elevated interseasonal RSV activity does not preclude a member from receiving more than 5 consecutive doses, so long as doses are limited to 5 per season*

B. Chronic Lung Disease of Prematurity (must meet all):
1. Diagnosis of chronic lung disease (CLD) of prematurity (i.e., bronchopulmonary dysplasia) defined as both of the following (a or b):
   a. Gestational age < 32 weeks;
   b. Requirement for > 21% oxygen for ≥ 28 days after birth;
2. Age at onset of RSV season (a or b):
   a. Age < 12 months;
   b. Age ≥ 12 months to < 24 months and continues to require supplemental oxygen, chronic systemic corticosteroid therapy, bronchodilator therapy, or diuretic therapy within 6 months of the start of the RSV season;
3. Request is for RSV prophylaxis;
4. For members less than or equal to 19 months of age, must use Beyfortus, if available*, unless contraindicated or clinically significant adverse effects are experienced;
   ** Confirm supply constraints prior to bypassing this requirement (see Appendix D).*
5. Medical justification supports requests for RSV beyond September through May* (*see Appendix D*);
   **Requests for RSV prophylaxis outside of the typical season (e.g., September through May) by region may be considered. Traditionally RSV season onset was defined by consecutive weeks when RSV antigen-based tests exceeded 10% positivity. Due to the increased use of PCR testing, alternative statistical methods are used to determine seasonality in real time. Local and State health departments should be consulted to determine the real-time RSV season. Additional information on RSV trends by state can be found by visiting:* https://www.cdc.gov/nrevss/php/dashboard/index.html.
6. Member has not been hospitalized with RSV disease during the current RSV season;
7. For the current RSV season, member has not previously received Beyfortus or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination (*see Appendix F for exceptions)*;
8. Dose does not exceed 15 mg/kg once a month by IM administration (*see Appendix E for dose rounding guidelines*).

Approval duration: up to 5 doses per RSV season** Overlap of two seasons due to elevated interseasonal RSV activity does not preclude a member from receiving more than 5 consecutive doses, so long as doses are limited to 5 per season*

C. Congenital Heart Disease (must meet all)**:**
1. Age and diagnosis at onset of RSV season (a or b):
   a. Age < 12 months and either (i or ii);
      i. Diagnosis of acyanotic heart disease and either (a or b):
         a) Receiving medication to control congestive heart failure AND will require a cardiac surgical procedure;
         b) Diagnosis of moderate to severe pulmonary hypertension;
      ii. Diagnosis of a cyanotic heart defect and RSV prophylaxis is recommended by a pediatric cardiologist;
   b. Age < 24 months and undergoing cardiac transplantation or cardio-pulmonary bypass during the current RSV season;

2. Request is for RSV prophylaxis;
3. For members less than or equal to 19 months of age, must use Beyfortus, if available*, unless contraindicated or clinically significant adverse effects are experienced;
   ** Confirm supply constraints prior to bypassing this requirement (see Appendix D).*
4. Medical justification supports requests for RSV beyond September through May* (see Appendix D);
   **Requests for RSV prophylaxis outside of the typical season (e.g., September through May) by region may be considered. Traditionally RSV season onset was defined by consecutive weeks when RSV antigen-based tests exceeded 10% positivity. Due to the increased use of PCR testing, alternative statistical methods are used to determine seasonality in real time. Local and State health departments should be consulted to determine the real-time RSV season. Additional information on RSV trends by state can be found by visiting:* https://www.cdc.gov/nrevss/php/dashboard/index.html
5. Member has not been hospitalized with RSV disease during the current RSV season;
6. For the current RSV season, member has not previously received Beyfortus or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination (*see Appendix F for exceptions)*;
7. Dose does not exceed 15 mg/kg once a month by IM administration (*see Appendix E for dose rounding guidelines*).

Approval duration: up to 5 doses per RSV season *(6 doses if cardio-pulmonary bypass)* Overlap of two seasons due to elevated interseasonal RSV activity does not preclude a member from receiving more than 5 consecutive doses, so long as doses are limited to 5 per season*

D. Anatomic Pulmonary Abnormalities, Neuromuscular Disorders, Infants Profoundly Immunocompromised (must meet all)**:**

1. Age and diagnosis at onset of RSV season (a or b):
   a. Age < 12 months and diagnosis of an anatomic pulmonary abnormality or neuromuscular disorder that impairs the ability to clear secretions from the upper airway (e.g., due to ineffective cough);
   b. Age < 24 months and will be profoundly immunocompromised during the RSV season (e.g., due to solid organ or hematopoietic stem cell transplantation, chemotherapy, severe combined immunodeficiency, chronic granulomatous disease);
2. Request is for RSV prophylaxis;
3. For members less than or equal to 19 months of age, must use Beyfortus, if available*, unless contraindicated or clinically significant adverse effects are experienced;
   ** Confirm supply constraints prior to bypassing this requirement (see Appendix D).*
4. Medical justification supports requests for RSV beyond September through May* (see Appendix D);
   **Requests for RSV prophylaxis outside of the typical season (e.g., September through May) by region may be considered. Traditionally RSV season onset was defined by consecutive weeks when RSV antigen-based tests exceeded 10% positivity. Due to the increased use of PCR testing, alternative statistical methods are used to determine seasonality in real time. Local and State health departments should be consulted to determine the real-time RSV season. Additional information on RSV trends by state can be found by visiting:* https://www.cdc.gov/nrevss/php/dashboard/index.html
5. Member has not been hospitalized with RSV disease during the current RSV season;

6. For the current RSV season, member has not previously received Beyfortus or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination (*see Appendix F for exceptions)*;
7. Dose does not exceed 15 mg/kg once a month by IM administration (*see Appendix E for dose rounding guidelines*).

Approval duration: up to 5 doses per RSV season * *Overlap of two seasons due to elevated interseasonal RSV activity does not preclude a member from receiving more than 5 consecutive doses, so long as doses are limited to 5 per season*

E. Cystic Fibrosis (off-label) (must meet all)**:**

1. Diagnosis of cystic fibrosis and one of the following (a or b);
   a. Clinical evidence of nutritional compromise;
   b. Diagnosis of CLD of prematurity defined as both of the following (i or ii):
      i. Gestational age < 32 weeks;
      ii. Requirement for > 21% oxygen for ≥ 28 days after birth;
2. Age at onset of RSV season (a or b):
   a. Age < 12 months;
   b. Age < 24 months and (i or ii):
      i. Manifestations of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable);
      ii. Weight for length < 10th percentile;
3. Request is for RSV prophylaxis;
4. For members less than or equal to 19 months of age, must use Beyfortus, if available*, unless contraindicated or clinically significant adverse effects are experienced;
   ** Confirm supply constraints prior to bypassing this requirement (see Appendix D).*
5. Medical justification supports requests for RSV beyond September through May* (*see Appendix D*);
   **Requests for RSV prophylaxis outside of the typical season (e.g., September through May) by region may be considered. Traditionally RSV season onset was defined by consecutive weeks when RSV antigen-based tests exceeded 10% positivity. Due to the increased use of PCR testing, alternative statistical methods are used to determine seasonality in real time. Local and State health departments should be consulted to determine the real-time RSV season. Additional information on RSV trends by state can be found by visiting:* https://www.cdc.gov/nrevss/php/dashboard/index.html
6. Member has not been hospitalized with RSV disease during the current RSV season;For the current RSV season, member has not previously received Beyfortus or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination (*see Appendix F for exceptions)*;
7. Dose does not exceed 15 mg/kg once a month by IM administration (*see Appendix E for dose rounding guidelines*).

Approval duration: up to 5 doses per RSV season * *Overlap of two seasons due to elevated interseasonal RSV activity does not preclude a member from receiving more than 5 consecutive doses, so long as doses are limited to 5 per season*

F. Alaska Native and Other American Indian Infants (off-label) (must meet all):

1. Medical director consultation is required for requests relating to Alaska native and other American Indian infants that fall outside the criteria outlined above;

2. Alaska native infants: Eligibility for prophylaxis may differ from the remainder of the U.S. on the basis of epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than in the general U.S. population,
3. Other American Indian infants: Limited information is available concerning the burden of RSV disease among American Indian populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.
4. Request is for RSV prophylaxis;
5. For members less than or equal to 19 months of age, must use Beyfortus, if available*, unless contraindicated or clinically significant adverse effects are experienced;
   ** Confirm supply constraints prior to bypassing this requirement (see Appendix D).*
6. Medical justification supports requests for RSV beyond September through May* (see Appendix D);
   **Requests for RSV prophylaxis outside of the typical season (e.g., September through May) by region may be considered. Traditionally RSV season onset was defined by consecutive weeks when RSV antigen-based tests exceeded 10% positivity. Due to the increased use of PCR testing, alternative statistical methods are used to determine seasonality in real time. Local and State health departments should be consulted to determine the real-time RSV season. Additional information on RSV trends by state can be found by visiting:* https://www.cdc.gov/nrevss/php/dashboard/index.html
7. Member has not been hospitalized with RSV disease during the current RSV season;
8. For the current RSV season, member has not previously received Beyfortus or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination (*see Appendix F for exceptions)*;
9. Dose does not exceed 15 mg/kg once a month by IM administration (*see Appendix E for dose rounding guidelines*).

Approval duration: up to 5 doses per RSV season ** Overlap of two seasons due to elevated interseasonal RSV activity does not preclude a member from receiving more than 5 consecutive doses, so long as doses are limited to 5 per season*

G. Other diagnoses/indications: Refer to PA.CP.PMN.53.

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.PHARM.01) applies;
2. Request is for RSV prophylaxis;
3. For members less than or equal to 19 months of age, must use Beyfortus, if available*, unless contraindicated or clinically significant adverse effects are experienced;
   ** Confirm supply constraints prior to bypassing this requirement (see Appendix D).*
4. Member will not reach 24 months of age at the start of RSV season;
5. Medical justification supports requests for RSV beyond September through May* (*see Appendix D*);
   **Requests for RSV prophylaxis outside of the typical season (e.g., September through May) by region may be considered. Traditionally RSV season onset was defined by consecutive weeks when RSV antigen-based tests exceeded 10% positivity. Due to the increased use of PCR testing, alternative*

statistical methods are used to determine seasonality in real time. Local and State health departments should be consulted to determine the real-time RSV season. Additional information on RSV trends by state can be found by visiting: https://www.cdc.gov/nrevss/php/dashboard/index.html.

6. Member has not received 5 doses of Synagis in the current RSV season *(6 doses if cardio-pulmonary bypass)*;
7. Member has not been hospitalized with RSV disease during the current RSV season;
8. For the current RSV season, member has not previously received Beyfortus or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination (*see Appendix F for exceptions)*;
9. If request is for a dose increase, new dose does not exceed 15 mg/kg once a month by IM administration (*see Appendix E for dose rounding guidelines*).

Approval duration: up to 5 doses per RSV season *(6 doses if cardio-pulmonary bypass) * Overlap of two seasons due to elevated interseasonal RSV activity does not preclude a member from receiving more than 5 consecutive doses, so long as doses are limited to 5 per season*

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies; or
2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BPD: bronchopulmonary dysplasia
CLD: chronic lung disease of prematurity
FDA: Food and Drug Administration
HHS: Health and Human Services
RSV: respiratory syncytial virus

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Beyfortus® (nirsevimab)	**Prophylaxis - First RSV Season** Single IM injection of: • Weight < 5 kg: 50 mg • Weight ≥ 5 kg: 100 mg **Prophylaxis - Second RSV Season** Single 200 mg dose IM	First RSV Season: 1 dose Second RSV Season: 1 dose (2 doses per lifetime if member is at increased risk of severe disease)

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- *Contraindication(s): previous significant hypersensitivity reaction to Synagis*
- *Boxed warning(s): none reported*

Appendix D: RSV Seasonal Durations across the United States - Initiation and Termination of RSV Prophylaxis

- Historical 2014-2017 CDC data from the 10 U.S. Department of Health and Human Services (HHS) regions, with the exception of Florida, shows RSV seasons commencing as early as September in some regions and ending as late as May in others.[2-3]
- Because 5 monthly Synagis doses at 15 mg/kg/dose will provide more than 6 months of serum palivizumab concentrations above the threshold for protection for most infants, administration of more than 5 monthly doses is not recommended within the continental U.S. Children who qualify for Synagis prophylaxis should receive the first dose at the onset of the RSV season. For qualifying infants born during the RSV season, fewer than 5 Synagis doses will be needed to provide protection until the RSV season ends in their region. A small number of sporadic RSV hospitalizations will occur before or after the main season in many areas of the U.S., but the greatest benefit from prophylaxis is derived during peak season and not when the incidence of RSV hospitalization is low.[4-7]
- Traditionally, the RSV season was defined by consecutive weeks when RSV antigen-based tests exceeded 10% positivity; however, since 2008, laboratories have shifted away from antigen-based RSV testing, and since 2014 the majority of tests and RSV detections among consistently reporting laboratories are determined by polymerase chain reaction (PCR). The method that consistently captured the highest percentage of PCR detections for retrospectively characterizing RSV seasons was determined to be the retrospective slope 10 (RS10) method. This method uses a centered 5-week moving average of RSV detections normalized to a season peak of 1,000 detections. The season onset was defined as the second of 2 consecutive weeks when the slope, or normalized 5-week moving average of RSV detections between subsequent weeks, exceeded 10. The season offset was the last week when the standardized (normalized) detections exceeded the standardized detections at onset. The peak was the week with the most standardized detections. The season duration was the inclusive weeks between onset and offset. The RS10 method captures a high proportion of RSV PCR detections for retrospectively determining RSV seasonality, but cannot be used to determine seasonal onset and offset in real time, and can only be employed after the season ends. Alternative statistical methods, including the tenfold baseline or 3% threshold methods might be used to determine seasonality in real time or near real time.
- The updated 2024 guidance provided by the AAP states that while the timing of the onset and duration of RSV season may vary, nirsevimab may be administered from October through the end of March in most of the continental United States. The timing of the onset, peak, and decline of RSV activity vary geographically, and providers may adjust timing of administration based on guidance from public health authorities (eg, CDC, health departments) or regional medical centers. The CDC expects the RSV season to fall within normal seasonal patterns.
- ACIP and AAP 2024 recommendations for the use of nirsevimab state the following regarding palivizumab:
  - If palivizumab was administered initially for the season and < 5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered.
  - If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available.

If nirsevimab is not available, palivizumab should be administered as previously recommended.

- AAP frequently asked questions regarding nirsevimab state that a shortage of niservimab is not expected this coming season. The AAP and CDC have been meeting regularly with the manufacturer to review the challenges from last season and plan for the 2024-2025 season. Nirsevimab is expected to be broadly available by October 1, 2024. The only instance when palivizumab should be administered is when nirsevimab is recommended but is not available and the patient is eligible to receive palivizumab.

Appendix E: Dose Rounding Guidelines

Weight-based Dose Range	Vial Quantity Recommendation
≤ 52.49 mg	1 vial of 50 mg/0.5 mL
52.5 mg – 104.99 mg	1 vial of 100 mg/1 mL
105 mg – 157.49 mg	1 vial of 50 mg/0.5 mL and 1 vial of 100 mg/1 mL
157.5 mg – 209.99 mg	2 vials of 100 mg/1 mL
210 mg – 262.49 mg	1 vial of 50 mg/0.5 mL and 2 vials of 100 mg/1 mL
262.5 mg – 314.99 mg	3 vials of 100 mg/1 mL

Appendix F: Infant Vaccination after Maternal Vaccination
Regarding maternal RSV vaccination, the CDC notes some exceptions for infants to be vaccinated for RSV:

- less than 14 days have elapsed between vaccination and birth
- Infants born to pregnant people who may not mount an adequate immune response to vaccination or have conditions associated with reduced transplacental antibody transfer
- Infants who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation leading to loss of maternal antibodies
- Infants with substantial increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease, intensive care admission and requiring oxygen at discharge)

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RSV prophylaxis in pediatric patients	15 mg/kg IM once a month	15 mg/kg/month; up to 5 doses per RSV season (1 extra dose if cardio-pulmonary bypass)

V. Product Availability

Single-dose vials: 50 mg/0.5 mL, 100 mg/1 mL

VI. References

1. Synagis Prescribing Information. Gaithersburg, MD: MedImmune, LLC; November 2021. Available at https://www.synagis.com/synagis.pdf. Accessed January 17, 2025.
2. Respiratory syncytial virus infection (RSV): Surveillance of RSV. Centers for Disease Control and Prevention website. Available at

https://www.cdc.gov/rsv/php/surveillance/index.html. Page last reviewed: August 30, 2024. Accessed February 4, 2025.
3. Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. MMWR Morb Mortal Wkly Rep 2018;67:71–76. DOI: http://dx.doi.org/10.15585/mmwr.mm6702a4.
4. 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 January 25, 2023.
5. Kimberlin DW, Barnett ED, Lynfield R, et al. Red Book: 2021-2024 Report of the Committee on Infectious Diseases (32nd Edition). American Academy of Pediatrics; Section 3: Respiratory Syncytial Virus. Available at: https://publications.aap.org/redbook/book/347/Red-Book-2021-2024-Report-of-the-Committee-on. Accessed February 21, 2022.
6. 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.
7. Technical Report: 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): e620-38. doi: 10.1542/peds.2014-1666.
8. Errata: RSV 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. *Pediatrics.* December 2014; 134(6): 1221.
9. Caserta MT, O'Leary ST, Munoz FM, et al. Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. American Academy of Pediatrics: Technical Report. Pediatrics. July 2023; 152 (1): e2023061803.
10. Robbie, G, Zhao, L, Mondick, J, et al. Population Pharmacokinetics of Palivizumab, a Humanized Anti-Respiratory Syncytial Virus Monoclonal Antibody in Adults and Children. Antimicrobial Agents and Chemotherapy. Sept 2012; 56(9): 4927-4936.
11. CDC Health Alert Network: Increased Interseasonal Respiratory Syncytial Virus (RSV) Activity in Parts of the Southern United States. June 10, 2021. Available at: https://emergency.cdc.gov/han/2021/han00443.asp.
12. Rose EB, Wheatley A, Langley G, et al. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. Morbidity and Mortality Weekly Report (MMWR). January 19, 2018. 67(2): 71-76. Available at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6702a4.htm.
13. Updated guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season. American Academy of Pediatrics. Pediatrics. November 17, 2022. Available at: https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-

guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/. Accessed January 31, 2024.
14. ACIP and AAP Recommendations for the Prevention of RSV Disease in Infants and Children. February 21, 2024. Available at: https://publications.aap.org/redbook/resources/25379?autologincheck=redirected. Accessed February 4, 2025.
15. AAP: Nirsevimab Frequently Asked Questions. Last updated November 8, 2024. Available at: https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-frequently-asked-questions. Accessed February 4, 2025.
16. Health Alert Network CDCHAN-00499: Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season. October 23, 2023. Available at: https://emergency.cdc.gov/han/2023/han00499.asp. Accessed January 31, 2024.
17. Moline HL, Tannis A, Toepfer AP, et al. Early Estimate of Nirsevimab Effectiveness for Prevention of Respiratory Syncytial Virus–Associated Hospitalization Among Infants Entering Their First Respiratory Syncytial Virus Season — New Vaccine Surveillance Network, October 2023–February 2024. Morbidity and Mortality Weekly Report (MMWR). March 7, 2024. 73(9): 209-214.
18. CDC Respiratory Syncytial Virus Infection (RSV): Clinical Overview of RSV. August 30, 2024. Available at: https://www.cdc.gov/rsv/hcp/clinical-overview/index.html. Accessed February 4, 2025.
19. CDC 2024-2025 Respiratory Disease Season Outlook. August 29, 2024. Available at: https://www.cdc.gov/cfa-qualitative-assessments/php/data-research/season-outlook24-25/index.html. Accessed February 5, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each
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

Reviews, Revisions, and Approvals	Date
2Q 2018 annual review: references reviewed and updated.	02/2018
2Q 2019 annual review: RSV seasonal patterns are updated in Appendix D per the CDC and state health departments to indicate a season onset as early as September extending to as late as May.	04/2019

Reviews, Revisions, and Approvals	Date
2Q 2020 annual review: change made to clarify preterm/gestational age requirement in Section I.A.: diagnosis of preterm birth is updated to indicate diagnosis of preterm infant; defined as gestational age < 29 weeks is updated to indicate with gestational age < 29 weeks; added appendix E: dose rounding guidelines; added reference to appendix E within criteria; references reviewed and updated.	04/2020
2Q 2021 annual review: Seasonal coverage criteria are added to all indications; related AAP/CDC guidance is added to Appendix D; per prescribing information, added requirement for continued therapy that member will not reach 24 months of age at the start of RSV season; references reviewed and updated.	04/2021
2Q 2022 annual review: Appendix D updated to include American Academy of Pediatrics (AAP) updated guidance for the 2021-2022 RSV season; references reviewed and updated.	04/2022
2Q 2023 annual review: for CLD added bronchodilator therapy as an additional option to confirm appropriateness of therapy in the second year of life per AAP guidance; references reviewed and updated.	04/2023
2Q 2024 annual review: Added redirection to Beyfortus per ACIP and AAP recommendations; clarified requirement for medical justification for use "outside" the typical RSV season; added the following requirement: "for the current RSV season, member has not previously received Beyfortus or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination."; updated Appendix D with AAP recommendations in the context of a limited supply of nirsevimab; added the following notation to clarify Beyfortus redirection if available: "For the 2023-2024 RSV season, supply issues are anticipated. Confirm supply constraints prior to bypassing this requirement (see Appendix D)."; added Appendix F: Infant Vaccination after Maternal Vaccination; references reviewed and updated.	04/2024
2Q 2025 annual review: for preterm infants added clarification regarding maternal vaccine exclusion if administered ≥ 14 days prior to delivery per ACIP/AAP recommendations; removed statement regarding redirection to Beyfortus "For the 2023-2024 RSV season, supply issues are anticipated" as the AAP states shortage of Beyfortus is not expected this coming season; removed statements referencing elevated interseasonal activity as per the CDC regular seasonal patterns are now expected; references reviewed and updated.	04/2025