Clinical Policy: Nirsevimab-alip (Beyfortus)

Reference Number: CP.PHAR.614
Effective Date: 07.17.23
Last Review Date: 08.24
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Nirsevimab-alip (Beyfortus®) is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor.

FDA Approved Indication(s)

Beyfortus is indicated for the prevention of RSV lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Beyfortus is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Preterm, Late Preterm or Term Infant (must meet all)**:**

1. Age at onset of RSV season ≤ 12 months;
2. Request is for RSV prophylaxis;
3. Medical justification supports requests for RSV prophylaxis outside the identified season* duration for the specific region (*see Appendix D*);
   **Elevated interseasonal activity has been observed since March 2021, the Centers for Disease Control and Prevention (CDC) has indicated that at this time it is not possible to anticipate the likely spread, peak, or duration of activity with any certainty; 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/surveillance/nrevss/rsv/state.html.*
4. Member has not previously received Beyfortus or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination (unless infant is born < 14 days after maternal RSV vaccination);
5. If member previously received Synagis® for the current RSV season, < 5 Synagis doses were administered;*
   **Synagis should no longer be administered following Beyfortus. Existing Synagis authorizations should be termed.*

6. Member has not been hospitalized or previously infected with RSV disease during the current RSV season;
7. Dose does not exceed a single dose of one of the following (a or b):
   a. Body weight < 5 kg: 50 mg;
   b. Body weight ≥ 5 kg: 100 mg.

Approval duration: 4 weeks (1 dose per lifetime)

B. Chronic Lung Disease of Prematurity (must meet all)**:**

1. Diagnosis of CLD of prematurity (i.e., bronchopulmonary dysplasia [BPD]) defined as both of the following (a and b):
   a. GA < 32 weeks;
   b. Requirement for > 21% oxygen for ≥ 28 days after birth;
2. Medical management (i.e., supplemental oxygen, bronchodilators, diuretics, or chronic corticosteroid therapy) of CLD was required within the previous 6 months;
3. One of the following (a or b):
   a. Age at onset of RSV season ≤ 12 months;
   b. Age ≤ 24 months and request is for members entering their second RSV season;
4. Request is for RSV prophylaxis;
5. Medical justification supports requests for RSV prophylaxis outside the identified season* duration for the specific region (*see Appendix D*);
   **Elevated interseasonal activity has been observed since March 2021, the CDC has indicated that at this time it is not possible to anticipate the likely spread, peak, or duration of activity with any certainty; 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/surveillance/nrevss/rsv/state.html.*
6. Member has not previously received any RSV vaccine, including maternal RSV vaccination (unless infant is born < 14 days after maternal RSV vaccination);
7. Member has not previously received ≥ 2 doses of Beyfortus;
8. If member previously received Synagis, one of the following (a or b):*
   a. Request for Beyfortus is not within the same RSV season in which Synagis was administered;
   b. < 5 Synagis doses were administered for the current RSV season;
   **Synagis should no longer be administered following Beyfortus. Existing Synagis authorizations should be termed.*
9. Member has not been hospitalized or previously infected with RSV disease during the current RSV season;
10. Dose does not exceed one of the following (a or b):
    a. First RSV season, a single dose of one of the following (i or ii):
       i. Weight < 5 kg: 50 mg;
       ii. Weight ≥ 5 kg: 100 mg;
    b. Second RSV season: 200 mg single dose.

Approval duration: 12 months (2 dose per lifetime)

C. Congenital Heart Disease (must meet all)**:**

1. Diagnosis of hemodynamically significant CHD and one of the following (a or b):

a. CHD is unoperated or partially corrected;
b. Presence of acyanotic cardiac lesions and one of the following (i or ii):
   i. Pulmonary hypertension with ≥ 40 mmHg measured pressure in the pulmonary artery;
   ii. Requirement of daily medication therapy to manage CHD;

2. One of the following (a or b):
   a. Age at onset of RSV season ≤ 12 months;
   b. Age ≤ 24 months and request is for members entering their second RSV season;
3. Request is for RSV prophylaxis;
4. Medical justification supports requests for RSV prophylaxis outside the identified season* duration for the specific region (*see Appendix D*);
   **Elevated interseasonal activity has been observed since March 2021, the CDC has indicated that at this time it is not possible to anticipate the likely spread, peak, or duration of activity with any certainty; 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/surveillance/nrevss/rsv/state.html.*
5. Member has not previously received any RSV vaccine, including maternal RSV vaccination (unless infant is born < 14 days after maternal RSV vaccination);
6. Member has not previously received ≥ 2 doses of Beyfortus;
7. If member previously received Synagis, one of the following (a or b):*
   a. Request for Beyfortus is not within the same RSV season in which Synagis was administered;
   b. < 5 Synagis doses were administered for the current RSV season;
   **Synagis should no longer be administered following Beyfortus. Existing Synagis authorizations should be termed.*
8. Member has not been hospitalized or previously infected with RSV disease during the current RSV season;
9. Dose does not exceed one of the following (a, b, or c):
   a. First RSV season, a single dose of one of the following (i or ii):
      i. Weight < 5 kg: 50 mg;
      ii. Weight ≥ 5 kg: 100 mg;
   b. Second RSV season: 200 mg single dose;
   c. Member is undergoing cardiac surgery with cardiopulmonary bypass (*see Appendix E*).

Approval duration: 12 months (2 doses total per lifetime)

D. Anatomic Pulmonary Abnormalities, Neuromuscular Disorders, Infants Profoundly Immunocompromised (off-label) (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. Medical justification supports requests for RSV prophylaxis outside the identified season* duration for the specific region (*see Appendix D*);
   **Elevated interseasonal activity has been observed since March 2021, the CDC has indicated that at this time it is not possible to anticipate the likely spread, peak, or duration of activity with any certainty; 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/surveillance/nrevss/rsv/state.html.*
4. Member has not previously received any RSV vaccine, including maternal RSV vaccination (unless infant is born < 14 days after maternal RSV vaccination);
5. Member has not previously received ≥ 2 doses of Beyfortus;
6. If member previously received Synagis, one of the following (a or b):*
   a. Request for Beyfortus is not within the same RSV season in which Synagis was administered;
   b. < 5 Synagis doses were administered for the current RSV season;
   **Synagis should no longer be administered following Beyfortus. Existing Synagis authorizations should be termed.*
7. Member has not been hospitalized or previously infected with RSV disease during the current RSV season;
8. Dose does not exceed one of the following (a or b):
   a. First RSV season, a single dose of one of the following (i or ii):
      i. Weight < 5 kg: 50 mg;
      ii. Weight ≥ 5 kg: 100 mg;
   b. Second RSV season: 200 mg single dose.

Approval duration: 12 months (2 dose per lifetime)

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 and ii):
      i. GA < 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. Medical justification supports requests for RSV prophylaxis outside the identified season* duration for the specific region (*see Appendix D*);

**Elevated interseasonal activity has been observed since March 2021, the CDC has indicated that at this time it is not possible to anticipate the likely spread, peak, or duration of activity with any certainty; 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/surveillance/nrevss/rsv/state.html.*

5. Member has not previously received any RSV vaccine, including maternal RSV vaccination (unless infant is born < 14 days after maternal RSV vaccination);
6. Member has not previously received ≥ 2 doses of Beyfortus;
7. If member previously received Synagis, one of the following (a or b):*
   a. Request for Beyfortus is not within the same RSV season in which Synagis was administered;
   b. < 5 Synagis doses were administered for the current RSV season;

   **Synagis should no longer be administered following Beyfortus. Existing Synagis authorizations should be termed.*
8. Member has not been hospitalized or previously infected with RSV disease during the current RSV season;
9. Dose does not exceed one of the following (a or b):
   a. First RSV season, a single dose of one of the following (i or ii):
      i. Weight < 5 kg: 50 mg;
      ii. Weight ≥ 5 kg: 100 mg;
   b. Second RSV season: 200 mg single dose.

Approval duration: 12 months (2 dose per lifetime)

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.
4. One of the following (a or b):
   a. Age at onset of RSV season ≤ 12 months;
   b. Age ≤ 24 months and request is for members entering their second RSV season;
5. Request is for RSV prophylaxis;
6. Medical justification supports requests for RSV prophylaxis outside the identified season* duration for the specific region (*see Appendix D*);

   **Elevated interseasonal activity has been observed since March 2021, the CDC has indicated that at this time it is not possible to anticipate the likely spread, peak, or duration of activity with any certainty; 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/surveillance/nrevss/rsv/state.html.

7. Member has not previously received any RSV vaccine, including maternal RSV vaccination (unless infant is born < 14 days after maternal RSV vaccination);
8. Member has not previously received ≥ 2 doses of Beyfortus;
9. If member previously received Synagis, one of the following (a or b):*
   a. Request for Beyfortus is not within the same RSV season in which Synagis was administered;
   b. < 5 Synagis doses were administered for the current RSV season;

   **Synagis should no longer be administered following Beyfortus. Existing Synagis authorizations should be termed.*
10. Member has not been hospitalized or previously infected with RSV disease during the current RSV season;
11. Dose does not exceed one of the following (a or b):
    a. First RSV season, a single dose of one of the following (i or ii):
       i. Weight < 5 kg: 50 mg;
       ii. Weight ≥ 5 kg: 100 mg;
    b. Second RSV season: 200 mg single dose.

Approval duration: 12 months (2 dose per lifetime)

G. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I

1. Continued therapy will not be authorized as Beyfortus is indicated to be dosed once, unless member is at increased risk of severe disease, in which case an additional dose may be administered (2 doses total per lifetime).

Approval duration: Not applicable

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BPD: bronchopulmonary dysplasia
CDC: Centers for Disease Control and Prevention
CHD: congenital heart disease
CLD: chronic lung disease
FDA: Food and Drug Administration
GA: gestational age
HHS: Health and Human Services
IM: intramuscular
PCR: polymerase chain reaction
RSV: respiratory syncytial virus

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients
- 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.

- The CDC issued a health advisory to notify clinicians and caregivers about increased interseasonal respiratory syncytial virus (RSV) activity across parts of the Southern United States. Compared with previous years, RSV activity remained relatively low from May 2020 to March 2021. However, since late March, CDC has observed an increase in RSV detections reported to the National Respiratory and Enteric Virus Surveillance System (NREVSS). CDC noted increases in laboratory detections and in the percentages of positive detections for both antigen and PCR testing in parts of HHS Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee) and Region 6 (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas). Due to limited testing outside of the typical RSV season, data are limited in some jurisdictions and may be incomplete for the most recent weeks. Since this elevated interseasonal activity is a deviation in the typical circulation patterns for RSV, at this time it is not possible to anticipate the likely spread, peak, or duration of activity with any certainty.
- 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.

Appendix E: Cardiac Surgery with Cardiopulmonary Bypass Additional Dose Administration

- For infants undergoing cardiac surgery with cardiopulmonary bypass, an additional dose may be administered as soon as the infant is stable after surgery to ensure adequate Beyfortus serum levels.
  - First RSV season: If surgery is within 90 days after receiving the first dose, the additional dose should be 50 mg or 100 mg according to body weight. If more than 90 days have elapsed since the first dose, the additional dose should be 50 mg regardless of body weight.
  - Second RSV season: If surgery is within 90 days after receiving Beyfortus, the additional dose should be 200 mg, regardless of body weight. If more than 90 days have elapsed since receiving Beyfortus, the additional dose should be 100 mg, regardless of body weight.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prophylaxis - First RSV Season	Single IM injection of: • Weight < 5 kg: 50 mg • Weight ≥ 5 kg: 100 mg Infants undergoing cardiac surgery with cardiopulmonary bypass (*see Appendix E*)	1 dose per lifetime
Prophylaxis - Second RSV Season	Single 200 mg dose IM Infants undergoing cardiac surgery with cardiopulmonary bypass (*see Appendix E*)	1 dose (2 doses per lifetime if member is at increased risk of severe disease)

VI. Product Availability

Single-dose pre-filled syringe: 50 mg/0.5 mL, 100 mg/mL

VII. References

1. Beyfortus Prescribing Information. Södertälje, Sweden: AstraZeneca AB. February 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761328s007lbl.pdf. Accessed May 6, 2024.
2. American Academy of Pediatrics Committee on Infectious Diseases. and American Academy of Pediatrics Bronchiolitis Guidelines Committee. "Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection." *Pediatrics* vol. 134,2 (2014): e620-38. doi:10.1542/peds.2014-1666
3. ClinicalTrials.gov. A Phase 2b Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody with an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm Infants. Last updated October 14, 2019. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02878330. Accessed November 29, 2022.
4. ClinicalTrials.gov. A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody with an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY). Last updated September 2, 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT03979313. Accessed November 15, 2022.
5. ClinicalTrials.gov. A Phase 2/3 Randomized, Double-blind, Palivizumab-controlled Study to Evaluate the Safety of MEDI8897, a Monoclonal Antibody with an Extended Half-life Against Respiratory Syncytial Virus, in High-risk Children (MEDLEY). Last updated August 22, 2022. Available at: https://clinicaltrials.gov/ct2/show/record/NCT03959488. Accessed November 28, 2022.
6. Domachowske J, Madhi SA, Simões EAF, et al. Safety of Nirsevimab for RSV in Infants with Heart or Lung Disease or Prematurity. N Engl J Med. 2022 Mar 3;386(9):892-894.
7. Ginsburg AS, Srikantiah P. Respiratory syncytial virus: promising progress against a leading cause of pneumonia. Lancet Glob Health. 2021 Dec; 9(12): e1644-e1645.
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9. Hammitt LL, Dagan R, Yuan Y, et al. Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants. N Engl J Med. 2022 Mar 3;386(9):837-846.
10. Kieffer A, Beuvelet M, Sardesai A, et al. Expected Impact of Universal Immunization with Nirsevimab against RSV-Related Outcomes and Costs Among All US Infants in Their First RSV Season: A Static Model. Journal of Infectious Diseases. 2022 August 15; 226(Suppl 2): S282-S292.
11. Respiratory syncytial virus infection (RSV): Trends and surveillance. Centers for Disease Control and Prevention website. Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases. Available at http://www.cdc.gov/rsv/research/us-surveillance.html. Page last reviewed: December 18, 2020. Accessed February 21, 2022.
12. Rha B, Curns AT, Lively JY, et al. Respiratory Syncytial Virus-Associated Hospitalizations Among Young Children: 2015-2016. Pediatrics. 2020 Jul; 146(1): e20193611.
13. 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.
14. Centers for Disease Control and Prevention [Presentation]: Proposed Clinical Consideration Updates for Nirsevimab. August 3, 2023. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-08-3/04-RSV-Jones-508.pdf. Accessed August 7, 2023.
15. ACIP and AAP Recommendations for Nirsevimab. Red Book Online. February 21, 2024. Available at: https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV. Accessed May 16, 2024.
16. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep. ePub: 6 October 2023. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm#print. Accessed May 16, 2024.
17. Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices - United States, August 25, 2023. MMWR Morb Mortal Wkly Rep 2023; 72: 920–925.
18. 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 May 16, 2024.

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
90380	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use
90381	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	01.17.23	02.23
RT4: policy updated per label following FDA approval and CDC recommendations; added off-label uses per CDC/American Academy of Pediatrics recommendations for anatomic pulmonary abnormalities, neuromuscular disorders, infants profoundly immunocompromised, cystic fibrosis, Alaska native and other American Indian infants; for CLD, CHD, and off-label uses included allowance for 2 lifetime doses and 12 month approval duration, including criteria if member previously received Synagis, request for Beyfortus is not within the same RSV season in which Synagis was administered or < 5 Synagis doses were administered for the current RSV season; for preterm, late preterm or term infant removed gestational age requirement.	08.21.23	
Added the following clarification to ensure Synagis is not continued following Beyfortus administration: "Synagis should no longer be administered following Beyfortus. Existing Synagis authorizations should be termed." Added the following bypass to the exclusion for prior use of maternal RSV vaccination: "unless infant is born < 14 days after maternal RSV vaccination."	10.11.23	
Clarified requirement for medical justification for use "outside" the typical RSV season by allowing region-by-region identified RSV season. Added HCPCS codes [90380, 90381].	10.26.23	
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.06.24	08.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.