CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Beyfortus (nirsevimab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Beyfortus is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in certain pediatric populations. The ACIP recommends all infants born during or entering their first RSV season receive Beyfortus. Infants entering their second RSV season should only receive the injection if they are at an increased risk of serious RSV infection. Beyfortus is not a vaccine; it delivers antibodies to fight RSV. The safety and effectiveness of Beyfortus in children older than 24 months of age at the start of dosing have not been established.

Beyfortus (nirsevimab) will be considered for coverage when the following criteria are met:

Respiratory Syncytial Virus (RSV) Prevention

For **initial** authorization:

1. Member is 0 to 7 months of age; OR
2. Member is 8 to 19 months of age entering their **second** RSV season (November to March)*; AND
   a) Member is at an increased risk of severe RSV disease and meets **ONE** of the following:
      i) Member has CLD of prematurity and continues to require supplemental oxygen, chronic systemic corticosteroid therapy, or diuretic therapy during the 6-month period before the start of the second RSV season;
      ii) Member is profoundly immunocompromised during the RSV season (e.g., concurrent chemotherapy, stem cell transplantation, organ transplantation, etc.);
      iii) Member undergoes cardiac transplantation during the RSV season;
      iv) Member has Cystic Fibrosis with **ONE** of the following:
         (1) Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life, or abnormalities on chest radiography or chest computed tomography that persist when stable);
         (2) Weight for length less than the 10th percentile on a pediatric growth chart;
      v) Member is an American Indian or Alaska native; AND
3. Beyfortus is **NOT** being prescribed for any of the following:
   a) Treatment of RSV infection;
   b) RSV prophylaxis for children who were previously infected with RSV in the current season;
   c) RSV prophylaxis for children with Down syndrome;
   d) RSV prophylaxis for health care-associated RSV disease;
   e) RSV prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing;
   f) RSV prophylaxis for infants and children with hemodynamically insignificant heart disease (e.g., Secundum atrial septal defect, small ventricular septal defect, pulmonary stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus); AND
4. Member has not received 5 doses of Synagis or 1 dose of Beyfortus in the current RSV season; AND
5. Member has not received RSV vaccinations including maternal vaccinations (ex. Abrysvo) in the current RSV season UNLESS less than 14 days has elapsed between maternal vaccination and birth.
6. **Dosage allowed/Quantity limit:** Quantity Limit: 2 syringes per 90 days. See package insert for dosage guidance in patients undergoing cardiopulmonary bypass surgery.

a) Infants and neonates entering their first RSV season:
   i) Less than 5 kg: 50 mg by IM injection.
   ii) Greater than or equal to 5 kg: 100 mg by IM injection.
b) Children entering their second RSV season: 200 mg by IM injection.

If all the above requirements are met, the medication will be approved for 3 months.

* Requests may be reviewed on a case-by-case basis outside of the typical RSV season window when increased interseasonal RSV activity is present. This will follow guidance from the American Academy of Pediatrics (AAP) and CDC trend data. State specific rules may also apply.

For **reauthorization**:
1. Beyfortus will not be reauthorized.

NOTE: if member is undergoing cardiopulmonary bypass surgery, a total of two doses per RSV season may be authorized.

CareSource considers Beyfortus (nirsevimab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/01/2023	New policy for Beyfortus created.
09/26/2023	Added references; updated criteria on coadministration with Synagis and Abrysvo; added pharmacy benefit option.

References:

1. Beyfortus [prescribing information]. AstraZeneca; 2023.
2. Hamid S, Winn A, Parikh R, et al. Seasonality of Respiratory Syncytial Virus — United States, 2017–2023. *MMWR Morb Mortal Wkly Rep.* 2023;72:355–361. DOI: http://dx.doi.org/10.15585/mmwr.mm7214a1.
3. Jones J. Evidence to recommendations framework: nirsevimab updates. Presented at: Advisory Committee on Immunization Practices (ACIP) Meeting; August 3, 2023. Accessed August 9, 2023. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-08-3/02-RSV-jones-508.pdf
4. 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;386(9):892-894. doi:10.1056/NEJMc2112186
5. IPD Analytics. Accessed August 15, 2023.
6. Respiratory Syncytial Virus Infection (RSV). Centers for Disease Control and Prevention. Updated August 4, 2023. Accessed August 15, 2023. https://www.cdc.gov/rsv/index.html
7. 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, 2023. *MMWR Morb Mortal Wkly Rep.* 2023;72(34):920-925
8. American Academy of Pediatrics. Nirsevimab Frequently Asked Questions. Updated September 26, 2023. Accessed September 26, 2023. https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-frequently-asked-questions/

Effective date: 01/01/2024
Revised date: 09/26/2023