

**Beyfortus (nirsevimab)**  
**Effective 11/10/2023**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	Beyfortus is covered under the Medical Benefit without prior authorization (PA)		

### Overview

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

### Coverage Guidelines

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Provider is requesting Beyfortus for the first or second RSV season for prevention of lower respiratory tract disease (LRTD) due to RSV
2. Member is  $\geq 8$  months to  $< 24$  months of age
3. **ONE** of the following:
  - a. Member is severely immunocompromised
  - b. Cystic fibrosis with manifestations of severe lung disease
  - c. Member is American Indian or Alaska Native descent
  - d. CLD of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the six-month period before start of RSV season or bronchopulmonary dysplasia
  - e. Congenital diaphragmatic hernia and comorbid chronic lung disease
  - f. Down syndrome and comorbid congenital heart disease, chronic lung disease, airway clearance issues, or prematurity
  - g. Congenital abnormality of the airway or neuromuscular disease
  - h. Congenital heart disease
  - i. Underwent cardio-pulmonary bypass procedure
4. Appropriate dosing (Recent weight must be provided to confirm appropriate dose)

## Limitations

1. Approvals will be granted for 1 dose for 6 months from the RSV season onset date.
  - a. One additional dose of Beyfortus® may be approved beyond the standard seasonal allocation of 1, if the provider documents the member has undergone a cardiopulmonary bypass procedure or is planned to undergo cardiopulmonary bypass procedure.
2. **Dosing information:**

Beyfortus (nirsevimab-alip)	15 mg/kg intramuscularly monthly
50mg/0.5 mL in a single-dose pre-filled syringe 100 mg/mL in a single-dose pre-filled syringe	<u>Members &lt;5 kg:</u> 50 mg intramuscularly once  <u>Members ≥5 kg:</u> 100 mg intramuscularly once  <u>Infants entering their second RSV season:</u> 200 mg intramuscularly once

## References

1. Beyfortus [package insert]. Sodertalje Sweden; AstraZeneca; 2023. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=2f08fa60-f674-432d-801b-1f9514bd9b39&type=display#section-2>
2. Food and Drug Administration. FDA Approves New Drug to Prevent RSV in Babies and Toddlers. July 17, 2023. Accessed July 19, 2023. <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-prevent-rsv-babies-and-toddlers>
3. 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;386(9):837-846. doi:10.1056/NEJMoa2110275
4. AstraZeneca. Beyfortus Approved in the US for the Prevention of RSV Lower Respiratory Tract Disease in Infants. July 17, 2023. Accessed July 19, 2023. <https://www.astrazeneca.com/media-centre/press-releases/2023/beyfortus-approved-in-the-us-for-the-prevention-of-rsv-lower-respiratory-tract-disease-in-infants.html3>
5. American Academy of Pediatrics. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization and respiratory syncytial virus infection. Pediatrics. 2014 July;134(2):415-20.

## Review History

11/15/23 – Created for P&T. Beyfortus will require PA for members ≥8 months of age, no PA <8 months of age. Effective 11/10/23

