

# Beyfortus (nirsevimab) Effective 12/01/2025

Plan	☐ MassHealth UPPL  ☐ Commercial/Exchange	Program Type	<ul><li>☑ Prior Authorization</li><li>☐ Quantity Limit</li></ul>
Benefit	<ul><li>☑ Pharmacy Benefit</li><li>☐ Medical Benefit</li></ul>		☐ Step Therapy
Specialty Limitations	N/A		
	Medical and Specialty Medications		
Contact	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Beyfortus is covered under the Medical Benefit without prior authorization (PA) Beyfortus is covered under the pharmacy benefit without PA up to 8 months of age		

#### 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:

- 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 ≥8 months to <24 months of age
- 3. **ONE** of the following:
  - a. Member is severely immunocompromised
  - b. Cystic fibrosis with at least ONE of the following:
    - Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable)
    - Weight-for-length that is less than the 10<sup>th</sup> percentile
  - 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)	Members <5 kg: 50 mg intramuscularly once
50mg/0.5 mL in a single-dose pre-filled syringe 100 mg/mL in a single-dose pre-filled syringe	Members ≥5 kg: 100 mg intramuscularly once
	Infants entering their second RSV season: 200 mg intramuscularly once

#### References

- 1. American Academy of Pediatrics. AAP recommendations for the prevention of RSV disease in infants and children. Accessed August 11, 2025.
- 2. American Academy of Pediatrics. ACIP and AAP recommendations for nirsevimab. February 2024. Accessed August 28, 2024. <a href="https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV?autologincheck=redirected">https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV?autologincheck=redirected</a>.
- 3. 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.
- 4. Beyfortus (nirsevimab-alip) [prescribing information]. Sodertalje, Sweden; AstraZeneca; August 2024.
- 5. 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

#### **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

09/11/2024 – Reviewed at September P&T. No updates.

09/10/2025 – Reviewed at September P&T. Updated criteria for cystic fibrosis to define severe lung disease and include weight-for-length less than 10<sup>th</sup> percentile as an approvable characteristic. Effective 12/1/2025.

