

Beyfortus (nirsevimab)
Effective 12/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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 10th 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)	<u>Members <5 kg:</u> 50 mg intramuscularly once
50mg/0.5 mL in a single-dose pre-filled syringe	<u>Members ≥5 kg:</u> 100 mg intramuscularly once
100 mg/mL in a single-dose pre-filled syringe	<u>Infants entering their second RSV season:</u> 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. <https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV?autologincheck=redirected>.
- 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 10th percentile as an approvable characteristic. Effective 12/1/2025.

