

REAL-WORLD EVIDENCE

Beyfortus[®] Effectiveness Against Medically Attended RSV Events in Infants (BEAR)

Sponsored by SANOFI and AstraZeneca and presented at the American College of Allergy, Asthma and Immunology Annual Scientific Meeting in Boston, MA, October 24-28, 2024.

Beyfortus is the **first and only long-acting antibody** indicated for the **prevention of RSV lower respiratory tract disease** in¹:

- 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

RSV, respiratory syncytial virus.

IMPORTANT SAFETY INFORMATION

Contraindication

Beyfortus is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients.

Please see additional Important Safety Information throughout this summary and accompanying full Prescribing Information.

 **Beyfortus[®]**
(nirsevimab-alip) | 50 mg
100 mg
Injection

Beyfortus® (nirsevimab-alip) Pivotal Trial Data¹

In pivotal trials, Beyfortus demonstrated strong and consistent efficacy against MA RSV-LRTI^{1*}

Beyfortus was evaluated in 2 randomized, placebo-controlled studies with the same primary endpoint: incidence of MA RSV-LRTI (including inpatient and outpatient) vs placebo through 150 days post 1 dose.^{1†}

Healthy term and late preterm infants ≥35 wGA (Trial 04)

↓74.9%
RRR

(95% CI: 50.6, 87.3; P<0.001)

Beyfortus: 1.2% (12/994)
Placebo: 5.0% (25/496)

Healthy preterm infants ≥29 to <35 wGA (Trial 03)

↓70.1%
RRR

(95% CI: 52.3, 81.2; P<0.001)

Beyfortus: 2.6% (25/969)
Placebo: 9.5% (46/484)

The most common adverse reactions in Trial 04 and Trial 03 were rash (0.9%) and injection site reactions (0.3%).^{1‡}

CI, confidence interval; IM, intramuscular; MA RSV-LRTI, medically attended respiratory syncytial virus lower respiratory tract infection; RRR, relative risk reduction; wGA, weeks gestational age.

*Results of Trials 04 and 03 for infants entering their first RSV season. Trial 04 evaluated the efficacy of a single dose of Beyfortus (50 mg IM if <5 kg weight, 100 mg IM if ≥5 kg weight) vs placebo in 1,490 healthy term and late preterm infants (≥35 wGA). Trial 03 evaluated the efficacy of a single 50 mg IM dose of Beyfortus vs placebo in 1,453 healthy preterm infants (≥29 to <35 wGA).

†Medically attended includes all healthcare provider visits such as physician's office, urgent care, emergency room, and hospitalizations.

‡The Safety Population includes all infants who received the recommended dose of Beyfortus in Trials 04 and 03: Primary and Safety cohorts from Trial 04; infants who weighed <5 kg and who received the recommended dose of Beyfortus (single 50 mg IM dose) in Trial 03.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- **Hypersensitivity Reactions Including Anaphylaxis:** Serious hypersensitivity reactions have been reported following Beyfortus administration. These reactions included urticaria, dyspnea, cyanosis, and/or hypotonia. Anaphylaxis has been observed with human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs and symptoms of anaphylaxis or other clinically significant hypersensitivity reactions occur, initiate appropriate treatment.
- **Use in Individuals with Clinically Significant Bleeding Disorders:** As with other IM injections, Beyfortus should be given with caution to infants and children with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy. Most common adverse reactions with Beyfortus were rash (0.9%) and injection site reactions (0.3%).

² Please see additional Important Safety Information throughout this summary and accompanying full [Prescribing Information](#).

BEAR Study²

Effectiveness of nirsevimab in infants against RSV and RSV-related events

Beyfortus® was evaluated in an observational, retrospective cohort study at Kaiser Permanente Northern California (KPNC) during the 2023-2024 RSV season. The study included healthy term infants (≥37 wGA) born between April 1, 2023, and April 30, 2024, without a predefined high-risk condition, with 2 co-primary endpoints^{2*}:

- First episode of PCR-confirmed RSV-LRTI during the RSV season[†]
- Healthcare utilization as measured by the total number of medical encounters related to each RSV-LRTI episode[‡]

Healthy term infants ≥37 wGA[§]

Estimated effectiveness against MA RSV-LRTI

↓87.2%

(95% CI: 81.7, 91.1)

Beyfortus (N=35/15,647)
Untreated (N=462/16,253)

Total RSV-LRTI medical encounters related to RSV-LRTI episodes

75 medical encounters

1,241 medical encounters

Beyfortus (n=35)
2.1 mean number of encounters

Untreated (n=462)
2.7 mean number of encounters

The findings in this analysis are subject to limitations²:

- The analysis population of healthy, term infants may not be generalizable to infants at higher risk of RSV-LRTI
- While KPNC has a large and diverse population, the study population may not be representative of other health systems' populations

This study is not included in the Beyfortus Prescribing Information.

ICD-10, International Classification of Diseases, 10th Revision; PCR, polymerase chain reaction.

*Administration of Beyfortus began on October 19, 2023. Eligible infants born on or after this date were offered the treatment before discharge, during urgent care visits, or at outpatient well-child appointments. Eligible infants born prior to this date were contacted by KPNC as part of routine care for catch-up dosing in outpatient clinics. The study assessed the effectiveness of a single dose of Beyfortus (50 mg IM if <5 kg weight, 100 mg IM if ≥5 kg weight) against PCR-confirmed MA RSV-LRTI. The study included 31,900 infants, 15,647 of whom received Beyfortus and 16,253 infants that were untreated.

†Defined as an LRTI-associated encounter in any setting (using ICD-10 codes) during the window of 7 days before and up to 10 days after a positive RSV PCR test result.

‡Each medical encounter was categorized as outpatient, emergency department, inpatient, or intensive care unit.

§Born from April 1, 2023, through April 30, 2024.

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Contact your Sanofi representative to access additional real-world evidence studies, or visit [Beyfortus.com](https://www.beyfortus.com) for more information



Scan to learn more about Beyfortus[®]

INDICATION

Beyfortus is indicated for the prevention of respiratory syncytial virus (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.

IMPORTANT SAFETY INFORMATION

Contraindication

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Warnings and Precautions

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- **Use in Individuals with Clinically Significant Bleeding Disorders:** As with other IM injections, Beyfortus should be given with caution to infants and children with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy.

Most common adverse reactions with Beyfortus were rash (0.9%) and injection site reactions (0.3%).

Please see accompanying full [Prescribing Information](#).

References: **1.** Beyfortus (nirsevimab-alip). Prescribing Information. Sanofi. **2.** Data on File. Effectiveness of nirsevimab in infants against RSV and RSV-related events. Presented at American College of Allergy, Asthma and Immunology Annual Scientific Meeting. October 24-28, 2024. Boston, MA.

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