ACOG and ACIP recommended[1,2]*

Beyfortus® (nirsevimab-alip) 50 mg 100 mg Injection

Beyfortus is not indicated for adults.

Beyfortus® helps protect against RSV disease through direct administration to the infant[3]

Beyfortus is the **first long-acting antibody** indicated for the **prevention of RSV lower respiratory tract disease** in[3]:

- 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

ACIP, Advisory Committee on Immunization Practices; **ACOG**, American College of Obstetricians and Gynecologists; **RSV**, respiratory syncytial virus.

*Infants <8 months born before or during their first RSV season are recommended to receive Beyfortus, which should be administered shortly after birth for those born during the season.[1]

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.

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.

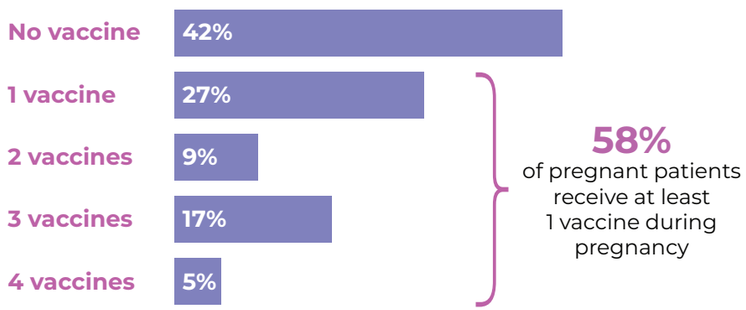
Most common adverse reactions with Beyfortus were rash (0.9%) and injection site reactions (0.3%).

Please see additional Important Safety Information on the following pages and accompanying full Prescribing Information.

Uptake of recommended maternal immunizations is low and drops with multiple vaccinations[4,5]

42% of eligible pregnant patients did not receive any immunization during the 2023-2024 season[6]

Number of immunizations eligible pregnant patients received in the 2023-2024 season (September-January)[6*]



*Source for maternal immunization rate data: IQVIA claims from September 2023 to January 2024. Within the data set there were 472,368 patients.[6]

IMPORTANT SAFETY INFORMATION

Contraindication

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Beyfortus® can be given shortly after birth during the RSV season[2]

- Common maternal immunizations such as flu, COVID-19, and Tdap **do not have an alternative option** to help protect the infant in the first few months of life prior to immunization[7,8]

Maternal immunization	Is the maternal immunization intended to protect the child?	Is the maternal immunization intended to protect the mother?	Is there an infant immunization available in the first week of life?	Gestational age at administration	Timing of administration for maternal immunization
Flu[7,9]	✔	✔		Anytime	Suggested between Sep-Oct*
COVID-19[7,10]	✔	✔		Anytime	Anytime
Tdap[7]	✔	✔		27-36 weeks	Anytime
RSV[7]	✔		✔	32-36 weeks	Sep-Jan†

Tdap, tetanus, diphtheria, and pertussis.

*Early vaccination (eg, during July and August) can be considered for persons who are in the third trimester during these months if vaccine is available because this can provide protection for the infant during the first months of life when they are too young to be vaccinated.[11]

†In most of the continental US. Recommended timing may vary depending on geography and gestation time in areas of RSV seasonality.[7]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- **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%).

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CDC recommends administering Beyfortus® to infants in specific months during their first RSV season[11]

RSV is seasonal, with infections peaking at certain times throughout the year. A typical RSV season runs roughly from fall through spring, with some exceptions, such as in Florida and Hawaii, where the RSV season may start earlier. In most of the continental US, RSV typically peaks between December and January.[3,11-13]

CDC-recommended timing of Beyfortus administration for most of the continental US[11]*

Date of birth:
April 1 through September 30

Administer beginning
October 1

Date of birth:
October 1 through March 31

Administer **within 1 week after birth, ideally in hospital**

For full recommendations, which include important guidance, visit the **CDC website**.

*Timing of administration for RSV immunization may differ in certain areas.

IMPORTANT SAFETY INFORMATION

Contraindication

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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.

Beyfortus® has demonstrated strong and consistent efficacy against MA RSV-LRTI[3]*

Primary endpoint: in 2 pivotal clinical trials, incidence of medically attended (MA) RSV-LRTI vs placebo through 150 days post 1 dose[3]

Medically attended (MA) includes all healthcare provider visits such as physician's office, urgent care, emergency room, and hospitalizations.[3]

Healthy term and late preterm infants ≥35 wGA (Trial 04)[3]

⬇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)[3]

⬇70.1% RRR

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

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

Long-acting RSV disease protection that extends through 5 months based on clinical data[3]

Scan to view pivotal trial data and real-world evidence for Beyfortus

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

Signs of LRTI involvement included rhonchi, rales, crackles, or wheezing and at least one sign of worsening clinical severity, including at least one of the following: increased respiratory rate, hypoxemia, acute hypoxic or ventilatory failure, new onset apnea, nasal flaring, retractions, grunting, or dehydration due to respiratory distress.[3]

*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 preterm infants (≥35 wGA). Trial 03 evaluated the efficacy of a single 50 mg dose of Beyfortus vs placebo in 1,453 healthy preterm infants (≥29 to <35 wGA).[3]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- **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%).

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Demonstrated safety profile vs placebo (Trials 04 and 03) and vs palivizumab (Trial 05)[3,14-16*†]

Trial 04 and Trial 03 were pooled to evaluate the safety of Beyfortus® (N=2,570) compared to placebo (N=1,284).[3]

- Adverse reactions were reported in 1.2% of infants who received Beyfortus; most (97%) adverse reactions were mild to moderate in severity[3]

Most Common Adverse Reactions Reported at an Incidence Higher Than Placebo in the Safety Population (Trial 04 and Trial 03)[3*]

Adverse reaction	Beyfortus N=2,570	Placebo N=1,284
Rash[‡] (occurring within 14 days post dose)	0.9%	0.6%
Injection Site Reaction[§] (occurring within 7 days post dose)	0.3%	0.0%

- Adverse reactions reported among Trial 05 subjects were similar to Trials 04 and 03[3§]

*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.[3]
†Trial 05 was a Phase 2/3, randomized, double-blind, palivizumab-controlled study evaluating the safety of Beyfortus in infants with chronic lung disease (CLD) or congenital heart disease (CHD) and preterm infants (<35 wGA) entering their first RSV season, as well as children with CLD or CHD up to 24 months of age continuing in the trial for a second RSV season.[3]
‡Rash was defined by the following grouped preferred terms: rash, rash macular, rash maculopapular, rash papular.[3]
§Injection site reaction was defined by the following grouped preferred terms: injection site reaction, injection site pain, injection site induration, injection site edema, injection site swelling.[3]

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.

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.

References: 1. Maternal respiratory syncytial virus vaccination. American College of Obstetricians and Gynecologists. Updated March 17, 2025. Accessed May 13, 2025. https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/09/maternal-respiratory-syncytial-virus-vaccination **2.** 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. **3.** Beyfortus (nirsevimab-alip). Prescribing Information. Sanofi. **4.** Razzaghi H, Kahn KE, Calhoun K, et al. Influenza, Tdap, and COVID-19 vaccination coverage and hesitancy among pregnant women – United States, April 2023. *MMWR Morb Mortal Wkly Rep*. 2023;72(39):1065-1071. **5.** Rand CM, Olson-Chen C. Maternal vaccination and vaccine hesitancy. *Pediatr Clin North Am*. 2023;70(2):259-269. **6.** Data on file. Sanofi. **7.** US Department of Health and Human Services. Vaccines for pregnant women. January 21, 2025. Accessed May 13, 2025. https://www.hhs.gov/immunization/who-and-when/pregnant/index.html **8.** ACOG committee opinion No. 741: maternal immunization. *Obstet Gynecol*. 2018;131(6):e214-e217. **9.** Flu vaccine safety and pregnancy. Centers for Disease Control and Prevention. September 17, 2024. Accessed November 16, 2024. https://www.cdc.gov/flu/vaccine-safety/vaccine-pregnant.html **10.** COVID-19 vaccination for people who are pregnant or breastfeeding. Centers for Disease Control and Prevention. September 10, 2024. Accessed November 23, 2024. https://www.cdc.gov/covid/vaccines/pregnant-or-breastfeeding.html **11.** Immunizations to protect infants. Centers for Disease Control and Prevention. August 30, 2024. Accessed November 23, 2024. https://www.cdc.gov/rsv/vaccines/protect-infants.html **12.** Surveillance of RSV. Centers for Disease Control and Prevention. August 30, 2024. Accessed November 23, 2024. https://www.cdc.gov/rsv/php/surveillance/index.html **13.** Rose EB, Wheatley A, Langley G, et al. Respiratory syncytial virus seasonality – United States, 2014-2017. *MMWR Morb Mortal Wkly Rep*. 2018;67(2):71-76. **14.** Griffin MP, Yuan Y, Takas T, et al. Single-dose nirsevimab for prevention of RSV in preterm infants. *N Engl J Med*. 2020;383(5):415-425. **15.** 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. **16.** 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. **17.** CDC's Vaccines for Children Program addendum: special considerations for nirsevimab. Centers for Disease Control and Prevention. Updated October 18, 2023. Accessed November 20, 2024. https://www.cdc.gov/vaccines-for-children/downloads/operations-guide-nirsevimab-addendum-508.pdf

Counsel your patients on how Beyfortus helps protect against RSV disease through direct administration to the infant.[3]
Visit Beyfortus.com to learn more.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- **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.

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Help patients make informed decisions by providing information about ACOG-aligned, CDC-recommended Beyfortus®[1]*†

✓ **ACOG supports the CDC recommendation for Beyfortus**[1]*†

Beyfortus is covered on nearly 100% of commercial plans‡

✓ **Available through Vaccines for Children Program (VFC)**[17]

*ACOG's guidance includes the importance of clinicians counseling patients on whether to administer Beyfortus to the infant or the maternal RSV vaccine during pregnancy based on their preference.[1]

†Infants <8 months born during or entering their first RSV season are recommended to receive Beyfortus. Providers should target the administration to the season. Beyfortus should be administered shortly after birth.[1]

‡Based on available information from national payer organizations.

Beyfortus is not indicated for adults.

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

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 on the previous pages and accompanying full Prescribing Information.

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