

Beyfortus

Consent for Treatment/Credit Card on File

Beyfortus (nirsevimab-alip) has been approved by the FDA and recommended by the ACIP for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, less than 8 months of age, and in children up to 19 months of age who remain vulnerable and high risk to severe RSV disease through their second RSV season.

Beyfortus is a monoclonal antibody with activity against RSV. Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses. One dose of Beyfortus, administered as a single intramuscular injection prior to or during RSV season, may provide protection during the RSV season.

IMPORTANT SAFETY INFORMATION

Contraindication

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

Warnings and Precautions

Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human IgG1 monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy.

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%).

I have reviewed and consent to my child: _____ dob: _____

Name of child

Signature of Parent

Beyfortus Billing Policy:

Beyfortus is a new injection available for RSV. When a new injection or immunization is available, insurance companies have 18 months to formulate reimbursement. Currently our total fee for this injection is \$730.16. We will bill your insurance carrier for all charges related to the injection. After two billing cycles, if your insurance carrier has not issued reimbursement, we will bill your credit card on file for the charges related to Beyfortus only. If during the appeal process your insurance carrier reimburses us for the cost of Beyfortus, we will issue a refund to your via check.

I have reviewed the Beyfortus Credit Card on File Policy- and agree to provide my credit card information for the sole purpose of payment for my child(ren)'s injection.

Name of Card: _____

email address for payment receipts: _____

Signature: _____

Date: _____

Visa ___ MC ___ Amex ___ Discover ___

Last 4 digits _____

****The card information is stored electronically in an encrypted form and cannot be viewed by our staff. We will call for your complete cc number security code and expiration date******

IMMUNIZATION INFORMATION STATEMENT

Respiratory Syncytial Virus (RSV) Preventive Antibody: *What You Need to Know*

Why get immunized with a RSV preventive antibody?

A respiratory syncytial virus (RSV) preventive antibody can prevent severe lung disease caused by RSV.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also affect the lungs. Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing.

Anyone can become infected by RSV, and almost all children get an RSV infection by the time they are 2 years old. While most children recover from an RSV infection in a week or two, RSV infection can be dangerous for infants and some young children, causing difficulty breathing, low oxygen levels, and dehydration. In the United States, RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (infection of the lungs) in children younger than 1 year of age. Children who get sick from RSV may need to be hospitalized, and some might even die.

RSV Preventive Antibodies

The RSV preventive antibody (generic name nirsevimab, trade name Beyfortus) is a shot that prevents severe RSV disease in infants and young children. Antibodies are proteins that the body's immune system uses to fight off harmful germs. Like traditional vaccines, preventive antibodies are immunizations that provide protection against a specific pathogen. While both are immunizations, the way they provide immunity is different. Nirsevimab is an immunization that provides antibodies directly to the recipient. Traditional vaccines are immunizations that stimulate the recipient's immune system to produce antibodies.

Infants born during the RSV season (typically fall through spring) should receive a single dose of the RSV Immunization within 1 week after birth. Most infants whose mothers got the RSV vaccine don't need to get nirsevimab, too. Both protect infants from severe RSV by providing antibodies, either from the mother to the infant or directly to the infant. Most infants will likely only need protection from either the maternal RSV vaccine or nirsevimab (not both). However, there may be some situations in which nirsevimab would be recommended for an infant after the mother received an RSV vaccine.

Infants born outside of the RSV season who are younger than 8 months should receive a single dose of the RSV Immunization shortly before their first RSV season (typically the fall), but infants who are younger than 8 months who have not yet received a dose may receive a dose at any time during the season.

Some infants and young children who are at increased risk for severe RSV disease may need a single dose of the RSV antibody before or during their second RSV season.

RSV preventive antibodies can be given at the same time as vaccines routinely recommended for infants and young children.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Talk with your health care provider

Tell your health care provider if the person getting the preventive antibody has a:

- History of serious allergic reactions to an RSV preventive antibody (nirsevimab) or any of its components,
- Bleeding disorder, or
- Moderate or severe acute illness.

In some cases, your child's health care provider may decide to postpone giving RSV preventive antibodies until a future visit.

People who have a minor illness, such as a cold, can safely receive an RSV preventive antibody. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

Risks of a reaction to RSV preventive antibodies

After getting an RSV preventive antibody, your child might have temporary pain, redness, swelling where the injection was given, or a rash.

As with any medicine, there is a very remote chance that RSV Immunization could cause a severe allergic reaction, other serious injury, or death.

An allergic reaction could occur after your child leaves the hospital or clinic. If you see signs of a severe allergic reaction (for example, hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get your child to the nearest hospital.

Call your health care provider if you see any other symptoms that concern you.

What if there is a serious problem?

If your child got an RSV preventive antibody without getting a vaccine at the same time, and you suspect an adverse reaction, you or your health care provider can submit a report through <https://www.fda.gov/medwatch> or by phone at 1-800-FDA-1088.

If your child got an RSV preventive antibody and a vaccine at the same time and you suspect an adverse reaction, you or your health care provider should report it to the [Vaccine Adverse Event Reporting System \(VAERS\)](https://vaers.hhs.gov/) <https://vaers.hhs.gov/> or call 1-800-822-7967. In your report, note that your child got an RSV Immunization along with a vaccine.

Note: MedWatch and VAERS are only for reporting reactions. MedWatch and VAERS staff members do not give medical advice.

How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit U.S. Food and Drug Administration website at [Drugs@FDA: FDA-Approved Drugs](https://www.fda.gov/drugs).
- Contact the Centers for Disease Control and Prevention (CDC):
 - o Call 1-800-232-4636 (1-800-CDC-INFO) or
 - o Visit the CDC website <https://www.cdc.gov/rsv/about/prevention.html>



RSV in Infants and Young Children

Respiratory syncytial virus, or RSV, is a common virus that affects the lungs. RSV season starts in the fall and peaks in the winter in most regions of the U.S.

Protect your young child from RSV.

There are two options to protect babies from severe RSV. Most babies only need one, not both.

RSV vaccine given during pregnancy:

- Protection passed to baby during pregnancy
- Recommended when 32-36 weeks pregnant
- Usually given during September-January

RSV antibody given to the baby:

- Directly provides protection to baby
- Recommended for babies younger than 8 months
- Usually given during October-March

A dose of RSV antibody is also recommended for the following children between the ages of 8 and 19 months entering their second RSV season:

- Children who have chronic lung disease from being born prematurely
- Children who are severely immunocompromised
- Children with cystic fibrosis who have severe disease
- American Indian and Alaska Native children

Talk to your healthcare provider to determine which option is best for you and your baby.



**RSV is the
LEADING CAUSE
of infant
hospitalization
in the U.S.**



www.cdc.gov/rsv