RSV Toolkit

What Pediatricians Need to Know About RSV Prevention

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Provided by:

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INTRODUCTION

Respiratory syncytial virus (RSV) is a highly contagious virus that causes respiratory illness. RSV can affect people of all ages, but is especially prevalent in infants and children. According to the CDC, RSV is one of the most common causes of childhood illness, as well as the most common cause of hospitalization in infants. Every year, thousands of infants and young children will contract RSV, representing a significant burden not only to patients and families, but also to pediatric health systems.

In 2023, the US Food and Drug Administration approved Nirsevimab (Beyfortus) for the prevention of severe RSV in infants and young children. During the same year, the FDA also approved Abrysvo, a RSV vaccine for pregnant women.

In June 2025, the Advisory Committee on Immunization Practices (ACIP) approved a second RSV monoclonal antibody for RSV immunization for infants. Effective August 4, 2025, the CDC accepted the ACIP recommendation and approved Enflonsia (Clesrovimab). Enflonsia will be available for the 2025-26 respiratory season and can be administered to commercially insured infants as well as those covered under the Vaccines for Children (VFC) Program (Georgia Vaccines for Children has not yet determined which product will be offered from VFC).

View the ACIP Recommendations | ACIP | CDC

Finally, effective December 2025, per the American Academy of Pediatrics, Synagis (Palivizumab) is no longer indicated for RSV and will be discontinued at the end of the year.

Sobi discontinues RSV injection Synagis | AAP News | American Academy of Pediatrics

The purpose of this toolkit is twofold. The first intent is to provide healthcare practitioners with data, science, and facts that they need to know about RSV and the new recommendations. The second intent is to provide resources and guidance to adequately prepare pediatric practices for implementation of Enflonsia and other RSV immunizations into daily operations.

Instructions for Using the Toolkit:

The RSV Toolkit will consist of both implementation information and strategies for RSV prevention. We encourage you to thoroughly read and digest all the information provided within this toolkit, and consult your professional advisors and associations for specific questions or situations.

Please note that the information provided in this toolkit is designed to be fluid in nature and will constantly evolve as new information is learned. We strongly encourage you to check back frequently for updated guidance as new developments arise.

OVERVIEW OF RSV

Respiratory syncytial virus (RSV) is a highly contagious virus that causes respiratory illness and most commonly affects infants and children. Much like the common cold, the virus can spread from person to person through direct or close contact with those infected. In the beginning stages of the virus, RSV typically presents as an upper respiratory infection. For more severe cases, the virus can eventually lead to lower respiratory tract infections that could require hospitalization.

Seasonality and Prevalence of RSV in Children

In the United States, RSV season typically occurs annually in the fall through the early spring months. RSV season usually starts in October, peaks in December and January, and then tapers off through April and May. Much like flu season, the precise start of RSV season may vary each year between different regions and communities.

RSV is a common illness among children. Research from CDC shows that virtually all children are likely to get an RSV infection by the time they are 2 years old. For the majority of healthy children, RSV will present with mild cold-like symptoms. However, in some populations such as infants and children with certain health conditions, RSV can lead to severe illness and hospitalization. Statistics from the American Academy of Pediatrics show that each year in the United States, an estimated 58,000-80,000 children under the age of 5 and up to 3% of children under one year of age, are hospitalized each year due to RSV infection. Of those children infected with RSV, approximately 20-30% are likely to develop a lower respiratory tract infection like bronchiolitis or pneumonia.

The risk of severe illness from RSV may increase in children with any of the following attributes:

- Prematurity
- Infants, especially those less than 8 months of age
- Children younger than 2 years old with chronic lung disease or congenital heart disease
- Children with suppressed or weakened immune systems
- Children who have neuromuscular disorders or a congenital anomaly, including those who have difficulty swallowing or clearing mucus secretions
- Children with severe cystic fibrosis

Most children with RSV will not need hospitalization. Those patients who do require hospitalization, may require supportive treatment including oxygen, rehydration through IV fluids, and/or mechanical ventilation to assist in recovery from illness.

Diagnosis and Testing of RSV

Typically, RSV causes cold-like symptoms. Sometimes, these symptoms can develop into symptoms often associated with lower respiratory tract infections. RSV symptoms may not be severe at the onset of the illness, but can become more severe on days 3 to 5, with symptoms generally lasting an average of 7-14 days.

This table from healthychildren.org summarizes the differences between commonly seen symptoms of both upper and lower respiratory infections in babies and young children.

Cold: Upper Respiratory Tract Infection	Bronchiolitis: Lower Respiratory Tract Infection
Cold symptoms may include:	May include **cold symptoms**, plus:
• Fever (temperature of 100.4 or higher)	• Fast breathing
• Cough (dry or wet sounding)	• Flaring of the nostrils & head bobbing with breathing
• Congestion	• Rhythmic grunting during breathing
• Runny nose	• Belly breathing, tugging between the ribs and/or the lower neck
• Sneezing	• Wheezing
• Fussiness	
• Poor feeding	

The CDC states that RSV symptoms are nonspecific and can often overlap with other viral respiratory infections, as well as some bacterial infections. There are laboratory tests available for confirming RSV infection which can be performed on upper and lower respiratory specimens.

The most common types of RSV clinical laboratory tests are:

- Real-time reverse transcription-polymerase chain reaction (rRT-PCR), which is more sensitive than culture and antigen testing
- Antigen testing, which may be less sensitive in adults than in children

The CDC states that for infants and young children, both rRT-PCR and antigen detection tests are shown to be effective methods for diagnosing RSV infection.

Treatment and Prevention of RSV

As with many viral infections, there is no specific treatment to cure RSV. Parents can follow routine comfort measures to help their child feel more comfortable during recovery from illness. Likewise, prevention measures should also be taken to lessen the likelihood of contracting RSV.

There are three RSV monoclonal antibody products on the market that can help protect children from severe disease from an RSV infection. It is important to note that monoclonal antibodies are not the same as vaccines. Rather, monoclonal antibodies help provide an extra layer of defense that helps fight off RSV infections and help safeguard children from severe illness. It is also important to note the effectiveness of these antibodies wane over time and should not be considered to be treatments for a child who already has an existing RSV infection.

On July 17, 2023, the US FDA approved a monoclonal antibody product called nirsevimab (Beyfortus™). According to the FDA news release, Beyfortus is a long-acting monoclonal antibody product used "for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season."

On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) voted unanimously in favor of recommending use of Beyfortus for the prevention of severe illness from RSV in infants and young children. According to the CDC press release, "Today, CDC director Mandy Cohen, MD, MPH, adopted the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for the use of nirsevimab, trade name Beyfortus™, a long-acting monoclonal antibody product, which has been shown to reduce the risk of both hospitalizations and healthcare visits for RSV in infants by about 80 percent." The ACIP also voted unanimously for inclusion of Beyfortus in the Vaccines for Children (VFC) program.

On June 21, 2025, the U.S. Food and Drug Administration (FDA) approved a new RSV vaccine, Enflonsia™, developed to help protect infants and young children from severe illness caused by respiratory syncytial virus (RSV). According to the FDA's approval announcement, Enflonsia is indicated for the prevention of RSV lower respiratory tract disease in infants entering their first RSV season.

On June 26, 2025 the Advisory Committee on Immunization Practices (ACIP) recommended the use of this new monoclonal antibody, Merck's Enflonsia, and was approved by the CDC in August 2025.

Aside from the newborn and infant RSV vaccines on the market, on September 22, 2023, the "CDC recommended the first respiratory syncytial virus (RSV) vaccine for pregnant people to protect their newborn from severe RSV illness." The new vaccine is produced by Pfizer and is a bivalent RSVpreF vaccine, that is also referred to by its trade name Abrysvo™. The CDC states that Abrysvo "has been shown to reduce the risk of RSV hospitalization for babies by 57 percent in the first six months after birth." To maximize protection for babies shortly after birth, the CDC recommends seasonal administration of one dose of the Abrysvo vaccine for pregnant people during weeks 32 through 36 of pregnancy. An important note from the CDC states that, "most infants will likely only need protection from either the maternal RSV vaccine or infant immunization, but not both. However, for example, if a baby is born less than two weeks after maternal immunization, then a doctor may recommend that the baby also receive the infant immunization."

Updated clinical guidance from the CDC on October 6, 2023 further details that maternal RSVpreF vaccine (Abrysvo), "should be administered to pregnant persons during September to January in most of the continental United States to target vaccine to pregnant persons whose infants will be in their first months of life, when protection from maternal vaccination would be at its highest, during the RSV season." The CDC also advises that Abrysvo can be safely coadministered with other commonly recommended vaccines for pregnant persons without regard to timing, including simultaneous vaccination on the same day, as long as the vaccines are received on different anatomic sites.

There are important differences between the two RSV immunizations available for infants. While the dose of Beyfortus depends on weight (0.5 mg for less than 11 lbs, 1 mg for 11 lbs and over), Enflonsia is the same dose for all infants regardless of weight. Beyfortus is indicated for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season; Enflonsia is only approved for use during an infant's first respiratory season.

BEYFORTUS CLINICAL INFORMATION

Description

Beyfortus™ is a monoclonal antibody product indicated for the prevention of RSV in newborns and infants born during, or entering their first RSV season and well as children up to 24 months of age who are entering their second RSV season.

According to the American Academy of Pediatrics, a RSV monoclonal antibody product considered to be a "passive immunization" that is being used in a similar manner to routine childhood vaccines.

The AAP also states that Beyfortus "confers long-lasting protection from RSV, with protection expected to last at least 5 months."

CDC recommends a RSV monoclonal antibody for a patient population that includes:

- **All infants younger than 8 months born during or entering their first RSV season**. Eligibility for the immunization is determined by age at the time of administration.
- **Infants and children aged 8 through 24 months who are at increased risk of severe RSV disease and entering their second RSV season** (Beyfortus only).

Recommended Timing

For the best outcomes in preventing RSV, ACIP and AAP recommend that providers should target administration of the antibody according to the following guidelines and their own clinical judgement.

- Providers should aim for Beyfortus administration in the first week of life for infants born shortly before and during the season, either within the birth hospitalization or in an outpatient setting such as the infant's pediatrician's office. For infants that experience longer birth hospitalizations either due to prematurity or other causes, Beyfortus may be given shortly before or promptly after hospital discharge.
- Beyfortus should be administered shortly before the start of the RSV season for infants aged <8 months
- Beyfortus should be administered shortly before the start of the RSV season for children aged 8–19 months who are at increased risk of severe RSV disease
- Beyfortus may be given to age-eligible infants and children who have not yet received a dose at any time during the season.
- Only children who meet high-risk criteria should receive more than one dose of Beyfortus – one dose in their first RSV season and one dose in their second RSV season. Healthy newborns born at the end of RSV season who received Beyfortus or Enflonsia around the time of delivery (first RSV season) should not receive a second dose entering their second season even if they are <8 months of age; conversely, healthy infants born at the end of their first RSV season who did NOT receive Beyfortus or Enflonsia and are <8 months of age entering their second RSV season may receive one dose of either vaccine.

Beyfortus can be administered in most of the United States between early October through the end of March, to coincide with the upcoming 2025-2026 RSV season. Providers who choose to administer Beyfortus outside of this recommended timeframe may run the risk of not being reimbursed by insurance carriers for these services. ACIP recommends that providers adjust administration schedules based on local epidemiology to account for regional differences of disease onset, peak, and decline periods of RSV in local communities.

ENFLONSIA CLINICAL INFORMATION

Description

ENFLONSIA is a preventive monoclonal antibody designed to protect infants born during or entering their first RSV season against a spectrum of RSV disease severity, including worsening disease requiring hospitalization. Enflonsia is the first and only RSV preventive option administered to infants using the same dose regardless of weight.

Recommended Timing

For the best outcomes in preventing RSV, ACIP and AAP recommend that providers should target administration of the antibody according to the following guidelines and their own clinical judgement.

- Providers should aim for Enflonsia administration in the first week of life for infants born shortly before and during the season, either within the birth hospitalization or in an outpatient setting such as the infant's pediatrician's office. For infants that experience longer birth hospitalizations either due to prematurity or other causes, Enflonsia may be given shortly before or promptly after hospital discharge.
- Enflonsia should be administered shortly before the start of the RSV season for infants aged <8 months
- Enflonsia is **not** approved for children older than 8 months or high-risk children in their second season.

Enflonsia can be administered in most of the United States between early October through the end of March, to coincide with the 2025-2026 RSV season. Providers who choose to administer Enflonsia outside of this recommended timeframe may run the risk of not being reimbursed by insurance carriers for these services. ACIP recommends that providers adjust administration schedules based on local epidemiology to account for regional differences of disease onset, peak, and decline periods of RSV in local communities.

Identifying Eligible Patients

The following criteria adapted from the AAP Nirsevimab Implementation Guide , updated 10/12/2023, and the FDA announcement regarding the approval of Enflonsia can help your practice identify eligible patients to receive Beyfortus or Enflonsia.

The criteria includes:

- Infants born shortly before or during RSV season (October through March)
    - Consider if any of these infants have a parent who was eligible to receive the maternal RSV vaccine. Make sure to flag these for parental follow-up in your EHR.
- Infants born earlier that year who will be <8 months at the start of RSV season (typically from February/March through September)

    - Tip: To determine who to reach out to, choose a start date in which it will be realistic to schedule those first appointments. This will ensure patients will be < 8 months of age at time of administration.
- High-risk children, who will be 8-19 months of age at the onset of the RSV season (October)
    - Note: Beyfortus is the only approved monoclonal antibody product that can be administered for a second RSV season
    - For Beyfortus only, include any high-risk patient who received one or more doses of Palivizumab this season (but < 5 doses) who will be eligible to receive nirsevimab 30 days after their last palivizumab dose.

The AAP Nirsevimab Administration Visual Guide, updated 10/12/2023, also provides tips to prioritize timely administration to eligible patients such as:

- Identify and prioritize those patients who are born in February/March and will turn 8 months old at the beginning of the RSV season (there is a narrow window for immunizing these children before they turn 8 months). This can now include immunization with Enflonsia.
- For Beyfortus only, identify and prioritize those patients who are high-risk and eligible and will turn 20 months of age at the beginning of the RSV season (narrow window).
- Implement your outreach plan to contact these patients and make sure they are appropriately scheduled.

Considerations for High-Risk Children

Following is a list of children 8 through 19 months of age who are recommended to receive Beyfortus when entering their second RSV season because of increased risk of severe disease, provided by CDC. Providers should use their own judgment to determine whether there may be other risks indicating that a patient should or should not receive Beyfortus entering their second RSV season.

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season.
- Children who are severely immunocompromised.
- Children with cystic fibrosis who have 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) or have weight-for-length that is <10th percentile.
- American Indian and Alaska Native children (note that this is a new group for whom second-season prophylaxis is recommended in contrast to the current palivizumab recommendations).

Beyfortus Dosage Information for Infants Entering Their First RSV Season

For routine cases, the single dose of Beyfortus or Enflonsia should be administered to all infants <8 months of age born during or entering their first RSV season, (typically starting October 1 through March 31 in most of the continental US). Eligibility is determined by age at the time of administration. Most infants with a prolonged hospital stay should get it shortly before or promptly after discharge.

Beyfortus Dosage Information by Weight/Age (See Appendix A for Beyfortus Prescribing Information):

- Infants weighing <5 kg: 50 mg dose (purple plunger rod)
- Infants weighing ≥5 kg: 100 mg dose (light blue plunger rod)

Recommended Dosage of Beyfortus in Neonates and Infants Born During or Entering Their First RSV Season[5]	
Body Weight at Time of Dosing	**Recommended Dosage**
Less than 5 kg	50 mg by IM injection
5 kg and greater	100 mg by IM injection

50 mg by
IM injection

100 mg by
IM injection

Beyfortus Dosage Information for Children at High Risk During Second RSV Season

Children 8 through 19 months of age who remain at high risk for RSV in their second RSV season should receive a single dose of 200 mg, administered through 2 separate 100 mg IM injections.

**Please refer to the Beyfortus prescribing information for additional information on dosing for high-risk children, as well as charts to determine proper timing of Beyfortus administration.*

Considerations for the 2025-2026 RSV season regarding palivizumab versus Beyfortus administration for high-risk infants during the same RSV season (adapted from ACIP and AAP Recommendations):

- Palivizumab is a short-acting monoclonal antibody product that is administered in monthly doses during the RSV season. Palivizumab is no longer routinely recommended for use. Shortages of nirsevimab occurred in the season after it was first recommended. If future shortages occur, and palivizumab is available, additional guidance will be provided.
- AAP has updated recommendations for the prevention of RSV Disease in infants and Children
- If Beyfortus is administered, palivizumab **should not** be administered later that season.
- **If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2**, the child should receive Beyfortus in season 2, if available. If Beyfortus is not available, palivizumab should be administered in accordance with prior recommendations from AAP and ACIP.

Enflonsia Dosage Information for Infants Entering Their First RSV Season

For routine cases, the single dose of Beyfortus or Enflonsia should be administered to all infants <8 months of age born during or entering their first RSV season, (typically starting October 1 through March 31 in most of the continental US). Eligibility is determined by age at the time of administration. Most infants with a prolonged hospital stay should get it shortly before or promptly after discharge.

The recommended dose for Enflonsia is 105 mg administered as a single intramuscular (IM) injection. (See Appendix B for Enflonsia Prescribing Information).

Co-administration with Routine Childhood Vaccines

CDC guidelines recommend simultaneous administration of Beyfortus or Enflonsia with age-appropriate vaccines. When co-administered with routine vaccinations, it is not expected to interfere with the immune response to other vaccines.

The CDC indicates that Flu, COVID-19, and RSV vaccines may be given at the same visit.
Getting a Flu Vaccine and other Recommended Vaccines at the Same Time | CDC

Precautions and Contraindications

Beyfortus is contraindicated in infants and young children with a history of serious hypersensitivity reactions, including anaphylaxis, to Beyfortus or to any of its components. Illness or febrile diseases are not contraindications to receiving Beyfortus.

Enflonsia Selected Safety Information:

- Do not administer ENFLONSIA to infants with a history of serious hypersensitivity reactions, including anaphylaxis, to any component of ENFLONSIA.
- Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy.
- The most common adverse reactions were injection-site erythema (3.8%), injection-site swelling (2.7%), and rash (2.3%).
- Before administering ENFLONSIA, please read the accompanying Prescribing Information. The Patient Information also is available.
- Please also refer to the Prescribing Information for Beyfortus.

The AAP recommends that vaccination should be deferred for persons with a moderate or severe acute illness, as this precaution avoids causing diagnostic confusion between the underlying illness and potential adverse effects of immunization. Similar to routine childhood vaccines, mild illness – with or without fever – should not be used as a reason to delay administration of a monoclonal antibody. General Best Practices for Immunization | Vaccines & Immunizations | CDC

For a detailed overview of both the Beyfortus and Enflonsia immunizations, please refer to Appendix C for a comparison chart.

Benefits and Challenges

In clinical trials, both Beyfortus and Enflonsia have proven to be effective in the prevention of RSV lower respiratory tract disease in infants born during or entering their first RSV season, and Beyfortus for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Unlike prior monoclonal antibody treatments, Beyfortus can be administered to a wider patient population.

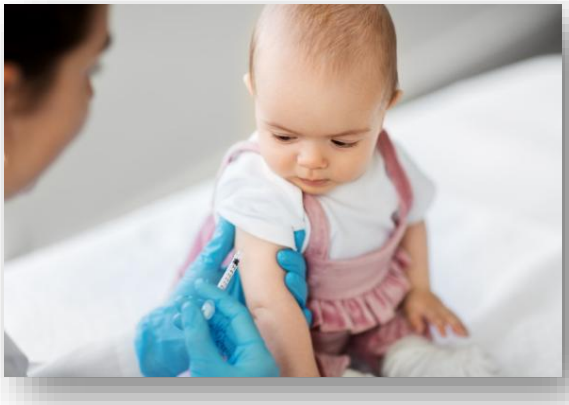
Considerations for Community Pediatricians

- As noted previously, reimbursement dynamics for RSV immunization is complex. In most cases, birthing hospitals are unlikely to administer the immunization at birth. The responsibility may fall to pediatricians to give it in their offices, at their discretion.
- **Pediatricians, at their sole discretion, may choose to give the immunization during October/November to babies who are 8 months or younger and who were not immunized in their birth hospital.**

For additional information, please refer to the following resource:

- Beyfortus Frequently Asked Questions (AAP.org)

ORDERING INFORMATION



Beyfortus Ordering Information

The AAP states that Beyfortus is part of the Vaccines for Children (VFC) program, and will be available for the 2025-2026 RSV season starting in October.

Practices can order Beyfortus for commercial stock from through their normal supply chain vendors.

Beyfortus is packaged in pre-filled syringes of either:

Dose Per Pre-Filled Syringe	Syringes Per Pack
• 50 mg (0.5mL) with purple plunger rod (for infants weighing <5 kg)	5
• 100 mg (1mL) with light blue plunger rod (weighing ≥5kg)	5

Beyfortus Purchase Cost

The private-sector cost for Beyfortus is:

- $545.01 per dose for 50mg and 100mg doses
- $1,090.02 per dose for a 200mg dose (Two 100mg doses)

Factors to Consider

- Beyfortus can be ordered as often as desired and in any quantity (there is no minimum order).
- The formulation of Beyfortus is not expected to change from year to year.
- The manufacturer states that Beyfortus has a shelf life of about 18 months when properly stored.

For additional guidance on ordering private vaccines as well as for the VFC program please see the AAP Ordering Vaccines page.

Enflonsia Ordering Information

It is anticipated that Enflonsia will be included in the Vaccines for Children (VFC) program once it receives CDC approval. Updated ordering information will be included as it becomes available.

Dose Per Pre-Filled Syringe	Syringes Per Pack
• 150 mg injection- Package containing 1 single-dose 0.7 ml prefilled syringe	1
• 150 mg injection- Package containing 10 single-dose 0.7 ml prefilled syringes	10

The private-sector cost for Enflonsia is:

- $556.00 per package containing 1 single-dose 0.7 ml prefilled syringe
- $5,560.00 per package containing 10 single-dose 0.7 ml prefilled syringes

Questions to Ask Before Ordering

The AAP lists several practical questions that every practice should consider before determining how much vaccine stock to order. Some of these questions are listed below:

When placing your order, consider the following in determining your order size:

- How many patients were born after March 31, 2025?
    - What is the monthly average of new patients who are newborns?
- How many patients who will be 8-19 months of age during the RSV season are at high risk and meet the eligibility criteria for Beyfortus during their 2nd RSV season?
- What percentage of your patients are insured privately?
- How much enthusiasm for this product is there in your practice? What % of families do you believe will agree to Beyfortus?
- How much storage space is in your vaccine refrigerators? (Remember that this product will be administered during influenza season, and as new COVID-19 vaccines become available.)
- How much cash is available to purchase this product? What financing options are available to purchase this product?
- How many local OB/GYN practices are administering Abrysvo?
- How many local birthing hospitals are administering Beyfortus/enrolled in VFC?

Vaccines for Children (VFC) Program

The CDC has reported that Beyfortus should be available through VFC starting in early October. It is anticipated that Enflonsia will also be available at some point in the season.

Important VFC Policy Updates (08/2025 VFC Newsletter)

RSV Requirements

All VFC-enrolled providers that serve VFC-eligible children 19 months of age or younger are required to carry VFC-supplied RSV monoclonal antibody products at the start of RSV season, which typically begins October 1.

Private Vaccine Stock

Providers that serve and plan to vaccinate privately insured, non-VFC eligible population, must continue to maintain a separate vaccine inventory to vaccinate their non-VFC-eligible population. CDC will no longer require VFC providers to maintain a full stock of all privately purchased ACIP-recommended vaccines for non-VFC-eligible patients if they do not plan to offer all ACIP-recommended vaccines to this population.

Included below is a table from [Sanofi listing administration fees and billing information for Georgia Medicaid.]

Georgia Medicaid

Administration Fee	Publicly-supplied VFC[b] Billing	Privately-purchased Adult Billing	Adult Coverage Policy
90460 - $22.15; 90471 - $23.78; 90472 - $12.99 or PCK[a] - $18.69; 90473 - $23.78; 90474 - $12.10 or PCK - $18.69; 96380 - $10.00 or PCK $18.50; 96381 - $10.00 or PCK $18.50[1]	For all immunizations, bill administration code immediately followed by product code to receive administration payment. Bill for administration of each vaccine using CPT®[c] 90460 or 90471-90474, billing multiple units when applicable. Multiple units of CPT 90460, 90472 or 90474 can be billed. Code the administration of nirsevimab using CPT code 96380 or 96381. Claims for injectable drugs and immunizations must include a CPT or HCPCS[d] code and must also have an NDC[e]. When provided at an EPSDT[f] visit add modifier –EP to the product and administration codes and the NDC is not required. When immunizations are provided at a visit, modifier -25 must be attached to the visit code.[1,2]	Bill vaccine code and administration code. Claims for injectable drugs and immunizations must include CPT or HCPCS code and must also have an NDC. The vaccine administration fee is covered for Medicaid members 21 years of age and older. Use modifier -25 on the visit code when billing vaccinations with a visit.[1-3]	All ACIP[g]-recommended vaccines are covered.[2,3]
Pharmacy Billing: Influenza, pneumococcal, zoster, human papillomavirus (HPV), and meningitis vaccines are covered for members 19 years of age and older, All claims must be submitted through the Pharmacy Point of Sale System using the product ID of the vaccine being administered by the pharmacist. Pharmacists can obtain member eligibility status from the GAMMIS web portal, eligibility transaction or via phone. Pharmacists must enter the patient's vaccination information in the Georgia Registry of Immunization Transactions and Services within 15 days. Pharmacy providers are reimbursed for the administration of select childhood vaccines for GA Medicaid Fee-for-Service (FFS) members 3 through 18 years of age. These vaccines are provided free of charge by the Vaccine for Children (VFC) program through the GA Department of Public Health.[4]			

[a] PCK = PeachCare for Kids; [b] VFC = Vaccines for Children; [c] CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association; [d] HCPCS = Healthcare Common Procedure Coding System; [e] NDC = National Drug Code; [f] EPSDT = Early Periodic Screening, Diagnosis, and Treatment; [g] ACIP = Advisory Committee on Immunization Practices.

References: 1. Georgia (GA) Medicaid. Georgia Medicaid Policies and procedures for the early periodic screening and diagnostic testing (EPSDT) program. https://www.mmis.georgia.gov/portal/PubAccess.Provider%20Information/Provider%20Manuals/tabId/18/Default.aspx. Accessed <Month Day, Year>. **2.** GA Medicaid. Policies and procedures for physician services. https://www.mmis.georgia.gov/portal/PubAccess.Provider%20Information/Provider%20Manuals/tabId/54/Default.aspx. Accessed April 24, 2024. **3.** GA Medicaid. Policies and procedures for physician administered drugs. https://www.mmis.georgia.gov/portal/PubAccess.Provider%20Information/Provider%20Manuals/tabId/54/Default.aspx. Accessed April 24, 2024. **4.** GA Medicaid. Policies and procedures for pharmacy services. https://www.mmis.georgia.gov/portal/PubAccess.Provider%20Information/Provider%20Manuals/tabId/18/Default.aspx. Accessed April 24, 2024.

sanofi

INFORMATION PERTAINS TO FEE-FOR-SERVICE PHYSICIAN AND PHARMACY BILLING AND PAYMENT AND IS SUBJECT TO CHANGE. ROUTINELY VERIFY ALL INFORMATION WITH YOUR STATE PLAN. NOT INTENDED AS LEGAL OR REIMBURSEMENT ADVICE.

Vaccine Reporting Requirements

- **Georgia Registry of Immunization Transactions and Services (GRITS)**

The Georgia Registry of Immunization Transactions and Services, better known as GRITS, is the Immunization Information System developed to comply with Georgia Law (OCGA 32-12-3.1). Immunization registries are confidential, computerized information systems that contain information about immunizations and clients of all ages. Individuals typically are entered into a registry at birth (often through a linkage with electronic birth records), or at first contact with the health-care system. If a registry includes all individuals in a given geographical area and all providers are reporting immunization information, a registry can provide a single data source for all community immunization partners.

GRITS interacts with the VFC program. When a provider utilizes the full capabilities of the Registry, the provider is able to manage his or her complete VFC vaccine inventory. The provider will be able to electronically report monthly vaccine usage to the VFC program office

- **Reporting Adverse Reactions**

Adverse reactions might occur after administration of Beyfortus or Enflonsia alone; these reactions should be reported to the [FDA's MedWatch Adverse Event Reporting Program].

The information provided is not intended to constitute professional, billing or legal advice and is made available for general information purposes only. Providers should contact their own counsel or advisers to obtain advice with respect to any particular matter.

If an adverse event occurs while co-administering Beyfortus or Enflonsia with a vaccine, it should also be reported to the Vaccine Adverse Event Reporting System (VAERS).

Additional information can also be found here: AAP Immunization Administration in Your Practice

FINANCIAL CONSIDERATIONS

Product Codes

CPT Codes have been released for respiratory syncytial virus, monoclonal antibody. Care should be taken to use the correct code for the dose given; to account for VFC-provided vaccines; and to differentiate among monoclonal antibody products, vaccines, and toxoid products. **Practices may choose to refer to Coding Vignettes outlined by the AAP for further clarification.**

Diagnosis Codes

There is also an ICD-10 CM code for prophylactic immunotherapy for RSV (currently Z29.11), which is distinct from the encounter for immunization code (currently Z23), specific to vaccines. Practices are responsible for remaining up to date on all coding rules.

Payment Tips

Also consider the following payment tips adapted from the AAP:

1. Payment policies vary by payer and your contract with them. CPT coding guidelines will not always align with a payer's payment policy. Payers must comply with ICD-10-CM coding conventions and guidelines but are not required to comply with CPT guidelines. It is important to verify coverage and reporting specifics and, if possible, confirm them in writing for each payer.
2. Contracts should be reviewed regarding payment levels for these immunizations. For information on the total direct and indirect costs of immunizations, see the *AAP Business Case for Pricing Vaccines*.
3. For health insurance plans that are compliant with the Affordable Care Act (ACA), Enflonsia or Beyfortus is generally a covered benefit with no patient responsibility. Practices should consider whether to require additional consents or charge authorizations from patients' responsible parties. ** Note, because Enflonsia is a new product with a new CPT code, payors may not yet have added this code to their fee schedules

EDUCATION AND TRAINING MATERIALS

The AAP recently updated the RSV section of its website to include tools for both inpatient and outpatient practices to begin implementation of Beyfortus.

These new resources include:

- A Practice Readiness Checklist- designed to help assess a practice's readiness to administer Beyfortus to patients
- Nirsevimab Implementation Guide- intended to serve as a guide for practices that have already used the Practice Readiness Checklist, and are ready to implement the administration of Beyfortus in their organization.
- crackingthecodestraining.com - Downloadableresources
- Now FDA-Approved ENFLONSIA™ (clesrovimab-cfor) 105 mg Injection | Official Consumer Site

The AAP also offers general resources that may help practices as they begin to administer Beyfortus within their own organization including:

- Nirsevimab Administration Visual Guide: Use this guide to help determine if and what dose is needed for administration.
- Immunization Information Statement: Provide this VIS-like information to parents/caregivers when administering Beyfortus. Note, this has not been updated to include Enflonsia.
- Coding Guidance: Initial guidance is included in the resources above but check in with the AAP on the latest coding guidance for Beyfortus.
- Refusal to Vaccinate Diagnosis Codes and Form

CONCLUSION

We hope that the information included in this guide is useful as you evaluate your path forward with Beyfortus and Enflonsia and their implications on the prevention of severe RSV illness in infants and young children.

Please reach out to the following contacts if you have any questions:

For risk management questions, please email Barbara Douglas at barbara.douglas@tccn-choa.org.

- For questions regarding payor updates, fee schedules, or billing and coding, please email our Provider Relations Team at providerrelations@tccn-choa.org.

- For clinical questions please email Laura Baldwin at quality@tccn-choa.org.

APPENDIX

CDC Resources:

- Clinical Overview of RSV | RSV | CDC
- RSV Vaccines | RSV | CDC
- General Best Practices for Immunization | Vaccines & Immunizations | CDC
- 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
- Current CDC Vaccine Price List | VFC Program | CDC

American Academy of Pediatrics:

- Respiratory Synctial Virus (RSV) Prevention
- RSV Immunization Frequently Asked Questions
- Recommendations for the Prevention of RSV Disease in Infants and Children: Policy Statement | Pediatrics | American Academy of Pediatrics

Additional Sources:

- U.S. Food & Drug Administration: FDA Approves New Drug to Prevent RSV in Babies and Toddlers
- U.S. FDA Approves Merck's ENFLONSIA™ (clesrovimab-cfor) for Prevention of Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease in Infants Born During or Entering Their First RSV Season - Merck.com
- Healthychildren.org- RSV: When It's More Than Just a Cold

Resources:

- Appendix A: Beyfortus Prescribing Information
- Appendix B: Enflonsia Prescribing Information
- Appendix C: Beyfortus vs. Enflonsia Chart

Appendix C: Beyfortus vs Enflonsia Comparison Chart

Feature	Beyfortus™	Enflonsia ™
Type	Monoclonal antibody	Monoclonal antibody
Indication	RSV prevention in infants and high-risk young children	RSV prevention in neonates and infants
Target Population	Neonates and Infants <8 months; high-risk children 8–24 months	Neonates and infants <8 months
Administration Timing	At birth, before season, or during RSV season	At birth, before season, or during RSV season
Protection Duration	At least 5 months	At least 5 months
Dosage (Infants <5 kg)	50 mg (purple plunger rod)	105 mg (not weight-based), Single IM injection
Dosage (Infants ≥5 kg)	100 mg (light blue plunger rod)	
Dosage (High-risk, 8–24 months)	200 mg (two 100 mg injections)	
Co-administration with Routine Vaccines	Yes	Yes
Storage Conditions	In Refrigerator: 36°F–46°F (2°C–8°C); Room Temperature 68°F–77°F (20°C–25°C); up to 8 hrs (light-protected) Do not freeze. Do not shake.	In Refrigerator: 36°F–46°F (2°C–8°C) Room Temperature 68°F–77°F (20°C–25°C); up to 48 hrs (light-protected) Do not freeze. Do not shake.
Shelf Life	36 months	30 Months
Availability	October 2024	October 2025
VFC Program Inclusion	Yes	Expected
Expected Cost (Per Dose) Pre-discounts	$545.01 (50mg/100mg) per pre-filled syringe	$556.00 single 0.7ml pre-filled syringe
Billing Code(s)	90380, 90381, 96380, 96381	90382, 96380, 96381
Special Considerations	Verify maternal RSV vaccine status (received weeks 32-36)	Verify maternal RSV vaccine status (received weeks 32-36)