RSV Toolkit

What Pediatricians Need to Know About RSV Prevention

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Provided by: The Children's Care Network

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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 addition to Synagis (Palivizumab), which has been on the market for some time, the U. S. Food & Drug Administration approved Nirsevimab (Beyfortus™) in 2023, for the prevention of severe RSV in infants and young children. In addition, the FDA has recently approved Abrysvo, an RSV vaccine for pregnant women.

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 Beyfortus 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 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 two 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.

The first monoclonal antibody product on the market is palivizumab, or more commonly referred to as Synagis. Palivizumab was approved in 1998 by the US FDA to reduce serious lower respiratory tract infection caused by RSV in children who are at increased risk of severe disease. There are two main limitations to the use of palivizumab in the prevention of RSV including:

- Palivizumab must be given once a month during RSV season.
- Palivizumab is limited to children under 24 months of age with certain conditions that place them at high risk for severe RSV disease. Thus, this antibody product is not applicable to the majority of pediatric patients who are susceptible to getting RSV.

**For more information on the clinical use of palivizumab as a RSV preventative method, please refer to the American Academy of Pediatrics' RSV Prevention Products site, which includes both the palivizumab policy and technical report.*

On July 17, 2023, the US FDA approved a second 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 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.

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, Beyfortus is 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 Beyfortus 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**.

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 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 and are <8 months of age entering their second RSV season may receive one dose of Beyfortus.

Beyfortus can be administered in most of the United States between early October through the end of March, to coincide with the 2024-2025 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.

Identifying Eligible Patients

The following criteria adapted from the AAP Nirsevimab Implementation Guide , updated 10/12/2023, can help your practice identify eligible patients to receive Beyfortus.

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)
    - 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 of Beyfortus 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).
- 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).

Dosage Information for Infants Entering Their First RSV Season

For routine cases, the single dose 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.

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

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 2024-2025 RSV season regarding palivizumab versus Beyfortus administration for high-risk infants during the same RSV season (adapted from ACIP and AAP Recommendations):

- If Beyfortus is administered, palivizumab **should not** be administered later that season.
- If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive **1 dose of Beyfortus**. No further palivizumab should be administered.
- **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.

Co-administration with Routine Childhood Vaccines

CDC guidelines allow simultaneous administration of Beyfortus with age-appropriate vaccines. When co-administered with routine vaccinations, Beyfortus 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.

The AAP refers to CDC General Best Practice Guidelines for Immunizations, which 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 Beyfortus.

Storage and Handling Considerations

Beyfortus should be stored the way many vaccines are stored according to the parameters below:

- **Routine Storage:** In a refrigerator at 2˚C– 8˚C ; **DO NOT FREEZE**
- **Short-term storage:** Room temperature (20˚C – 25˚C), for 8 hours, if protected from light

For more information on best practices for vaccine storage and handling, please refer to the resources below:

- AAP Vaccine Storage and Handling page
- CDC Vaccine Storage and Handling Toolkit
- CDC Data Table of Infant Weight-for-age Charts

Benefits and Challenges

In clinical trials, Beyfortus has proven to be effective in the prevention of RSV lower respiratory tract disease in infants born during or entering their first RSV season, and 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.

It should be noted that Beyfortus reimbursement dynamics can be complex. As such, pediatricians may find that birthing hospitals will not be the primary source of Beyfortus administration.

Prenatal care providers should discuss potential nirsevimab supply concerns when counseling pregnant people about RSVpreF vaccine (Abrysvo), as maternal vaccination is effective and will reduce the number of infants requiring nirsevimab during the RSV season.

Considerations for Community Pediatricians

- As noted previously, reimbursement dynamics for Beyfortus is complex. In most cases, birthing hospitals are unlikely to administer Beyfortus 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.**

The ACIP and AAP further recommends that if Beyfortus is not available or not feasible to administer, **high-risk infants should receive palivizumab in the first or second year of life**, as previously recommended, until Beyfortus becomes more readily available.

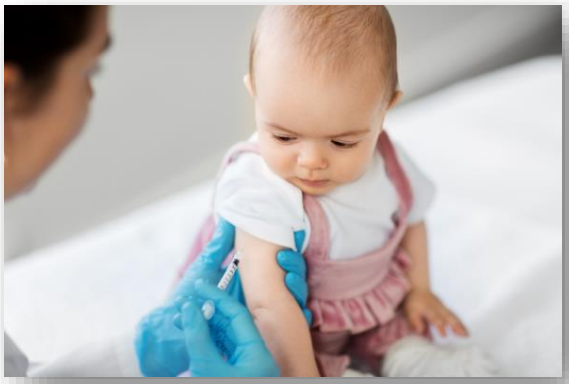
For additional information, please refer to the following resources:

- ACIP Recommendations for the Use of Beyfortus for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children

- AAP Technical Report- Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection
- AAP Policy Statement- Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection
- Respiratory Syncytial Virus (Red Book)
- 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 2024-2025 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 expected to be:

- $519.75 per dose for 50mg and 100mg doses
- $1,039.50 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 (see above).

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

Questions to Ask Before Ordering

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

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

- How many patients were born after March 1, 2024?
    - What is the monthly average of new patients who are newborns?
    - What % of these patients are likely to be under 5kg?
- 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. The Georgia Department of Public Health has indicated that, to meet VFC contract provisions, **practices who obtain Beyfortus through the VFC program will need to keep at least a few doses on hand for commercial patients**. **VFC also requires that a participating practice receive all offered vaccines and immunizations.**

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.

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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.

COMPLIANCE & RISK MANAGEMENT

Included below is a statement from our partners at Curi and Sterling Seacrest Pritchard:

We believe providers are obligated to make parents aware of the recommendations from the FDA and ACIP, and if the parents elect to have their child vaccinated, to direct them to places where they can obtain the vaccine. We recommend that providers maintain a list of locations where the vaccine can be obtained. Patients may prefer this option because of flexible scheduling (i.e., at times other than usual medical practice hours) and the cost-effectiveness of not having to pay for an office visit in addition to the vaccine.

It is not unusual for providers to make evidence-based recommendations and subsequently refer the patient to other providers to obtain the service. In short, while it is a business decision whether to keep the vaccines in-house, providers need to discuss the recommendations related to the vaccine with parents, thoroughly document their recommendations, and inform the parents where they can obtain the vaccine.

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 alone; these reactions should be reported to the FDA's MedWatch Adverse Event Reporting Program.

If an adverse event occurs while co-administering Beyfortus 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

Current Economics

Since Beyfortus is the first product of its kind, the AAP recognizes that prompt and appropriate payment for Beyfortus will be challenging. According to a letter from the AAP to CDC/CMS Directors, the AAP is advocating for a comprehensive strategy to ensure equitable access to Beyfortus, as well as improved reporting and reimbursement strategies.

Product Codes

As of the date of publication, the billing codes for Beyfortus are:

CPT Code	CPT Description
90380	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage for intramuscular use
90381	1 mL dosage, for intramuscular use (for 200 mg dose, code as 90381 X2)

- Follow state specifications for reporting the immunization when the immunoglobulin product is provided through the Vaccines for Children program. For example, report **90380 SL** to indicate state-supplied product.
- Keep up to date on CPT code and modifier changes.

Administration Codes

As of October 6, 2023, two new CPT codes were released for reporting the administration and counseling of monoclonal antibodies for RSV. Providers must stay up to date on CPT codes and select the correct code for their services.

CPT Code	CPT Description
96380	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional
96381	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection

- Code selection is based on if a physician or QHP provided counseling on the same date as the administration of Beyfortus.

- Do not report immunization administration codes **90461–90462** or **90471–90472** for the injection of Beyfortus, as these codes are limited to the administration of vaccine and toxoid products
- The AAP is working with payers to update payment systems and payment guidance. In the meantime, the AAP recommends that practices "contact your payers and get their guidance on reporting nirsevimab in writing and report any discrepancies in CPT guidelines that appear in their guidance to the coding hotline with an attachment of the documented guidance. Using the appropriate diagnosis CPT code is important for billing, claims payment, data collection, and quality metrics."
- To prevent cost share from being passed on to the patient, append **modifier 33** to the administration code. This indicates to the payer that this was part of a preventive service. Stay up to date on modifier rules.
- Practices may choose to refer to Coding Vignettes outlined by the AAP for further clarification.

Diagnosis Codes

While Beyfortus is categorized as a monoclonal antibody by CPT, ICD-10 CM's index recommends use of the following diagnosis code; practices must remain up to date on all coding rules.

Diagnosis Code	Description (ICD-10)
Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV).

Note: **Administration of Beyfortus is not reported with Z23 Encounter for immunization. Z23 is specific to immunization related to vaccines.**

Please also refer to the Beyfortus Coding and Billing Sheet for additional guidance.

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 frequently verify coverage and reporting specifics and, if possible, confirm them in writing for each payer.
2. Contracts should be reviewed regarding payment levels for Beyfortus. 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), 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.

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

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.
- Vaccine Refusal/Declination form: Document declination from any patient who is eligible (use the "other" category).
- Coding Guidance: Initial guidance is included in the resources above but check in with the AAP on the latest coding guidance for Beyfortus.

CONCLUSION

We hope that the information included in this guide is useful as you evaluate your path forward with Beyfortus and its implication 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:

- RSV For Healthcare Providers
- RSV Prevention- How to Protect Yourself and Others
- CDC Recommends a Powerful New Tool to Protect Infants from the Leading Cause of Hospitalization
- General Best Practice Guidelines for Immunization
- 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
- CDC Vaccine Price List

American Academy of Pediatrics:

- Respiratory Synctial Virus (RSV) Prevention
- Nirsevimab Frequently Asked Questions
- ACIP and AAP Recommendations for Nirsevimab
- Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection
- Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

Additional Sources:

- U.S. Food & Drug Administration: FDA Approves New Drug to Prevent RSV in Babies and Toddlers
- Healthychildren.org- RSV: When It's More Than Just a Cold

Resources:

- Appendix A: Beyfortus Prescribing Information