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.

The U. S. Food & Drug Administration recently approved Nirsevimab (Beyfortus™) for the prevention of severe RSV in infants and young children. Beyfortus is a new product in the market that may significantly impact the way pediatricians and healthcare entities approach RSV prevention.

The current RSV landscape is dynamic and changing every day. New information is being released frequently, and it can be overwhelming to keep up with all of the latest updates. 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.

TCCN is dedicated to joining the fight against RSV. Our mission is to provide our community practitioners with ongoing support, education, and tools to lead prevention efforts.

Instructions for Using the Toolkit:

The RSV Toolkit will consist of both implementation information and best practice strategies for RSV prevention. We encourage you to thoroughly read and digest all the information provided within this toolkit.

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 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 is sensitive in children but less sensitive in adults

For infants and young children, both rRT-PCR and antigen detection tests are shown to be effective methods for diagnosing RSV infection. The sensitivity of RSV antigen detection tests generally ranges from 80% to 90% in this age group.

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.

The CDC lists 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. However, 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 it 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' 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. Abrysvo is currently available in some locations within the US, with its availability expected to increase over the coming weeks. 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.

At this time, both Abrysvo and Beyfortus are new to the market and may not be widely available yet in its first implementation season. Included in this toolkit is what we know about its availability as of today.

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 upcoming 2023-2024 RSV season. 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 on best practices 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 2023-2024 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 recommend 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 and COVID vaccines can be given at the same time and along with other vaccines. It is possible that RSV Monoclonal Antibody can also be given with Flu and COVID vaccines. **We anticipate an update from the CDC when Beyfortus becomes available in October.**

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.

Widespread access to Beyfortus can prove to be one of its biggest challenges; especially in its first implementation year. According to a message from Sandy Chung, M.D., President of the AAP, (Appendix B), "the barriers to offering Beyfortus (Beyfortus) to all infants are significant and complex." Although the AAP is "currently advocating to find workable solutions, it is highly likely that due to logistical and financial barriers, Beyfortus will not be available in all communities this fall."

Thus, providers may find that Beyfortus may not be readily available in all clinical settings, including birthing hospitals and primary care settings, particularly in the first season of recommendation.

Challenges Regarding Beyfortus Availability and Supply

On October 19, 2023, the AAP released an update stating that the CDC is "resuming limited ordering of nirsevimab through the Vaccines for Children (VFC) program." At this time, only the 50 mg dose is available to order. Previously, as mentioned from this article from the AAP dated October 17, 2023, ordering of Beyfortus through the Vaccine for Children (VFC) program was temporarily put on hold, and the 100-milligram formulation is currently not available for ordering from Sanofi.

The article also states that "the CDC cited a high demand and limited supply for causing the pause in ordering." The CDC expects VFC ordering to resume with a new allocation system in place. The allocation system will initially target awardees who have not yet ordered Beyfortus, or who ordered a small amount. Doses allocated to awardees will be based on ordering history. In addition to the VFC

ordering pause, a statement from a Sanofi spokesperson said that “while deliveries of 100 m doses continue, new orders are not being taken by Sanofi at this time."

Sanofi released a statement that “Despite an aggressive supply plan built to outperform past pediatric vaccine launches, demand for this product, especially for the 100 mg doses used primarily for babies born before the RSV season, has been higher than anticipated.” Sanofi is said to be working with manufacturing partner AstraZeneca to accelerate availability of Beyfortus, however at this time a specific timeline has not been announced.

Interim Recommendations for the 2023-24 RSV Season

On October 23, 2023, CDC released interim recommendations for clinicians in the midst of limited supply of nirsevimab (Beyfortus). **The interim recommendations below apply only to the 2023-’24 season.**

- In the context of limited supply during the 2023–2024 RSV season, CDC recommends prioritizing available nirsevimab 100mg doses for infants at the highest risk for severe RSV disease: young infants (age <6 months) and infants with underlying conditions that place them at highest risk for severe RSV disease.
- Recommendations for using 50mg doses remain unchanged at this time.
- Avoid using two 50mg doses for infants weighing ≥5 kilograms (≥11 pounds) to preserve supply of 50mg doses for infants weighing <5 kilograms (<11 pounds). Providers should be aware that some insurers may not cover the cost of two 50mg doses for an individual infant.
- CDC further recommends that providers suspend using nirsevimab in palivizumab-eligible children aged 8–19 months for the 2023–2024 RSV season. These children should receive palivizumab per American Academy of Pediatrics (AAP) recommendations.
    - Nirsevimab should continue to be offered to American Indian and Alaska Native children aged 8–19 months who are not palivizumab-eligible and who live in remote regions, where transporting children with severe RSV for escalation of medical care is more challenging or in communities with known high rates of RSV among older infants and toddlers.
- 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

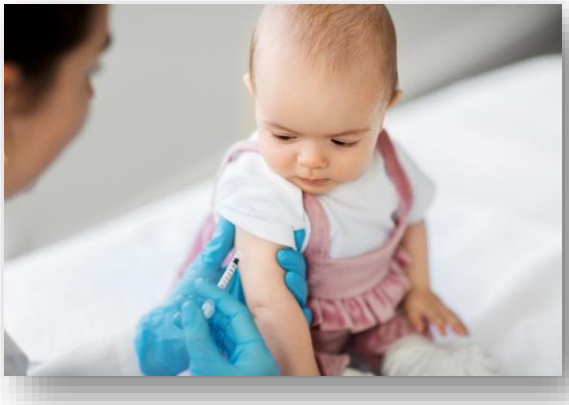
- Until hospitals are set up to give the immunization to newborns, the responsibility may fall to pediatricians to give it in their offices, at their discretion.
- **Pediatricians, at their sole discretion, may choose to give the immunization during October/November to babies who are 8 months or younger 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



***Please refer to page 10 of this document for current updates regarding Beyfortus supply and page 14-15 to view updates regarding GRITS and the VFC program.**

Beyfortus Ordering Information

The AAP states that Beyfortus is part of the Vaccines for Children (VFC) program, and will be available for the 2023-2024 RSV season starting in October. As of September 15, 2023, Beyfortus has also been added to the CDC Vaccine Price List for Pediatric/VFC vaccines.

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:

- $495 per dose for 50mg and 100mg doses
- $990 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.

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 1, 2023?
    - 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?
- The number of units your practice needs to order is also dependent on the number of eligible patients on your recall list. Please refer to recall list calculations and criteria to determine this amount.

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**.

***Please refer to page 10 of this document for current updates regarding Beyfortus supply and interim CDC recommendations for the 2023-24 RSV season.**

On October 25, 2023 the AAP released updates regarding Beyfortus availability under the VFC program. These updates include:

- The Georgia VFC Program has been allocated a limited amount of Beyfortus-50 mg.
- The Georgia VFC Program was not allocated any Beyfortus-100 mg.
- The Georgia VFC Program has not been allocated to any 317 funded RSV vaccines for uninsured/underinsured adults.

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)**

  Beyfortus is available for reporting through GRITS for the 50mg injection for VFC supplied requests. As stated in this news release from the AAP, healthcare organization must update their vaccine preferences in GRITS before ordering. Additionally, clinics can place VFC vaccine requests in GRITS every 14 days.

  Due to limited supply for Beyfortus for the 2023-24 season, the Georgia VFC Program will need to cap the number of Beyfortus doses VFC providers can request to 20 doses. VFC Providers can request less than 20 doses, but the amount needs to be an increment of 5 doses.

- **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

Interim 2023-2024 COVID-19 Vaccine and Beyfortus Borrowing Policy

The CDC has approved a temporary authorization of bi-directional COVID-19 vaccine and Beyfortus borrowing for the 2023-2024 respiratory vaccine season. According to a statement from the Georgia DPH, "two-way borrowing will allow providers to administer state supplied COVID-19 vaccine and nirsevimab to fully insured children and adults or to administer privately purchased COVID-19 vaccine and nirsevimab to VFC eligible children and uninsured or underinsured adults in the event there is a delay in shipment of either stock. The purpose of this policy is to prevent missed COVID-19 vaccine and nirsevimab administration opportunities for both VFC/AVP-eligible and fully insured patients."

It is important to note that doses for both COVID-19 vaccines and Beyfortus must be replaced within 30 days.

Additional information regarding the COVID-19 and Beyfortus Vaccine Borrowing Policy can be obtained from this resource from Georgia DPH, this communication from the AAP, or from updated addendums shared by the AAP. **Providers should check frequently for updated policies.**

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 in the first year of implementation. 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.

TCCN is working with payors with whom it is contracted to determine coverage and fee schedules for Beyfortus.

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.

Administration Codes

As of October 6, 2023, two new CPT codes were released for reporting the administration and counseling of monoclonal antibodies for RSV.

Diagnosis Codes

There is also an ICD-10 CM code (currently Z29.11) for prophylactic immunotherapy for RSV, which is distinct from the encounter for immunization code specific to vaccines (Z23).

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. As per the Affordable Care Act (ACA) payors have until 12 months after the new plan year following ACIP recommendations to recognize and pay for new vaccines. ACIP recommended Beyfortus on 8-3-2023. The AAP will be notifying the major national health plans about the recommendations and urge timely benefits coverage and appropriate payment for the vaccine and administration.
3. 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*.
4. The RSV injection has been recently approved by the FDA, and thus may not be included as a covered benefit under a patient's insurance plan. 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.

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
- Appendix B: A Message from AAP President Sandy Chung, M.D., FAAP

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

A Message from AAP President Sandy Chung, M.D., FAAP

September 8, 2023

Dear colleagues,

This fall brings several concurrent challenges to pediatric practice: Covid-19 vaccines will transition to the commercial marketplace, Medicaid unwinding has pushed thousands of families off their insurance plans, and we face myriad obstacles to offer nirsevimab, the new RSV immunization recommended for all infants.

Today, I wanted to give you a few updates on where we are with all three of these issues, starting with RSV.

1. RSV: First of all, this new immunization presents tremendous potential benefits for infant health, which is why the AAP and other groups have recommended it be made available to everyone. But the barriers to offering nirsevimab (Beyfortus) to all infants are significant and complex. AAP is advocating on behalf of our members and the families you care for to find workable solutions, but it is highly likely that due to logistical and financial barriers, nirsevimab will not be available in all communities this fall.

Delivering this product will require significant changes for Medicaid and private payers, hospital systems, and pediatric practices, and these systems are all interdependent in complicated ways. Unfortunately, our list of questions right now is longer than our list of answers, but here are a few updates I can share:

- AAP is meeting with leaders at the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) following our July letter urging them to create a comprehensive strategy to ensure equitable access to nirsevimab. These discussions are ongoing, and we continue to urge our government partners to create strategies that do not impose financial and logistical burdens on pediatricians.
- Nirsevimab will be available in pre-filled syringes, and Sanofi has agreed to a 150-day payment period from the product ship date. We expect CDC to update the price list for nirsevimab this month. AAP anticipates doses in the Vaccines for Children program will be available starting in early October, but there could be variation among states in terms of distribution.
- AAP is advocating for a new CPT code to adequately cover the costs of counseling and administration. AAP is in discussions with payers to request prompt loading of nirsevimab product codes (and the administration code once available), as well as continued coverage of palivizumab.
- We anticipate that after the Sept. 22 meeting of the CDC's Advisory Committee on Immunization Practices (ACIP), there will be recommendations on RSV vaccines for

pregnant people. As soon as we know more about those recommendations and how they relate to nirsevimab, we will share them with you.

- Meanwhile, experts are tracking an uptick of RSV cases in the southeastern U.S., which could lead to cases spreading north and west in the next 2 to 3 months according to historical patterns.

AAP.org has a web page with information on RSV, including AAP recommendations, FAQs; ordering and product information; administration, dosing and scheduling; and payment and coding information including vignettes. This information is rapidly changing, and we anticipate more updates later this month. We also anticipate additional information from CDC in October, including information sheets for families. The AAP.org pages will be updated frequently, and AAP News will continue to cover new developments and share them in On Call.

AAP also offers information for families in the HealthyChildren.org article, RSV: When It's More Than Just a Cold.