# Birthing Hospitals and VFC: A Learning Collaborative to Protect Infants from RSV



# HOUSEKEEPING

- We encourage discussion but please remain muted when not speaking
- This call is being recorded
- Please introduce yourself in the chat and tell us your role in these efforts
- All slides and resources will be sent after the call
- Use the chat box for any questions



Purpose of the Learning Collaborative



**Update on RSV Vaccination** 





Intermountain Health: RSV Prevention Coordination in an Integrated Health System



2025-2026 Order Strategies with Tennessee **Immunization Program** 



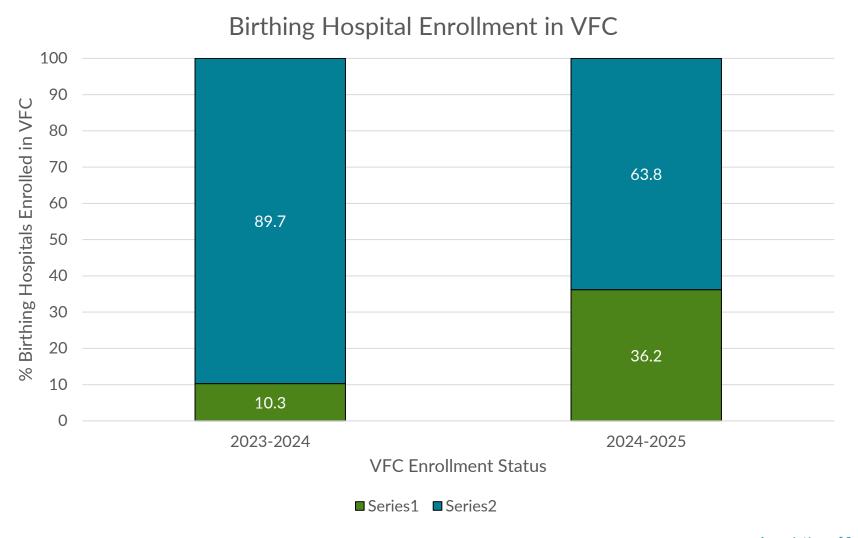
Resources and Next Steps

# Purpose

- Increase the capacity to equitably protect infants from serious illness and death due to RSV infection by
  - Understanding challenges to hospital participation in the VFC program
  - Sharing promising practices to overcome these challenges
  - Increasing birthing hospital participation in the VFC program

# RSV Vaccination Data Update

# **Progress**



# **Estimated Effectiveness of Nirsevimab**

against medically attended **RSV**-associated acute respiratory illness

Against RSV-associated hospitalization

# **RSV Vaccination: Maternal and Infant**

Figure 6. Infant Protection Against RSV by Maternal RSV Vaccination\* or Receipt of Nirsevimab,† and Intent for Nirservimab Receipt, \* Reported By Females Aged 18-49 Years Who Have an Infant < 8 Months During the RSV season (born since April 1, 2024), by Month of Interview, United States §, ± Data Source: National Immunization Survey-Adult COVID Module

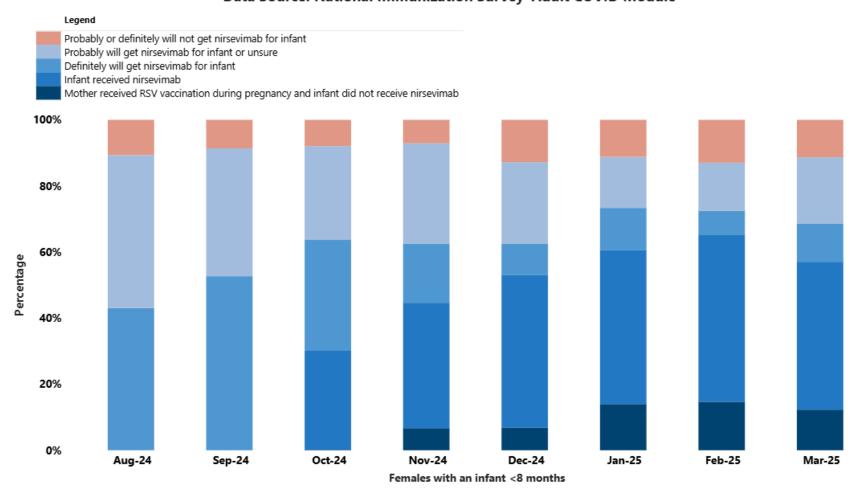


Figure 6. Infant Protection Against RSV by Maternal RSV Vaccination\* or Receipt of Nirsevimab,<sup>†</sup> and Intent for Nirservimab Receipt,<sup>‡</sup> Reported By Females Aged 18–49 Years Who Have an Infant <8 Months During the RSV season (born since April 1, 2024), by Month of Interview, United States<sup>§</sup>, <sup>±</sup>

Data Source: National Immunization Survey–Adult COVID Module

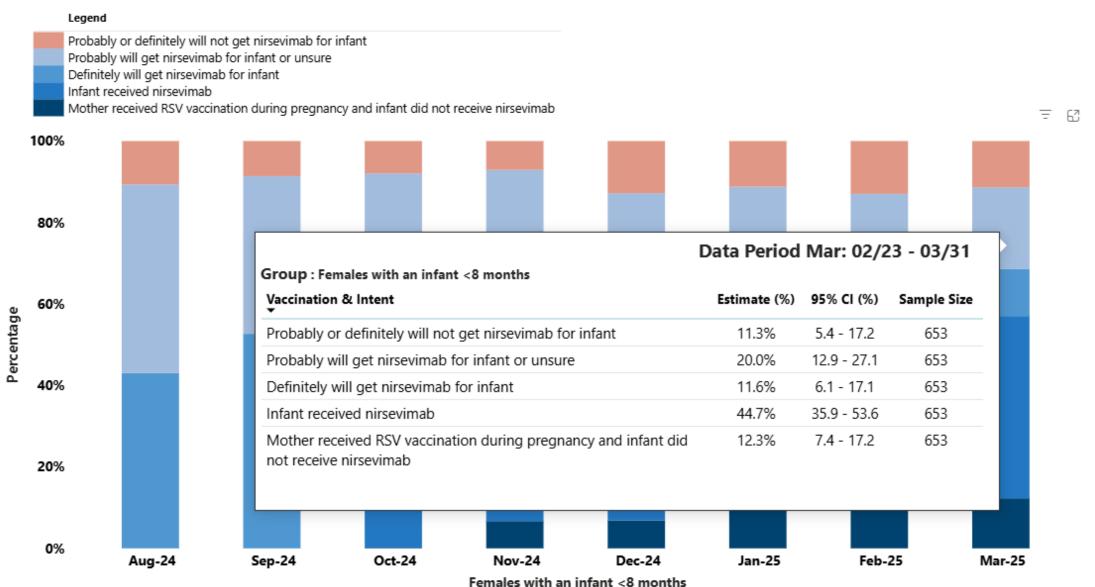
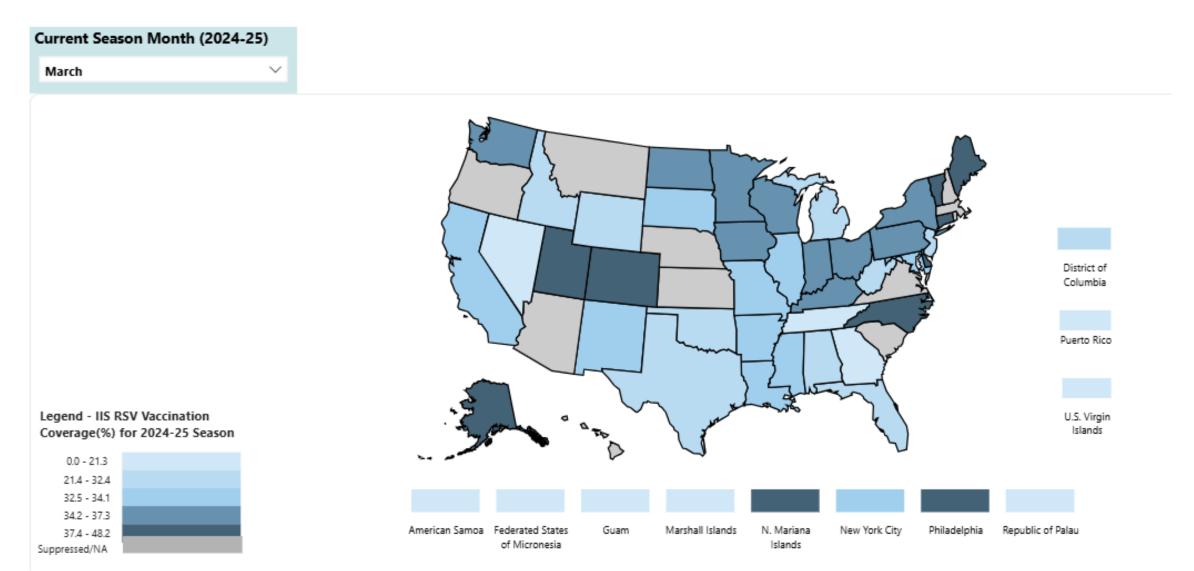


Figure 7B. Monthly Cumulative Number and Percent of Children <8 Months Who Received
Nirsevimab\*,† by Jurisdiction, United States
Data Source: U.S. Jurisdiction Immunization Information Systems (IIS)



# **RSV Vaccination: ACIP Recommendations**

### August 2023 – nirsevimab recommendation

ACIP recommended nirsevimab for infants aged <8 months born during or entering their first RSV season and for infants and children aged 8-19 months who are at increased risk of severe RSV disease entering their second RSV season.

### June 2025 - clesrovimab recommendation

ACIP recommends infants aged < 8 months born during or entering their first RSV season who are not protected by maternal vaccination receive one dose of clesrovimab.

Feature	Nirsevimab	Clesrovimab
Infant's first RSV season	All infants <8 months	All infants <8 months
Infant's second RSV season	High-risk infants, 8-19 months	Not recommended
Dosing	50 mg if <5 kg 100 mg if ≥5 kg	105 mg, regardless of weight
Storage	Fridge (2-8 °C)	Fridge (2-8 °C)
Room temp shelf life	Up to 8 hours	Up to 48 hours
Presentation	Pre-filled syringe	Pre-filled syringe

There is no preferential recommendation between nirsevimab and clesrovimab.

# Intermountain Health:

Whitney Buckel, PharmD, Rick Carlson, PharmD, and Isabel C. Pande, PharmD

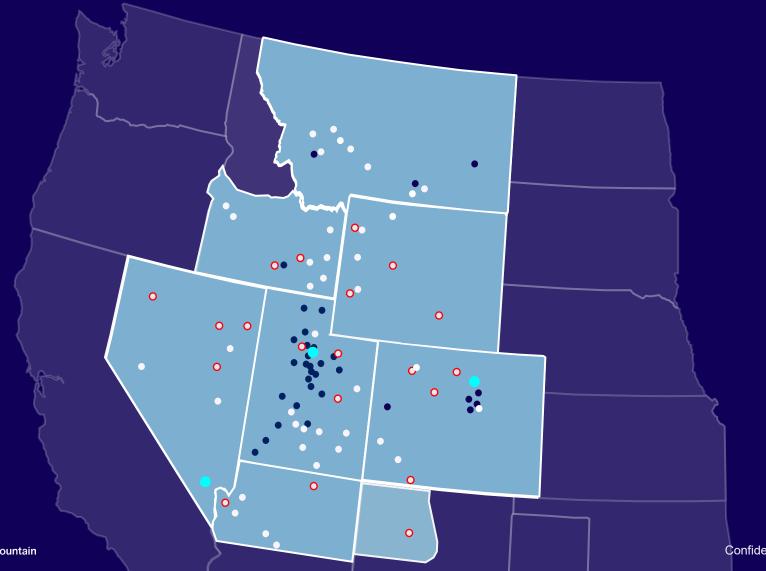


# RSV Prevention Coordination in an Integrated Health System: Inpatient Focus

Whitney Buckel, PharmD, BCIDP/
System Antimicrobial Stewardship Program Manager
Intermountain Health

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### Intermountain Health's Current Footprint



- Hospitals
- Region HQ
- Affiliate/Outreach Partnerships
- Classic Air Medical Bases

# Intermountain by the Numbers<sup>1</sup>







**33 Hospitals**Including 1
Virtual Hospital











**Licensed Beds** 



<sup>&</sup>lt;sup>1</sup> Numbers reflect through year end, December 31, 2023

<sup>&</sup>lt;sup>2</sup> Intermountain also provides air medical transport services in other states through Classic Air Medical

# Helping People Live the Healthiest Lives Possible®

#### **Our Values**

We are leaders in clinical excellence



We serve with empathy

We are partners in health

We do the right thing

We are better together

#### **Our Vision**

Be a model health system by providing extraordinary care and superior service at an affordable cost

#### **Our Brand Promise**

Health for you, with you

#### **Our Caregiver Promise**

Together, for the healthiest lives

### Mission for our Catholic entities:

"We reveal and foster God's healing love by improving the health of the people and communities we serve, especially those who are poor and vulnerable."

# Bridge statement for Catholic mission and values:

Our Catholic health Ministry and Mission are entrusted to us to honor the sacred dignity of human life and the inherent worth of every person and are aligned with our common values.



### **Nirsevimab Implementation Team**





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Seth Andrews, MD AVP Children's Health



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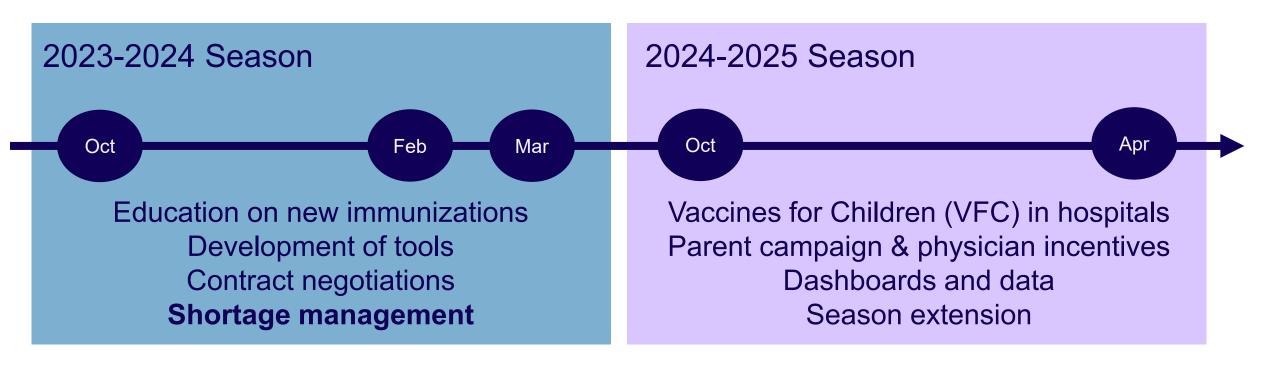


Liz O'Brien, MD Neonatologist



Kevin Chen, MD Stanford/Intermountain Fellow

### Timeline Over Two RSV Seasons





### Initial Plan in October 2023

### **Hospitals**

- Infants who previously qualified for palivizumab (Synagis), or
- Any newborn infants discharged or transferred from a level 2, 3 or 4 neonatal intensive care unit (NICU) or other intensive care unit (e.g., PICU, CCU)

### **Clinics**

- Wait for VFC supply to implement, monitor RSV rates
- Planned for all eligible patients
  - <8 months old and first RSV season</li>
  - Newborns who did not receive nirsevimab in the inpatient setting
  - High risk children aged 8 19 months entering their second RSV season



# Implementation Tool: Operational Checklist

### **Multidisciplinary Calls with Numerous Stakeholders**

- Availability from distributor (*Purchasing*)
- Ordering Nirsevimab,
   Abrysvo (EHR analysts)
- Palivizumab recommendations (Specialty)
- Formulary restrictions (P&T Committee)

- Referral to Health
   Departments (State
   Health Departments)
- RSV rate monitoring (Pediatric ID)
- Abrysvo Guidance/Ed (OBGYN)
- Nirsevimab Guidance/Ed (Neonatology, Pediatrics)

- Finance (Contracting, Billing, Reimbursement, Budgeting)
- VFC (Clinic Managers, Pharmacy Directors)
- State Immunization Reporting (analyst)
- Policy/Procedure
   (Operations Managers)



### Implementation Tools

### Intermountain Respiratory Syncytial Virus (RSV) Vaccine (ABRYSVO™, AREXVY™) Standing Order

#### **Standing Order Purpose Statement**

To provide information on the correct storage, administration and documentation of **Respiratory Syncytial Virus Vaccine**(ABRYSO<sup>IN)</sup>) and **Respirator**members served by Intermount

#### Scope

IHC Health Services, Inc., Inter Pharmacies

#### **Definitions**

Licensed Independent Practicare, treatment, and services to and corresponding state law and

#### Diagnosis and Dia

Immunization Z23

#### Standing Order

- RSV vaccine MAY be adm technician AFTER shared
  - Persons ages 60 years
- 2. ABRYSVO™ RSV vaccine
  - nurse, medical assistant,
     Pregnant persons from alip RSV monoclonal ar
  - An LP should review wire vaccine or their infant r
  - · If you have any ques

Manufacturer:	
Vaccines:	ABRY
	• Sin
	f
	F

#### . Dose:

- · Store refrigerated betw
- Store in original pack

# Intermountain Respiratory Syncytial Virus (RSV) Monoclonal Antibody, Nirsevimab-alip (BEYFORTUS™) Standing Order

#### **Standing Order Purpose Statement**

To provide information on the correct storage, administration and documentation of Respiratory Syncytial Virus (RSV) F-protein directed fusion inhibitor monoclonal antibody nirsevimab-alip (BEYFORTUS<sup>TN</sup>) given to patients and community members served by Intermountain Health.

#### Scope

IHC Health Services, Inc., Intermountain Health Hospitals, Intermountain Medical Group

#### Definitions

Licensed Practitioner (LP) – An individual permitted by law and privileged by the organization to provide care, treatment, and services to patients. A licensed independent practitioner operates within the scope of their license and corresponding state law and operates consistently with individually granted clinical privileges.

#### **Diagnosis and Diagnosis Code**

Immunization Z23

#### Standing Order

- RSV monoclonal antibody nirsevimab-alip (BEYFORTUS™) is administered by an LP, registered nurse, medical assistant to:
  - Neonates and infants born during RSV season (from October through March)
  - . Infants younger than 8 months born from April through September entering their first RSV season
  - High-risk infants (as determined by an LP, using criteria below) ages 8 months through 19 months entering their second RSV season
  - . If you have any questions or concerns, consult with the LP before administering product

Manufacturer:	AstraZeneca	
Product:	BEYFORTUS™	
	Single-dose pre-filled syringe, 50 mg/0.5 mL – no preservative     Single-dose pre-filled syringe, 100 mg/1 mL – no preservative	

#### Dose

- Store refrigerated between 2°C and 8°C (36°F and 46°F). May be kept at room temperature between 20°C and 25°C (68°F and 77°F) for a maximum to 8 hours. After removal from the refrigerator, it must be used within 8 hours or discarded. Do not freeze.
- Store in original package to protect from light.
- Do not chake
- Administer 0.5 mL or 1 mL intramuscularly (IM) in the anterolateral aspect of the thigh. If two 1 mL injections
  are required, administer second injection preferably in opposite limb or at least 1 inch from prior injection.



Patient name:	
Patient DOB:	
Patient weight:	

#### Nirsevimab (BEYFORTUS) Monoclonal Antibody Patient Checklist

1	Has the patient been diagnosed with RSV this season (Oct. 2024-March 2025)?		
	Yes – Do <b>NOT</b> give Nirsevimab No – Go to question 2	Yes	No
2	Is this the infant's first RSV season (born after March 31, 2024)?  Yes – Go to question 3  No – Go to question 8	Yes	No
3	Is the patient younger than 8 months? Yes – Go to question 4 No – Go to question 8	Yes	No
4	Has the patient received a prior dose of Nirsevimab (BEYFORTUS), such as in the hospital at birth?  Yes – Do <b>NOT</b> give Nirsevimab No – Go to question 5	Yes	No
5	Did the mother receive Abrysvo between 32-36 weeks gestation?  Yes – Go to question 6  No – Go to question 7	Yes	No
6	Was Abrysvo given to the mother at least 14 days before giving birth?  Yes – Do <b>NOT</b> give Nirsevimab No – Go to question 7	Yes	No
7	Does the patient weigh less than 5kg today?  Yes – Administer (1) 50 mg doses  No – Administer (1) 100mg dose	Yes	No
8	Physician/APP: Is the infant a high-risk infant* younger than 19 months, in their 2 <sup>nd</sup> RSV season? Yes – Administer (2) 100 mg doses	Yes	No
	No – Do <b>NOT</b> give Nirsevimab		

#### \*Definition of high-risk infant:

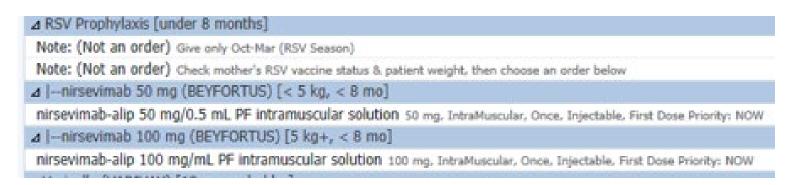
- Children with chronic lung disease of prematurity if they require medical support such as any of the following during the 6-month period prior to the start of their 2<sup>nd</sup> RSV season: Chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen
- Children severely immunocompromised
- -Children with cystic fibrosis if manifestation of severe lung disease include any of the following: previous hospitalization for pulmonary exacerbation in the 1<sup>st</sup> year of life, abnormalities on chest imaging that persist when stable, or weight for length <10<sup>th</sup> percentile
- American Indian or Alaska Native

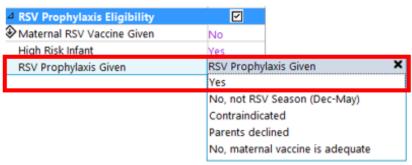
\*\*FAQ: Baby was born in March 2024 so baby is <8 months in October 2024. Should they receive Nirsevimab? Technically babies born in February and March 2024 have been through their 1st RSV season and would not qualify for Nirsevimab. Babies born after 3/31/2024 would be entering their 1st RSV season and qualify for Nirsevimab.

Last update: 09/17/2024

<sup>\*</sup>Scan this document into patient chart under 'Medications and Injections'

# Implementation Tools





- ▼ Hepatitis B Vaccinations
- For infants of mothers with POSITIVE hepatitis B status (give within 12 hours in two different legs) (GS LM PVB SJ SJB SMG SPH SVB)——Click for more
- For infants of mothers with UNKNOWN hepatitis B status (give in two different legs) (GS LM PVB SJ SJB SMG SPH SVB)——Click for more
- ▶ For infants of mothers with NEGATIVE hepatitis status (GS LM PVB SJ SJB SMG SPH SVB)—
- ▼ RSV Protection with Nirsevimab (ONLY applicable October 1st to March 31st during RSV season)
  - ▼ For infants of mother with UNKNOWN RSV vaccination status

Notify pediatrician that mom's RSV vaccination status needs to be clarified prior to ordering. If indicated, provider will need to place orders.

- ▼ For infants of mothers who did NOT receive the RSV vaccine between 32 and 36 weeks gestation AND at least 14 days prior to delivery
  - nirsevimab immunization

0.5 mL, ONE TIME AS NEEDED, Give prior to discharge, \* Give prior to discharge, contact pharmacy prior to discharge to have immunization sent to floor \* Administer intramuscularly in the thigh. Do NOT inject into the gluteal muscle. \* Give additional vaccines in separate syringes and at different injection sites. \* Do NOT shake \* Discontinue if refused or not indicated



-Click for more

# Implementation Educational Material – RSV





### Virus respiratorio protección de los

¿Qué es el RSV?

#### Let's talk about...



\_

Respiratory Syncytial Virus (RSV): Protection for Newborns

El virus respiratorio sincitial (RSV, por s inglés), es un virus común que afecta a la Provoca síntomas similares a los del res tos, secreción nasal, fiebre y sibilancias.

Estos síntomas suelen ser leves y las per en una o dos semanas, pero algunos bet infecciones graves y necesitan hospitali: bebés menores de 6 meses son los que riesgo de ir al hospital.

	Abrysv
¿Quién lo consigue?	Madres, d semanas
¿En qué época del año se da?	Entre sep
¿Cómo se administra?	Inyección parte sup
¿Cuáles son los efectos secundarios?	Dolor en e Dolor de d Náuseas Puede au
¿Es necesaria una segunda dosis?	Basta cor

#### What is RSV?

Respiratory syncytial [sin-SIS-shul] virus, or RSV, is a common virus that affects the lungs. It causes cold-like symptoms such as coughing, runny nose, fever, and wheezing.

These symptoms are usually mild, and people get better in a week or two, but some babies develop severe infections and need hospitalization.

Babies younger than 6 months old are at highest risk for going to the hospital.

#### Can RSV be prevented?

Yes! Newborns can be protected from RSV infection in 2 ways: a vaccine (Abrysvo®) given to the mother during pregnancy and nirsevimab (Beyfortus®), an RSV antibody immunization for newborns.

In most cases, only the mother or the baby need immunization in order to provide enough protection for an infant. Review the comparison chart below below and talk with your doctor about your options.

	Abrysvo (RSV vaccine)	Nirsevimab (RSV antibody)	
Who gets it?	Mothers, during pregnancy, between 32 to 36 weeks gestation	Babies younger than 8 months old	
What time of year is it given?	Between September and January	Once at the beginning of, or during, RSV season (October through March) Only needed if the mother did not get the vaccine at least 14 days before delivery	
How it it given?	Injection (shot) into a large muscle, like the upper arm	Injection (shot) into a large muscle, like the upper leg or buttocks	
What are the side effects?	Pain where the shot was given Headache Nausea May increase the risk of pre-term birth	Pain where the shot was given	
Is a second dose needed?	One dose is all that is needed.	Babies age 8 months to 19 months may need a dose in their second RSV season if they have: Long-term lung disease	
		A	

### **Patient Education**

Long-term lung disease
A weak disease-fighting system
(immunocompromised)
Severe cystic fibrosis
American Indian or Alaska Native heritage





#### Respiratory Syncytial Virus (RSV) Infection Prevention

09/2024

Applies to Obstetric, Neonatal, Pediatric, and Family Medicine Providers

Why it's important | Two novel agents are recommended to prevent RSV infection in pediatric patients: a maternal PSV vaccine (AbnavaTM) and a pediatric PSV manufacture and patients.

[Beyfortus™]).1 themselves and

#### Table 1. Comparison of RSV Vaccine and RSV Monoclonal Antibody

emseives and		Almond (DOV)	Description TM (education to a line)
ey Points		Abrysvo (RSV vaccine, recombinant)	Beyfortus™ (nirsevimab-alip)
	What is it?	RSV vaccine	RSV antibody
RSV infe infants h like syml     Two age	Who gets it?	Pregnant persons between 32- and 36- weeks gestation	All neonates and infants younger than 8 months old whose mothers did not receive RSV vaccine <sup>a</sup> High-risk children ages 8 to 19 months entering their second RSV season
0 F	When is it given?	Once, September through January	Once, at the beginning of RSV season or during RSV season (October to March)
Nirsevim newborr	How is it given?	Intramuscular injection     May be given with other maternal vaccinations a	Intramuscular injection     May be given with other newborn vaccinations
• The Advi (Abrysvc	What is the dosing?	• 0.5 mL	50 mg (0.5 mL) for patients < 5 kg     100 mg (1 mL) for patients ≥ 5 kg     200 mg (1 mL x 2 syringes) for high-risk 8-19 month old children
is not pro	Adverse effects <sup>b</sup>	Pain at injection site     Headache     Nausea	Pain at injection site
n o A c o C v a	Risks	May be an increased risk of preterm birth following RSV vaccine be     Decreased pertussis antibodies when Tdap and RSV vaccine given concomitantly a     Reduced newborn protection if fewer antibodies transfer from mother to baby     Hypersensitivity reaction is possible	Hypersensitivity reaction is possible, though no cases were observed in clinical trials
season. l	Donofte	Provides newborn with protection immediately after birth a     Provides material PSV protection	Antibody titers may wane more slowly, providing longer protection     Provides direct antibodies rather than pending on maternal antibodies.

### **Provider Education**

insurance companies regarding coverage of nirsevimab.

risk of adverse pregnancy out to maximize vaccination rates<sup>1,4</sup>

A (Abrysvo\*) or co-administration of nirsevimab-alip with a vaccine, it should be reported to the Vaccine Adverse Event
Reporting System (VAERS).

Reporting System (VAERS).

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Fact Sheet 1



# Implementation Educational Material - Abrysvo





### Start Date for Abrysvo® in Pregnant Women | August 2024

Applies to Obstetrics and Gynecology Providers in all regions

Why it's important | Respiratory Syncytial Virus (RSV) is one of the most common causes of childhood illness and causes cold-like symptoms and can progress to lower respiratory infection, leading to 80,000 hospitalizations annually in the United States. RSV is seasonal, and maternal vaccination with Abrysvo® to protect infants is timed to match peak incidence periods.

Key Points On September 1st, Abrysvo® administration for pregnant women is again an option for pregnant women 32-36 weeks gestation. However, if a woman received Abrysvo® with a prior pregnancy, it is recommended to administer nirsevimab to their infant for RSV protection.

#### Abrysvo® for Pregnant Women Eligibility

Abrysvo® use in pregnant women is a strategy to prevent RSV infection in one of our highest risk populations, children 6 months and younger. Administration of Abrysvo® provides passive immunity to the newborn infant. The Advisory Committee on Immunization Practices (ACIP) and Centers for Disease Control and Prevention (CDC) recommend administration of Abrysvo® starting September and continuing through January in eligible pregnant women to maximize cost-effectiveness and benefits.

Start of Season	End of Season	Gestational Eligibility
September 1st	February 1st	32 to 36 weeks gestation

Infant immunization with Beyfortus® (nirsevimab) in the first week of life is also a highly effective option for RSV protection to the infant and should be presented as an option to pregnant women. Conduct a shared clinical decision-making discussion with the patient prior to administering Abrysvo®. Only one product should be used per infant for protection. Exceptions to this include if the infant was born within 14 days of maternal RSV vaccination. For additional details, see section on special situations and populations.

For more information on shared clinical decision, please see the following links:

- Provider Information RSV Prevention Fact Sheet
- . Respiratory Syncytial Virus (RSV): Protection for Newborns Patient Fact Sheet: English and Spanish

#### Check yourself

- 1 What time of year does Abrysvo® administration start?
- 2 For what gestational weeks is Abrysvo® recommended?
- 3 What if a woman received Abrysvo® with a prior pregnancy?
- 4 What other option besides Abrysvo® is available to infants for RSV protection?

References | Fleming-Dutra KE, Jones JM, Roper LE, et al. MMWR;72(41):1115-1122. DOI: http://dx.doi.org/10.15585/mmwr.mm7241e1

About this factsheet Author(s): Whitney Buckel, PharmD, BCIDP; Approved by: Tamara Sheffield, MD, MPH; Date written: 10/2024; next review: 08/2025

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Fact Sheet 1





### End Date for Administering Abrysvo® to Pregnant Women

Applies to All hospitals and clinics

Why it's important | Respiratory Syncytial Virus (RSV) is one of the most common causes of childhood illness and causes cold-like symptoms but can progress to lower respiratory infection, leading to 80,000 hospitalizations annually in the United States. RSV is seasonal, and maternal vaccination with Abrysvo® to protect infants is timed to match peak incidence periods.

Key Points | On February 1st, Abrysvo® administration for pregnant women should discontinue.

Administration of Abrysvo® will start again on September 1st for pregnant women 32-36 weeks gestation.

#### Abrysvo® for Pregnant Women Eligibility

Abrysvo® use in pregnant women is a strategy to prevent RSV infection in one of our highest risk populations, children 6 months and younger. Administration of Abrysvo® provides passive immunity to the newborn infant. The Advisory Committee on Immunization Practices (ACIP) and Centers for Disease Control and Prevention (CDC) recommend administration of Abrysvo® starting September and continuing through January in eligible pregnant women to maximize cost-effectiveness and benefits.

Start of Season	End of Season	Gestational Eligibility
September 1st	February 1st	32 to 36 weeks gestation

For more information on shared decision making regarding Abrysvo® (maternal RSVpreF vaccine) and Beyfortus® (nirsevimab), please see the following links:

- Provider Information RSV Prevention Fact Sheet
- Respiratory Syncytial Virus (RSV): Protection for Newborns Patient Fact Sheet in English
- Respiratory Syncytial Virus (RSV): Protection for Newborns Patient Fact Sheet in Spanish

#### Check yourself

- 1 What time of year does Abrysvo® administration end?
- 2 When will Abrysvo® administration begin again?
- 3 For what gestational weeks is Abrysvo® recommended?

References | Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR;72(41):115-1122. DOI: http://dx.doi.org/10.15585/mmwr.mm7241e1

#### About this factsheet

Author(s): Whitney Buckel, PharmD, BCIDP Approved by: Tamara Sheffield, MD, MPH Date written: 01/2024; next review: 01/2025

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Fact Sheet 1

# Implementation Educational Material - Nirsevimab

#### Practice Change Update



### Nirsevimab | Respiratory Syncytial Virus (RSV) Infection

Applies to NICU, PICU, and CICU Neonatal and Pediatric Nursing

Respiratory Syncytial Virus (RSV) is a common virus that affects the lungs and causes cold-like symptoms such as coughing, runny nose, fever, and wheezing. These symptoms are usually mild, and people get better in a week or two, but some babies develop severe infections and need hospitalization.

#### Practice change

Historically, Synagis (palivizumab) has been administered for RSV prophylaxis in babies who met clinical criteria. After October 1, 2023, a new practice will be implemented in Neonatal and Pediatric departments in the Desert and Canvon Rezions.

Two novel agents are now recommended to prevent RSV infection in neonatal and pediatric patients:

- Neonatal /Pediatric RSV antibody (nirsevimab-alip [Beyfortus™])
- Maternal RSV vaccine (Abrysvo™)

Nirsevimab is a monoclonal antibody product that provides newborns and infants passive immunization. While not technically a "vaccine" in a traditional sense (active immunization), it is being used in a manner similar to routine childhood vaccines and may be referred to as a vaccine by some entities.

Nirsevimab confers long-lasting protection from RSV, with protection expected to last at least 5 months (about the length of a typical RSV season). Nirsevimab is part of the Vaccines for Children program.

Unlike palivizumab (Synagis®), nirsevimab-alip (Beyfortus™) requires just 1 injection at the onset of RSV season, rather than monthly injections with palivizumab.3-5

#### Key Points

- RSV infection is the most common cause of infant hospitalization in the US and nearly 80% of infants hospitalized with RSV were not considered high-risk at baseline<sup>2</sup>
- RSV infection is characterized by cold-like symptoms; however, bronchiolitis and pneum develop in about 20% to 30% of cases.<sup>12</sup>
- Only 1 product is required to provide newborns with RSV protection (either maternal RSV
  pediatric RSV monoclonal antibody); however, both may be indicated for neonates born less than
  14 days after maternal RSV vaccination, and some other rare circumstances.1
- High-risk infants and children ages 8 to 19 months require <u>nirsevimab-alip</u> in their second RSV season. Determination of risk and order for this dose must be performed by a licensed provider.
  - Criteria are defined as follows¹:
    - Children who have chronic lung disease of prematurity who required medical support any time during the 6-month period before the start of the second RSV season
    - · Severely immunocompromised children
    - Children with cystic fibrosis who have severe disease
    - American Indian and Alaska Native children

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Practice Change Update 1

#### Practice Change Update



Practice Change Update 1

#### RSV Immunization | Nirsevimab (Beyfortus)

#### Applies to MG clinics

RSV is Respiratory Syncytial Virus a common illness that causes cold like symptoms. For infants and children under 5 it can affect the lungs and is a leading cause of hospitalization for them. 100-300 children in the United States will die from this per year.

#### Prevention of RSV

- Vaccination of pregnant women with Abrysvo, after 14 days the antibodies are fully transferred to unborn infant.
- 2. Administer monoclonal antibodies to infant using Nirsevimab (Beyfortus)

Nirsevimab provides long-lasting protection from RSV with a onetime dose (per season). It is not a vaccine but provides immunity using monoclonal antibodies.

The physician or APP will determine who receives this vaccine following risk criteria. MA may order from standing order and administer as per vaccine procedure. It is given in a large muscle; preferred site is vastus lateralis.

RSV momoclonal antibody Nirsevimab (Beyfortus) is to be given to:

- . Neonates and infants born during RSV season (October through March)
- . Infants younger than 8 months born from April through September entering their first RSV season
- High-risk infants as determined by physician or APP, ages 8 months through 19 months entering their second RSV season, and according to risk criteria at <u>Primary Care</u>. System RSV Monoclonal Nirsevimab Standing Order:10.23.all states.off - All Documents (sharepoint.com)

Dose is 0.5ml or 1 ml depending on weight or if patient received previous year:

Nurse Education 5 kg r mor

received Nirsevimab the previous year (2 vials of 1 ml, only 1 ml per leg)

ge Store in original packaging to protect from light

Approved by Sheila Rude, RN, BSN, Service Line Nurse Director. Learning Network Contact: Sallie Calder MSN, RN, Clinical Education Consultant. Next Review Date 10/17/2024

#### References

- 1 CDC.gov [website orline]. Respiratory Syncytial Virus Infaction (RSV). Atlanta(GA): Centers for Disease Control and Prevention [updated 2023.Jul 2]; cited 2023 Jul 25). Available from: https://www.cdc.gov/rsv/clinicalfIndex.ht ml.
- 2 Committee on Infectious Diseases, American Academy of Pediatrics. Red Book® Online [electronic book], 32nd edition. Respiratory Syncytial Virus, AAP Publications, 2021to 2024; [cited 2023 Jul 25]. Available from: https://publications.aap.org/redbook
- 3 Beyfortus (nirsevimab injection)[package insert]. Swiftwater (PA): Sanofi Pasteur Inc. [updated 2023 Jul; cited 2023 Jul 25]. Available from: https://dailymed.nlm.nih.gov/dailymed/index.cfm.
- 4 Lexicomp [database online]. Hudson (OH): Wolters Kluwer Clinical <u>DrugInformation</u>, Inc; 2023 [updated 2023 May 15; cited 2023 Jul 251, Available from: https://www.online.lexi.com.

25]. Available from: https://www.online.lexi.com.

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# Vaccines for Children (VFC)

### Task: Enroll hospitals in VFC

- Hospitals were in general NOT enrolled in VFC
  - Kick off call regarding enrollment: September 2023
  - Update calls: October 2023
  - Barriers encountered: shortage PLUS insurance identification
  - All sites able to give VFC: January 2024



# Expansion to Inpatient Well Newborns (Feb 2024)

### Why?

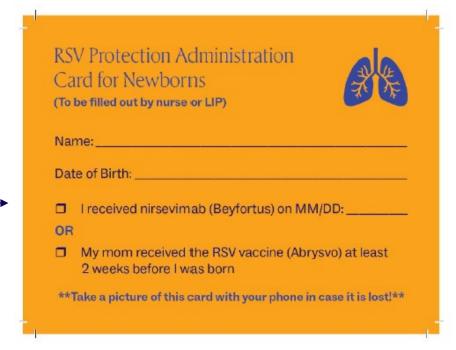
- Safety and efficacy
- Equitable access
- Payer contract negotiations (Inpatient DRGs)
- Other organizations are doing it (Kaiser, Health Partners, Columbia)
- The child first and always



# Second Season Approach

### **Process Improvements**

- Consistency and alignment enterprise-wide
- Communication to pediatricians
  - Especially affiliated providers
- Digital marketing campaign
- Value-based care incentive program
- New Utah VFC Nirsevimab Pilot
- Defined process for stop date extensions





### New Utah VFC Nirsevimab Go Live October 2024

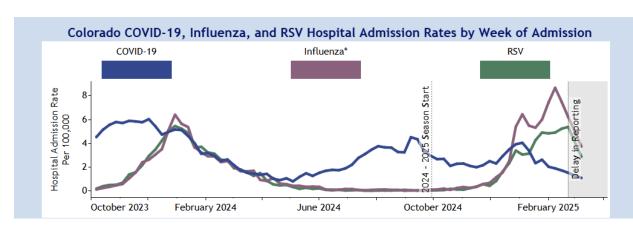
### In collaboration with the CDC, Utah VFC program pilot

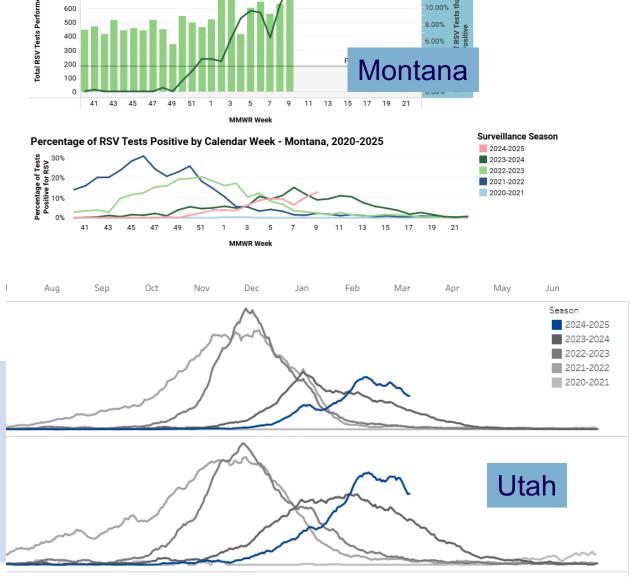
- Hospitals may replace privately administered vaccines with VFC stock after patient screening, reconciliation, and approval from Vaccine Manager or designee
- Hospitals must submit a reconciliation report to the VFC manager that includes:
  - Inventory designating NDC, lot # and VFC stock
  - Cumulative number of private doses given during 2-week time period
  - Patient administration roster (including patient IDs)
  - Inventory reconciliation, including VFC doses on hand
- After the report is reviewed and approved, replacement doses will be ordered to the location utilizing the product which may be added to the sites private stock.



# **Stop Date Extension**

**Situation:** Your neonatologist comes to you worried that community rates of RSV are still high, should they really stop providing nirsevimab on March 31st?





RSV Percent Positivity from Participating Laboratories in Montana - 2024-2025



Legend

RSV Tests Performed
Percent Positive

# Implementation Challenges

### **Barriers**

VFC delays: access, new VFC applications

Financial implications: inpatient, outpatient, health departments

Change in approach compared with palivizumab (criteria, timing, cost-savings approaches)

Nirsevimab shortage

Concerns about Abrysvo and miscarriages, narrow gestational window, 4<sup>th</sup> vaccine

History taking regarding Abrysvo in pregnancy

Communication at transitions of care regarding receipt of nirsevimab



### **Facilitators**

Strong relationships with the state health department, ability to share VFC supply across clinics

Select Health as an internal insurance company, significant value-based care population

Electronic health record decision support within order sets

Town Halls, presentations, emails

Leveraged daily and weekly huddles of integrated clinical teams for real-time communication and reminders

General motivation and engagement to reduce RSV with previous high-rate seasons

Multidisciplinary engagement, including neonatal, pediatric, vaccine and pharmacy champions

# System-level Metrics and Monitoring





# System-level Metrics and Monitoring

### Value-Based Care Dashboard for Medical Group Clinics

Infant Birth Month	% Maternal Abrysvo	% Eligible Infant Beyfortus*	% Either Abrysvo or Befortus
Apr '24 – Sep '24	0.3%	54%	56%
Oct '24 – Mar '25	15%	49%	57%

<sup>\*</sup>In eligible patients whose mothers did not receive Abrysvo.



### Conclusions

### It truly takes a village to protect our most vulnerable!

- Leadership approval prior to assurance of reimbursement was key to moving forward expeditiously and supported "it is the right thing to do"
- Integrated clinical teams and system leaders facilitate fast decision making
- Huddle systems facilitate rapid communication and reminders to clinicians
- Longstanding trusted relationships between public and private systems and between manufacturers, providers and payers
- Operations support is critical from electronic health records and state registries



# Thank you.



# 2025-2026 RSV Ordering: TN Immunization Program

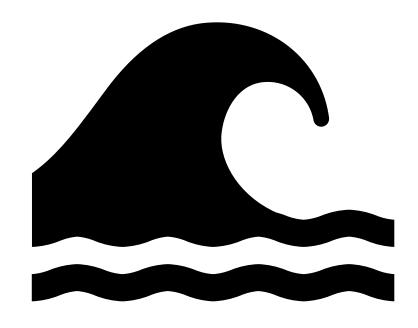
Nena Bowman, PharmD and Christina Clapp, BSN, RN



#### **RSV Rollout- From Chaos to Coordination**

# The 2024-2025 RSV Season: Addressing Stock Complications with an Efficient Vaccine Ordering System

- The stock complications during the 2024-2025 RSV season necessitated the implementation of a roll-out strategy based on reports generated from our Immunization Information System (IIS).
- This approach allowed us to efficiently prioritize birthing facilities and providers administering immunizations to infants.
- By leveraging Excel and the reporting capabilities of our IIS, we developed a roll-out method termed "WAVES." This method evaluated patient administration data by age across the state to determine the appropriate "WAVE" placement for each facility.
- Although this process was demanding for our internal team, it ensured that birthing hospitals and providers administering immunizations to infants remained our top priority in the WAVE placement.





#### **Effective WAVE Communication with Facilities**

With the heightened urgency to stock nirsevimab in facility inventories while prioritizing providers who actively administer immunizations to infants:



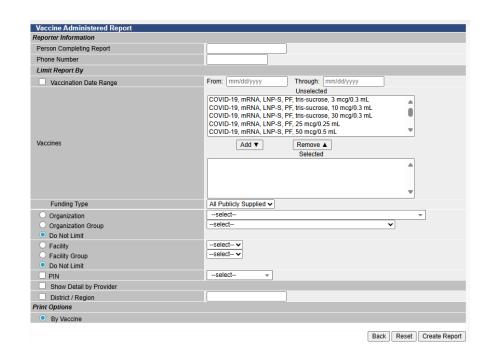
#### **COMMUNICATION WAS KEY!**



- Before and during the roll-out, our internal leadership held frequent meetings to strategize
  the best communication methods with facilities across Tennessee.
- We disseminated information through our Emma-generated memos to providers, detailing the process and providing lists with pin numbers to help them determine their WAVE placements.

# Evaluating Patient Administration Data and Prioritizing Facilities for WAVE Placement

- Report Generation: Utilized IIS to run comprehensive reports evaluating patient administration data across various age groups.
- Data Analysis: Assessed patient administration data to identify trends and needs.
- Facility Segmentation: Split facilities into WAVE categories based on current allocation.
- Prioritization Strategy: Focused on birthing hospitals and provider facilities that demonstrated higher rates of infant administrations compared to other facilities in the year prior.
- Outcome: Ensured optimal distribution and administration of vaccines to high-priority groups before allowing open ordering to facilities.





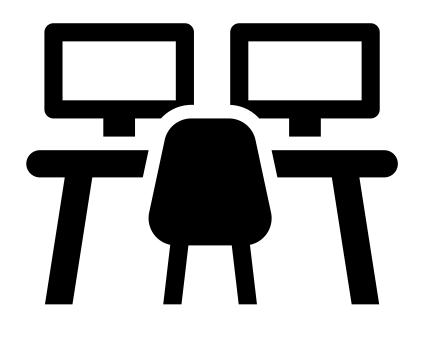
#### **Maintaining Provider Rapport During the Intensive RSV Roll-Out**

- One of our primary concerns during last year's intensive RSV roll-out was the potential impact on the rapport our department has diligently established and maintained with providers across the state.
- We take pride in our ability to serve Tennessee providers effectively, ensuring that we navigate these stress-filled circumstances as smoothly as possible for them.
- Our commitment to delivering excellent customer service to providers across Tennessee placed significant pressure on our internal central staff to ensure a seamless process amidst the complexity of the roll-out. Despite the chaos, our team succeeded in this endeavor, effectively maintaining rapport with our providers through clear communication and unwavering support.





## **Challenges in the WAVE Process**



- The turnaround time between communication from our CDC partner and the development of the WAVE strategy was swift.
- We quickly identified that seemingly minor complications, such as our IIS reports generating only facility names without VFC PIN numbers, significantly increased workload and potential for error.
- Much of the work behind the WAVE process was manually intensive due to the limitations of our generated reports.



#### **Order from Chaos: Our Creation**

To address the need for a quick way to share nirsevimab top-off status from the CDC, we developed an internally-shared spreadsheet. This living document has been carried into the current season and serves as an excellent overview for our internal team and upper leadership, allowing them to quickly assess Tennessee's allocation status.

WEEKLY NIRSEVIMAB UPDATES							
<u>DATA ITEM</u> <u>50MG</u>	TOP-OFF 8.18.25	TOP-OFF 9.2.25	TOP-OFF 9.15.25	TOP-OFF 9.29.25	TOP-OFF 10.14.25	TOP-OFF 10.27.25	TOP-OFF 11.10.25
DOSES ORDERED THIS WEEK							
CURRENT DOSES AVAILABLE							
# OF EXPECTED TOP-OFF THRESHOLD	2255	2855	2855	2855	2855	2855	2855
# DOSES TOPPED OFF							
TOTAL SEASON ORDERED TO DATE							
CURRENT TENNIIS INVENTORY							
<u>100MG</u>							
DOSES ORDERED THIS WEEK							
CURRENT DOSES AVAILABLE							
# OF EXPECTED TOP-OFF THRESHOLD	2055	2600	2600	2600	2600	2600	2600
# DOSES TOPPED OFF							
TOTAL SEASON ORDERED TO DATE							
CURRENT TENNIIS INVENTORY							
SCHEDULED TOP OFF DATES							
#DOSES WE MISSED OUT ON 50MG	2255	1165	2855	2855	2855		2855
#DOSES WE MISSED OUT ON 100MG	2055	1440	2600	2600	2600		2600



## **Navigating the New Top-Offs System**

- The top-offs system was a new concept for our team, as we had not previously encountered new VFC products released in this manner.
- This created an urgency to order the full weekly allocation promptly, as we were concerned about missing out on needed doses later.
- Through both individual contacts and our weekly memos, our team dedicated significant time to encouraging facilities to place orders.

50mg	
TOTAL EXPECTED SEASON ALLOCATIONS:	50820
TOTAL ACTUAL SEASON ALLOCATIONS:	16140
100MG	
TOTAL EXPECTED SEASON ALLOCATIONS:	30120
TOTAL EXPECTED SEASON ALLOCATIONS: TOTAL ACTUAL SEASON ALLOCATIONS:	30120 14630
TOTAL ACTUAL SEASON ALLOCATIONS:	14630

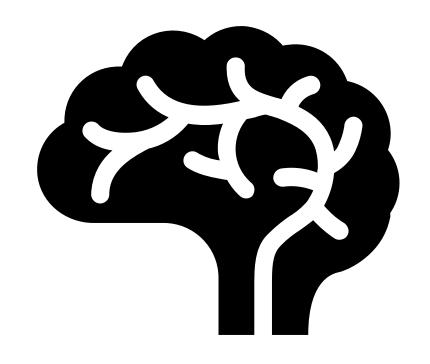


### Key Learnings from the Challenging Roll-Out Process

**Evaluate IIS Report Capabilities**: We recognized the need to assess our IIS report capabilities and limitations to better prepare for future roll-outs.

**Streamline Information Sharing**: We identified the necessity for a quick and concise method to communicate the complex weekly top-off schedule.

Team Resilience and Excellence: Our team demonstrated remarkable resilience, capability under pressure, and a strong commitment to providing excellent customer service despite challenging circumstances.





# Streamlined Nirsevimab Distribution for the 2025 RSV Season



- Tennessee received its first allotment of nirsevimab on August 1st, 2025.
- Due to improved stock availability and the presence of doses from the previous season already in facility inventories, we were able to incorporate nirsevimab into the ordering sets for providers statewide this year from the start.
- Additionally, we are entering the upcoming RSV season with nearly 5,000 doses of 50mg nirsevimab and 7,000 doses of 100mg nirsevimab already available in facility inventories from last season's orders.
- This existing stock specifically has reduced the initial demand across the state, allowing for a smoother roll-out compared to last season and eliminating the need for a WAVE approach this year.





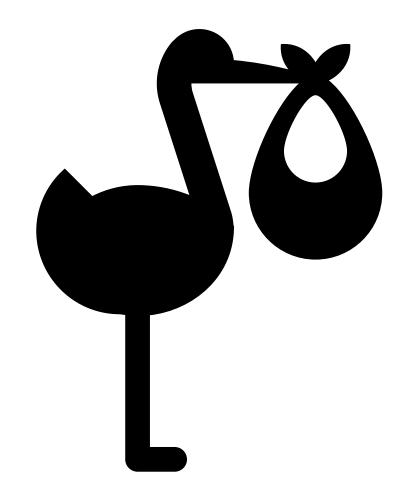
#### Maternal RSV in Tennessee

**ABRYSVO** 

Although this presentation is primarily focused on RSV immunizations for infants, it is important to mention maternal RSV, as it also is an important method of RSV protection for our infant population. Due to limited 317 discretionary funds, we are currently able to provide Abrysvo only to our pregnant teen population through VFC funds in Tennessee.

Ordering for Abrysvo is limited due to the relatively low number of pregnant teens in our provider offices, but it remains available to all VFC providers upon request during the RSV season.

To avoid confusion and ensure the correct ordering of nirsevimab (Beyfortus) for infant immunization, we have established a "request only" ordering process for Abrysvo. This approach has proven effective, as we have not observed any incorrect orders since its implementation.





#### **Questions and Connections?**

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Mobile: 629-259-7706 Nena.Bowman@tn.gov



## Resources:

- Birthing hospitals and immunization programs can work together to troubleshoot challenges and process VFC program enrollment
- Next call: Fall 2025
- Previous Call Resources
  - https://www.immunizationmanagers.org/reso urces/learning-collaborative/
- Be on the lookout for...

An MMWR publication, "Estimated respiratory syncytial virus immunization coverage among infants through maternal vaccination or infant receipt of respiratory syncytial virus antibody (nirsevimab) — 34 U.S. states, 2023-2024", is scheduled for publication on Friday, August 15, 2025, and will be available online after 1 p.m. EST on Thursday, August 14, 2025



# Thank you!



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