

RSV Immunization in Outpatient Settings

Philadelphia Immunization Program
Tuesday, August 29, 2023



Department of Public Health
Immunization Program
CITY OF PHILADELPHIA

*Note on Intended Audience

This townhall is intended to address the implementation process in primary care and other outpatient settings.

If you have questions about the implementation process for birthing hospitals and other inpatient settings, please reach out to our team after this meeting.

Today's Presenters

- Jillian Brown, MPH – Deputy Immunization Program Manager
- Hannah Liebow, MPH – IIS Informatics Manager
- Victor Obeck – VFC Coordinator

Agenda

Disease Burden

Overview of Beyfortus (Nirsevimab)

Administration and Storage & Handling

Reporting to PhilaVax

VFC & Beyfortus (Nirsevimab)

Implementation Planning

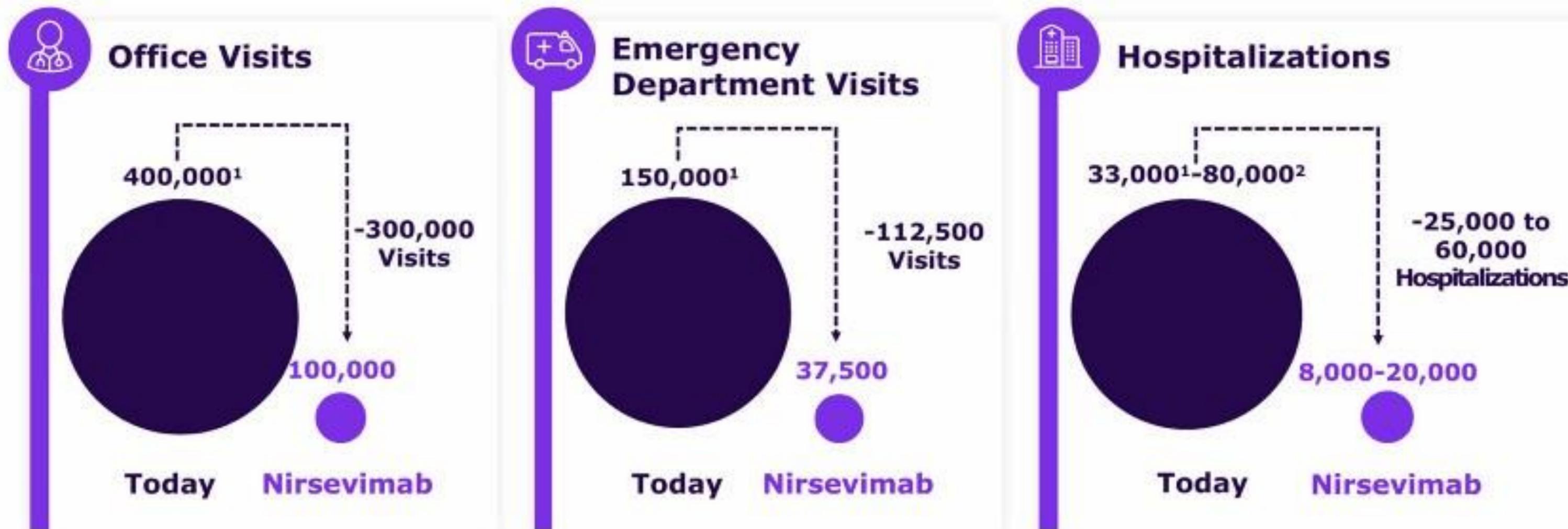
Open Discussion

RSV Disease Burden

Disease Burden

- RSV is the most common cause of hospitalization in U.S. infants
 - Highest hospitalization rates in first months of life
 - Risk declines by month with increasing age in infancy and early childhood
- Prematurity and other chronic diseases increase risk of RSV-associated hospitalization, but **most hospitalizations occur in healthy, term infants**
- ACIP work group felt that RSV-associated disease in infants born or entering their first RSV season is of public health importance

Nirsevimab in All Infants Could Prevent 500,000 Medical Interventions due to RSV in the US Annually



Assuming 100% uptake of nirsevimab and a conservative estimate of 75% relative risk reduction against key medically attended interventions

Introduction Beyfortus (Nirsevimab)

Regulatory Information

- On July 17, 2023, the FDA licensed nirsevimab (Beyfortus), a long-acting monoclonal antibody for the prevention of RSV in infants and young children.
- On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) recommended this product and its inclusion in the Vaccines for Children (VFC) program.

Type of Immunization

Nirsevimab is a passive immunization. Its protective effects can last for 5 months.

- Active immunity results from infection or vaccination, which triggers an immune response
- Passive immunity is when a person receives antibodies from an external source:
 - From birthing parent to baby through transplacental or breastmilk transfer
 - Direct administration of antibodies, such as IVIG or monoclonal antibodies

Nomenclature

Nirsevimab (Beyfortus) is an immunization.

It is not a vaccine or vaccination.

Administration

- Similar to other routine vaccines for children
- Administered as intramuscular injection using single-dose pre-filled syringe
 - Can be administered simultaneously with other childhood vaccines

Ideally, nirsevimab should be administered shortly before the start of RSV season, typically in October; however, nirsevimab may be administered to age-eligible infants and children who have not yet received a dose at any time during the season, October – March.

Administration (con't)

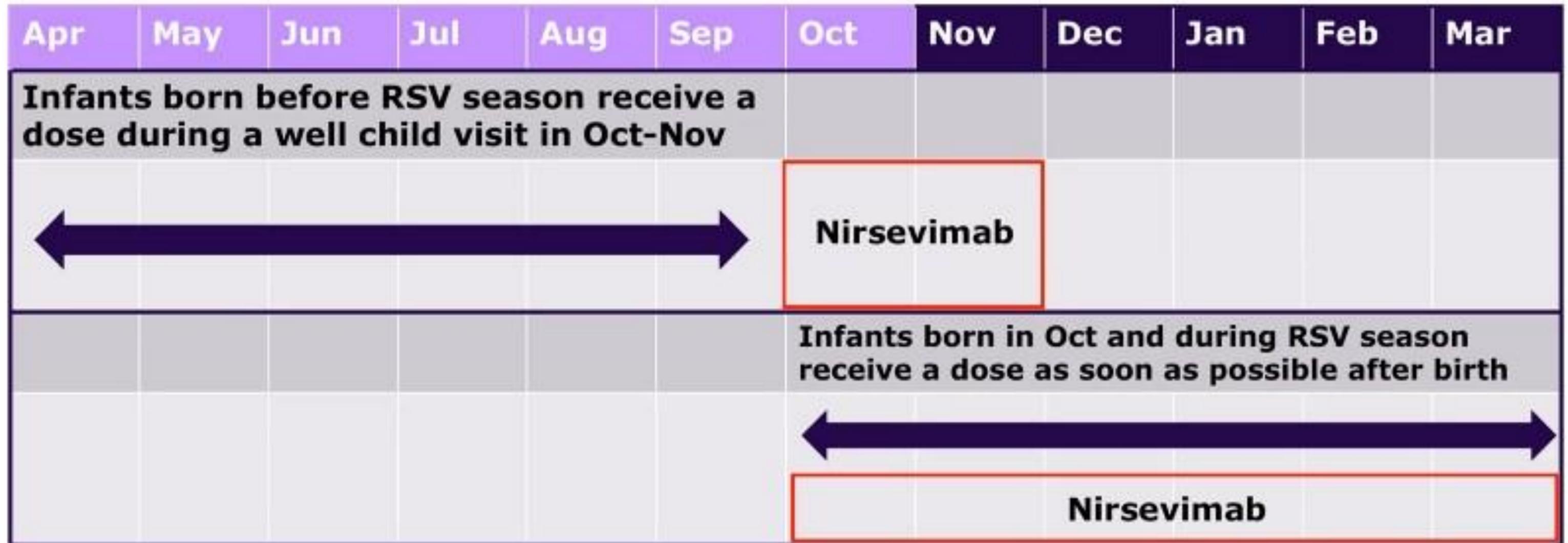
For Infants in their first RSV season, 1 dose of nirsevimab should be administered to healthy infants, < 8 months of age, based on weight:

- 50 mg if <5 kg (< 11 lb)
- 100 mg if \geq 5 kg (\geq 11 lb)

For Infants 8 – 19 months of age, in their second RSV season, at increased risk of severe RSV disease, 1 dose of nirsevimab (200 mg, administered as two 100 mg injections given at the same time at different injection sites) should be administered.

Implementation of Nirsevimab for Infants Entering First RSV Season

Typical RSV Season



Packaging & Pricing

Beyfortus (nirsevimab) will be:

- \$495 a syringe for both dosages, when purchased privately
- \$395 a syringe for both dosages, through the VFC



Storage & Handling

- Stored in refrigerator at 2-8° C (36 – 46° F)
- May be kept at room temperature, 20-25° C (68 – 77° F) for up to 8 hours
- After removal from the refrigerator, must be used within 8 hours or discarded.
- Store in original carton to protect from light until time of use.
- Do not freeze.
- Do not shake.
- Do not expose to heat.

Reporting Adverse Events

Reporting of suspected adverse events (AEs) is more complicated for nirsevimab than other immunizations:

- **If nirsevimab is administered alone**, suspected AEs are reported to MedWatch
- **If nirsevimab is administered simultaneously with any vaccine**, suspected AEs are reported to the **Vaccine Adverse Event Reporting System (VAERS)**; additional reporting to Medwatch not needed

Reporting Administration

PhilaVax IIS

About PhilaVax

- PhilaVax is a secure web-based application that offers healthcare providers consolidated immunization records for their patients as well as recommendations based on the most recent immunization schedule.
- All healthcare providers who administer immunizations in Philadelphia are required to report all vaccine doses.



PhilaVax

PhilaVax IIS

Reporting

There are two versions of Beyfortus (nirsevimab) to account for the two doses

- Dose one – 0.5 mL
 - Neonates and infants born during or entering their first RSV season: 50 mg if less than 5 kg in body weight
- Dose two – 1.0 mL
 - Neonates and infants born during or entering their first RSV season: 100 mg if greater than or equal to 5 kg in body weight
 - Children who remain vulnerable through their second RSV season: 200 mg (2 x 100 mg injections)

Add both versions of Beyfortus (nirsevimab) to your EHR system

Beyfortus Immunization

CVX Code 306 Under 5kg body weight

Respiratory syncytial virus (RSV) monoclonal antibody	
Product Name	Beyfortus
Manufacturer	Sanofi Pasteur
CVX Code	306
CPT Code	90380
MVX Code	PMC
Age Limit	Neonate to 24 months of age
Packaging	One 50 mg/0.5 mL single-dose pre-filled syringe in a carton: NDC 49281-575-00
	Five 50 mg/0.5 mL single-dose pre-filled syringes in a carton: NDC 49281-575-15
Dosage and Administration	Neonates and infants born during or entering their first RSV season: 50 mg if less than 5 kg in body weight
Dose	0.5 mL
Administration Route	Intramuscular

Beyfortus Immunization

CVX Code 307

Over 5kg or vulnerable children in their second RSV season.

Respiratory syncytial virus (RSV) monoclonal antibody	
Product Name	Beyfortus
Manufacturer	Sanofi Pasteur
CVX Code	307
CPT Code	90381
MVX Code	PMC
Age Limit	Neonate to 24 months of age
Packaging	10 pack - 1 dose syringe
	One 100 mg/mL single-dose pre-filled syringe in a carton: NDC 49281-574-88
	Five 100 mg/mL single-dose pre-filled syringes in a carton: NDC 49281-574-15
Dosage and Administration	Neonates and infants born during or entering their first RSV season: 100 mg if greater than or equal to 5 kg in body weight
	Children who remain vulnerable through their second RSV season: 200 mg (2 x 100 mg injections)
Dose	1.0 mL
Administration Route	Intramuscular

VFC & Beyfortus (Nirsevimab)

Inclusion in VFC

CDC has determined that nirsevimab is eligible for inclusion in the childhood immunization schedule and Vaccines for Children (VFC) program

- No statutory definition of vaccine in the statute for the VFC program (section 1928 of the Social Security Act)
- No statutory definition of vaccine in the Affordable Care Act (section 2713 of PHS Act), or its implementing regulations, which has a provision that mandates coverage of vaccine recommendations included on CDC's immunization schedules

VFC & Beyfortus (Nirsevimab)

- We anticipate that nirsevimab will be available to order from VFC in early October. Our team will work with sites to order as needed throughout the season.
- VFC providers are required to carry all the ACIP recommended immunizations, for the **patients that they serve, VFC eligible, privately insured and CHIP insured.**
 - Providers should plan to order vaccine through VFC and purchase privately, as needed.
- Providers enrolled in VFC can not refer VFC patients to other practices or pharmacies for nirsevimab administration in place of carrying the product themselves.

VFC & Beyfortus (Nirsevimab) (con't)

- Providers should work with their EMR to assess how many current patients will be eligible for nirsvimab this year:
 - under 8 months of age in October
 - 8 – 19 months of age at risk for severe disease in October

Implementation Planning

Planning Checklist

Our program put together a checklist of important steps and considerations for the implementation of Nirsevimab.

It has sections related to each of the topics we discussed today including:

- Reporting
- Storage and Handling
- Staff Education
- Patient Education
- Timing

It will be linked in the follow-up email sent after this call next week

Nirsevimab Planning Checklist

The U.S. Food and Drug Administration [approved](#) Beyfortus (nirsevimab-alip) 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.

The Advisory Committee on Immunization Practices (ACIP) recommends one dose of Nirsevimab for infants ages <8 months born during or entering their first RSV season* (50 mg for infants <5kg and 100 mg for infants ≥5 kg). Additionally, one dose of Nirsevimab is recommended for children ages 8 through 19 months who are at increased risk* for severe RSV disease and entering their second RSV season (200 mg).

Below is a planning checklist that is subject to change depending on forthcoming federal guidance. The Philadelphia Department of Public Health (PDPH) Immunization Program will update this list and further educate healthcare providers about Nirsevimab when additional information becomes available.

Nirsevimab Planning Checklist

Philadelphia Immunization Information System (PhilaVax)/Documentation
<ul style="list-style-type: none">• Request PhilaVax user access for individuals at your facility who may administer Nirsevimab monoclonal antibody or need to look up immunization/administration records.• Verify that your electronic health record (EHR) is set up to document Nirsevimab doses, and how it will electronically send doses to PhilaVax. If not, establish a process for reporting doses to the PhilaVax. CVX codes: IIS Code Sets CVX Vaccines CDC
Product Storage and Handling
<ul style="list-style-type: none">• Plan for purchasing Nirsevimab for privately insured children. According to the manufacturer, Nirsevimab will cost about \$495 per dose on the private market.• Ensure storage units are working well, have adequate storage space for prefilled syringes (on top of influenza, COVID-19 and other vaccines) and temperatures are being monitored 24 hours a day using a digital data logger. Nirsevimab is stored in the refrigerator at 2-8 C.• Ensure staff review CDC's vaccine storage and handling toolkit.
Facility Protocol and Education
<ul style="list-style-type: none">• Ensure that your facility is enrolled in the VFC Program. Nirsevimab will be included in the VFC Program. Your facility should establish a process to document VFC eligibility in the EHR/patient record for each Nirsevimab dose administered.• Establish a process to make birthing hospital and clinic staff aware of Nirsevimab availability and recommendations. Please note that IM dosage varies by weight, 50 mg if <5 kg, 100 mg if ≥5 kg, 200 mg (2x100 mg) for high risk entering 2nd RSV season.

Facility Protocol and Education

- Establish a process to make clinic staff aware of nirsevimab availability and recommendations. Please note that IM dosage varies by weight, 50 mg if <5 kg, 100 mg if ≥5 kg, 200 mg (2x100 mg) for high risk entering 2nd RSV season.
- Plan how to communicate nirsevimab availability, priority groups and safety/efficacy to patients.
- Ensure education on documentation needs (EHR, electronic birth certificate, PhilaVax) are provided to staff.
- Develop a process for outpatient clinic administration to infants born outside of RSV season (well-child visits, walk-in clinics, influenza clinics, etc.). Nirsevimab can be co-administered with vaccines.

Facility Protocol and Education (con't)

- Establish a mechanism to inform parents of infants born outside of traditional RSV season of the need to return for Nirsevimab administration ahead of their first RSV season.
- Develop a process for administration of Nirsevimab to infants at higher risk of RSV complications entering their second RSV season.

Come Learn More!



Philadelphia Immunization Coalition

<https://phillyimmunize.org/>

Annual Conference Agenda

Wednesday, October 4, 2023, 9am-3:30pm

Join us for presentations and conversations on pediatric and adult immunizations in Philadelphia!

Two presenters that may be interesting to hospitals include:

Influenza/RSV/COVID: Dr. Andrew Kroger, MD, MPH, CDC

Maternal RSV: Dr. Paul Offit, MD, CHOP

Open Discussion

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Thank You

