RSV Immunization in Inpatient Settings

PDPH Immunization Program
Friday, August 25, 2023

Department of Public Health
Immunization Program
CITY OF PHILADELPHIA

*Note on Intended Audience

This townhall is intended to address the implementation process for birthing hospitals and other inpatient settings.

A separate townhall is scheduled for Tuesday, August 29 at noon for discussion at primary care practices and other outpatient settings.

Today's Presenters

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

Agenda

- Disease Burden
- Overview of Beyfortus (Nirsevimab)
- Reporting to PhilaVax
- VFC Program Enrollment Overview
- Implementation Planning
- Open Discussion

RSV Disease Burden

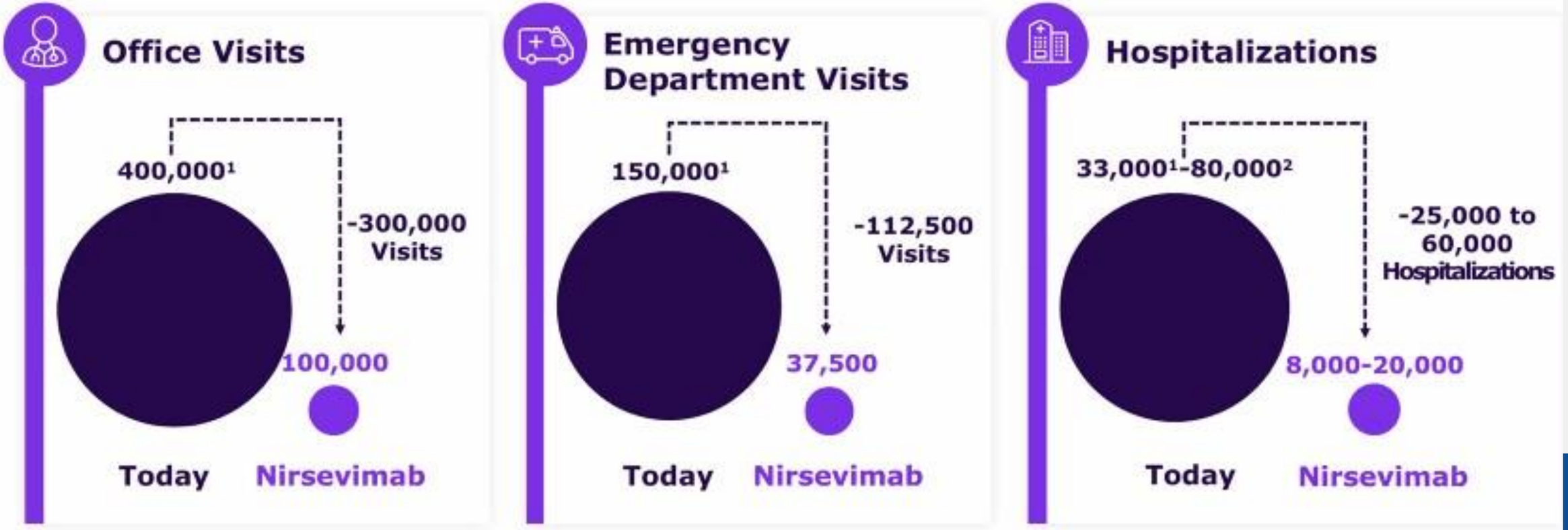
Disease Burden

- 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.

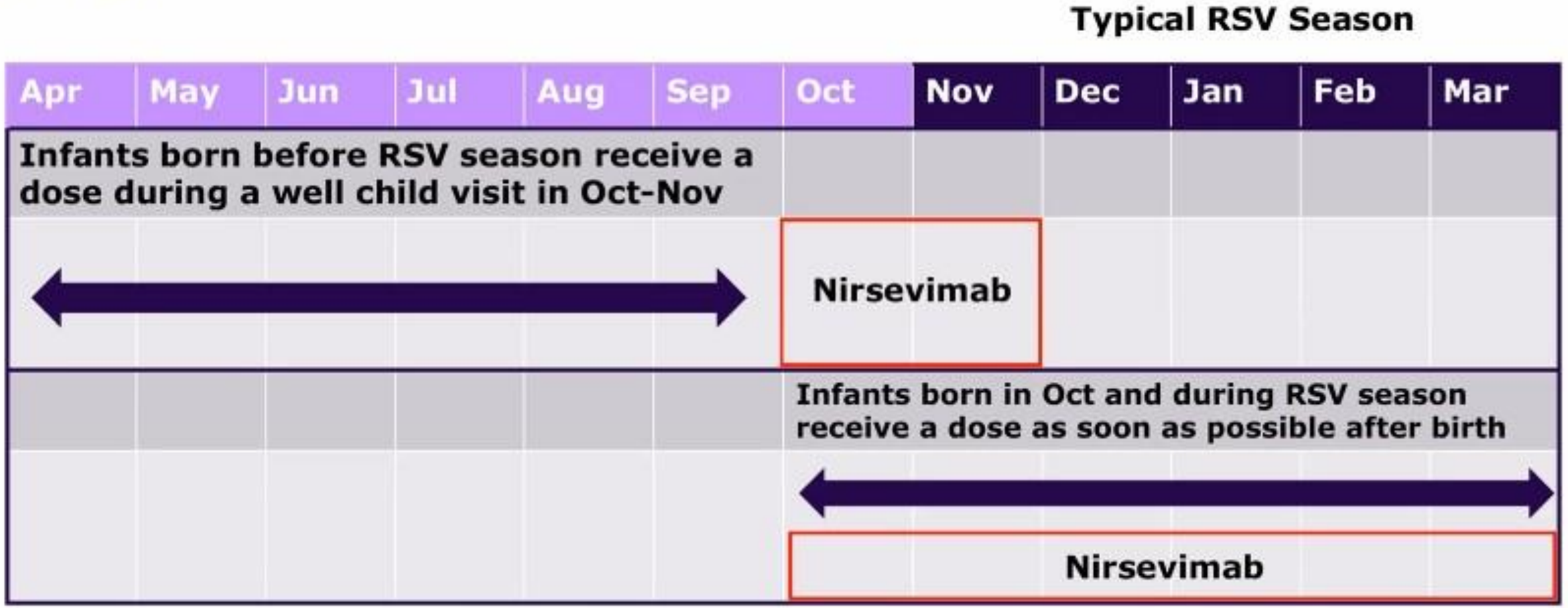
Administration

- 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

- Dosed by weight/age:
  - 50 mg if <5 kg
  - 100 mg if ≥5 kg
  - 200 mg (2x100 mg) for high-risk children entering 2nd RSV season

Implementation of Nirsevimab for Infants Entering First RSV Season



Packaging


NDC 49281-575-15
Rx only
Beyfortus™
50 mg / 0.5 mL
(nirsevimab-alip)
Injection
For Intramuscular Injection Only
Store the pre-filled syringe in original carton to protect from light until time of use.
Must be administered by a healthcare provider.
Five 0.5 mL single-dose prefilled syringes
sanofi


Beyfortus™ 100 mg/mL (nirsevimab-alip) Injection Rx Only
NDC 49281-574-15
Rx only
Beyfortus™
100 mg/mL
(nirsevimab-alip)
Injection
For Intramuscular Injection Only
Store the pre-filled syringe in original carton to protect from light until time of use.
Must be administered by a healthcare provider.
Five 1 mL single-dose prefilled syringes
sanofi

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 doses to PhilaVax.

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

PhilaVax

Beyfortus Immunization

CVX Code 306

Neonate to 24 Mo. Under 5kg body weight

Respiratory syncytial virus (RSV) monoclonal antibody	
Product Name	Beyfortus
Manufacturer	Sanofi Pasture
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

Neonates -24 mo. Over 5kg or vulnerable children in their second RSV season.

Respiratory syncytial virus (RSV) monoclonal antibody	
Product Name	Beyfortus
Manufacturer	Sanofi Pasture
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 Enrollment

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.

Why Participate in VFC?

- Nirsevimab will be provided to your site at no cost, for eligible babies.
- Ensures neonates are protected during the RSV season.
- Ensures optimal uptake of Nirsevimab and minimizes access disparities.
  - 4-10% of infants are not seen at their pediatrician's office within a week of hospital discharge.*
    - 73.8% of Medicaid infants vs 84.7% of commercially insured infants have a visit within a week.

*Christopher B. Nelson et al., *Vaccine*, https://doi.org/10.1016/j.vaccine.2023.06.089

VFC Eligibility

A child is eligible for the VFC Program if he or she **is younger than 19 years of age** and is one of the following:

1. Medicaid-eligible
2. Uninsured
3. Under-insured (FQHC only)
4. Native American or Alaska Native

A child is <u>not</u> eligible for the VFC program if they are privately insured.

- For neonates, the birthing parent's insurance status should be assessed to determine which Nirsevimab product should be used (privately secured or VFC secured).

Enrolling in VFC

- **Identify key staff.**
  - These individuals will be the main contacts with our program:
    - Medical director
    - 2 Primary contacts (Primary and Back-up Vaccine Coordinators)

- **Complete the VFC Enrollment form.**
  - Completed by the Vaccine Coordinators
  - Information collected includes:
    - Patient Population counts (only need information for <1)
    - License numbers for the attending physicians

- **Confirm ability to report RSV administration to PhilaVax.**

Enrolling in VFC (con't)

- **Set-up the unit(s) that will be used to store the Beyfortus (nirsevimab) at your site.**
  - Our Storage and Handling team will coordinate with the pharmacy to ensure CDC requirements are meet.

- **Complete a VFC Enrollment Visit**
  - A teach the teacher virtural meeting will be scheduled once the other steps are completed. The vaccine coordinator, medicial director, representatives from the teams that will be involoved with Nirservamab in the hospital will need to attend.

Implementation Planning

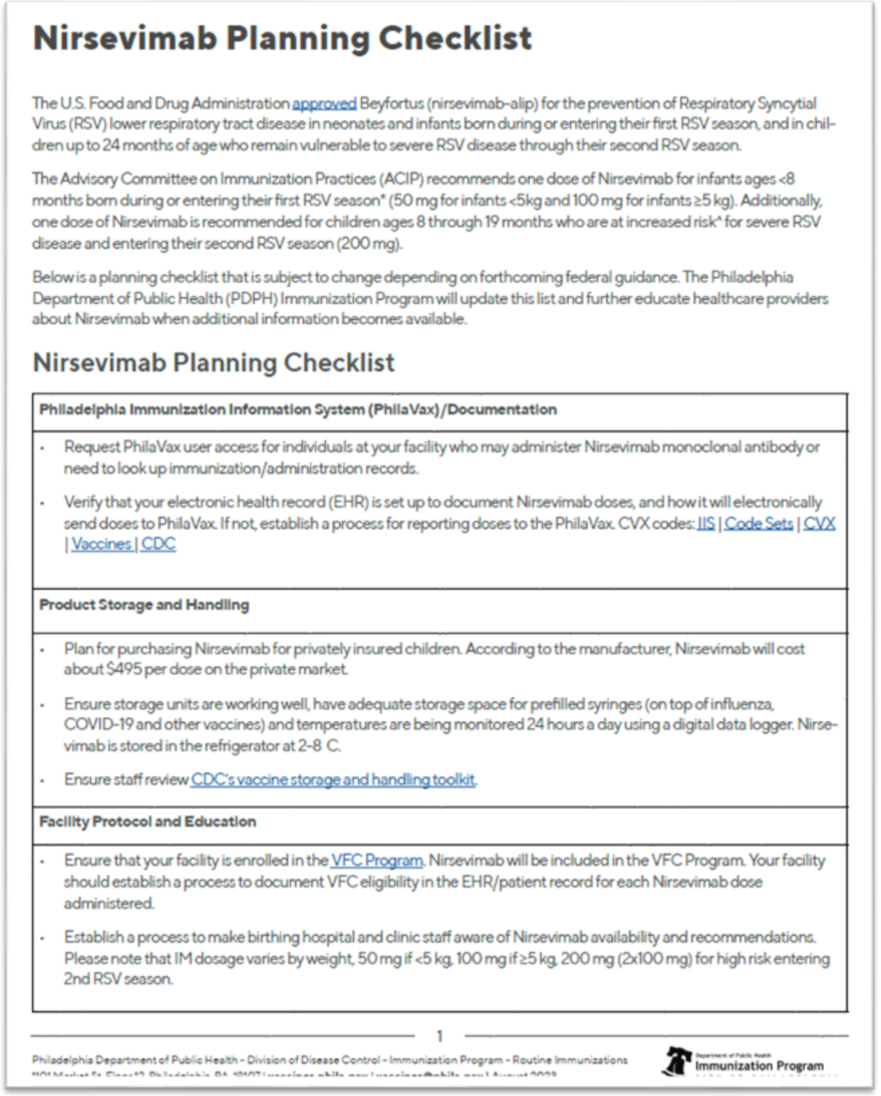
Planning Checklist

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

- 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

- 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

- 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.

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Philadelphia Department of Public Health - Division of Disease Control - Immunization Program - Routine Immunizations

Immunization Program

Facility Protocol and Education

- 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.

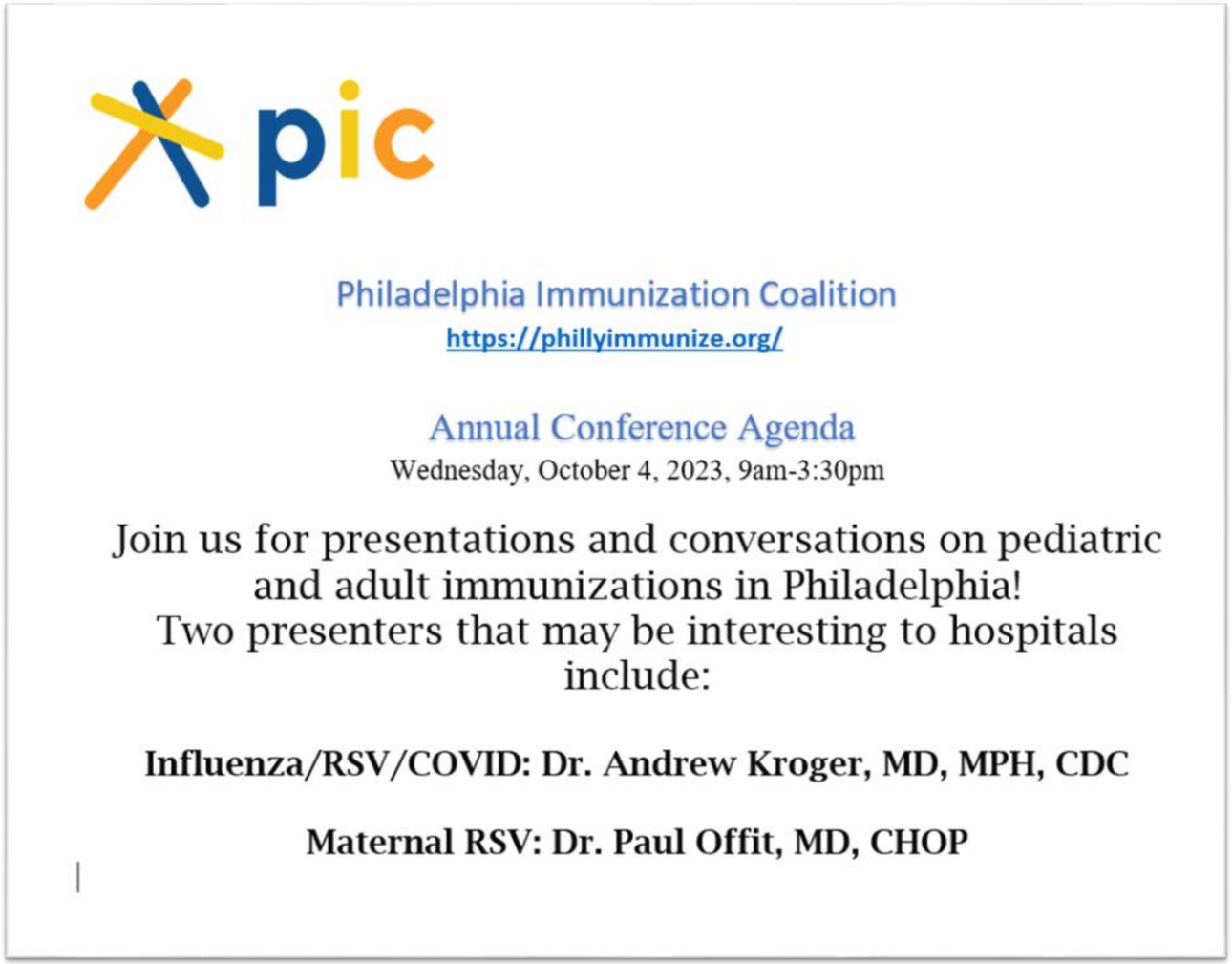
- Plan how to communicate nirsevimab availability, priority groups and safety/efficacy to patients.

- Ensure education on documentation needs (EHR, electronic birth certificate, PhilaVax) are provided to staff.

Facility Protocol and Education (con't)

- Update billing processes for private insurance and VFC-eligible children, as needed.
- Establish a process to obtain parental consent for nirsevimab. A patient information sheet is forthcoming from CDC.
- Update current facility vaccination/medication administration protocols, if needed.
- Determine when nirsevimab will be administered post-delivery and pre-discharge at the hospital.
- Determine where nirsevimab will be stored and how it will be dispensed for immunization.

Come Learn More!



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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