RSV AND NIRSEVIMAB RECOMMENDATIONS WEBINAR
FEBRUARY 1, 2024
Before We Start

• All participants will be muted for the presentation.
• You may ask questions using the Q&A box, and questions will be answered at the end of the presentation.
• Continuing education is available for nurses and medical assistants.
• If you’re watching in a group setting and wish to claim CE credit, please make sure you register for the webinar and complete the evaluation as an individual.
• You can find more information here: RSV and Nirsevimab Recommendations Webinar | Washington State Department of Health
Continuing Education

• This nursing continuing professional development activity was approved by Montana Nurses Association, an accredited approver with distinction by the American Nurses Credentialing Center’s Commission on Accreditation. Upon successful completion of this activity, 1.0 contact hours will be awarded.

• This program has been granted prior approval by the American Association of Medical Assistants (AAMA) for 1.0 administrative continuing education unit.
Disclosures

The planners and speakers of this activity have no relevant financial relationships with any commercial interests pertaining to this activity.
Learning Objectives

- Learn about nirsevimab recommendations
- Discuss nirsevimab supply and ordering updates
- Describe tips for talking with families about nirsevimab
Presenters

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Seattle Children’s

Stephanie Keller
Vaccine Accountability and Assurance Supervisor
Office of Immunization, Washington State Department of Health

Frank Bell, MD
Swedish Pediatric Infectious Disease
RSV and nirsevimab recommendations
Addressing vaccine administration errors

PAIGE KILLELEA, MD
Overview

• RSV signs and symptoms
• Disease burden
• Nirsevimab guidelines
• Quickly talk about Palivizumab (‘Synagis’)
• Abrysvo: for pregnant people
• Contraindications/Precautions & Safety
• FAQs
RSV Signs & Symptoms

- Common virus that affects the lungs
- RSV season starts in the fall and peaks in the winter in most regions of the U.S.
- Symptoms include cough, fever, wheezing, congestion, increased work of breathing, decreased appetite/feeding
- Spreads through coughing, sneezing, touching surfaces and then touching face (can live up to 6 hours on hard surfaces)
- Highest risk children: premature babies, children with heart or lung disease, infants < 6 months

[Image: How to Tell the Difference Between FLU, RSV, COVID-19, and the Common Cold]

National Foundation for Infectious Diseases

https://doh.wa.gov/you-and-your-family/immunization/diseases-and-vaccines/respiratory-syncytial-virus-rsv#rsv
Disease Burden

- RSV is the leading cause of infant hospitalization in the US\(^1\)
  - Up to 3% of children in their first year of life are hospitalized due to RSV infection\(^2\)
  - Approximately 75% of infants hospitalized for RSV were born healthy and at term with no underlying conditions\(^3\)
- RSV is the most common cause of bronchiolitis & pneumonia in babies <1 year old
- Most children will get an RSV infection before the age of 2 years, and 20-30% will develop a lower respiratory tract infection, such as bronchiolitis or pneumonia\(^4\)
- 68% of parents said an RSV hospitalization of their child affected their mental health\(^4\)
- 66% of interviewed parents described RSV as a financial burden or crisis\(^4\)

1: [www.cdc.gov/rsv](http://www.cdc.gov/rsv)
About Nirsevimab ‘Beyfortus’

• Approved by FDA July 2023
  o Clinical trials began Nov 2016

• Monoclonal antibody product = passive immunization

• Protection expected to last at least 5 months

• Approved for all infants aged < 8 months who are born during or entering their first RSV season, whose mother did NOT receive RSV vaccine 14 days or more prior to birth

• Also approved for children 8-19 months at increased risk in their second RSV season
  1. Chronic lung disease of prematurity
  2. Severe immune compromise
  3. Severe cystic fibrosis
  4. American Indian or Alaskan Natives

https://doh.wa.gov/you-and-your-family/immunization/diseases-and-vaccines/respiratory-syncytial-virus-rsv#rsv
Pooled efficacy from phase 2 and 3 clinical trials in preventing medically attended RSV-associated lower respiratory tract infection (LRTI) was 79.0%.

Efficacy in preventing RSV-associated LRTI with hospitalization was 80.6%.

Efficacy in preventing RSV-associated LRTI with admission to an intensive care unit (ICU) was 90.0%.

https://www.cdc.gov/vaccines/vpd/rsv/hcp/child.html
**Recommended Timing of Immunization**

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<tr>
<th>Month of birth</th>
<th>Recommended timing of nirsevimab immunization</th>
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<td>Within 1 week of birth</td>
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<td>April–September</td>
<td>Beginning in October, for example at a 2-, 4-, or 6-month well child visit</td>
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Current Recommendations

Age < 8 months
  • 50 mg for infants weighing <5 kg
  • 100 mg for infants weighing ≥5 kg

Age 8 - 19 months & at increased risk
  • 200 mg, administered as two 100 mg injections
    1. Chronic lung disease of prematurity
    2. Severe immune compromise
    3. Severe cystic fibrosis
    4. American Indian or Alaskan Natives

https://emergency.cdc.gov/han/2023/han00499.asp
Updated Guidance for Healthcare Providers on Increased Supply of Nirsevimab to Protect Young Children from Severe Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season

Infants and children recommended to receive nirsevimab should be immunized as quickly as possible. Healthcare providers should not reserve nirsevimab doses for infants born later in the season when RSV circulation and risk for exposure to RSV may be lower. RSV activity remains elevated nationwide and is continuing to increase in many parts of the country, though decreased activity has been observed in the Southeast.

emergency.cdc.gov/newsletters/coca/2024/010524a.html
Respiratory Syncytial Virus Infection (RSV)

Healthcare providers are encouraged to administer nirsevimab to protect infants against severe RSV. Do not save doses for later in the season. More nirsevimab is expected in early 2024.
Nirsevimab to replace Palivizumab (“Synagis”)

- Previous RSV immunization for premature infants born <29w0d, premature infants with chronic lung disease, and infants with hemodynamically significant heart disease, neuromuscular or pulmonary abnormalities that impair secretion clearance
- Required monthly doses x 5
- **Children who receive Nirsevimab should not receive palivizumab during the same RSV season**
- There had been a recommendation in the fall from the CDC to suspend using Nirsevimab in Palivizumab-eligible children aged 8-19 months; however currently if Nirsevimab is available it should be used instead of Palivizumab
Abrysvo: for pregnant people

- Recommended during weeks 32-36 of pregnancy
- September to January
- Infant is covered if born >14 days after mother receives Abrysvo (NOT recommended for infant to also receive Nirsevimab)
  - Exceptions:
    - Pregnant person is immunocompromised or has condition associated with reduced transplacental antibody transfer (HIV)
    - Infant requiring ECMO/cardio pulmonary bypass
    - Infant with substantial increased risk for severe RSV disease (hemodynamically significant congenital heart disease, ICU admission with a requirement of oxygen at discharge)
Abrysvo: recommended through January 31

Seasonal administration of maternal RSV vaccine is only recommended through the end of January for most of the continental United States

• Infants born to unvaccinated mothers during RSV season should receive nirsevimab through the end of March (i.e., February 1–March 31)

• After January 31, infants will be born when RSV activity is expected to be lower, and there is less benefit relative to the cost of Abrysvo
Relative Advantages and Disadvantages of Each Product

<table>
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<th>Advantages</th>
<th>Disadvantages</th>
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| - Immediate protection after birth
  - Might be more resistant to potential mutations in F protein | - Potentially reduced protection in some situations (e.g., pregnant person is immunocompromised or infant born soon after vaccination)
  - Potential risk for preterm birth and hypertensive disorders of pregnancy |
| ![](maternal_rsv_vaccine.png) Maternal RSV vaccine | ![](nirsevimab.png) Nirsevimab |
| - Protection from nirsevimab may wane more slowly than from maternal RSV vaccine
  - Direct receipt of antibodies rather than relying on transplacental transfer
  - No risk for adverse pregnancy outcomes | - Potentially limited availability during 2023–24 RSV season
  - Requires infant injection |

RSV Vaccine Administration Errors

• CDC has received reports of vaccine administration errors with RSV vaccines.
• Pfizer’s Abrysvo is the only RSV vaccine recommended for use in pregnant people. GSK’s Arexvy is not recommended for use in pregnant people.
• Nirsevimab is the only RSV immunization approved and recommended for infants.
Avoid Vaccine Administration Errors

1. Order and stock the vaccine product that fits best with your patient population.
2. Avoid stocking multiple products, if possible.
3. If multiple RSV vaccine products are stocked, label each with the correct indications.
4. Educate staff on vaccine recommendations. If multiple RSV products are stocked, train staff about the differences in preparation and indications.
5. Follow medication administration best practices—read and check the vaccine product label at least 3 times and ask another staff member to confirm that it is the correct vaccine product for the patient.
6. If referring pregnant people to another vaccine provider, tell them to get Abrysvo (Pfizer) vaccine and confirm the vaccine product prior to administration.

emergency.cdc.gov/newsletters/coca/2024/012224.html
Preparing Patients for 2023 Virus Season | CDC
Further Guidance

• If Arexvy is given to a pregnant person instead of Abrysvo: Do not give the pregnant person a dose of Abrysvo
  • Experts suggest no special monitoring for the pregnant person beyond routine prenatal care is needed

• The infant after birth should receive Nirsevimab shortly before or during their first RSV season (at age less than 8 months) for RSV prevention
Further Guidance

• If Arexvy or Abrysvo is given to an infant instead of Nirsevimab, the infant should receive Nirsevimab to prevent severe RSV disease, if otherwise eligible

• **Administration of Nirsevimab may be done as soon as the error is identified** (no minimum interval), but it could be reasonable to consider waiting 48 to 72 hours between administration of the vaccine and Nirsevimab administration

• If Nirsevimab will be administered at the same visit or within 72 hours, Nirsevimab should be administered at a different anatomic site
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*Recommended timing for immunization除外in limited situations (as indicated in chart)*

CDC/NCIRD/ISD All-Awardee Call
National Center for Immunization & Respiratory Diseases
Mimi Eckert, MPH
RSV Updates — Elisha Hall, PhD, RD
Contraindications/Precautions

- Nirsevimab is contraindicated in children and infants with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of Nirsevimab or to a product component.

- Nirsevimab should be used with caution in infants and children with bleeding disorders. Use a 23-gauge or smaller caliber needle and steady pressure to the site for 1-2 minutes.

- In accordance with CDC General Best Practice Guidelines for Immunization, children who have a moderate or severe acute illness should usually wait until they recover before getting Nirsevimab.
Safety

- Adverse events reported in only 1.2% of participants
- Only 2 adverse reactions that occurred significantly more than in the placebo arm:
  1. Rash occurring within 14 days of injection
  2. Injection site reactions (swelling, pain)
- No anaphylaxis was reported
FREQUENTLY ASKED QUESTIONS
Can I give Nirsevimab to children ages 20 months and older who are at increased risk for RSV disease?

Nirsevimab is not recommended for any child who is age 20 months and older.
Can Nirsevimab be given with routine childhood vaccines?

Yes!
What if an infant is diagnosed with RSV that day? Would a dose of nirsevimab be helpful to reduce the severity of the illness?

Nirsevimab has not been studied as a treatment in infants with RSV and is not licensed for treatment of RSV disease.

Nirsevimab should be given prior to onset of the RSV season or as soon as possible after birth for infants born during the season to prevent severe RSV disease.
If a dose of maternal RSV vaccine is inadvertently administered to pregnant person after January 31st, is it considered valid?

Yes, even if vaccination occurs after January 31st, the dose is considered valid.

If the dose was given >14 days before birth, Nirsevimab is not recommended for the infant after they are born.
For children ages 8-19 months who are recommended to receive Nirsevimab during their second RSV season, what is the minimal interval between doses?

Only one dose of Nirsevimab is recommended for each season. Each dose of Nirsevimab provides protection for at least 5 months, and a second dose of Nirsevimab is not recommended to be given within 5 months of the first dose.
Links and Resources

• Report vaccine administration errors: Vaccine Adverse Event Reporting System (VAERS). In the event that a vaccine administration error occurs, please reach out to CDC at NIPINFO@cdc.gov for further guidance.

• RSV (Respiratory Syncytial Virus) Immunizations | CDC

• Healthcare Providers: RSV Immunization for Children 19 Months and Younger | CDC

• Frequently Asked Questions About RSV Immunization with Monoclonal Antibody for Children 19 Months and Younger | CDC

• RSV Vaccination: What Parents Should Know | CDC

• ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics

• Health Alert Network: Limited Availability of Nirsevimab in the United States – Interim CDC Recommendations to Protect Infants from RSV During the 2023-2024 Respiratory Virus Season

• Washington Childhood Vaccine Program: Childhood Vaccine Program | Washington State Department of Health
Nirsevimab supply update
Abrysvo and Childhood Vaccine Program/
Adult Vaccine Program

STEPHANIE KELLER
## Nirsevimab Supply Update

### Original Orders Placed
Oct 5 – Oct 13:

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<th>Product Description</th>
<th>Quantity Ordered</th>
<th>Quantity Shipped</th>
<th># of Facilities</th>
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<td>RSV; 50mg; SYR; 5-pack</td>
<td>6,445</td>
<td>6,440</td>
<td>125</td>
</tr>
<tr>
<td>RSV; 100mg; SYR; 5-pack</td>
<td>7,795</td>
<td>7,780</td>
<td>133</td>
</tr>
<tr>
<td><strong>Totals:</strong></td>
<td><strong>14,240</strong></td>
<td><strong>14,220</strong></td>
<td>136*</td>
</tr>
</tbody>
</table>

*Most facilities requesting both formulations

### Orders Placed Nov:

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Quantity Ordered</th>
<th>Quantity Shipped</th>
<th># of Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV; 50mg; SYR; 5-pack</td>
<td>1,030</td>
<td>1,030</td>
<td>20</td>
</tr>
</tbody>
</table>

### Orders Placed Dec:

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Quantity Ordered</th>
<th>Quantity Shipped</th>
<th># of Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV; 50mg; SYR; 5-pack</td>
<td>2,275</td>
<td>2,275</td>
<td>52</td>
</tr>
</tbody>
</table>

### Orders Placed Jan:

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Quantity Ordered</th>
<th>Quantity Shipped</th>
<th># of Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV; 50mg; SYR; 5-pack</td>
<td>5,460</td>
<td>3,590</td>
<td>116</td>
</tr>
<tr>
<td>RSV; 100mg; SYR; 5-pack</td>
<td>4,160</td>
<td>3,625</td>
<td>166</td>
</tr>
</tbody>
</table>
Nirsevimab Supply Update (cont.)

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Quantity Shipped (doses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV; 50mg; SYR; 5-pack</td>
<td>13,345</td>
</tr>
<tr>
<td>RSV; 100mg; SYR; 5-pack</td>
<td>11,425</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV; 50mg; SYR; 5-pack</td>
<td>2,595</td>
</tr>
<tr>
<td>RSV; 100mg; SYR; 5-pack</td>
<td>45</td>
</tr>
</tbody>
</table>

- Limited amount in early 2024.
- Readout of Latest White House Meeting with RSV Immunization Manufacturers | The White House
- Sanofi Beyfortus™ (nirsevimab-alip) Injection Update
Recent Nirsevimab Messaging

➢ Important to fully use existing nirsevimab supply now to maximize protection against RSV among infants while RSV illness circulates
   o Use doses when possible, do not stockpile.
   o Use nirsevimab for any eligible baby.
   o Use the vaccine advertisement tool in the WAIIS to advertise doses you aren't using, or to search for available doses to transfer. Find directions on using the tool here.
   o For infants age less than 8 months born to unvaccinated mothers, healthcare providers should administer nirsevimab from October 1 through March 31; however healthcare providers can administer nirsevimab outside of this timeframe based on local epidemiology

➢ Limited Nirsevimab available for ordering now
   o Prioritization for 50 mg product continues to be for birthing hospitals, tribal health clinics, and provider clinics in counties that have yet to receive much product.
   o Prioritization for the 100 mg product will be for provider clinics in counties with no or low supply, and tribal health clinics.
   o Received full allocation from the CDC. Ordering to stay open and processed weekly until allocation is depleted.
   o According to IIS data, administration is low compared to the number of doses we have shipped; only half has been administered. Please utilize product and report in the IIS
Abrysvo through Childhood and Adult Vaccine Programs

• CDC and ACIP recommend Abrysvo for pregnant persons between 32-36 weeks of pregnancy during RSV season.
• In most of continental US, the RSV vaccine should be given to pregnant people from September 1 through January 31.
• Abrysvo is no longer available to order in either the Adult Vaccine Program or Childhood Vaccine Program.
• Healthcare providers who administer the RSV vaccine to pregnant people after January 31 should encourage patients to check with their insurance plans on coverage details, as coverage and cost sharing by private insurance plans may vary after January 31. Providers should consider submitting an insurance test claim to estimate out-of-pocket costs.
Talking with Families about Nirsevimab
- the Preventive Antibody against RSV -

Frank Bell MD
Pediatric Infectious Disease
Swedish Medical Center, Seattle WA
Why care about RSV?

- Every baby will get infected with RSV
- RSV is the commonest reason for hospitalization in childhood
- RSV accounts for infant deaths every year in the US
What can we do?

There are two ways to provide infants with antibody protection to help prevent serious lower respiratory tract infection (LRTI) with RSV:

- Vaccination in pregnancy
- Immunization in infancy
How does nirsevimab work?

Nirsevimab provides an antibody to protect infants against RSV

Nirsevimab is a form of ‘passive immunization’

providing protection as ‘pre-exposure prophylaxis’
## Components of the Immune Response

<table>
<thead>
<tr>
<th></th>
<th>Innate</th>
<th>Adaptive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cellular</strong></td>
<td>Neutrophil</td>
<td>Lymphocyte</td>
</tr>
<tr>
<td></td>
<td>Monocyte</td>
<td></td>
</tr>
<tr>
<td><strong>Humoral</strong></td>
<td>Complement</td>
<td>Antibody</td>
</tr>
</tbody>
</table>
# Components of the Adaptive Immune Response

<table>
<thead>
<tr>
<th></th>
<th>Innate</th>
<th>Adaptive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellular</td>
<td>Neutrophil</td>
<td>T &amp; B Lymphocytes</td>
</tr>
<tr>
<td></td>
<td>Monocyte</td>
<td></td>
</tr>
<tr>
<td>Humoral</td>
<td>Complement</td>
<td>Antibody</td>
</tr>
</tbody>
</table>
The 1925 Serum Run, Alaska
What is a monoclonal antibody?

A monoclonal antibody is a highly-specific, effective, man-made antibody, manufactured from a single line of B-cells. It gets to work immediately!
What is nirsevimab?

A recombinant human IgG<sub>1k</sub> monoclonal antibody

Binding to a highly-conserved site (the ‘Ø’ epitope) present on the prefusion conformation of the RSV Fusion protein

With a modification to the Fc portion of the antibody to extend the half-life
Has nirsevimab been studied? - is it safe for my baby?

1. FDA-approval, based on pre-clinical and clinical studies
2. CDC Advisory Committee on Immunization Practices > ACIP-recommendation
3. Post-licensure monitoring and reporting, including VAERS, VSD
An approach in the clinic

“Your baby is due for nirsevimab today, which will help protect them from severe respiratory illness”
RSV Preventive Antibody: What you need to know

https://www.cdc.gov/vaccines/vpd/rsv/immunization-information-statement.html
Strategies for discussion, shared decision-making

- Explore understanding, leaning, invite questions
- Make a strong recommendation for infant immunization against RSV
- Use every opportunity to immunize
Resources

US Centers for Disease Control and Prevention (CDC)
RSV Prevention for Healthcare Providers:
https://www.cdc.gov/vaccines/vpd/rsv/hcp/child.html
Nirsevimab Immunization Information Statement (IIS):
https://www.cdc.gov/vaccines/vpd/rsv/immunization-information-information-statement.html

American Academy of Pediatrics (AAP)
For Healthcare Providers: Communication around immunization
For Parents (Healthy Children.org):
https://www.healthychildren.org/English/health-issues/conditions/chest-lungs/Pages/rsv-when-its-more-than-just-a-cold.aspx

Vaccine Education Center, Children’s Hospital of Philadelphia
Obtaining Continuing Education

• Continuing education is available for nurses and medical assistants

• There is no cost for CEs

• Expiration date is 05/01/24

• Successful completion of this continuing education activity includes the following:
  • Attending the entire live webinar or watching the webinar recording, and completing the evaluation
  • On the evaluation, please specify which type of continuing education you wish to obtain

• Please note: CE certificates are NOT generated after evaluation completion—CE certificates will be sent by DOH via email within a few weeks after evaluation completion

• If you have any questions about CEs, contact Trang Kuss at trang.kuss@doh.wa.gov
Questions?