

What: WVA Payer Call: Special Purpose Meeting Agenda

When: August 29, 2023; 9:00 – 10:00 am PT

Where: Zoom Meeting

+1 253 215 8782 US (Tacoma) or +1 646 558 8656 US (New York)

<https://us02web.zoom.us/j/81477854804?pwd=Rk5ML0ltKzR3RXdUOHJGUlQ2OW4yUT09>

Meeting ID: 814 7785 4804

Passcode: 999620

Notice: The meeting may be recorded for the benefit of the minute-taker. The WVA intends to delete the recording after the minutes are approved.

AGENDA

Approx. Time	*	Page	Topic/[Anticipated Action]	Presented by:
9:00-9:05 am			1. Welcome & Introductions a) Notice of Meeting Recording	J. Zell
9:05-9:55 am	* *	Pgs. 2-3 Pgs. 4-8	2. Overview a) Brief History and DOH Funding Request b) WVA Options c) Discussion d) Consensus on Moving Forward	J. Zell K. Griffith Any
10:00 am			3. Closing	J. Zell

*Indicates agenda item attached

Nirsevimab (RSV Immunization)

August 2023

Nirsevimab is a new immunization that helps protect infants under 8 months and some older babies at increased risk of severe illness caused by respiratory syncytial virus (RSV).

What is RSV?

RSV is a seasonal, highly contagious virus that affects 97% of children by the age of 2¹. Low-income children of color are at high risk of severe RSV². Although common, the virus can be dangerous for infants and young children:

- **It is the leading cause of hospitalization for babies less than a year old.**³ Each year in the United States, an estimated 58,000-80,000 children younger than 5 years are hospitalized due to RSV infection.⁴ Infants who are hospitalized with RSV may require oxygen, IV fluids, and mechanical ventilation.
- **RSV can have lasting health impacts.** It is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia in children younger than 1⁵ and it increases long-term risks of developing asthma.⁶
- **Each year RSV leads to approximately 100–300 deaths** in children younger than 5 years old.⁷

A powerful new tool to protect against RSV

In August 2023, Nirsevimab was recommended by the CDC Advisory Committee on Immunization Practices (ACIP). It is a long-acting monoclonal antibody product (*monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses*) which has been shown to reduce the risk of both hospitalizations and healthcare visits for RSV in infants by about 80 percent. It is administered as an injection and provides critical protection during a baby's first RSV season, when they're most at risk for severe illness.

To ensure protection is available to babies and infants in Washington, the state needs to act now

The Department of Health (DOH) oversees the state's Childhood Vaccine Program which provides publicly purchased vaccines to participating providers for all children less than 19 years of age regardless of insurance status. The program supplies vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and eliminates or reduces cost barriers to receiving vaccinations.

¹ "RSV and Infants: a Respiratory Disease That Can Be Deadly." American Lung Association. October 20, 2021. <https://www.lung.org/blog/about-rsv-and-infants>

² "RSV Health Equity Action Report." National Minority Quality Forum. August 23 2023. https://rsvequityaction.org/wp-content/uploads/2023/07/RSV_Report.pdf

³ "RSV in Infants and Young Children." Centers for Disease Control and Prevention. August 21 2023. <https://www.cdc.gov/rsv/high-risk/infants-young-children.html>

⁴ "RSV in Infants and Young Children." Centers for Disease Control and Prevention. August 21 2023. <https://www.cdc.gov/rsv/high-risk/infants-young-children.html>

⁵ "RSV (Respiratory Syncytial Virus)." Yale Medicine. August 21 2023. <https://www.yalemedicine.org/conditions/rsv-respiratory-syncytial-virus>

⁶ "Is there a link between RSV and asthma development?" Rachel Zimlich, RN, BSN. Contemporary Pediatrics, September 3, 2019.

<https://www.contemporarypediatrics.com/view/there-link-between-rsv-and-asthma-development>

⁷ Hansen CL, Chaves SS, Demont C, Viboud C. Mortality Associated With Influenza and Respiratory Syncytial Virus in the US, 1999-2018. JAMA Network Open. 2022 Feb 1;5(2):e220527.

DOH, working with the Washington Vaccine Association (WVA), are planning to make the Nirsevimab injection available upon release through the Childhood Vaccine Program, but are facing barriers due to the narrow statutory definition of “vaccine”. Currently, Nirsevimab does not meet the definition of “vaccine” in state law (RCW 70.290). To address this barrier, DOH is proposing a technical fix to align the definition in state law with the federal definition of vaccine. The proposal also includes an emergency clause so providers and families are able to access Nirsevimab immediately if passed.

Nirsevimab is expected to be available in the fall of 2023 which coincides with the start of the respiratory virus season. Having the immunization available quickly will help prevent RSV in Washington’s babies and infants at a critical time of year.

Additionally, not being able to include Nirsevimab in the state’s Childhood Vaccine Program would result in a two-product system where DOH could only supply RSV vaccine for children covered by the federal VFC program. Providers would be responsible for purchasing a separate supply for children with private insurance who are not covered by VFC. This complicates the procurement, storage, and assessment process for providers, creating additional administrative burden and can impact their ability to provide Nirsevimab. This would also impact access for families and raises equity concerns. **Reducing barriers to accessing Nirsevimab for all children will have the most positive public health impact.**

Contact

If you would like additional information or want to provide feedback directly, please contact Kelly Cooper, Director of Policy and Legislative Relations, 360-688-0857, Kelly.Cooper@doh.wa.gov.



For persons with disabilities, this document is available in other formats. Please call 800-525-0127 (TDD/TTY 711) or email

civil.rights@doh.wa.gov.



WVA Payer RSV Discussion

August 29, 2023

Nirsevimab (Beyfortus)

- Monoclonal antibody providing passive immunity against RSV for infants and toddlers; anticipated to be available for 2023-24 RSV season
- ACIP recommendation for CDC's immunization schedule and for Vaccines for Children program (VFC)
- Will be required for plans and issuers subject to the ACA's preventive services mandate
- CDC contract soon to be finalized; provider orders could begin as early as Oct 1
- Unprecedented industrywide efforts for significant public health impact

WVA and Nirsevimab

- WA DOH request of funding from WVA
- WVA's vaccine statutory definition: "preparation of killed or attenuated live microorganisms, or fraction thereof"
 - Legislative intent to apply to ACIP-recommended immunizations
 - Efforts underway to amend statute to align with intent and avoid unintended health care disparities
- Engagement of key stakeholders to partner on universal access and mitigation of health disparities for babies in Washington State

Bridging the Gap: 2023-24 RSV Season

- What do payers expect or anticipate they will do for Nirsevimab during the 2023-24 RSV season?
- Request for payer partnership to support equitable access and to enable commercial payer participation in state universal purchase
- Proposal for written agreement under which:
 - Payer authorizes use of WVA assets as needed to cover Nirsevimab costs (*including if legislative efforts are unsuccessful*)
 - Payer commits to pay its share (*see next slide for options*)
 - WVA commits to make reasonable efforts, including offsetting future assessments if needed, to ensure the payer's total contribution aligns with what WVA determines to be its share of Nirsevimab administered in 2023-24 RSV season

Bridging the Gap: 2023-24 RSV Season

Advancement of Funds: Payer agrees to advance funds to WVA in an amount based on the payer's estimated market share of anticipated Nirsevimab uptake for 2023-24 RSV season, or an agreed-upon share of anticipated commercially-insured portion, with "true-up" by payer or WVA following the season based on payer's estimated market share of actual administration.

Ongoing Contributions: Payer agrees to make periodic contributions (e.g., monthly, quarterly) to WVA during the 2023-24 RSV season, in amounts based on the payer's estimated market share of actual Nirsevimab administration.

Commitment to Pay: Payer agrees to pay funds to WVA following end of 2023-24 RSV season, to cover the payer's estimated market share of actual Nirsevimab administration during the 2023-24 RSV season.

Other Options? We invite your input!