

What: Special RSV Vaccine Committee Agenda

When: September 21, 2023; 7:00-8:00 a.m. PT

Where: Zoom Meeting

<https://us02web.zoom.us/j/87645875685?pwd=VlJ5d1JldjRxZENVY1Vwbmw1R0kwdz09>

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

Meeting ID: 876 4587 5685

Passcode: 900926

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 for Vaccine Committee Meeting

| Approx. Time | Pg. | | Topic/[Anticipated Action] | Presented by: |
|----------------|----------|---|--|--------------------------|
| 7:00-7:05 a.m. | Pg. 3-5 | * | 1. Introductions & Minutes a. ACIP Recommendation b. WVA Vaccine Committee Role/Responsibilities | E. Marcuse/J. Zell |
| 7:05-7:20 a.m. | | | 2. WCAAP Presentations a. Program Perspective i. Disease Burden ii. Vaccine Development, Passive Immunity iii. Potential Individual and Public Health Benefit iv. WCAAP Position b. Clinician's Perspective i. Demand ii. Feasibility of Inclusion in State Supply iii. Barriers to Access if WVA cannot provide funding iv. Cost to practice of purchasing and contracting v. WCAAP Position | F. Bell A. Carter |
| 7:20-7:25 a.m. | Pg. 6-7 | * | 3. Department of Health (DOH) a. DOH Nirsevimab One-Pager b. Public Health Benefits to Washington State of Universal Purchase c. DOH Position | J. Jorgenson |
| 7:25-7:30 a.m. | Pg. 8-10 | * | 4. WVA a. WVA Statutory Challenges b. Proposed Funding Mechanism | J. Zell |
| 7:30-7:59 a.m. | Pg. 11 | * | 5. Next Steps a. Discussion b. Vote on Course of Action | E. Marcuse |

| | | | | |
|-------------------|--|--|-------------------|------------|
| 7:59-8:00 a.m. | | | 6. Public Comment | Any |
| 8:00 a.m. | | | 7. Closing | E. Marcuse |

*Indicates agenda item attached

Red text indicates an action item

Washington Vaccine Association VACCINE COMMITTEE CHARTER

Purpose:

The Washington Vaccine Association (the Association) Vaccine Committee (the Committee) is established pursuant to the requirements of Chapter 70.290 RCW for the purpose of making recommendations to the WVA Board of Directors (the Board) on specific vaccines to be purchased in each upcoming year by the Washington State Department of Health (the Department). As required by RCW 70.290.050, factors the Committee will strongly consider when making recommendations to the Association Board on selecting vaccines include:

- Patient safety and clinical efficacy
- Public health and purchaser value
- Patient and provider choice
- Stability of vaccine supply
- Compliance with RCW 70.95M.115 recodified at RCW 70A.230.120.

Key Activities:

The Committee will fulfill its responsibilities through the following activities:

- Evaluate the use of vaccines from a clinical, pharmacoeconomic and ethical perspective
- Promote safety, effectiveness, and improved health outcomes from vaccination
- Be informed by the deliberations and recommendations of the Department Vaccine Advisory Committee (the VAC).

Meeting Frequency and Notice:

The Committee will meet at least two times per year with notice provided in the manner set forth in the Association bylaws for Board meetings. Committee members are required to attend meetings in person, by conference telephone, or by videoconference.

Reporting Frequency:

- The Committee will report to the Board at least two times per year.

Membership:

As required by RCW 70.29.050, the Committee shall consist of five voting Board members, one non-voting member and two non-voting ex officio members as set forth below. The representative of the vaccine manufacturer must be chosen by the Secretary of the Department from a list of three nominees submitted collectively by vaccine manufacturers on an annual basis as required by RCW 70.290.050. Other participants and/or consultants may be invited from time to time to assist the committee. The Chair or Vice-chair will be a physician and Association Board member.

Washington Vaccine Association VACCINE COMMITTEE CHARTER

Description of Committee Membership Positions:

| Position/Title | Qualifications |
|--|---------------------------------|
| <i>Vaccine Committee Voting Members</i> | |
| 1. Physician (Chair) | Member of the Association Board |
| 2. Health Carrier/TPA Member | Member of the Association Board |
| 3. Health Carrier/TPA Member | Member of the Association Board |
| 4. Health Carrier/TPA Member | Member of the Association Board |
| 5. DOH Secretary Designee | Member of the Association Board |

| | |
|------------------------------------|---|
| <i>Non-voting Member</i> | |
| 1. Representative of Manufacturers | Designated by the Secretary, the Department |

| | |
|--|--|
| <i>Ex Officio Members (Without Vote)</i> | |
| 1. Executive Director of the Association | |
| 2. Director Department Immunization Program/ Child Profile | |

Member Responsibilities:

Members will comply with the Conflict of Interest policy of the Association and complete and sign a statement declaring potential conflicts of interest annually and are responsible for informing the Committee Chair and Executive Director of any pertinent changes during the year.

Motions may be made and seconded only by voting members. Majority vote of voting members carries a motion.

Members are responsible for rendering decisions regarding the recommendations as required, based upon best available vaccine clinical evidence and on outcomes modeling current best practice standards.

Members shall not have responsibility for making business decisions involving Association processes for vaccine assessment amounts.

Quorum:

A quorum consists of at least three voting members of the Committee.

Consultants and/or Other Participants

To ensure that the Committee's deliberations are informed by the perspectives of primary care clinicians (pediatricians, or family practice physicians including physicians engaged in office-based practice (versus institutional practices)), local health officers, pharmacists and Department staff with expertise in vaccine supply and, from time to time others with needed special expertise, the Committee may request that consultants participate in its meetings.

**Washington Vaccine Association
VACCINE COMMITTEE
CHARTER**

Approval and Review:

This charter will be periodically reviewed by the Committee and any recommended revisions approved by the WVA Board.

| | |
|------------------------|---|
| Charge Author: | WVA Vaccine Committee |
| Approving Body: | WVA Board of Directors and Executive Director |

| | |
|--|--------------------------------|
| Reviewed By: Vaccine Committee | Date: November 17, 2022 |
| Approved By: WVA Board of Directors | Date: |

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.



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civil.rights@doh.wa.gov.

BILL REQUEST - CODE REVISER'S OFFICE

BILL REQ. #: Z-0415.2/24 2nd draft

ATTY/TYPIST: MW:akl

BRIEF DESCRIPTION: Updating the Washington vaccine association's definitions.

1 AN ACT Relating to updating the Washington vaccine association's
2 definitions; amending RCW 70.290.010; and declaring an emergency.

3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

4 **Sec. 1.** RCW 70.290.010 and 2010 c 174 s 1 are each amended to
5 read as follows:

6 The definitions in this section apply throughout this chapter
7 unless the context clearly requires otherwise.

8 (1) "Association" means the Washington vaccine association.

9 (2) "Covered lives" means all persons under the age of nineteen
10 in Washington state who are:

11 (a) Covered under an individual or group health benefit plan
12 issued or delivered in Washington state or an individual or group
13 health benefit plan that otherwise provides benefits to Washington
14 residents; or

15 (b) Enrolled in a group health benefit plan administered by a
16 third-party administrator. Persons under the age of nineteen for whom
17 federal funding is used to purchase vaccines or who are enrolled in
18 state purchased health care programs covering low-income children
19 including, but not limited to, apple health for kids under RCW
20 74.09.470 and the basic health plan under chapter 70.47 RCW are not
21 considered "covered lives" under this chapter.

1 (3) "Estimated vaccine cost" means the estimated cost to the
2 state over the course of a state fiscal year for the purchase and
3 distribution of vaccines purchased at the federal discount rate by
4 the department of health.

5 (4) "Health benefit plan" has the same meaning as defined in RCW
6 48.43.005 and also includes health benefit plans administered by a
7 third-party administrator.

8 (5) "Health carrier" has the same meaning as defined in RCW
9 48.43.005.

10 (6) "Secretary" means the secretary of the department of health.

11 (7) "State supplied vaccine" means vaccine purchased by the state
12 department of health for covered lives for whom the state is
13 purchasing vaccine using state funds raised via assessments on health
14 carriers and third-party administrators as provided in this chapter.

15 (8) "Third-party administrator" means any person or entity who,
16 on behalf of a health insurer or health care purchaser, receives or
17 collects charges, contributions, or premiums for, or adjusts or
18 settles claims on or for, residents of Washington state or Washington
19 health care providers and facilities.

20 (9) "Total nonfederal program cost" means the estimated vaccine
21 cost less the amount of federal revenue available to the state for
22 the purchase and distribution of vaccines.

23 (10) "Vaccine" means ~~((a preparation of killed or attenuated~~
24 ~~living microorganisms, or fraction thereof, that upon administration~~
25 ~~stimulates immunity that protects against disease and is))~~ an
26 immunization approved by the federal food and drug administration as
27 safe and effective and recommended by the advisory committee on
28 immunization practices of the centers for disease control and
29 prevention for administration to children under the age of nineteen
30 years.

31 NEW SECTION. **Sec. 2.** This act is necessary for the immediate
32 preservation of the public peace, health, or safety, or support of
33 the state government and its existing public institutions, and takes
34 effect immediately.

--- END ---

September 21, 2023

WVA Meeting of the Vaccine Committee

Proposed Form of Votes

The following are suggested forms of votes only. They are intended to be an aid to facilitate work by individual directors and committee members.

Items under Agenda Section 5:

VOTE ON COURSE
OF ACTION:

OPTION 1: WVA to Work with DOH to Make RSV Monoclonal Antibody Part of WA State Universal Vaccine Purchase Program

OPTION 2: WVA to Develop a Funding Mechanism to Protect Against Liability Pending Modification of Statute Governing WVA

OPTION 3: WVA to Collaborate with DOH, WCAAP, and Others to Modify Statute this Legislative Session to Update Definition of a Vaccine