

Hawaii Vaccines for Children Newsletter



Winter Edition / January 2024

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Recent Hawaii VFC Vaccine Formulary Updates

Sharing recent and upcoming additions to the Hawaii VFC Program vaccine formulary:

Sanofi Nirsevimab (Beyfortus) RSV Monoclonal Antibody

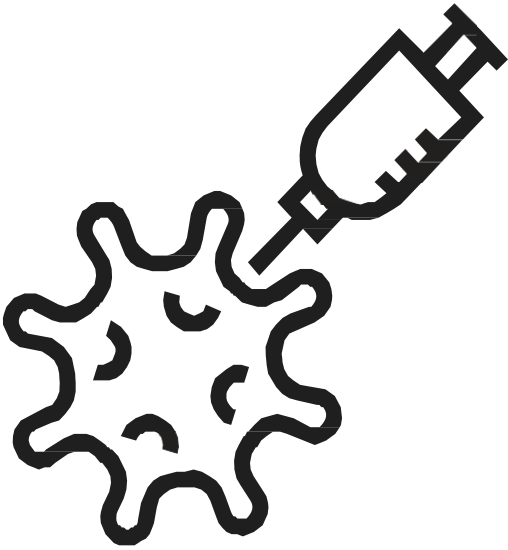
- Due to extremely limited supply and the current nationwide shortage:
 - ❖ **50mg** doses for administration to VFC-eligible newborns remain available for distribution to VFC-enrolled Birthing Hospitals only.
 - ❖ **100mg** doses (for administration to infants weighing >5kg) are available for limited VFC provider order/distribution.
- Orders may be placed via submission of the attached VFC Nirsevimab Monoclonal Antibody Order Form (1/3/24).
- VFC Nirsevimab orders/administration must adhere to prioritization criteria specified in: [Med-Advisory-RSV-mAb-and-Vaccine-12_27_2023.pdf \(hawaii.gov\)](#) (see: "During Times of Beyfortus Shortage", p. 4-5).

Pfizer Abrysvo Maternal RSV Vaccine (NDC 00069-0344-01)

- Abrysvo RSV vaccine is available for special order from the Hawaii VFC program for administration to VFC-eligible pregnant persons (18 years of age or younger) during 32 – 36 weeks gestation only.
- Due to limited availability, Hawaii VFC providers may request Abrysvo **ONLY** if they have specific VFC-eligible patient(s) for which it is indicated, and they intend to administer the vaccine to. Abrysvo must be requested at specific patient-level single-dose increments.
- See: [Med-Advisory-RSV-mAb-and-Vaccine-12_27_2023.pdf \(hawaii.gov\)](#) for Hawaii-specific maternal RSV vaccination guidance.



Pfizer Comirnaty 12y+ Prefilled Syringes (NDC 00069- 2377-10)



- Effective 12/20/23, CDC discontinued distribution of Pfizer Comirnaty COVID-19 vaccine in single dose vials (NDC 00069-2362-10).
- Instead, CDC is now supplying a new Pfizer Comirnaty 12y+ COVID-19 prefilled syringe presentation (NDC 00069-2377-10).
- This new presentation will be direct-shipped from Pfizer at refrigerated temperatures (2°C - 8°C), must continue to be stored at refrigerated temperatures (2°C - 8°C) upon arrival, and may be used through the expiration date printed on the carton. ***The 10-week beyond-use-date (BUD) for refrigerated storage does not apply to this new prefilled syringe formulation.***
- **OF NOTE:** Pfizer will continue to allow providers to privately order the original manufacturer-filled syringes for age 12y+. Therefore, providers may have BOTH presentations in their storage units; private-stock prefilled syringes with a 10-week BUD and the new VFC-supplied prefilled syringes that can be used through the expiration date printed on the carton. If this occurs, please ensure staff are educated regarding the different storage requirements and ensure strategies are implemented to prevent potential errors.

ON THE HORIZON...

Pfizer Penbraya Combined Pentavalent Serogroup A, C, W, Y, and B Meningococcal (MenACWY-MenB) vaccine

- In October 2023, the ACIP voted to include Penbraya (MenACWY-MenB) vaccine in the VFC Program.
- After ACIP adds a vaccine to the VFC program, CDC must establish purchasing contracts with the vaccine manufacturer before it can be ordered/distributed to VFC-enrolled providers.
- ***The Hawaii VFC program is currently waiting for CDC to announce the availability of purchasing contracts before we can begin supplying this vaccine.***
- ***Until purchasing contracts are established, it is also not yet known which Penbraya NDCs will be available for order from the VFC program.***
- For ACIP/VFC Penbraya vaccine administration guidance, please see the table below (excerpted from [ACIP Vaccines for Children Program-Resolution No. 10/23/1 \(cdc.gov\)](#), p. 4).



Recommended Vaccination Schedule and Intervals

The table below displays dosing schedules for MenACWY-TT-MenB-FHbp (Penbraya) (1).

Children at Increased Risk		Children not at Increased Risk
Dosing Schedule (Primary Series)	Dosing Schedule (Boosters)	
<p>For children with persistent complement deficiencies, complement inhibitor use (2), or functional or anatomic asplenia who are due for both MenACWY and MenB vaccination: 1 dose may be given in lieu of the first dose of MenACWY and MenB-FHbp</p> <p>If subsequent doses of MenACWY and MenB-FHbp (3) are indicated less than 6 months after the first dose, the vaccines should be given separately according to the MenACWY and MenB tables above.</p>	<p>For subsequent doses, where both MenACWY and MenB are indicated and at least 6 months have passed since administration of a previous dose of MenACWY-TT-MenB-FHbp, MenACWY-TT-MenB-FHbp may be used.</p>	<p>Initial dose: may be given in lieu of MenACWY and MenB when both vaccines are indicated in the same visit (e.g., age 16 years) and shared clinical decision-making favors administration of MenB</p> <p>Second dose: The MenB series should then be completed with monovalent MenB-FHbp.</p>

(1) Use of brand names is not meant to preclude the use of other comparable US licensed vaccines

(2) Includes eculizumab (Soliris) and ravulizumab (Ultomiris)

(3) MenB vaccines are not interchangeable by manufacturer. Administration of a B component vaccine (MenB or MenACWY-TT-MenB-FHbp) requires that subsequent B component vaccine doses be from the same manufacturer.

Combination Refrigerator/ Freezer Units

If you are considering purchasing a new storage unit, please contact the Hawaii VFC Program to ensure the unit meets VFC requirements.

Hawaii Vaccines for Children Program

Phone: (808) 586-8300,

(Toll-Free) Neighbor Islands 1-800-933-4832

Email: HawaiiVFC@doh.hawaii.gov

- If you are currently using a household combination refrigerator/freezer, we strongly recommend the purchase of a stand-alone freezer. Should either section of your combination unit experiences a temperature excursion, you would be required to purchase a stand-alone freezer.
- Starting July 2024, if you are using a household combination unit, it will be necessary that you use only the refrigerator section of your unit and purchase a stand-alone freezer for your frozen vaccine. **The use of the freezer section of a household combination unit will no longer be allowed by the VFC program for vaccine storage.**
- Research conducted by the National Institute of Standards and Technology (NIST) indicate that household combination units are not as efficient in maintaining appropriate storage temperatures for both the refrigerator and freezer sections. This is primarily because many combination units share a single compressor, resulting in a direct transfer of cold air from the freezer to the refrigerator compartment. This airflow pattern may cause temperature excursions that could potentially affect the integrity of sensitive vaccines.

Talk to a Clinician

Respiratory Syncytial Virus (RSV) prevention has grown, but it has become confusing! I heard Hawaii is unique. Can you help us make sense of it? What is Nirsevimab (Beyfortus), the new recommendations for Abrysvo, and when will we have it in the office?

RSV Season Here in Hawaii

What makes Hawai'i "unique" is the pattern of RSV circulation that does not fit a classic "seasonal" pattern. Epidemiologic data reveals RSV peak incidence in Hawaii often extends from the beginning of August through the end of March but can vary considerably from year to year, and circulation generally continues with at least low to moderate incidence even when the U.S. mainland season has ended. Based on review of RSV trends in Hawai'i from 2017 to present, the Hawai'i Department of Health (HDOH), in collaboration with the CDC and Hawai'i RSV Prevention Committee (a Hawai'i based committee consisting of local pediatric subspecialties, community physicians and pharmacies from the major healthcare systems), recommend year-round administration of Beyfortus and Abrysvo. For more detailed information on Beyfortus, Abrysvo and recommendations during times of Beyfortus shortages, please see:

[Hawai'i Medical Advisory on Maternal RSV Vaccination and Infant RSV Monoclonal Antibody for Year-Round RSV Prevention](#)

HERE ARE SOME HIGHLIGHTS:

Dosing:

- Once for all infants under 8 months of age
- Some [high-risk populations](#)* < 20 months of age should receive a second dose of Beyfortus to protect them during their 2nd RSV season. Synagis (Palivizumab, SOBI) is recommended for this population if Beyfortus is not available.

Beyfortus (Nirsevimab)

We here at the Hawai'i Department of Health are excited! Finally, we can protect our most vulnerable keiki with the new RSV monoclonal antibody (mAb), Beyfortus which received FDA and ACIP approval this summer. Beyfortus is a recombinant human IgG1 kappa mAb targeting the conserved binding pre-fusion RSV F protein preventing the virus uptake into the cell. However, there is a shortage of supply this first season. Beyfortus has been approved by CDC to be included in the VFC Program for eligible infants and children, however the doses are being allocated out in small quantities. The Hawai'i Immunization Branch does not have visibility into the commercial sector, but we have heard that doses are scarce there as well. While doses are difficult to obtain, we highly recommend pregnant individuals between 32 weeks and 0 days through 36 weeks and 6 days' gestation get vaccinated with Abrysvo vaccine. Providers please keep in mind, if a child does not receive this monoclonal antibody in the hospital, their primary care provider or in some cases specialty provider will be their only access point.

Beyfortus™ comes in a ready-to-use pre-filled syringe¹

A single administration based on infant's weight at the time of Beyfortus™ administration*



- Can be administered concomitantly with childhood vaccines[†]
- IM injection, preferably in the anterolateral aspect of the thigh[‡]

Dose & Indication

- **50 mg:** Infants <8 months old, weight <5kg (11 lbs)
- **100 mg:** Infants <8 months old, weight ≥5kg (≥11 lbs)
- **200mg (administer two 100mg injections on same day at different sites):** Infants and Children 8–19 months with increased risk of severe RSV disease

Highlights cont...

- Timing: Ideally, Beyfortus is given in the birthing hospital before discharge for all infants. For NICU infants, this may be delayed until graduating from the NICU. Otherwise, administer in the first week of life in the provider's office.
 - For infants aged <8 months, administer as soon as Beyfortus available. See the Hawai'i Medical Advisory on Maternal RSV Vaccination and Infant RSV Monoclonal Antibody for specific clinical situations when Beyfortus is recommended even if maternal RSV vaccination was given ≥ 14 days prior to delivery (e.g., maternal immunocompromise, infant placed on ECMO, etc), and for recommendations regarding timing of dose in preterm infants requiring admission to the neonatal intensive care unit.
 - For children aged 8-19 months who are at increased risk of severe RSV disease, administer at least 6 months after first dose.
- Distribution: VFC providers may receive VFC supplied vaccine based on availability of allocated doses from CDC. Commercial avenues are open to purchase for privately insured, but as stated before, there are large supply constraints currently.
- Co-administration: May be given with age-appropriate routine childhood vaccines.
- Safety and Efficacy: Provides high, consistent efficacy against medically attended RSV lower respiratory tract disease with a [favorable safety profile](#).
- Coding: Please find a link to CPT codes here [AAP CPT Codes Befortus™](#). Current CPT codes do not include counseling of families.
- During times of Beyfortus shortage:

For Pregnant Individuals

- Strongly encourage vaccination with Abrysvo during 32 weeks and 0 days through 36 weeks and 6 days' gestation as this protects their newborn after birth, by transferring antibodies to their unborn child. Maternal antibodies can provide passive immune protection to infants that lasts several months, significantly decreasing the risk of severe RSV infection during the first months of life. In addition, Abrysvo provides protection against RSV for the pregnant individual as well.
- Beyfortus is not recommended for most infants born to women who received Abrysvo ≥ 14 days prior to birth.
- There are currently no Abrysvo supply concerns or manufacturing shortages.

For Infants age <8 months:

- Recommend Beyfortus for infants born to patient who did not receive maternal RSV vaccine ≥ 14 days prior to birth, or if special clinical circumstances that impede the efficacy of Abrysvo.
- Prioritize in the following manner:
 - Those at [increased risk for severe RSV disease](#) (Note that there is a difference between risk factors for this group and the 8-19 month category)
 - American Indian and Alaska Native
- Follow [AAP recommendations on the use of Synagis](#) for infants aged <8 months when the appropriate dose of Beyfortus is not available.

For infants and children 8 months–19 months of age at continued [increased risk for severe RSV disease](#)

- Prioritize Beyfortus for the following patients:
 - Those living in remote regions or in communities known to have high rates of RSV among older infants and toddlers, such as those children outside of Oahu who would require air transportation to receive a higher level of medical care for RSV infection.
 - American Indian and Alaska Native children who are not Synagis-eligible
- Utilize Synagis for [palivizumab-eligible children](#)



Abrysvo (RSVpreFVaccine, Pfizer) for Maternal Vaccination

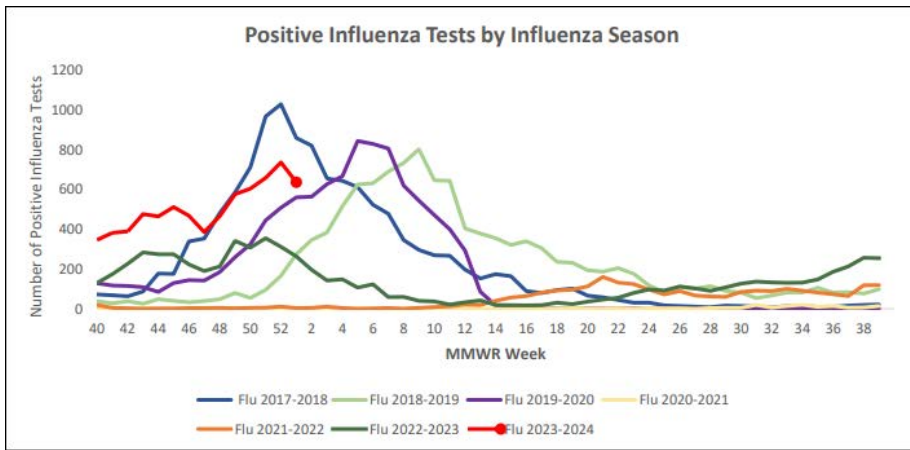
In September 2023, CDC's Advisory Committee on Immunization Practices (ACIP) recommended [RSV vaccination of pregnant women](#) between 32 weeks and 0 days through 36 weeks and 6 days' gestation with Abrysvo. Abrysvo had previously been recommended with [shared clinical decision making for those 60+](#). Abrysvo must be given ≥ 14 days prior to delivery in order to provide full protection to the infant. Maternal antibodies provide passive immune protection to infants for several months. Abrysvo is included in the Vaccines for Children (VFC) program for pregnant people under 19 years of age who meet VFC requirements. Abrysvo vaccine is NOT recommended for infants, children or nonpregnant teens.

There are currently no recommendations for additional doses of Abrysvo during subsequent pregnancies, and this is being actively researched.

*Arexvy (RSVpreF3 Vaccine, GSK) is **NOT** approved or recommended for use in pregnant people or children.*

For more information, please see [Hawaii VFC Office Hours presentation: RSV Updates For Hawaii](#)

SCHOOL LOCATED FLU VACCINATION EFFORTS



With Hawaii Influenza cases increasing, DOH is aiming to protect the community at large by coordinating school-located vaccination clinics to help protect more school-aged children. These school-located vaccination clinics are being provided through partnerships between DOH and several Community Vaccination Providers. Some of the providers include: **Kalihi Palama Health Center, Wahiawa Center for Community Health, Waikiki Health Center, Pharmicare, Kaiser Permanente and CHAMPS Pediatrics.** DOH has collaborated with these providers to offer 24 total flu vaccination clinics in 20 schools on Oahu and Maui.

As we continue our efforts for 2024, our goal is to facilitate more school-located vaccination clinics on Kauai, Maui, and the Big Island. Currently, DOH is seeking Community Vaccination Providers to conduct community and/or school-located vaccination clinics.

If you are interested in partnering to conduct vaccination event, please contact our HDOH Community Vaccination Program Specialist, Bridget Anthony at bridget.anthony.nsw@doh.hawaii.gov Phone: 808-927-9294

HELP BOX

Planning to ship expired/spoiled VFC vaccine as a return to the McKesson (CDC-contracted vaccine distributor)? A friendly reminder, VFC Providers should not reuse boxes with shipping warning labels to return VFC vaccines to McKesson. Boxes shipped with warning labels are **held** at the UPS facility in Honolulu and require pick-up by either Provider staff (on Oahu) or HDOH staff (for Neighbor Island Providers) for correction/repackaging.

Here are a few common examples of what those labels look like:



If you are unsure about a previously used box, and to avoid the inconvenience of having to pick-up and repackage VFC vaccine returns, please ensure all warning labels are completely covered or simply use a new blank box.

	U.S.	Hawaii
Influenza Activity Level	High	High
Predominant Circulating Influenza Strain	Influenza A (H1N1)	Influenza A (H1N1)
Age Groups most Affected	0-4 Years old	0-4 Years old



5 tips for reusing boxes (and staying out of trouble):

1. Cover all old text and unfamiliar markings/symbols.
2. Remove all previously used mailing address labels.
3. Avoid unusual boxes/containers.
4. Check the integrity of the box (if stable or flimsy).
5. Always remember, safety first – don't have your shipments feature warning labels that don't apply to the contents!

What is IQIP?

IQIP is CDC's national, Vaccines for Children (VFC) provider-level immunization quality improvement (QI) program. IQIP serves to assist and support health care providers by identifying opportunities to improve vaccine uptake and to help providers be:

- Motivated to try new vaccination service delivery strategies and incorporate changes into their current practices
- Supported in sustaining changes and improvement to their vaccination service delivery
- Aware of and knowledgeable about vaccination coverage and missed opportunities to vaccinate
- Able to use available data from the IIS to improve services and coverage

What are IQIP's Strategies?

Immunization Quality Improvement for Providers (IQIP) promotes and supports implementation of provider-level strategies designed to help increase on-time vaccination of children and adolescents. The IQIP strategies call for quality improvement activities that focus on improvements to the vaccination workflow.

IQIP supports both **implementation** and **improvement** of these strategies. If your practice is already using one of these strategies, IQIP may give you the opportunity to further advance that strategy and develop new action items to improve your vaccination workflow.

Schedule the next vaccination visit before the patient leaves the provider location

On-time vaccination depends upon returning for subsequent doses as recommended in the **Advisory Committee on Immunization Practices (ACIP)** recommended immunization schedule.

Scheduling the next visit before the patient leaves the office promotes adherence to the schedule by:

- Explicitly specifying when future doses are due and why
- Establishing continuity of care by supporting the patient's return to the office
- Creating a commitment to return and reducing barriers to act on favorable intentions to vaccinate

Leveraging the Hawaii Immunization Registry (HIR)/Electronic Medical Records (EMR) functionality to improve immunization practice

On-time vaccination depends on knowing what vaccines a patient is due for and when. High-quality data in the IIS can support providers by:

- Providing consolidated vaccination records for each patient
- Generating lists of patients due for vaccines
- Forecasting future dose due dates to assist with scheduling
- Delivering reminders for upcoming appointments
- Providing practice-based coverage assessments

IQIP

*The purpose of IQIP is to **promote and support the implementation of provider-level strategies designed to help increase on-time vaccination of children and adolescents***

Give A Strong Vaccine Recommendation (include HPV vaccine if the provider has adolescent patients)

On-time vaccination is dependent upon parents choosing to vaccinate their children and adolescents. As parents' most trusted source of vaccine information, health care professionals are well positioned to increase vaccine acceptance.

Strengthen Vaccination Communications

Myths and misinformation about vaccines put on-time vaccination at risk. Trust in vaccines is not built through a top-down approach, but through conversations between parents, doctors, nurses, pharmacists, and community members. Patients and parents can feel more confident about vaccinating when everyone in the practice shares the same message. Strengthening vaccine communications engages provider staff as vaccine partners by helping them:

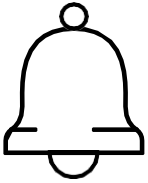
- Increase positive vaccination messaging throughout their practice
- Provide accurate, easily accessible information on vaccines
- Engage in effective vaccine conversations with parents

If you have any questions about the program, or are interested in participating in the IQIP cycle, please contact Danrie Miral at danrie.miral.nsw@doh.hawaii.gov

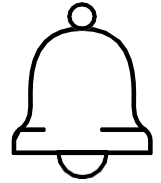
2024 VFC Re-enrollment Reminder!

2024 Hawaii Vaccines for Children Program enrollment forms are due by **1/31/24**.

Enrollment packets were mailed to all VFC provider offices during the week of 11/15/23. If you did not receive or are unable to locate your VFC enrollment packet, please contact:



Hawaii Vaccines for Children Program
Phone: (808) 586-8300, Neighbor islands 1-800-933-4832 (Toll-Free) Email: HawaiiVFC@doh.hawaii.gov.



***Note, re-enrollment is a four-step process this year:**

Step 1: Complete the VFC Enrollment/Profile form and ensure it is signed and dated.

Step 2: Ensure your VFC Vaccine Coordinator and Back-Up Coordinator complete the two required CDC “You Call the Shots” modules indicated below. Completion of the modules is also recommended for anyone in your office who handles, prepares, or administers VFC vaccine.

- Vaccines For Children Program: [You Call the Shots-Module 16-Vaccines for Children Program - 2024 WB4724 - CDC TRAIN](#)
- Vaccine Storage and Handling: [You Call the Shots-Module 10-Storage and Handling - 2024 WB4723 - CDC TRAIN](#)

Step 3: Complete the annual review/update of your office’s VFC Vaccine Management Plan. Be sure to document the “Annual Review Date” and the name, signature, and credentials of the Vaccine Coordinator or Back-Up Coordinator who completed the review on the first page of your VFC Vaccine Management Plan.

Step 4: By **January 31, 2024**, submit completed VFC Enrollment/Profile forms (Step 1), Training Certificates of Participation (Step 2), and your entire reviewed VFC Vaccine Management Plan (Step 3) via email, fax or mail:

Email: HawaiiVFC@doh.hawaii.gov

Fax: 808-586-8302

Mail to:

Hawaii Department of Health

ATTN: Vaccines for Children Program

P.O. Box 3378

Honolulu, HI 96801

VFC vaccine ordering privileges will be **suspended** for providers/facilities that do not submit VFC enrollment information by January 31, 2024.

For more information, please see:

[Hawaii Vaccines for Children \(VFC\) 2024 Re-Enrollment](#)

HIR Annual Enrollment Reminder!

January 31, 2024 is the due date for the HIR users to complete the annual enrollment forms: Facility Agreement (FA) and Confidentiality and Security Statement (CSS) forms. If you are the physician or organization/site administrator for your location, please fill out the online FA form upon logging in HIR. After January 31, if FA has not been completed, the HIR users at your site will not be able to access the system. Please also ensure that all the users submit their CSS form (pdf version), which is available on our HIR log-in page under the “Forms” tab.

If you have any questions, please contact registryhelp@doh.hawaii.gov Mahalo!

CDC Continuing Education Update

CDC's continuing education (CE) process is moving from Training and Continuing Education Online (TCEO) to CDC TRAIN.

- Beginning on January 1, 2024, new activities that offer CE from CDC such as the following modules are required for VFC Re-enrollment and will be listed in CDC TRAIN (<https://courses.cdc.train.org>).
 - [You Call the Shots Module 10 - Storage and Handling](#)
 - [You Call the Shots Module 16 - Vaccines for Children Program](#)

If you do not already have a TRAIN account, please create one. All new activities that offer continuing education (CE) from CDC will only be listed in CDC TRAIN.

- Tutorials on CDC Train can be found here: <https://www.train.org/tutorials/>

For further assistance, we encourage you to participate in our Virtual Hours every Tuesday at 8 am! A member of our Quality Assurance team will be available live to help you with any questions, concerns or feedback you might have regarding the VFC program.

Kindly refer to the link provided [here](#).

Hawaii Department of Health Immunization Branch VFC Program



Email: HawaiiVFC@doh.hawaii.gov

Telephone: 808-586-8300

Toll Free for Neighbor Islands: 1-800-933-4832

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