



STATE OF HAWAII
DEPARTMENT OF HEALTH
KA 'OIHANA OLAKINO
P. O. BOX 3378
HONOLULU, HI 96801-3378

In reply, please refer to:
File:

August 24, 2024

MEDICAL ADVISORY: INFANT RSV MONOCLONAL ANTIBODY FOR YEAR-ROUND RSV PREVENTION IN INFANTS IN HAWAII

- RSV protection is recommended year-round in Hawaii; Hawaii Department of Health (HDOH) in collaboration with the Hawaii RSV Prevention Committee and CDC recommend prevention of RSV for *all* infants through either maternal vaccination or administration of Beyfortus (Nirsevimab-alip, Sanofi and Astra Zeneca) to the infant.
- Since its introduction, supply of Beyfortus doses has been constrained in both the public (Vaccines For Children Program [VFC]) and private (commercial) sector. Constraints are expected to ease in the coming months, and given the limited window to immunize Hawaii's keiki under 8 months of age, providers are encouraged to act quickly to appropriately immunize indicated patients.
- Beyfortus formulations are administered based on infant's weight. Due to supply constraints, Hawaii VFC program distribution remains restricted as follows:
 - 50 mg doses available from the VFC program for administration to newborns weighing less than 5kg are only supplied to Hawaii Birthing Hospitals. Birthing Hospitals are encouraged to immunize all VFC-eligible and privately insured newborns with supply obtained through the Vaccine for Children (VFC) Program (VFC-eligible infants only) or the commercial sector (non-VFC-eligible newborns).
 - Outpatient provider practices seeing newborns are encouraged to immunize indicated patients less than 8 months of age and weighing ≥ 5 kg with 100mg doses of Beyfortus obtained through VFC (for VFC-eligible infants only) and the commercial sector (for non-VFC eligible infants).

Dear Healthcare Providers,

Respiratory Syncytial Virus (RSV) continues to be the leading cause of hospitalization among U.S. infants. In 2023, two new medications were approved by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to provide RSV protection for infants: Abrysvo (RSVpreF Vaccine, Pfizer), a vaccine given to pregnant patients to create maternal antibodies that are passed to the newborn, and Beyfortus (Nirsevimab, Sanofi and Astra Zeneca), a monoclonal antibody administered to infants. Due to continued Beyfortus supply constraints, providers are strongly advised to encourage vaccination of pregnant patients with Abrysvo. For more information on these vaccines, dosing and recommendations see the [State of Hawaii Medical Advisory issued on December 27, 2023](#).

What Has Changed?

Current availability of private-sector Beyfortus doses and updates to the Federal Vaccines for Children (VFC) program Beyfortus distribution strategy.

HDOH has confirmed with Sanofi that there is currently an opportunity for ALL providers to directly order commercially-supplied Beyfortus doses for administration to privately insured patients. Please contact your local Sanofi representative or call 1-855-BEYFORTUS to learn more. CDC has implemented a new “top-off” strategy for VFC Beyfortus supply, which involves replenishing doses allocated to the Hawai‘i VFC program every 2 weeks. Note, if Hawai‘i’s VFC Beyfortus allocation is above a CDC-determined threshold, no additional Beyfortus doses will be apportioned to the Hawai‘i VFC Program. **In order to successfully distribute supply needed to immunize Hawai‘i’s VFC-eligible newborn population, HDOH is requesting that providers place orders with the Hawai‘i VFC Program to ensure maximum CDC replenishment of Hawaii VFC allocations every two weeks.** Note that if VFC provider requests exceed available CDC VFC allocations, VFC provider orders will be waitlisted and/or partially fulfilled as supply permits.

Guidance for Birthing Hospitals:

Please continue to order the amount of VFC 50mg doses needed for a two-week period. The Hawai‘i VFC program will work with your facilities to distribute as many doses as possible for administration to VFC-eligible newborns. With the amount of VFC doses currently allocated to the Hawaii VFC program, inclusive of CDC “top-offs” every two weeks, we anticipate supply should be sufficient to cover estimated birthing cohorts, provided birthing trends are similar to previous years.

Guidance for Outpatient VFC Providers:

Please order the amount of 100mg doses needed to immunize VFC-eligible patient population aged 8 months or less and weighing ≥ 5 kg for a one-month period. Note that if VFC provider requests exceed available VFC allocations, VFC provider orders may be waitlisted and/or processed for partial fulfillment as supply permits. It is anticipated that VFC providers should be able to order enough doses to vaccinate their entire VFC-eligible population by December 2024. Please do not delay in offering VFC doses to eligible patients during their routine well baby visits.

What Has Not Changed?

HDOH and the Hawai‘i VFC program understand that the ideal distribution strategy would include a supply of Beyfortus 50mg doses sufficient to distribute to ALL VFC providers. Unfortunately, limited allocations currently remain insufficient. In the meantime, HDOH and the Hawai‘i VFC program strongly encourages Birthing Hospitals to immunize ALL VFC-eligible

newborns before discharge and for outpatient VFC providers to focus on immunizing patients under the age of 8 months, weighing ≥ 5 kg with VFC-supplied 100mg doses. If a VFC-eligible newborn is unable to receive VFC-supplied Beyfortus in their birthing hospital, we encourage the hospital to coordinate the transfer of a 50 mg VFC Beyfortus dose to the infant’s outpatient VFC provider to facilitate immunization.

Beyfortus Dosing:

Dose	Indications
50mg	Infants <8 months old, weight <5kg (11 lbs)
100mg	Infants <8 months old, weight ≥ 5 kg (≥ 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*

HDOH recognizes that implementation of RSV immunization in the public and private sector remains challenging, but we encourage your persistence as we work toward ongoing resolution of supply and reimbursement issues. There is incredible benefit to immunizing as many of our keiki as possible against RSV. We appreciate your efforts and are committed to supporting you in this endeavor to the best of our ability with the doses we have available. If you have any questions, comments, or concerns regarding VFC Beyfortus ordering or distribution, please contact the Hawai‘i VFC Program at 808-586-8300, 1-800-933-4832 (toll-free) or HawaiiVFC@doh.hawaii.gov.

Sincerely,



Sarah K. Kemble, M.D.
State Epidemiologist

Additional Resources:

AAP Recommendations on Palivizumab:

<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/>

[AAP Guidance on RSV Prevention Resources for Providers: https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/](https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/)

ACIP Abrysvo Recommendations for Pregnant Individuals:

<https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm>

Adverse Event Reporting after Immunization:

- For Beyfortus use the FDA Medwatch:
<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>
- For Abrysvo use the Vaccine Adverse Event Reporting System (VAERS):
<https://vaers.hhs.gov/>

CDC HAN on Nirsevimab shortage:

<https://emergency.cdc.gov/han/2023/han00499.asp>

CDC MMWR on Nirsevimab:

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm?s_cid=mm7234a4_w

CDC’s List of Who is at High Risk for Disease:

<https://www.cdc.gov/rsv/high-risk/infants-young-children.html>

[Beyfortus can be considered even when maternal RSV vaccination was completed](#) ≥ 14 days prior to delivery. These circumstances may include, but are not limited to:

- Infants born to pregnant people who may not mount an adequate immune response to RSV vaccination (e.g., people with immunocompromising conditions)
- Infants born to pregnant people who have medical conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)
- Infants who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation (ECMO), leading to loss of maternal antibodies
- Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with a requirement of oxygen at discharge).

High Risk Categories for RSV requiring prioritization by Season:

1st Season:

- Premature birth at <29 weeks’ gestation
- Chronic lung disease of prematurity

- Hemodynamically significant congenital heart disease
- Severe immunocompromise
- Severe cystic fibrosis (either manifestations of severe lung disease or weight-for-length less than 10th percentile)
- Neuromuscular disease
- Congenital pulmonary abnormalities that impair the ability to clear secretions.

Reference: CDC HAN <https://emergency.cdc.gov/han/2023/han00499.asp>

2nd Season (Additionally, a dose of RSV antibody is also recommended for children between the ages of 8 – 19 months entering their second RSV season who are in at least one of these groups):

- Children who have chronic lung disease from being born premature and are requiring medical therapy for their lung disease
- Children who are severely immunocompromised
- Children with cystic fibrosis who have severe disease
- American Indian and Alaska Native children

Reference: CDC MMWR <https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm>

Hawaii Department of Health Influenza and Respiratory Surveillance Weekly Report
<https://health.hawaii.gov/docd/resources/reports/influenza-reports/>.