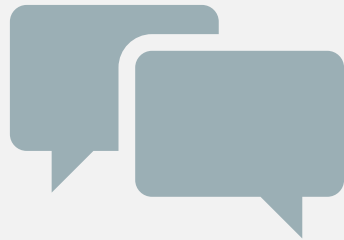


RESPIRATORY SYNCYTIAL VIRUS (RSV) UPDATES

January 9, 2024

QUESTIONS

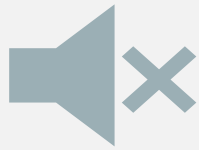


During today's webinar, please use the chat to ask your questions so the Hawaii VFC Program subject matter experts can respond directly.



We will be answering your questions at the end of the presentation.

HOUSEKEEPING



Reminder for QA Team:

Please mute yourself when not speaking.

Please monitor the chat for questions you may be able to answer.



Reminder to Attendees:

Today's session is being recorded. Slides and webinar recordings will be uploaded to:

<https://health.hawaii.gov/docd/for-healthcare-providers/vaccination-resources/vaccines-for-children-program-vfc/>



To be added to the Hawaii VFC Program email list, please email your request to hawaiiafc@doh.hawaii.gov. In the subject line of the email, please write **EMAIL LIST.**

RSV UPDATES FOR HAWAII

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CDC Public Health Advisor

OBJECTIVES

- By the end of the presentation, attendees should be able to:
 - Describe the RSV season in Hawaii
 - Describe RSV immunization recommendations

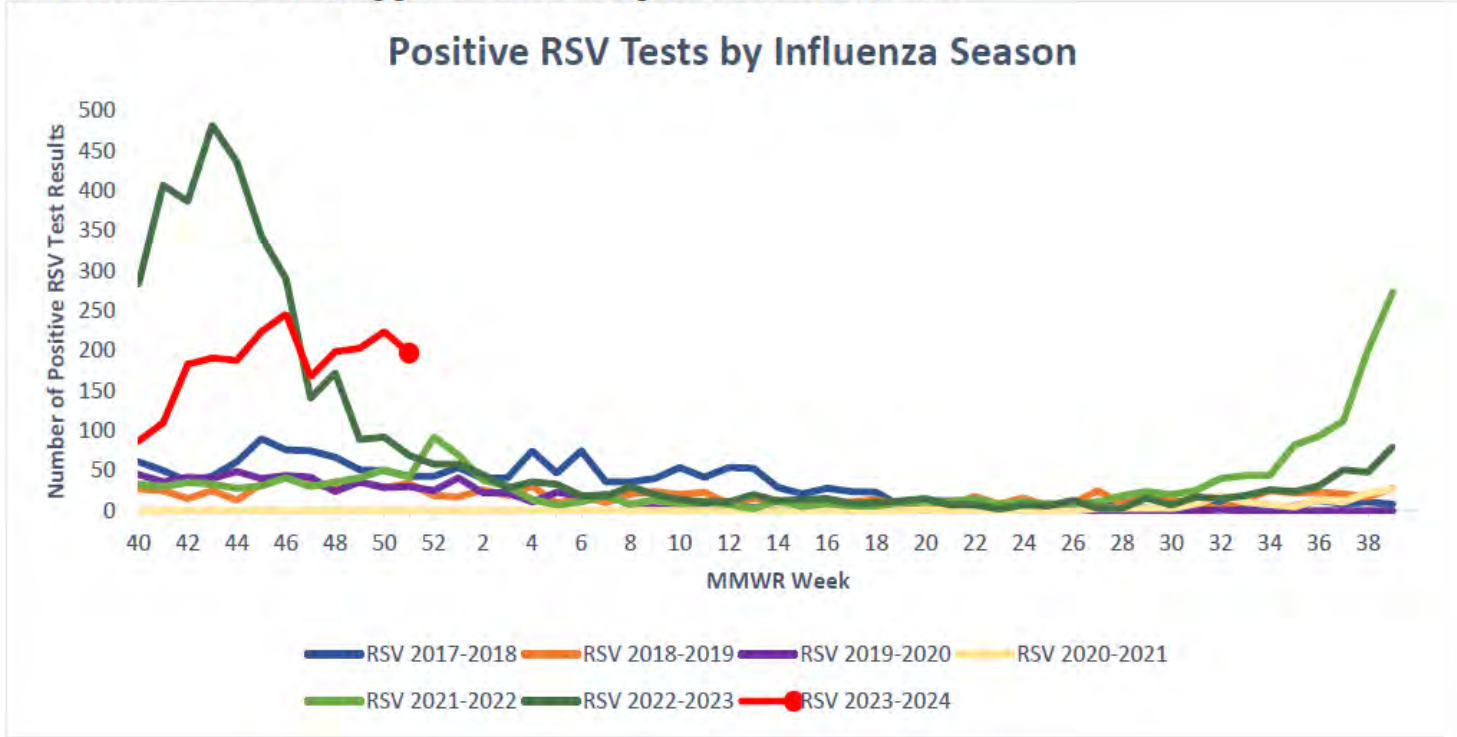
WHEN IS THE RSV SEASON IN HAWAII?

ALL YEAR



RSV BY
INFLUENZA
SEASON IN
HAWAII
1/5/24

RESPIRATORY SYNCYTIAL VIRUS (RSV) POSITIVE TEST RESULTS BY INFLUENZA SEASON: RSV case counts are lower than the previous season but is currently trending upwards for the 2023-2024 season. Of note, significantly more tests for RSV are being performed than in pre-COVID-19 seasons.





RECOMMENDATION

- Respiratory Syncytial Virus (RSV) continues to be the leading cause of hospitalization among U.S. infants
- In 2023, two 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
 - Previously this was just approved for those over 60 along with Arexvy
 - Beyfortus (Nirsevimab, Sanofi and Astra Zeneca), a monoclonal antibody administered to infants.



BEYFORTUS

- Approved for use by ACIP in August, 2023
- RSV monoclonal antibody (mAb)
- Recombinant human IgG1 kappa mAb targeting the conserved binding pre-fusion RSV F protein preventing the virus uptake into the cell
- Provides longer protection (at least 150 days) vs previous RSV monoclonal antibody, Synagis (30 days)
- Currently a national shortage for both the public (VFC) and private (commercially ordered) products
 - 1st discuss recommendations for when Beyfortus is available
 - 2nd discuss how to prioritize in times of Beyfortus shortages

BEYFORTUS RECOMMENDATIONS FOR HAWAI'I WHEN AVAILABLE

- Year-round immunization of every newborn, preferably before hospital discharge, with Beyfortus if the individual giving birth to the infant has not been vaccinated with Abrysvo ≥ 14 days prior to delivery.
 - If a birthing hospital dose of Beyfortus is not available, give Beyfortus within 1 week of birth.
- A second dose of Beyfortus should be administered to infants/children at continued risk for severe disease
 - 8-19 months old
 - At least 6 months between 1st and 2nd dose
 - Not enough data to recommend a 3rd dose for high-risk individuals

BEYFORTUS

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	Indications
50mg	Infants <8 months old, weight <5kg (11 lbs)
100mg	Infants <8 months old, weight ≥5kg (≥11 lbs)
100mg	Infants 6 to <8 months old and weight ≥5kg (≥11 lbs) with increased risk of severe RSV disease*
200mg (administer two 100mg injections on same day at different sites)	Infants and Children 8–19 months with increased risk of severe RSV disease

BEYFORTUS ADMINISTRATION WHEN AVAILABLE IN HAWAI'I

- Administer in the birthing hospital before discharge for all infants. For NICU infants, this may be delayed until graduating from the NICU.
- Administer in the first week of life in the provider's office if not given in birthing hospital
- For infants aged <8 months, administer as soon as Beyfortus™ available. For children aged 8-19 months who are at increased risk of severe RSV disease, administer at least 6 months after first dose.
- Given IM
- May be given with age-appropriate routine childhood vaccines

BEYFORTUS ADMINISTRATION REGARDLESS OF MATERNAL RSV VACCINATION

- There are a few instances when Beyfortus can be considered even if maternal RSV vaccination was completed ≥ 14 days prior to delivery. These circumstances may include, but are not limited to:
 - Infants born to a pregnant individual who may not mount an adequate immune response to RSV vaccination (e.g., people with immunocompromising conditions)
 - Infants born to a pregnant individual who has 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).

BEYFORTUS RECOMMENDATIONS FOR HAWAII DURING TIMES OF SHORTAGE

- Strongly encourage vaccination with Abrysvo during 32 weeks and 0 days through 36 weeks and 6 days' gestation
- 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 (see Additional Resources).
 - Prioritize in the following manner:
 - those at [increased risk for severe RSV disease](#)
 - 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.

BEYFORTUS RECOMMENDATIONS FOR HAWAII DURING TIMES OF SHORTAGE

- 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](#)

BEYFORTUS: HIGH RISK CATEGORIES

1st Season

- Premature birth at <29 weeks' gestation
- Chronic lung disease of prematurity
- Hemodynamically significant congenital heart disease
- Severely immunocompromised
- 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.

2nd Season

- 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

BEYFORTUS ORDERING

- Limited allocations received from CDC for Hawaii VFC Program
 - Orders may be reduced or waitlisted
- Due to extremely limited supply, VFC ordering for the 50mg presentation will remain restricted to Birthing Hospitals only
- Any VFC provider may request the 100mg presentation for administration to VFC-eligible infants that meet Hawaii-specific prioritization criteria
- **Orders must be placed using the VFC Nirsevimab Monoclonal Antibody Order Form**

BEYFORTUS ORDERING

NDC	Product/Presentation	Weight Indication	NOTES
49281-0575-15	Nirsevimab-alip 50mg Beyfortus™, single dose syringe, 5 syringes/carton	50mg for VFC eligible infants <5kg	Available to Birthing Hospitals only. Birthing Hospital VFC orders/administration must adhere to prioritization criteria specified in HDOH Medical Advisory issued 12/27/23 (see: "During Times of Beyfortus Shortage", p. 4-5).
49281-0574-15	Nirsevimab-alip 100mg Beyfortus™, single dose syringe, 5 syringes/carton	100mg for VFC eligible infants ≥5kg	Available to all VFC providers, however VFC Vaccine orders/administration must adhere to prioritization criteria specified in HDOH Medical Advisory issued 12/27/23 (see: "During Times of Beyfortus Shortage", p. 4-5).

ABRYSVO VACCINE

- Approved by ACIP for use in pregnant people under 19 years of age who meet VFC requirements
 - **Medicaid** (Quest) eligible
 - **Uninsured**
 - A child who has no health insurance coverage
 - **American Indian or Alaska Native**
 - A patient who self-identifies as uninsured or American Indian/Alaska Native requires no additional proof, and providers are not required to verify the patient's eligibility declaration.
 - **Underinsured**
 - A child who has private health insurance, but the coverage does not include vaccines
 - A child whose insurance covers only selected vaccines.
 - Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Center (RHC).

No other factor can be considered when screening for eligibility.

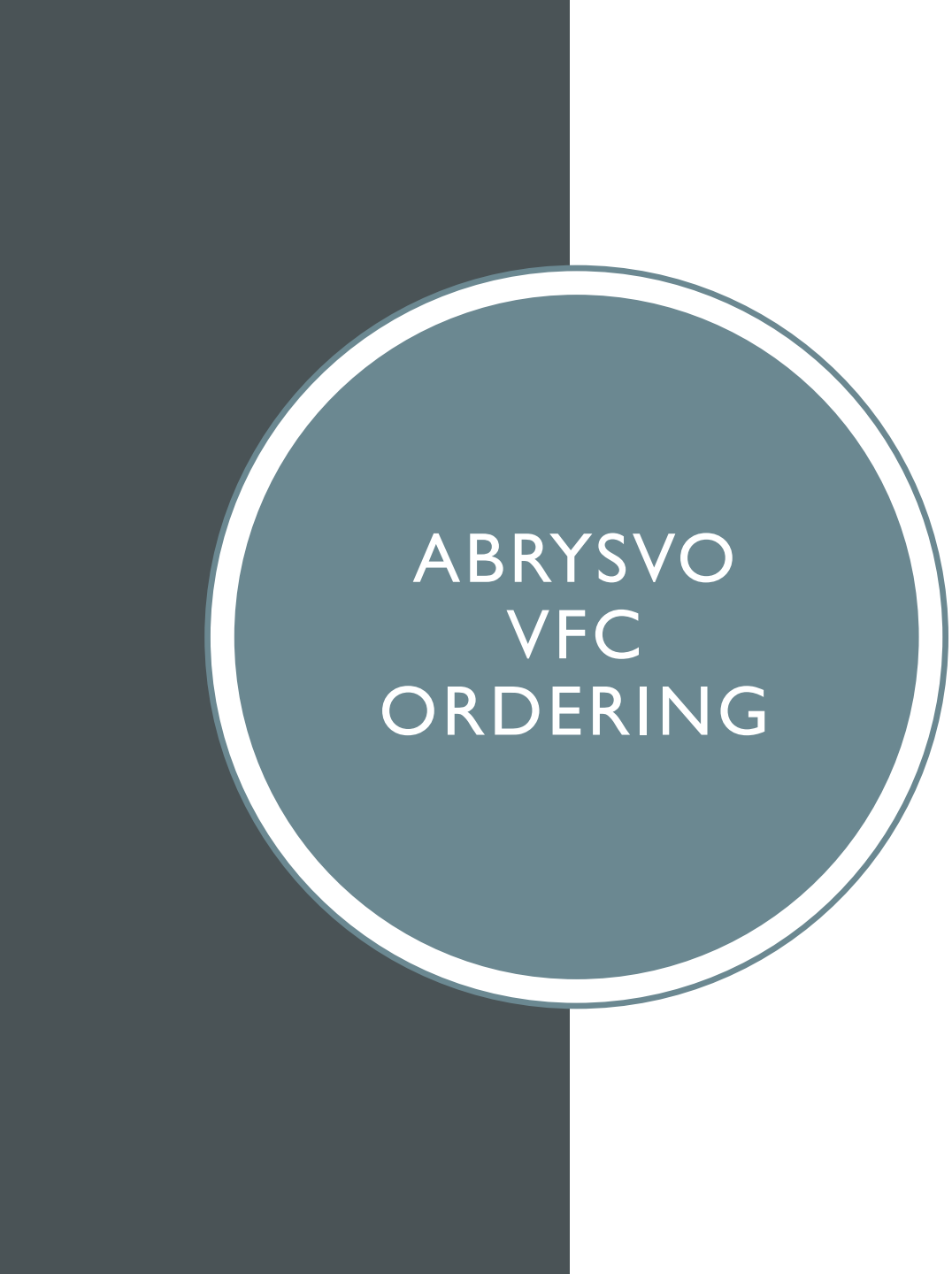
ABRYSVO RECOMMENDATIONS FOR PREGNANT WOMEN

- Recommended for pregnant women during 32 weeks and 0 days through 36 weeks and 6 days' gestation
 - No preference for Abrysvo vs Beyfortus in times of ample supply
 - Beyfortus is not recommended for most infants born to women who received Abrysvo ≥ 14 days prior to birth.
- Provides protection to infant
 - Maternal antibodies provide passive immune protection to infants that lasts several months, significantly decreasing the risk of severe RSV infection during the first months of life.
- Protection against RSV for the pregnant individual as well.

ABRYSVO RECOMMENDATIONS FOR PREGNANT WOMEN

- There are currently no Abrysvo supply concerns or manufacturing shortages.
- Not recommended for:
 - Infants
 - Children
 - Nonpregnant teens
- Currently no recommendations for additional doses of Abrysvo during subsequent pregnancies

NOTE: Arexvy (RSVpreF3 Vaccine, GSK) is NOT approved or recommended for use in pregnant people and is not available through Hawaii VFC Program



ABRYSSVO
VFC
ORDERING

- VFC providers will not be permitted to routinely stock Abrysvo vaccine.
- Special order via the Hawaii Immunization Registry (HIR)
- ONLY for administration to VFC-eligible pregnant patients (i.e., pregnant individual must be VFC eligible-and under the age of 19 years) between 32 weeks and 0 days through 36 weeks and 6 days' gestation
- May only be ordered if a VFC provider has **specific** VFC-eligible pregnant patients that are indicated to receive it.



SYNAGIS

- Monoclonal antibody
- Duration of protection is only 30 days, which is why monthly dosing is indicated during the RSV season for infants at high risk for severe RSV infection.
- Recommended by CDC and American Academy of Pediatrics (AAP) if Nirsevimab is unavailable for continued use for high-risk patients
 - If Beyfortus becomes available, and the infant or child has received less than 5 monthly doses the child should receive a 200mg dose of Beyfortus no later than 30 days after the last dose of Synagis.
 - No recommended minimum interval between dosing of Synagis and Beyfortus.
 - No further doses of Synagis will be required.
- **Not included in the VFC program, and prior insurance authorization is needed according to AAP guidelines for use.**

Q & A

CONTACT INFO

- For HIR technical/login issues please contact Registry Help Desk at (808) 586-4665, 1-888-447-1023 (toll-free), or registryhelp@doh.hawaii.gov.
- For Immunization Clinical Consultation, please call the Hawai'i Immunization Branch at (808)286-8349
- For any VFC-related questions/concerns, feel free to contact any member of our VFC QA Team

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POST
WEBINAR
SURVEY

- Please use the following link to complete the satisfaction survey
- https://forms.office.com/g/XStX9e_wn6e