

State of California—Health and Human Services Agency California Department of Public Health



November 3, 2023

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TO:	California Vaccines for Children (VFC) Providers
FROM:	Robert Schechter, M.D., Chief Are Successive Center for Infectious Diseases Division of Communicable Disease Control, Immunization Branch
SUBJECT:	Initial Allocation of Limited Nirsevimab (Beyfortus™) Supply; Interim CDC Clinical Guidance

BACKGROUND

On October 13, 2023, CDC paused ordering of nirsevimab for VFC programs in the US due to a shortage in supply. The shortage is expected to continue in both the public and private sector supplies throughout the 2023-2024 RSV season. According to the manufacturer, the anticipated supply of 100mg doses of nirsevimab is insufficient to protect all eligible infants and children weighing ≥5 kg this season. Supplies of 50mg doses will be less limited. As additional limited supplies are made available by the manufacturer, CDC is allocating these doses to states, at an interval currently estimated at every 2 to 3 weeks.

NIRSEVIMAB VFC ORDERING

The current allocation to the California VFC Program for both 50mg and 100mg formulation for nirsevimab is too small to resume ordering for all VFC providers. As a result, this current allocation is available only to hospitals, Tribal Health Clinics, selected Federally Qualified Health Centers (FQHCs)/Rural Health Centers (RHCs) and Public Health Department Clinics. Additional doses will be made available to additional VFC Providers as more doses are received. The VFC Program will provide timely updates on availability and ordering policies.

VFC ORDERING LIMITS

VFC orders for nirsevimab are limited, based on prior utilization of Hepatitis B vaccine birth doses at hospitals and pneumococcal conjugate vaccine for outpatient providers. The limits may be changed depending on supply.



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VFC PEDIATRIC RSV INVENTORY REQUIREMENT

VFC providers are typically required to maintain an inventory of both VFC and privately purchased immunizations. Given the shortage, the VFC program is temporarily suspending the requirement for providers that serve privately-insured patients to stock a private supply of nirsevimab. This requirement will go back into effect August 1, 2024.

NO IMMUNIZATION BORROWING

The California Vaccines for Children Program does not permit immunization borrowing. Although earlier this fall CDC allowed states to determine the feasibility of implementing borrowing, CDC now acknowledges that borrowing and replacing doses is not feasible during the shortage.

Limited VFC supply must remain prioritized for VFC eligible children. VFC providers are not allowed to use VFC doses for privately-insured individuals or vice versa. Private immunizations administered to VFC eligible children may not be able to be replaced by the VFC Program given limited supplies.

RECOMMENDATIONS FOR USE OF NIRSEVIMAB

During the shortage, providers should not administer more than one 50 mg dose of nirsevimab to children indicated for a larger dose.

Additional recommendations are described in: <u>Health Alert Network (HAN) - 00499</u> | Limited Availability of nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season

Thank you for your efforts and patience in these challenging circumstances.

RESOURCES

- CDC: <u>RSV for Healthcare Providers</u>
- CDC MMWR: Use of Nirsevimab for the Prevention of RSV Disease
- CDPH: <u>RSV webpage</u>
- AAP: <u>Palivizumab Prophylaxis in Infants and Young Children at</u> <u>Increased Risk of Hospitalization for Respiratory Syncytial Virus</u> <u>Infection</u>
- AAP: <u>Nirsevimab Frequently Asked Questions</u>