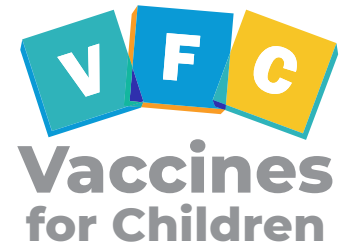


CDC's Vaccines for Children Program Addendum: Special Considerations for Nirsevimab

Updated 10/18/2023

Nirsevimab is an FDA-licensed monoclonal antibody that provides passive immunity against RSV-associated infection. On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) voted to recommend nirsevimab as an immunization for all infants aged <8 months, as well as some children up to age 20 months (see [ACIP recommendations](#)), and a [VFC resolution](#) was passed to include nirsevimab in the VFC program. This addendum provides supplemental information and guidance related to the addition of the nirsevimab immunization to the VFC formulary.



Inventory

- VFC providers will be allowed a flexible, time-limited ramp-up period to meet the private inventory requirement for nirsevimab. During this time, awardees will not require VFC providers to meet the private inventory minimum requirements for nirsevimab if they do not intend to vaccinate their private pay patients. VFC providers are required to meet the private inventory requirement no later than August 1, 2024.
 - This includes VFC providers who serve only Medicaid-eligible patients and no privately insured children; they are not required to privately purchase nirsevimab.
- If VFC providers utilize this flexibility to not maintain private stock during this season, providers should explore if other in-network options exist for their nirsevimab-insured private patients to access nirsevimab (i.e., from another local in-network practice or system that does have private inventory of nirsevimab, or FQHC, RHC, or deputized VFC provider authorized to immunize underinsured children).
 - CDC recognizes that with current supply and demand issues, this may not be possible, but if supply changes, we encourage providers to assist their private patients in identifying access routes.
- In locations where providers report that demand for nirsevimab is low, awardees are to allow providers to order the minimum packaging of VFC nirsevimab that is feasible. In these cases, site visit reviewers will observe

that nirsevimab inventory is a much lower quantity than other ACIP-recommended vaccines.

- At the discretion of the awardee, certain specialty VFC providers, including birthing facilities (e.g., birthing hospitals or centers), may offer a limited formulary of VFC vaccines, based on the populations served in their facility. VFC-enrolled birthing facilities offering nirsevimab must offer hepatitis B vaccine at birth as well (and vice versa).

Eligibility Criteria

- A child's eligibility criteria for VFC nirsevimab are the same as for other VFC vaccines.

Borrowing

- For those VFC providers who maintain private stock of nirsevimab and vaccinating privately insured children, bidirectional borrowing of nirsevimab will be allowed for the 2023-2024 respiratory virus season as described below.
- CDC's borrowing guidance does not supersede jurisdictional policy related to borrowing. VFC providers should refer to awardee or jurisdictional policy to determine if borrowing is allowed in their jurisdictional.



- Borrowing is only applicable if the provider is purchasing private stock and is approved only for instances when:
 - There is a lack of vaccine stock because of delayed or spoiled shipments.
 - As part of the initial set up of private purchasing contracts and ordering systems, there has been a delay for the provider in being able to procure private stock of nirsevimab.
 - Vaccine will expire soon and will be lost if not used. Provider locations with a small privately insured patient population can use this option to administer short-dated, privately purchased vaccine to a VFC-eligible child and replace it with a longer-dated, VFC dose.
 - New staff calculated ordering intervals incorrectly, leading to a lack of sufficient private or public vaccine stock.
- Borrowed nirsevimab must be repaid (dose for dose) **within one month** or after every 5 doses borrowed (after use of 5 doses for small practices, at the discretion of the awardee) and administered to the appropriate population (i.e., if federally VFC purchased VFC vaccine is borrowed for a privately insured patient and then repaid to VFC inventory, the repaid dose must be administered to a federally vaccine-eligible VFC child).
- Awardees must receive proof of privately purchased doses that includes the number of doses, lot numbers, and documentation that authenticates doses returned or doses repaid were administered to the appropriate recipients.

Vaccine Borrowing Documentation

- A Vaccine Borrowing Report must be completed when either:
 - Privately purchased vaccine is administered to a VFC-eligible child, or
 - VFC vaccine is administered to a privately insured child.
- Awardees may report the information using CDC's template or by developing their own as long as it contains all the components of the CDC template. The template can be found on the ISD Awardees SharePoint Portal.

Replacement

- Awardees with replacement models must be extremely cautious in applying these models for nirsevimab, based on the cost of this product and the potential for fraud.

Virtual Enrollment

- Awardees will be allowed to conduct virtual enrollment visits for specialty VFC providers, including birthing facilities.
- Virtual enrollment site visits must be approved in writing (email) by CDC VFC staff. Minimally, awardees must review the following at the virtual enrollment visit:
 - Provider Agreement
 - Provider Profile
 - Vaccine Management Plan
 - Training documentation (if not done by program)
 - Electronic storage and handling documentation
 - Pictures of storage units
 - Pictures of DDL probe placement
 - Certificates of calibration
 - Pictures of "Do Not Disconnect" Signage Placement

NOTE: All awardees will be required to resume conducting enrollment visits in-person if CDC designates.

