

Addendum: Special Considerations for COVID-19 vaccine and Nirsevimab

Updated 03/29/2024

This addendum to the VFC Operations Guide provides supplemental information and guidance related to COVID-19 vaccine and nirsevimab in the VFC formulary.



Inventory

- VFC providers will be allowed a flexible, time-limited ramp-up period to meet the private inventory requirement for COVID-19 vaccine and nirsevimab. During this time, awardees will not require VFC providers to meet the private inventory minimum requirements for COVID-19 vaccine or 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 31, 2025.
- If a provider serves only Medicaid-eligible and no privately insured children, they are not required to privately purchase COVID-19 vaccine or 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 privately insured patients to access COVID-19 vaccine and nirsevimab (i.e., from another local in-network practice or system, Federally Qualified Health Center, Rural Health Clinic, or deputized VFC provider authorized to immunize underinsured children that does have private inventory of COVID-19 vaccine or nirsevimab).
- In locations where providers report that demand for COVID-19 vaccine or nirsevimab is low, awardees are to allow providers to order the minimum packaging of COVID-19 vaccine and nirsevimab that is feasible. In these cases, site visit reviewers will observe that COVID-19 vaccine or nirsevimab inventory may be a much lower quantity than other ACIP-recommended vaccines.
- At the discretion of the awardee, certain specialty providers, including pharmacies and birthing facilities (e.g., birthing hospitals or centers), may offer a limited formulary of vaccines, based on the populations served in their facility.

VFC-enrolled birthing facilities offering nirsevimab should offer hepatitis B vaccine at birth, as well (and vice versa).

Eligibility Criteria

- A child's eligibility criteria for VFC COVID-19 vaccine or nirsevimab are the same as for other VFC vaccines.

Borrowing

- For those VFC providers who maintain private stock of COVID-19 vaccine or nirsevimab and vaccinating privately insured children, bidirectional borrowing of COVID-19 vaccine and nirsevimab will be allowed for the 2024-2025 respiratory virus season at the discretion of the awardee and as described below. VFC providers should ensure they have funds to procure sufficient private stock before COVID-19 vaccine or nirsevimab is borrowed from VFC stock for a non-VFC eligible child.
- 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 jurisdiction.
- 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 COVID-19 vaccine or 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 COVID-19 vaccine or nirsevimab must be repaid (dose for dose) within 1 month or after five doses borrowed (for small practices, at the discretion of the awardee) and administered to the appropriate population (i.e., if VFC vaccine is borrowed for a privately insured patient and then repaid to VFC inventory, the repaid dose must be administered to a VFC-eligible 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 document the information using CDC's template or by developing their own once it contains all the components of the CDC template. Awardees may access the template on the [ISD Awardees SharePoint](#) portal. See Module 6 - Program Operations for additional information.
- If awardees are not able to capture and provide oversight of vaccine borrowing across their jurisdiction using their Immunization Information System, they should create and maintain a separate internal database.

Replacement

- Awardees with replacement models may include COVID-19 vaccine or nirsevimab in these models, but should be extremely judicious in applying these models. New replacement models must be approved in writing (via VFC@cdc.gov) by VFC staff.

Restitution

- Given the uncertainty with COVID-19 vaccine or nirsevimab demand and/or the potential for packaging size concerns, awardees with vaccine restitution policies may not penalize providers for COVID-19 vaccine or nirsevimab wastage due to expiration.

Virtual Enrollment Visits

- Awardees will be allowed to conduct virtual enrollment visits for specialty providers, including birthing facilities

and pharmacies, if unable to rapidly enroll these providers through in-person enrollment visits during the respiratory season.

- Virtual enrollment site visits must be approved in writing (via VFC@cdc.gov) by VFC staff. Minimally, awardees should review the following at the virtual enrollment visit:
 - Provider Agreement
 - Provider Profile
 - Vaccine Management Plan
 - Training documentation (if not conducted by program)
 - 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 the entire enrollment visit in-person, if CDC designates.

