



Department of Health

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July 19, 2024

Vaccines for Children Program
Immunization Operations and Services Branch
Immunization Services Division
National Center of Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Re: New York State Nirsevimab Order Replacement Model Proposal for Birthing Hospitals

The New York State Department of Health (NYSDOH) is requesting approval to use the Vaccine Order Replacement Model specifically for use of RSV monoclonal antibody, nirsevimab (Beyfortus™), in enrolled birthing hospitals. For many years, NYSDOH has enrolled birthing hospitals in a state-funded, universal Hepatitis B Birth Dose program. However, due to funding limitations, a universal birth dose program is not possible for nirsevimab. NYSDOH enrolls birthing hospitals as specialty providers in the Vaccines for Children (VFC) program for nirsevimab. The New York State Department of Health is committed to overcoming barriers in the inpatient setting to ensure that our most vulnerable population is fully vaccinated as early as possible. We are asking that CDC approve our request for a vaccine replacement model for birthing hospitals.

In May 2024, New York State's Bureau of Vaccine Programs engaged birthing hospitals in a survey to determine whether the Nirsevimab Order Replacement Model would be preferred. Of 62 birthing hospitals that participated in the survey, 60% said they would prefer the order replacement model. Two thirds of hospitals that participated in the survey did not enroll in VFC during 2023-24 season. Of those, 40% (16 of 40) said they would be more likely to enroll in 2024-25 season if an order replacement model was available.

The key benefit to using the Nirsevimab Order Replacement Model for birthing hospitals is to reduce the administrative burden associated with VFC program requirements. This model would exempt birthing hospitals from the requirement to maintain separate public and private stock and instead combine stock in accordance with VFC storage and handling requirements.

Using the Nirsevimab Order Replacement Model will allow birthing hospitals to vaccinate newborns without waiting for insurance enrollment and proof of coverage and instead make

the determination of eligibility during the billing process and prior to upload of administration data to the New York State Immunization Information System (NYSIIS). Reducing the administrative burden will incentivize hospitals to stock nirsevimab and ultimately ensure that infants are protected when they leave the hospital.

Proposed Process for Nirsevimab Order Replacement (Birthing Hospitals only)

After submission and review of the Vaccines for Children Enrollment Packet, birthing hospitals will be sent an “Enrollment Addendum for Birthing Hospitals: Nirsevimab Ordering Model Selection” for completion. This document explains the requirements with each model, Traditional VFC Ordering Model and Vaccine Ordering Replacement Model, and allows the birthing hospital to choose one. (see sample in Appendix 1)

Replacement Process for Providers Selecting Vaccine Order Replacement Model

New York State Public Health Law Section 2168 requires providers to report doses administered, with patient eligibility, to NYSIIS within 14 days of administration. Therefore, on the 15th of each month, the Vaccine Ordering and Technical Assistance team will run two NYSIIS reports for each enrolled birthing hospital to assess eligible doses administered the prior month:

1. VFC Report by trade name: this report is run for the prior 30-day reporting period (i.e., replacement order 11/15 will assess doses administered 10/1-10/31). This report will identify total doses (aggregate) of 50mg Beyfortus and 100mg Beyfortus administered by eligibility category. (See sample in Appendix 2)
2. Ad-Hoc patient list: This report identifies patient-level doses administered by eligibility. This will be run for the same time period (prior month) to confirm doses administered and counted on the VFC report. (See de-identified sample in Appendix 3)

The vaccine ordering and technical assistance team will then log the number of eligible replacement doses, by product and specific eligibility, for the birthing hospital on a Nirsevimab Order Replacement Tracking Sheet. Eligibility will distinguish specific funding sources: VFC (Medicaid, Uninsured, American Indian/Alaskan Native), State (Underinsured), and Children’s Health Insurance Program (CHIP). The tracking sheet will round doses owed to the birthing hospital to the nearest package size of five doses. For example, if a birthing hospital administered 27 doses to VFC/State/CHIP eligible infants, 25 doses will be replaced, with 2 doses “owed” and to be accounted for on the next replacement order.

Within the NYSIIS Inventory Module, the vaccine ordering and technical assistance team will:

1. Enter the replacement order by product (50mg and 100mg) into the NYSIIS Order Module on behalf of the provider. This will ensure shipment directly to the birthing hospital.
2. Update the provider’s inventory in NYSIIS to represent the public portion based on the VFC-eligible proportion on the VFC report.

The order and inventory files are uploaded from NYSIIS to VTrckS via the ExIS process the following morning. Birthing hospitals opting for the Nirsevimab Order Replacement Model will have the nirsevimab NDCs set to reject in the VTrckS provider template, enabling staff to split the funding based on VFC/CHIP/State eligible documented on the Nirsevimab Order Replacement Tracking Sheet.

The birthing hospitals will receive an email informing them that their replacement order has been placed and should arrive in the next week. Providers may track their order status and accept the shipment into inventory in NYSIIS as they normally would.

Birthing hospitals are eager to participate in the order replacement model this season, pending CDC approval. Please do not hesitate to contact me at 518-486-1604 or Lyndsey.hoyt@health.ny.gov should you need to speak to anyone regarding this request.

Thank you in advance for your consideration of this request.

Sincerely,

A handwritten signature in cursive script that reads "Lyndsey Hoyt".

Lyndsey Hoyt, MPH
Director, Bureau of Vaccine Programs
Immunization Program Manager
Division of Vaccine Excellence

Cc: Heidi Reukauf, Director, Division of Vaccine Excellence
Kara Connelly, Associate Director, Division of Vaccine Excellence
Debra Blog, MD, Medical Director, Division of Vaccine Excellence
Dileep Sarecha, CDC Field Assignee, NYSDOH
J. Reiss Lueken, CDC Project Officer



New York State Vaccines for Children Program

Enrollment Addendum for Birthing Hospitals: Nirsevimab Ordering Model Selection

Birthing Hospital Name: _____ PIN: _____ Date: _____

New York State Vaccines for Children Program (VFC) is allowing birthing hospitals to choose an ordering model to use for nirsevimab during the 2024-2025 respiratory syncytial virus season. Please select ONE.

Traditional VFC Ordering Model. In addition to the terms of the Vaccines for Children Provider Agreement, we understand the following requirements for using the Traditional VFC Ordering Model:

- 1. Nirsevimab orders will be placed in the New York State Immunization Information System (NYSIIS) for only those that meet VFC eligibility criteria. VFC supply will be maintained throughout the RSV season (up to 3-month supply on hand). NYSIIS orders may be placed every 30 days.
2. Public supply of nirsevimab will be labeled and stored separately from privately purchased supply (if applicable).
3. Infants will be screened for eligibility prior to administration, with correct supply used based on eligibility.
4. Any doses later determined to be administered to ineligible infants with commercial health insurance coverage will be documented on the Vaccine Borrowing Form and replaced with privately purchased doses.
5. Publicly funded vaccine may not be repackaged or redistributed.

Vaccine Ordering Replacement Model. In addition to the terms of the Vaccines for Children Provider Agreement, we understand the following requirements for using the Vaccine Ordering Replacement Model:

- 1. Both VFC eligible and privately insured infants will be immunized.
2. Initial supply will be privately purchased to cover at least six weeks of administration to all infants.
3. All doses, with VFC eligibility type, will be documented in NYSIIS within 14 days of administration.
4. New York State VFC Program will automatically place replacement orders monthly (November through April) for doses administered to VFC eligible infants. These doses do not require separate labeling and may be administered to any infants.
5. Publicly funded vaccine may not be repackaged or redistributed.
6. In the event any doses of nirsevimab expire or become non-viable prior to administration, the proportion of public vaccine eligible supply will be returned to CDC's centralized distributor, McKesson, for Federal Excise Tax credit.
7. Upon request, we will make procurement records (vaccine orders/invoices/payment records) for a 12-month period available to the NYS Vaccines for Children Program.

Medical Director or Equivalent Name: _____ Signature: _____

Primary Vaccine Coordinator Name: _____ Signature: _____

Backup Vaccine Coordinator Name: _____ Signature: _____

Appendix 2: Sample VFC Report

Vaccines for Children and Child Health Plus by Trade Name.

For Dates Between 02/01/2024 and 02/29/2024

Report Run on: 07/18/2024

Page 1

Organization: RGMG ROCH GEN HOSP VFCBH 91883

VFC PIN: 91883

Vaccine Name [Trade Name]	VFC Eligible Doses Administered				Total # of VFC Eligible Doses Administered (V02-V05)	Total # of Non- VFC Eligible Doses Administered (V00,V01)	Total # of Child Health Plus Doses Administered (V22)	317 (V23)	Total # of Doses Given to Adults not in NYSIS (V00)
	Medicaid/ Medicare Managed Care (V02)	Uninsured (V03)	American Indian/ Alaskan Native (V04)	Underinsured (V05)					
COVID-19 Vaccine, mRNA, 2023-24[PFR COV19 COMIRNATY 2023]	0.0	0.0	0.0	0.0	0.0	6.0	0.0	0.0	0.0
COVID-19, mRNA,LNP-S,PF, 0.3mL[Pfizer Covid-19]	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0
DTaP[**]	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
Flu quadrivalent injectable p-free[**]	0.0	0.0	0.0	0.0	0.0	17.0	0.0	0.0	0.0
HepB-Adult[**]	0.0	0.0	0.0	0.0	0.0	4.0	0.0	0.0	0.0
HepB-CpG[HepLisav-B]	0.0	0.0	0.0	0.0	0.0	6.0	0.0	0.0	0.0
HepB-Peds[**]	1.0	0.0	0.0	0.0	1.0	112.0	0.0	0.0	0.0
Influenza, High-dose Quadrivalent P-free[Fluzone High-Dose Quadrivalent]	0.0	0.0	0.0	0.0	0.0	14.0	0.0	0.0	0.0
MMR[**]	0.0	0.0	0.0	0.0	0.0	25.0	0.0	0.0	0.0
Rabies intramuscular[Imovax Rabies IM]	0.0	0.0	0.0	0.0	0.0	10.0	0.0	0.0	0.0
RSV,mAb, nirsevimab-alip, 0.5 ml,0-24m[Beyfortus 0.5ml]	27.0	1.0	0.0	0.0	28.0	10.0	1.0	0.0	0.0
Tdap > 7 years[**]	1.0	0.0	0.0	0.0	1.0	22.0	1.0	0.0	0.0

Vaccines for Children and Child Health Plus by Trade Name.

For Dates Between 02/01/2024 and 02/29/2024

Report Run on: 07/18/2024

Organization: RGMG ROCH GEN HOSP VFCBH 91883

Vaccine Name [Trade Name] ** No Trade Name specified	VFC Eligible Doses Administered				Total # of VFC Eligible Doses Administered (V02-V05)	Total # of Non-VFC Eligible Doses Administered (V00,V01)	Total # of Child Health Plus Doses Administered (V22)	317 (V23)	Total # of Doses Given to Adults not in NYSIS (V00)
	Medicaid/Medicare Managed Care (V02)	Uninsured (V03)	American Indian/ Alaskan Native (V04)	Underinsured (V05)					
Total	29.0	1.0	0.0	0.0	30.0	229.0	2.0	0.0	0.0

Appendix 3: Sample Ad-Hoc Patient List

Vaccination date	Vaccine group	Trade name	VFC Eligibility Description	First name	Last name	Birth date
2/4/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			1/31/2024
2/5/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/3/2024
2/5/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			1/12/2024
2/6/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			12/18/2023
2/7/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/3/2024
2/8/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/6/2024
2/8/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/6/2024
2/8/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/7/2024
2/9/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/6/2024
2/9/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/6/2024
2/10/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/7/2024
2/11/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/9/2024
2/12/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/10/2024
2/13/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/11/2024
2/18/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/13/2024
2/19/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/16/2024
2/19/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/16/2024
2/19/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/17/2024
2/19/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/17/2024
2/19/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/17/2024
2/20/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/7/2024
2/20/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/18/2024
2/20/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/18/2024
2/21/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/19/2024
2/21/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/19/2024
2/24/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/21/2024
2/29/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Medicaid/Medicare Managed Care			2/27/2024
2/7/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Uninsured			1/31/2024
2/2/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Not VFC Eligible			1/31/2024
2/8/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Not VFC Eligible			2/1/2024
2/17/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Not VFC Eligible			2/15/2024
2/22/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Not VFC Eligible			2/20/2024
2/23/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Not VFC Eligible			2/16/2024
2/29/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Not VFC Eligible			2/26/2024
2/11/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	Child Health Plus			2/9/2024
2/16/2024	Respiratory Syncytial Virus	Beyfortus 0.5ml	VFC Eligibility Unknown			2/1/2024

2/20/2024
2/21/2024

Respiratory Syncytial Virus
Respiratory Syncytial Virus

Beyfortus 0.5ml
Beyfortus 0.5ml

VFC Eligibility Unknown
VFC Eligibility Unknown



2/16/2024
2/18/2024