NORTH Dakota | Health & Human Services
Be Legendary.

The U.S. Food and Drug Administration approved Beyfortus (nirsevimab-alip) for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

The Advisory Committee on Immunization Practices (ACIP) recommends one dose of nirsevimab for infants ages <8 months born during or entering their first RSV season* (50 mg for infants <5kg and 100 mg for infants ≥5 kg). Additionally, one dose of Nirsevimab is recommended for children ages 8 through 19 months who are at increased risk^ for severe RSV disease and entering their second RSV season (200 mg).

Below is a planning checklist that is subject to change depending on forthcoming federal guidance. The North Dakota Department of Health and Human Services (ND HHS) Immunization Unit will update this list and further educate healthcare providers if changes occur.

Nirsevimab Planning Checklist

North Dakota Immunization Information System (NDIIS)/Documentation	
	Update and/or complete NDIIS provider agreement, if needed.
	Request NDIIS user access for individuals at your facility who may administer nirsevimab monoclonal antibody or need to look up immunization/administration records.
	Verify that your electronic medical record (EMR) is set up to document Nirsevimab doses, and how it will electronically send doses to NDIIS. If not, establish a process for reporting doses to the NDIIS. CVX codes: IIS | Code Sets | CVX | Vaccines | CDC
Product Storage and Handling	
	Plan for purchasing nirsevimab for privately insured children. According to the manufacturer, nirsevimab will cost about $495 per dose on the private market.
	Ensure storage units are working well, have adequate storage space for prefilled syringes (on top of influenza, COVID-19 and other vaccines) and temperatures are being monitored 24 hours a day using a digital data logger. Nirsevimab is stored in the refrigerator at 2-8˚C.
	Ensure staff review CDC's vaccine storage and handling toolkit.
Facility Protocol and Education	
	Ensure that your facility is enrolled in the VFC Program. Nirsevimab is included in the VFC Program. Your facility should establish a process to document VFC eligibility in the EMR/ patient record for each nirsevimab dose administered.

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	Establish a process to make birthing hospital and clinic staff aware of nirsevimab availability and recommendations. Please note that IM dosage varies by weight, 50 mg if <5 kg, 100 mg if ≥5 kg, 200 mg (2x100 mg) for high risk entering 2nd RSV season.
	Plan how to communicate nirsevimab availability, priority groups and safety/efficacy to patients.
	Ensure education on documentation needs (EMR, electronic birth certificate, NDIIS) are provided to staff.
	Update billing processes for private insurance and VFC-eligible children, as needed. ☐ BCBS of ND inpatient vaccination billing policy
	Establish a process to obtain parental consent for nirsevimab. A nirsevimab **Immunization Information Statement** is available from CDC.
	Update current facility vaccination/medication administration protocols, if needed.
	Determine when nirsevimab will be administered post-delivery and pre-hospital discharge, or how patients will be referred for nirsevimab adminstration within 7 days of birth.
	Develop a process for outpatient clinic administration to infants born outside of RSV season (well-child visits, walk-in clinics, influenza clinics, etc.). Nirsevimab can be coadministered with recommended vaccines.
	Establish a mechanism to inform parents of infants born outside of traditional RSV season of the need to return for nirsevimab administration ahead of their first RSV season.
	Develop a process for administration of nirsevimab to infants at higher risk of RSV complications entering their second RSV season. Please note that ACIP recommendations for second RSV season administration include ALL American Indian children.
	Adverse events following administration of nirsevimab should be reported. Educate staff that if administered alone, adverse events should be reported to MedWatch. If administered simultaneously with any vaccine, report to VAERS.

*Based on pre-pandemic patterns, Nirsevimab could be administered from October through the end of March. Providers can adjust administration schedules based on local epidemiology, which will be communicated by ND HHS.

^Infants at increased risk:

- Children with chronic lung disease of prematurity who required medical support any time during the six-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight-for-length <10th percentile
- American Indian and Alaska Native Children

Please contact the ND HHS Immunization Unit at vaccine@nd.gov with any immunization-related questions.

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