Information and Planning Checklist

Nirsevimab (Beyfortus)

October 30, 2023

The U.S. Food and Drug Administration (FDA) approved nirsevimab (Beyfortus) 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) and the American Academy of Pediatrics (AAP) recommend:

- All infants younger than 8 months born during or entering their first RSV season* receive one dose of Nirsevimab (50 mg < 5 kg and 100 mg ≥ 5 kg).
    - **Note:** Dose is based on patient's weight. Use a medical grade scale that meets quality standards, and weigh patients according to best practice.
- Infants and children aged 8 through 19 months who are at increased risk^ of severe RSV disease and entering their second RSV season receive one dose of nirsevimab (200 mg, 2x 100mg).
    - **Note:** Nirsevimab is FDA approved up to 24 months of age and can be given after 19 months if the patient is at increased risk of severe infection.
- CDC recommends prioritizing available nirsevimab 100mg doses for infants at the highest risk for severe RSV disease: young infants (age <6 months) and infants with underlying conditions that place them at highest risk for severe RSV disease. Avoid using two 50mg doses for infants weighing ≥5 kilograms (≥11 pounds) to preserve supply of 50mg doses for infants weighing <5 kilograms (<11 pounds).

The planning checklist below is subject to change as additional federal guidance becomes available. Please visit the www.cdc.gov/vaccines/vpd/rsv or contact the Indiana Department of Health, Immunization Division at immunize@health.in.gov for more information.

Nirsevimab Planning Checklist	
✓	**Indiana Immunization Information System (CHIRP)/Documentation**
	Request CHIRP access for individuals at your facility who may administer nirsevimab monoclonal antibody or need to look up immunization records.
	Verify that your electronic medical record (EMR) is set up to document nirsevimab doses (CVX codes) and how it will electronically send doses to CHIRP. If not, establish a process for reporting doses to CHIRP. Nirsevimab will be added to CHIRP via VOMs by the beginning of October.
	Verify that HL7 messages are **not** set to a default volume as the dose will vary based on the patient's weight.
	Birthing Hospitals: Ensure data quality of messages by standardizing patient name, mother's name, and phone number to establish accurate patient records.
✓	**Product Storage and Handling**
	Establish plan for purchasing nirsevimab for privately insured children. According to the manufacturer, nirsevimab will cost about $495 per dose on the private market. Minimum order

	quantity is expected to be 5 doses.
	Ensure storage units are functioning properly, have adequate storage space for prefilled syringes (in addition to influenza, COVID-19 and other vaccines) and temperatures are being monitored 24 hours/day using a digital data logger. Footprint of the cartons is expected to be: 144 mm x 51 mm x 24 mm.
	Ensure nirsevimab is stored in the refrigerator at 2-8 °C and that staff reports temperature excursions to your region's accountability specialist.
	Ensure staff review Indiana's vaccine storage and handling toolkit.
✓	**Facility Protocol and Education**
	Ensure that your facility is enrolled in the VFC Program. Nirsevimab will be included in the VFC Program. Your facility should establish a process to document VFC eligibility in the EMR/patient record for each dose administered. Email program enrollment questions toenrollments@health.in.gov.
	Establish a process to make birthing hospital and clinic staff aware of nirsevimab availability and recommendations. Dosage will vary based on the patient's weight: 50 mg if <5 kg, 100 mg if ≥5 kg and 200 mg (2x100 mg) for patients at an increased risk^ of severe infection entering their second RSV season.
	Plan how to communicate nirsevimab availability, priority groups and safety/efficacy to patients.
	Ensure education on documentation needs (EMR, electronic birth certificate, LMS: INvest, etc.) are provided to staff.
	Update billing processes for private insurance and VFC-eligible children as needed.
	Establish a process to obtain parental consent for nirsevimab. A patient information sheet is forthcoming from CDC.
	Update current facility vaccination/medication administration protocols, if needed. Implement standing orders for your practice, if applicable. See templates and FAQs here.
	Determine when nirsevimab will be administered post-delivery and pre-discharge at the hospital.
	Develop a process for outpatient clinic administration to infants born outside of RSV season (well-child visits, walk-in clinics, influenza clinics, etc.), including outreach to patients/parents to inform of the need to return to clinic for nirsevimab administration ahead of their first RSV season. Nirsevimab can be co-administered with all routine vaccines.
	Develop a process for administration of nirsevimab to infants at an increased risk^ of RSV complications entering their second RSV season. **Note:** ACIP recommendations for second RSV season administration include **all** American Indian and Alaska Native children.
	Report adverse events following administration of nirsevimab to VAERS only if co-administered with a vaccine. If not co-administered with a vaccine, report adverse events following administration of nirsevimab to MedWatch.

* Based on pre-pandemic patterns, nirsevimab could be administered in the months leading up to October through the end of March. Providers can adjust administration schedules based on local epidemiology, which will be communicated by IDOH as needed.

^ Infants at increased risk of severe RSV disease:

- Children with chronic lung disease of prematurity who required medical support at 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