Enrollment Checklist for Birthing and Pediatric Hospitals: Nirsevimab (Beyfortus™)

This planning checklist is for birthing hospitals and hospitals with birthing wards who want to enroll in California's Vaccines For Children (VFC) Program which offers eligible newborns no-cost immunizations at birth to prevent respiratory syncytial virus (RSV) and Hepatitis B. This checklist will help your site meet VFC enrollment requirements and prepare to receive RSV immunization nirsevimab (Beyfortus™). A brief summary of nirsevimab clinical guidance is available at the end of this document.

Nirsevimab Planning Checklist

✓	Facility Protocol and Education
	Ensure that your facility is enrolled in the California VFC Program. Your facility should establish a process to document VFC eligibility in your EMR/patient record and/or CAIR for each dose administered. Email program enrollment questions to VFCEnrollment@cdph.ca.gov.
	Update billing processes for private insurance and VFC-eligible children if needed.
	Establish a process to make birthing hospital and clinic staff aware of nirsevimab availability and recommendations. Download the CDPH Nirsevimab timing tool. Dosage depends on patient age and weight: • Age 0-8 months old: 50 mg if <5 kg, 100 mg if ≥5 kg • Age 8-19 months old at high risk of severe RSV: 200 mg (2x100 mg)
	Plan how to communicate nirsevimab availability, priority groups, safety, and efficacy to patients. Share nirsevimab effectiveness and safety information from CDC, including Nirsevimab Immunization Information Sheet (IIS), and the FDA.
	Ensure education on documentation needs (EMR, electronic birth certificate, etc.) are provided to staff.
	Develop a process to screen newborns for birth parent's RSV vaccine status during pregnancy.
	Establish a process to obtain parental consent for nirsevimab. Share with parents the CDC's Nirsevimab Immunization Information Sheet (IIS).
	Update current facility vaccination/medication administration protocols, if needed.
	Implement standing orders for your practice, if applicable. See templates and FAQs.
	Determine when nirsevimab will be administered post-delivery and pre-discharge at the hospital. Infants with prolonged hospitalization (e.g., preterm infants) should be immunized ideally shortly before discharge or promptly after discharge.
	Develop a process for outpatient clinic administration to eligible infants born outside of RSV season (well-child visits, walk-in clinics, influenza clinics, etc.), including **outreach to parents/ caregivers about coming to clinic for RSV immunization ahead of their first RSV season**. Providers should use every opportunity to administer nirsevimab to eligible infants. This includes administration during well-child visits as well as other visits to ensure no missed opportunities for immunization.
	Develop a process for administration to children 8 to 19 months old at increased risk of severe RSV entering their second RSV season. **Note:** ACIP recommendations for second RSV season administration include all American Indian and Alaska Native children. Report adverse events: • If nirsevimab is administered alone, report adverse events to MedWatch. • If nirsevimab is co-administered with a vaccine, report adverse events to VAERS only.

✓	California Immunization Registry (CAIR) Documentation
	Request CAIR access for individuals at your facility who administer nirsevimab or other immunizations and for individuals who need to look up immunization records. Contact the CAIRHelpdesk@cdph.ca.gov.
	If you are participating in data exchange with CAIR, verify that your EMR is set up to document nirsevimab doses (CVX codes or NDC codes) and to submit the doses electronically to CAIR. If not, establish a process for reporting doses to CAIR. For Data Exchange assistance email CAIRDataExchange@cdph.ca.gov. For manual submission contact CAIRHelpDesk@cdph.ca.gov.
	Verify that HL7 messages are NOT set to a default volume as the dose will vary based on the patient's weight.
	Ensure data quality of messages by standardizing patient name, mother's name, and phone number to establish accurate patient records. Use this CAIR data guide to help.

✓	Product Storage and Handling
	Ensure vaccine storage units are functioning properly, have adequate space for prefilled syringes (in addition to other vaccines) and temperatures are being monitored 24 hours/day using an acceptable digital data logger.
	Ensure nirsevimab is stored in the refrigerator at 2-8°C (36.5 - 46.4°F), temperatures are routinely monitored and documented, and that staff are trained on reporting temperature excursions according to established protocols. Providers participating in the VFC Program must report temperature excursions to VFC at myvfcvaccines.org.
	Ensure staff review the storage and handling section of the VFC Program Provider Operations Manual.

✓	Vaccine Supply
	Establish plan for purchasing nirsevimab for privately insured children. Minimum orderquantity is expected to be 5 doses.
	Establish a plan to order vaccines for VFC-eligible babies. If not enrolled in the CA Vaccines for Children Program, review VFC Program enrollment information.
	Nirsevimab injection is a sterile, preservative-free, clear to opalescent, colorless to yellow solution supplied as follows: **Five 50 mg/0.5 mL** single-dose pre-filled syringes in a carton: NDC 49281-575-15  **Five 100 mg/1 mL** single-dose pre-filled syringes in a carton: NDC 49281-574-15  Each nirsevimab pre-filled syringe is for one-time use only.

Nirsevimab Background and Clinical Summary

Nirsevimab (Beyfortus™) is a long-acting monoclonal antibody product that provides passive immunization to protect infants against RSV. Nirsevimab was approved by the U.S. Food and Drug Administration (FDA) and recommended by CDC's Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) for the prevention of RSV lower respiratory tract disease in neonates and infants. Nirsevimab should be given just before and during RSV season, usually October-March. One dose of nirsevimab is expected to last at least 5 months. Nirsevimab co-administration with other immunizations, including the birth dose of Hepatitis B vaccine, is recommended.

All infants from birth to 8 months born during or entering their **first RSV season** are recommended to receive one dose of nirsevimab (50 mg if <5 kg or 100 mg if ≥5 kg) if:

- The birth parent did not receive RSV vaccine during pregnancy.
- The birth parent's RSV vaccination status is unknown.
- The infant was born within 14 days of birth parent's RSV vaccination.

Young children aged 8 through 19 months entering their **second RSV season** are recommended to receive one dose of nirsevimab (200 mg) if they are 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.

Other Helpful Resources:

- Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (CDC)
- ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics
- Nirsevimab Frequently Asked Questions (AAP.org)
- Nirsevimab (BeyfortusTM) Product Insert (FDA.gov)
- RSV (Respiratory Syncytial Virus) (CDPH.CA.gov)
- Other RSV resources for providers and patients
- RSV FAQs

*Note: This planning checklist is subject to change in the event of future guidance updates from CDC or California Department of Public Health.