Nirsevimab: Implementation Considerations

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Implementation Considerations

• Definition of Vaccine
• Cost
• Storage and Handling
• Hospital Dosing
• Outpatient Dosing
• Coding and Immunization Information Systems
• Timing of Vaccination
• 2nd Year Vaccinations
• Vaccine Administration
• Safety Reporting
• Vaccine Confidence and Demand
Definition of “Vaccine”

- No statutory definition of vaccine in the statute for the Vaccines for Children (VFC) program (section 1928 of the Social Security Act)

- No statutory definition of vaccine in the Affordable Care Act (section 2713 of PHS Act), or its implementing regulations, which has a provision that mandates coverage of vaccine recommendations included on CDC’s immunization schedules

- CDC has determined that nirsevimab is eligible for inclusion in the childhood immunization schedule and Vaccines for Children program
Cost

- Cost of nirsevimab estimated at $495 per dose in the private sector
- If recommended by ACIP, nirsevimab will be covered by insurance and included in the VFC program
  - Importance of ensuring equitable access to nirsevimab
- However, nirsevimab cost will still be a potential implementation barrier particularly for ambulatory practices
  - If nirsevimab included in VFC, practices must carry both VFC and private stock, which may be challenging for some practices
Nirsevimab Storage, Handling, and Administration

- Similar to other routine vaccines for children
- Administered as intramuscular injection using single-dose pre-filled syringe
  - Can be administered simultaneously with other childhood vaccines
- Dosed by weight/age
  - 50 mg if <5 kg
  - 100 mg if ≥5 kg
  - 200 mg (2x100 mg) for high-risk children entering 2nd RSV season
- Stored in refrigerator at 2-8°C
- May be kept at room temperature (20-25°C) for up to 8 hours

Source: California Department of Public Health
Jurisdictions may have different scope of practice statutes for who can administer injectable therapeutics vs. vaccines.

Scan of state laws indicates that most states allow medical assistants (who frequently administer vaccines) to also deliver injection drugs.
   - However, organizations may have varied practices.

American Association of Medical Assistants
Hospital Administration

- Approximately 10% of birthing hospitals participate in the VFC program
- Bundled payment model for newborn care
  - Hepatitis B vaccine more feasible to cover at ~$13–16/dose
  - Will nirsevimab be included in bundled payments?
- Critical to ensure documentation of in-hospital nirsevimab administration in records sent to primary care provider
  - Potential challenges entering nirsevimab in the immunization information system (IIS)
  - Comprehensive maternal-neonatal records will become even more critical if maternal RSV vaccine is licensed and recommended

CDC Vaccine Price List
Outpatient Administration

- Communication from birthing hospital
- Communication about maternal RSV vaccine
- Initial investment by pediatricians – unsure on price and demand for nirsevimab nor demand for new product
- Historical lag in insurance payment for new products
CPT coding and AMA decision around CPT codes — classified as a drug/therapeutic

• Administration codes do not include a counseling component

• Not eligible for stand-alone counseling

• Potential challenges with recording doses in Immunization Information Systems
Preparing Systems for Administering a Newly Authorized Vaccine Across the U.S.

Timeline represents standards for vaccines. Incorporating a MAB into vaccine systems has the potential to expand timeline due to increased complexity.

1. BLA Approved

2. Data publication partners (FDA, CDC, formulary vendors, & AMA) Prepare & publish vaccine & drug code set files for systems development
   1-4+ weeks post authorization

3. IIS systems prepare for new vaccine codes
   1-4+ weeks post authorization

4. Vaccine ready for VTrckS ordering & distribution
   ~2 weeks post authorization

5. Code set subscription services activate. CDSi resources are published. Provider & payer systems use these for system development & deployment.
   1-4+ weeks post authorization

6. Provider & payer systems ready to record & report vaccine administration
   6-12+ weeks post authorization
IIS and Vaccine Forecasting Considerations

• Nirsevimab coded as a therapeutic instead of vaccine could create challenges with:
  o Internal provider ordering
  o Provision of a vaccine record
  o Interoperability/data exchange with electronic health record (EHR) and IIS

• Forecasting (Clinical Decision-Support [CDS] for immunization)
  o Dosage by weight: CDS does not have access to patient weight
  o 2nd season recommendations
  o Future considerations: CDS systems unable to take into account maternal vaccination history for forecasting for infant nirsevimab immunization
Special Considerations Add Complexity

- Timing of vaccination based on RSV season
  - Tropical climates may have different/unpredictable seasonality when compared to most of continental U.S.
- Variability in different localities
  - For example, seasonality in AK less predictable and longer duration
- Second year dosing
  - High risk populations
  - Clarifying palivizumab recommendations in the setting of nirsevimab availability
Reporting of Adverse Events by Patients and Providers

- Reporting of suspected adverse events (AEs) more complicated for nirsevimab than other immunizations:
  - If nirsevimab is administered alone, suspected AEs are reported to MedWatch
  - If nirsevimab is administered simultaneously with any vaccine, suspected AEs are reported to the Vaccine Adverse Event Reporting System (VAERS); additional reporting to MedWatch not needed
Vaccine Confidence/Demand

• Will physicians and public accept a new vaccine
• Occurring at the same time as commercialization of COVID-19 vaccine and seasonal influenza administration
• Vaccine hesitancy and anticipated need for counseling around all vaccines and products
• Efforts to weaken school immunization requirements and expand vaccine exemptions at the state level
Conclusion and Discussion

• Considerations for implementation
• Risks during this season’s roll out
  o Timing of availability of doses
  o Provider hesitancy
  o Uptake
• Complexity of recommendations
  o Hospital vs. Outpatient
  o Seasonality / Timing
  o Lessons learned with Hepatitis A and B
• Unintended consequences
Thank You!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.