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**

Program For Distribution Of Pediatric Vaccines
Coverage of Certain Preventive Services Under the Affordable Care Act

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

Scope of Practice Issues

- 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

Coding

- 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 FDA

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

5 Code set subscription services activate. CDSi resources are published. Provider & payer systems use these for system development & deployment.

1-4+ weeks post authorization

1 Week | 2 Weeks | 3 Weeks | 4 Weeks | 5 Weeks | 6 Weeks | 7 Weeks | 8 Weeks | 9 Weeks | 10-12+ Weeks

4 Vaccine ready for VTrckS ordering & distribution

~2 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:
  - Internal provider ordering
  - Provision of a vaccine record
  - Interoperability/data exchange with electronic health record (EHR) and IIS

- Forecasting (Clinical Decision-Support [CDS] for immunization)
  - Dosage by weight: CDS does not have access to patient weight
  - 2nd season recommendations
  - 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
  - Timing of availability of doses
  - Provider hesitancy
  - Uptake
- Complexity of recommendations
  - Hospital vs. Outpatient
  - Seasonality / Timing
  - Lessons learned with Hepatitis A and B
- Unintended consequences

Thank You!

For more information, contact CDC
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