Draft Interim Clinical Considerations:

Nirsevimab

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Goals of recommendations

- Provide simple, uniform recommendations that apply to most U.S. health care providers
- Provide flexibility for specific situations

Policy Question

- Should one dose of nirsevimab be recommended a) at birth for all infants born during October to March and b) when entering first RSV season and <8 months of age for all infants born during April through September?

Important considerations for timing of administration

- Efficacy beyond 150 days is unknown
- Majority of infants will only be eligible for a single dose of nirsevimab
- Only 1 dose is recommended per season
- If nirsevimab given too early, efficacy might wane during the RSV season
- For infants born during October–March, the optimal timing of nirsevimab dosing is at birth
- For infants born during April-September, the ideal timing for nirsevimab dosing is just before or near the start of the RSV season

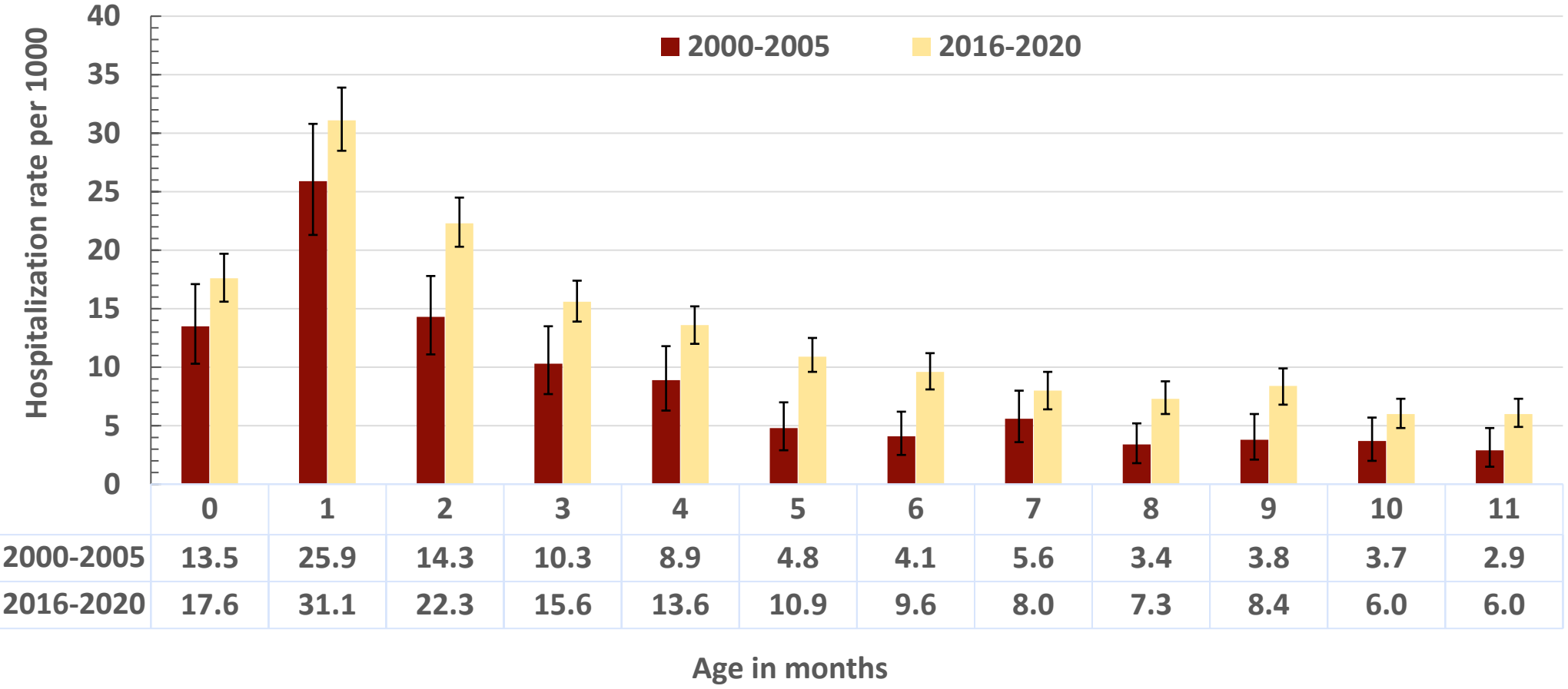
Timing and location of nirsevimab administration

- For infants born during Oct–Mar, shortly after birth or as soon as possible
  - Administration in hospital prior to discharge would be optimal to ensure early protection
  - If not given prior to discharge, administration at first visit to primary care provider, ideally within 1 week of discharge
- For infants born Apr–Sep
  - Nirsevimab administration recommended during Oct-Nov (e.g., during regularly scheduled 2-, 4-, or 6-month well child visits)

Additional considerations

- During COVID-19 pandemic, interseasonal RSV transmission has occurred
- Work Group has expressed it is important to allow for flexibility of timing in nirsevimab administration during periods of significant interseasonal RSV transmission
- During 2023-2024 season, nirsevimab may not be available prior to October 2023

RSV-associated hospitalization rates in children aged 0-11 months, New Vaccine Surveillance Network



	0	1	2	3	4	5	6	7	8	9	10	11
2000-2005	13.5	25.9	14.3	10.3	8.9	4.8	4.1	5.6	3.4	3.8	3.7	2.9
2016-2020	17.6	31.1	22.3	15.6	13.6	10.9	9.6	8.0	7.3	8.4	6.0	6.0

2000-2005: Adapted from Hall et al, Pediatrics 2013; 2016-2020: CDC unpublished data

Timing of beginning nirsevimab administration

- If increased RSV transmission is occurring locally in August or September, nirsevimab could be administered to eligible infants earlier than October, if available
- Local epidemiology data may be best indicator but recommend establishing evidence-based threshold
- National Respiratory and Enteric Virus Surveillance System (NREVSS)
  - May be used as one source of evidence
  - Census Division-level or HHS regional-level data recommended[1]
  - In NREVVS, >3% percent positivity of PCR tests for 2 consecutive weeks can indicate increased level of RSV detections

[1] Data from a single state may not be representative and should be interpreted with caution

https://www.cdc.gov/surveillance/nrevss/index.html

Timing of ending nirsevimab administration

- To determine if nirsevimab should continue to be administered to newborns shortly after birth beyond March, local jurisdictions can alter administration schedules based on local transmission conditions with clear evidence of ongoing increased transmission
  - Local data may be best indicator but recommend establishing evidence-based threshold
  - NREVSS
    - May be used as one source of evidence
    - Census Division-level or HHS Region-level data recommended[1]
    - For NREVVS data, <5% percent positivity of PCR tests for 2 consecutive weeks can indicate decreasing transmission

[1] Data from a single state may not be representative and should be interpreted with caution

https://www.cdc.gov/surveillance/nrevss/rsv/index.html

Tropical climates

- Tropical climates (e.g., Hawaii, Guam, and US-affiliated Pacific Islands) may have RSV seasonality that differs from most of the continental US or is unpredictable
- Nirsevimab administration recommended to newborns shortly after birth throughout the year
- Certain jurisdictions with tropical climates (e.g., Puerto Rico) recommend birth dose nirsevimab administration during Aug–Mar. For infants born Apr-July, recommended in Aug–Sep.
- Consult with local, state, or territorial health department for recommendations

Alaska

- In Alaska, RSV seasonality is less predictable, and the duration of RSV activity is often longer than the national average
  - Providers are advised to use RSV laboratory surveillance data generated by the state of Alaska to assist in determining the appropriate timing of nirsevimab
- The Alaska Department of Health will continue to provide clinicians with updated Alaska-specific guidance

Infants residing in remote areas

- Infants born during April–September and residing in remote areas (e.g., would require medical evacuation by air for severe disease) can be given nirsevimab as early as August if there is concern that the infant may not have access to nirsevimab at the recommended time (Oct–Nov)

Policy question

- Should one dose of nirsevimab be recommended for children <20 months of age entering their second RSV season who are eligible for palivizumab in their second RSV season?

Population recommended for nirsevimab when entering 2nd RSV season

- Same groups eligible for palivizumab when entering 2nd RSV season per American Academy of Pediatrics recommendations
  - Children with chronic lung disease of prematurity if require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season
  - Children who are profoundly immunocompromised
  - Children with cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest XR or CT that persist when stable) or weight for length < 10th percentile
- Other conditions are under review

American Academy of Pediatrics Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014;134(2):415-20.

Timing of nirsevimab administration for 2nd RSV season

- Nirsevimab should be administered during October to November

- Nirsevimab is not recommend to be used after the 2nd RSV season

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov