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Cost-Effectiveness of Nirsevimab Against Respiratory Syncytial Virus Lower Respiratory Tract Disease (RSV LRTD) in the US Birth Cohort

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BACKGROUND

- Respiratory syncytial virus (RSV) is the leading cause of hospitalizations in all infants in North America and imposes a substantial burden on ambulatory care settings. Most hospitalizations due to RSV (~67% to 87%) occur in healthy infants born at term, and between 45% and 66% of infants admitted to the ICU due to RSV are previously healthy.[1-5]
- Nirsevimab is the first monoclonal antibody approved to protect all infants through their first RSV season. On August 3rd , 2023, ACIP voted unanimously the recommendations of nirsevimab use to protect infants entering or born during their first RSV season, and its use in infants who remain vulnerable to severe RSV disease through their second RSV season.

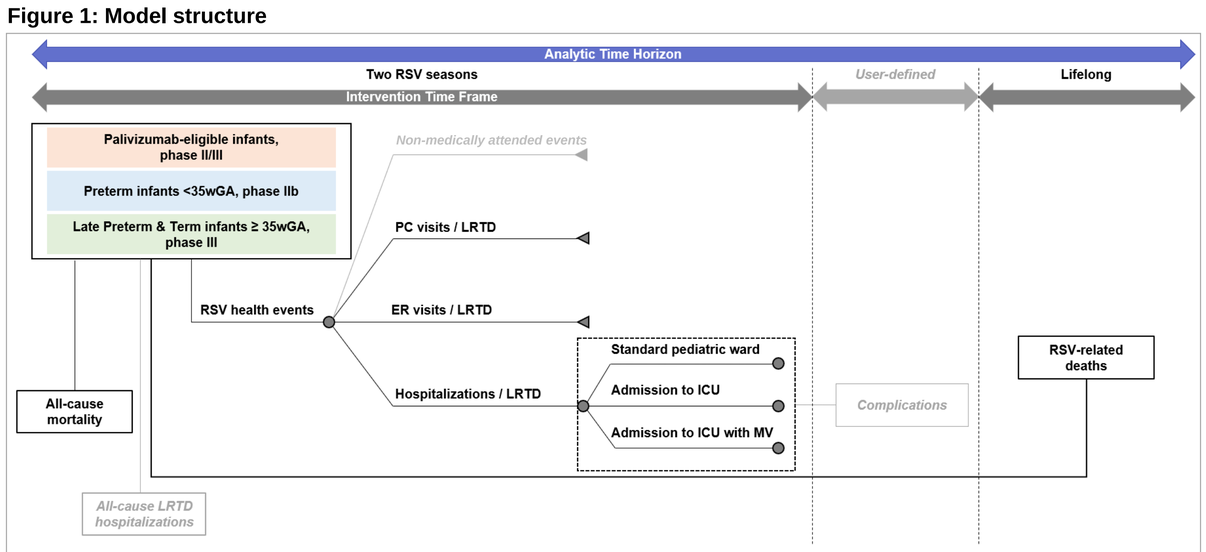
OBJECTIVES

- To analyze the impact of nirsevimab for the prevention of RSV lower respiratory tract diseases (LRTD) in the US birth cohort over the first RSV season of the infants' life, and the second RSV seasons for infants eligible for palivizumab as per recommendations:
  - Comparison of the health and cost outcomes associated with the use of nirsevimab vs. the current standard of practice (SoP)
  - Estimation of the incremental cost-effectiveness ratio (ICER) of the use of nirsevimab

METHODS

- **Static decision analytic model** to estimate health, cost and quality-of-life outcomes related to RSV with or without nirsevimab immunization (**Figure 1**).
- **The target population** includes 3 groups, corresponding to the ones assessed in the nirsevimab clinical trials
  - Palivizumab-eligible infants (**palivizumab-eligible** ; <2 years of age per the latest AAP recommendations.[6]
  - Preterm infants (**preterm**; <1 year of age): includes infants born between 29 weeks of gestational age (wGA) and 34 weeks, six days of gestational age (not eligible for immunization with palivizumab).
  - Term and late preterm infants (**term**; <1 year of age): include infants born at or after 35 wGA (not eligible for immunization with palivizumab).

Figure 1: Model structure



Abbreviations: ER = emergency room; ICU = intensive care unit; LRTD = lower respiratory tract disease; MV = mechanical ventilation; PC = primary care; RSV = respiratory syncytial virus; wGA = week of gestational age. Grey outcomes are not included in the base case and are tested in scenario analyses.

- **Intervention strategy**
  - **Comparative strategy – Standard of Practice**: monthly administrations of palivizumab during the RSV season for palivizumab-eligible infants only (with a maximum of five doses), as per the AAP recommendations,[6] and no prophylaxis for the preterm and term infant populations.
  - **Intervention strategy – "All infants"**: Protection with nirsevimab for the entire birth cohort, with infants born before the RSV season receiving one dose of nirsevimab at the start of the RSV season (i.e., October) and those born within the RSV season receiving one dose at birth.
- **The RSV season** modeled in the base case assumes virus circulation from October through March, a peak in December - January and low RSV circulation between April and September.[7]
- The unit acquisition **cost of palivizumab** was $1,228.[8] **Net price** per unit of **nirsevimab** was at $500
- **Inputs** were obtained from literature and are presented in **Table 1**

Table 1: Inputs

	Palivizumab-eligible Population	Preterm infants (<35wGA)	Late preterm and term infants (≥35 wGA)
Demographics			
Size of the US birth Cohort	1.58% (57,907)[9-10]	4.22% (154,663)[9,11]	94.20% (3,452,430)[11]
Efficacy			
Nirsevimab	51%*[12]	86.2% (95% CI 68.0, 94.0)[13]	74.5% (95% CI 49.6 to 87.1)[14]
Palivizumab	51%[12]	NA	NA
Coverage rate			
Nirsevimab	82%	80.4%[16]	80.4%[16]
Palivizumab	82%[15]	NA	NA
Event rates			
Hospitalizations[1-2,17-21]			
0-11 months	8.85%**	2.23%	1.20% (0.84% - 2.6%)
ICU admission	29.25%	31.25	22% (10% - 35.5%)
ICU with MV	8%	10.25%	3.75%
12-24 months	2.02%	NA	NA
ICU admission	25%		
ICU with MV	3%		
Emergency room (ER) visits[9,22]			
0-11 months	6.62% (5.66% - 7.57%)		
% of LRTD	57.5%		
12-24 months	5.3%	NA	NA
% of LRTD	50%	NA	NA
Primary care (PC) visits[9,22]			
0-11 months	23.09% (19.25% - 26.93%)		
% of LRTD	47.5%		
12-24months	18.03%	NA	NA
% of LRTD	30%	NA	NA
RSV related mortality (per 100,000)[23]			
0-11 months	2.4 (1.2 – 2.9)		
12-24 months	0		
Direct costs[20,24]			
Hospitalization (standard ward)	$50,752	$24,613	$12,316
ICU admission	$89,101	$68,459	$46,615
ICU with MV	$162,343	$107,868	$100,943
ER visit	$597	$597	$597
PC visit	$87	$87	$87
QALY loss[17]			
Infants			
Hospitalizations	0.0170 (0.0101 – 0.0726)		
Emergency room visits	0.0134 (0.0079 – 0.0455)		
Primary care visits	0.0085 (0.0049 – 0.0455)		
Caregivers			
Hospitalizations	0.0066 (0 – 0.0373)		
Emergency room visits	0.0068 (0 – 0.0249)		
Primary care visits	0.0041 (0 – 0.0249)		

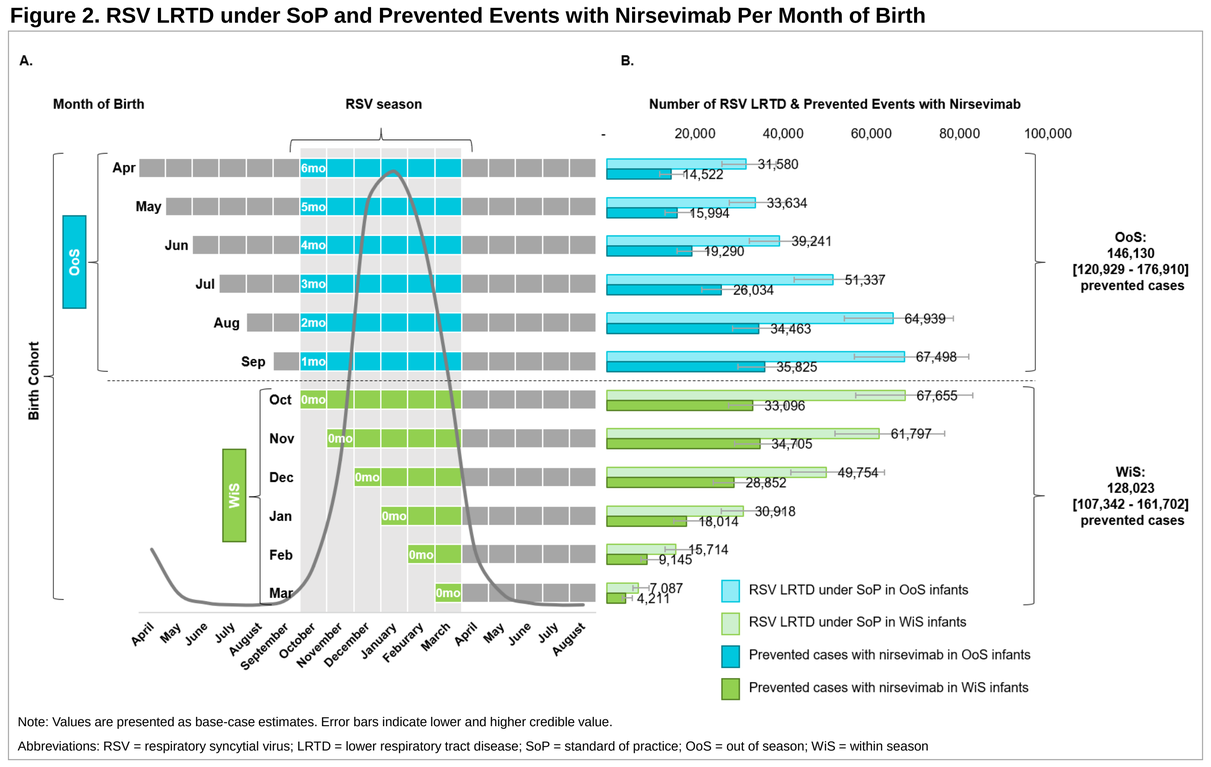
Abbreviations: ER = emergency room; ICU = intensive care unit; MV = mechanical ventilation; PC: primary care, LRTD = lower respiratory tract disease

*Nirsevimab efficacy for the palivizumab-eligible population is assumed to be non-inferior to that of palivizumab in the same population. **Incidence rates reflect epidemiological situation prior the introduction of palivizumab.

RESULTS

- **Comparative strategy**: From a US societal perspective, the current SoP results in 521,155 [433,952 - 642,138] RSV LRTD related health events over the first RSV season, including 44,218 [33,459 - 88,767] hospitalizations (incl. ICU and MV) annually, $1,831 million [$1,358 - $3,454] in both direct and indirect costs related to health events, and 10,078 [7,696 - 12,657] QALYs lost.
- **Intervention strategy**: All-infant immunization with nirsevimab at a single dose at the beginning of the RSV season among infants born out-of-season (OoS) and at birth among infants born within the season (WiS) is expected to result in 274,153 [228,271 - 338,612] fewer RSV-related health events, 22,658 [17,082 - 46,814] fewer hospitalizations (including ICU admissions and MV), 5,264 [4,029 - 6,631] QALYs saved, and a total increase of $316.8 [-$568.3 - $567.0] million, with respect to SoP at a net price of $500. No additional health events were prevented in season two as a non-inferior assumption was used. A saving of $27.9 million is observed due to the replacement of palivizumab with nirsevimab during the second RSV season for palivizumab eligible infants.
  - **Prevented cases per month of birth:** Among infants born OoS, a seasonal-based immunization strategy is estimated to prevent 146,130 [120,929 - 176,910] RSV-related health events (Figure 4), save an additional 2,816 [2,128 - 3,469] QALYs and result in an increase of $278 million [-$20 - $398]. Among infants born WiS, a seasonal-based immunization strategy is expected to prevent 128,023 [107,342 - 161,702] RSV-related health events (**Figure 2**), save an additional 2,448 [1,900 – 3,162] QALYs and increase total costs by $66 million [-$520 - $197].

Figure 2. RSV LRTD under SoP and Prevented Events with Nirsevimab Per Month of Birth

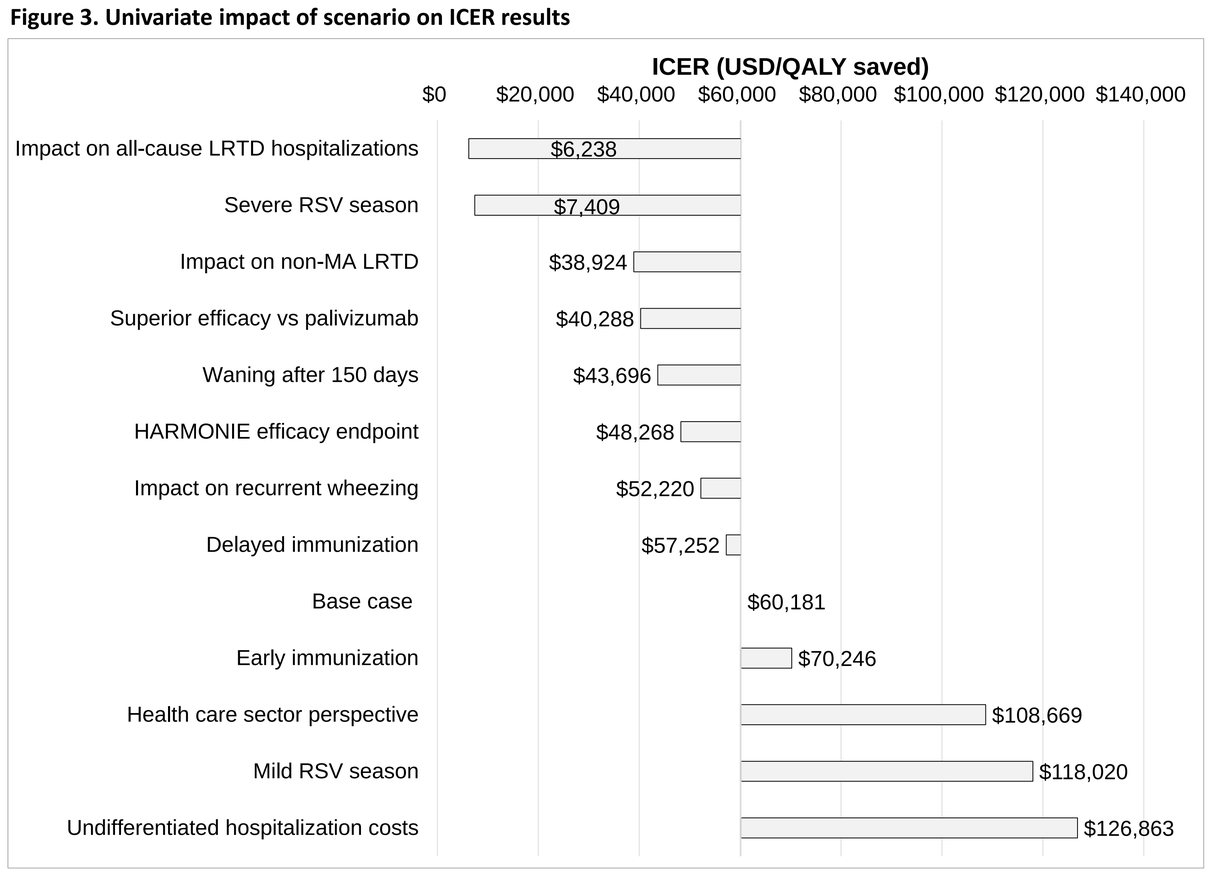


Note: Values are presented as base-case estimates. Error bars indicate lower and higher credible value.

Abbreviations: RSV = respiratory syncytial virus; LRTD = lower respiratory tract disease; SoP = standard of practice; OoS = out of season; WiS = within season

- **Incremental cost-effectiveness ratio (ICER)**: Over the first and second RSV season, the estimated ICER in the all-infant population at a net price of $500 is $60,181/QALY saved [Dominant - $140,751].
- **Number Needed to Immunize (NNI)**: With the introduction of nirsevimab, the estimated NNI to prevent one RSV LRTD in any setting was 11 [9 - 13] in the overall infant population, 131 [64 - 173] to prevent one RSV LRTD-related hospitalization
- **Scenario analysis and impact on ICER**: Twelve scenarios were tested, on (i) product profile with HARMONIE clinical trials efficacy readouts on RSV related hospitalizations and all-cause LRTD hospitalizations; waning after 5 months of protection; (ii) implementation, with early or delayed immunization, leveraging on pediatric routine visits; (iii) severity of the RSV season; (iv) costs ; (v) impact on additional events, such as non-medically attended or recurrent wheezing. Results are presented in **Figure 3.**

Figure 3. Univariate impact of scenario on ICER results



CONCLUSIONS

- **The use of nirsevimab in all infants could reduce healthcare resource use and infant deaths by 52% as well as cut total direct and indirect costs to the societal burden of RSV by 48%.**
- **The timely immunization with nirsevimab allows a consistent protection of the entire birth cohort, regardless of the month of birth, during the annual epidemic of RSV.**
- **Immunization in all infant is cost-effective approach, with the estimated ICER at $60,181/QALY saved**
- **The ongoing evidence generation on the broader impact of nirsevimab will support improved cost-effectiveness results.**

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CONFLICTS OF INTEREST:
AK, MB, JL, CR and MG: Sanofi — employees, may hold stock and/or stock options in the company.
AS, RM— salaried employees; EVIDERA, received professional service fees from Sanofi for conducting this research

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