# Cost-utility Analysis of an All-Preterm Infant Immunization with Nirsevimab Against Respiratory Syncytial Virus (RSV): Associated Disease at the Brazilian Private Healthcare System

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## INTRODUCTION

- Respiratory syncytial virus (RSV) is the leading cause of lower respiratory tract disease (LRTD) in infants and young children, contributing significantly to morbidity and mortality worldwide.
- Approximately 50% of children are infected within their first year of life, and nearly 100% by the age of two.
- Among children infected during their first year, it is estimated that 30% to 70% develop LRTD.
- Until 2023, the only available RSV prophylaxis in Brazil was the monoclonal antibody palivizumab, which was limited to a specific group: children under one year old born prematurely (with a gestational age (GA) of up to 28 weeks), children up to two years old with chronic lung disease of prematurity (CLDP) or pulmonary dysplasia, and those with congenital heart disease.
- ANVISA recently approved nirsevimab, a long-acting monoclonal antibody, without GA restrictions. It is indicated for neonates and infants entering or during their first RSV season, and children up to two years old with several comorbidities, including CLDP, hemodynamically significant cardiac disease, immunocompromised states, Down syndrome, cystic fibrosis, neuromuscular disease, and congenital airway anomalies.

## OBJECTIVE

- **This study aims to estimate the cost-effectiveness of nirsevimab compared to standard of practice (SoP) to prevent RSV in preterm infants at the Brazilian Private Healthcare System.**

## METHODS

### *Economic model and Comparators*

- A static model was developed to compare health and cost outcomes associated with nirsevimab use versus current SoP (palivizumab for preterm <29 weeks of GA and children <2 years old with CLDP or pulmonary dysplasia, and those with congenital heart disease, or no prophylaxis for infants 29-37 weeks of GA) (Figure 1).

### *RSV season*

- Due to varying seasonality across Brazilian regions[3], data was harmonized, so prophylaxis corresponds to the same period at the cost-effectiveness model.

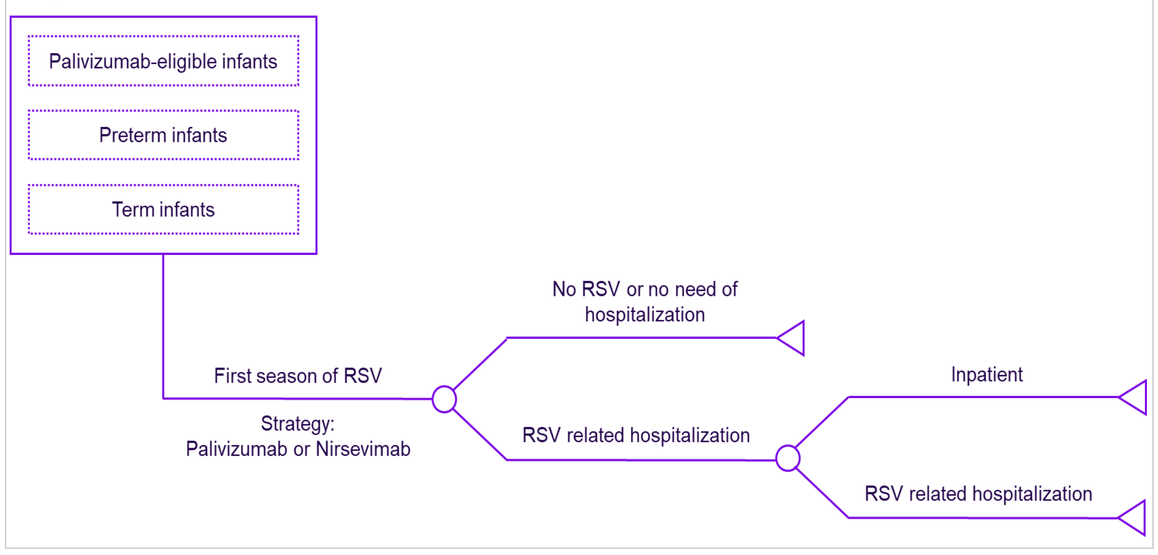
### *Parameters*

- Parameters were obtained from Brazilian databases DATASUS (SINASC, SIA-AIH and ANS-TABNET), D-TISS panel, CMED, IBGE, and published articles[4-8]. All costs were updated to present values, adjusted by National monetary correction indicator (IPCA), for January 31st, 2024.

### *Time horizon and Discount rates*

- The analysis horizon was defined as lifetime.
- Discount rates of 5% were applied.

**Figure 1: Static model**

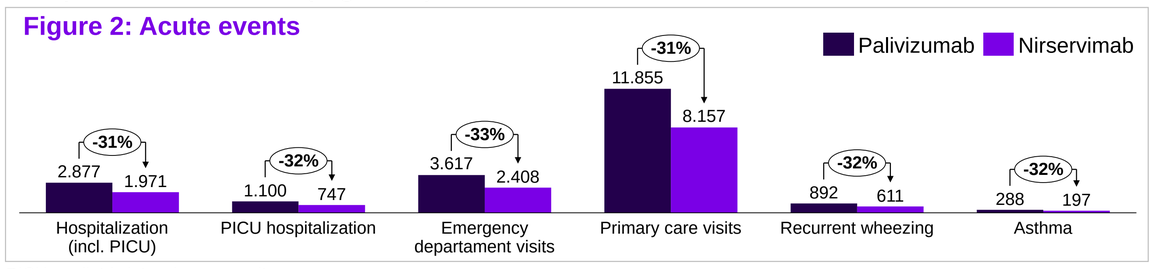



RSV: respiratory syncytial virus.

## RESULTS

According to the analysis, nowadays, 4,882 infants were palivizumab eligible in private healthcare system. Expanding prophylaxis to include all preterm infants and those with comorbidities, nirsevimab would protect an additional 36,275 infants, preventing 906 hospitalizations (including 353 in the PICU [pediatric intensive care unit]), 1,209 emergency department visits, and 3,698 primary care visits. Nirsevimab would also prevent 281 cases of recurrent wheezing and 91 cases of asthma, respectively, compared to the SoP. (Figure 2).

**Figure 2: Acute events**




PICU: pediatric intensive care unit.

The cost of prophylaxis was approximately 1,698.90 BRL with nirsevimab and 1,420.70 BRL with SoP, resulting in an increase of 278.20 BRL per child.

Although prophylaxis with nirsevimab will result in an incremental cost of approximately R$5.3 million (Figure 3), the population covered against the virus will increase 8.4-fold.

However, it also yielded a gain of 195.6 QALYs, resulting in an incremental cost-utility ratio of 27,118 BRL/QALY (Table 1).

**Figure 3: Costs (BRL)**

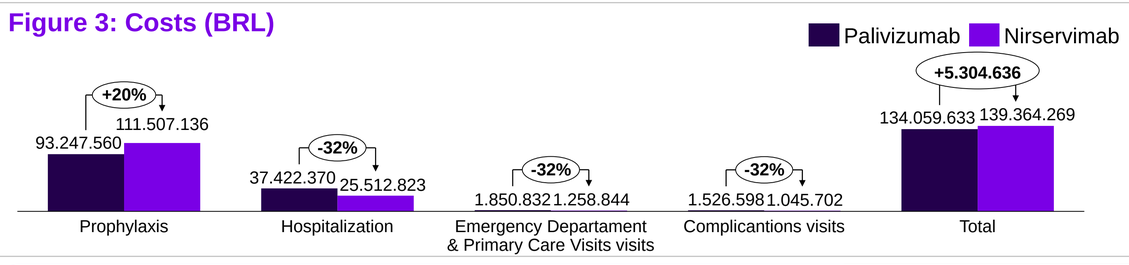


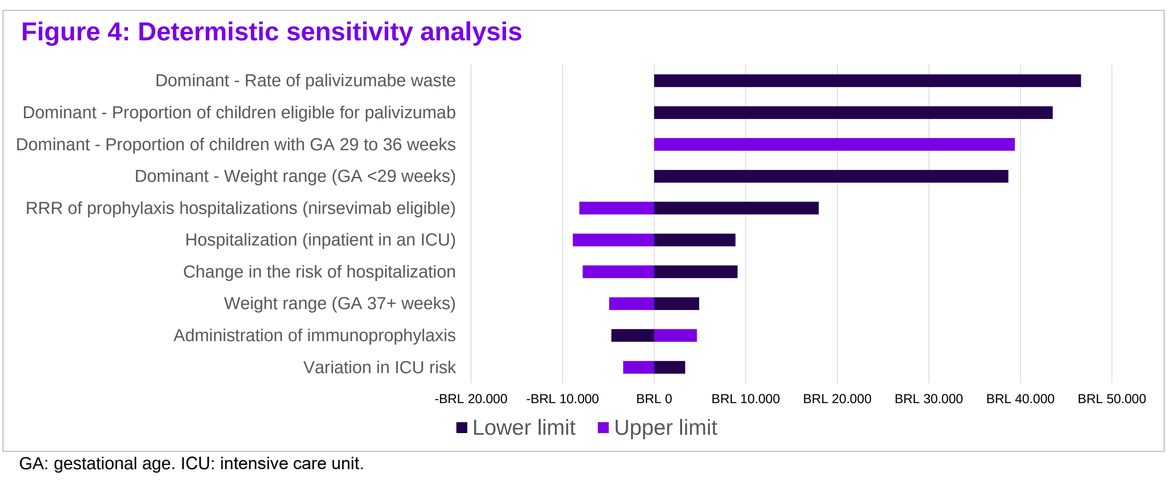

**Table 1: Incremental cost effectiveness**

| Parameter | Total population | |
|---|---|---|
| | Population | Per child |
| Incremental cost | BRL 5,304,636 | BRL 80.82 |
| Incremental QALY | 195,6 | 0,0030 |
| **ICER** | **BRL 27,118/QALY** | |

QALY: quality-adjusted life year. ICER: incremental cost-effectiveness ratio.

The deterministic sensitivity analysis (Figure 4) identified that the main factors impacting the results were the rate of palivizumab waste, the proportion of children eligible for palivizumab, the proportion of children with a GA of 29 to 36 weeks, and weight change in children with GA under 29 weeks. Probabilistic sensitivity analysis (Figure 5) shows that 27% of simulations indicate cost-saving (dominance) and 99.7% indicate cost-effectiveness.

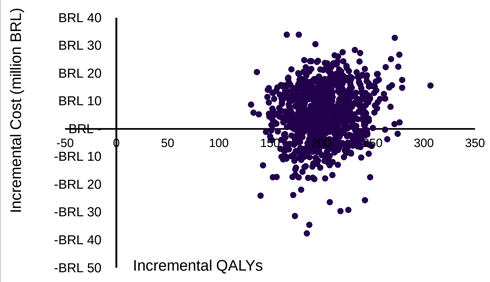
**Figure 4: Determistic sensitivity analysis**




GA: gestational age. ICU: intensive care unit.

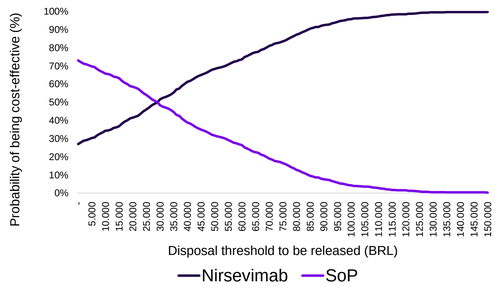
The acceptability curve indicated that there is a 99.7% probability that the intervention would be considered cost-effective at a threshold of three times the GDP per capita (2023 Brazilian GDP per capita = 50,194 BRL) (Figure 6).

**Figure 5: Incremental cost effectiveness plan**




QALY: quality-adjusted life year.

**Figure 6: Acceptability curve**




QALY: quality-adjusted life year.

## CONCLUSIONS

Immunizing all premature babies with nirsevimab, compared to the SoP, has been shown to be a cost-effective strategy within the Brazilian private healthcare system. This approach can reduce events such as hospitalizations – including ICU and emergency room visits – as well as outpatient visits, promoting more efficient utilization of healthcare resources. Moreover, it presents an extremely attractive strategy for payers and policymakers, while also providing broad benefits to society

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**CONFLICTS OF INTEREST**

SFW, JS, AT and SS: Sanofi employee, may hold stock and/or stock options in the company. MS, RTS, MF, NBS and BM: : received professional service fees from Sanofi for conducting this research.

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