

BACKGROUND

Respiratory syncytial virus (RSV) is the leading cause of severe lower respiratory tract infection in preterm infants, the primary cause of bronchiolitis, pneumonia and hospitalisation in this vulnerable population. Globally, RSV is responsible for approximately 33 million acute lower respiratory tract infections annually in children under 5, with the highest burden concentrated in low- and middle-income countries.

In **Ecuador**, epidemiological data on RSV incidence remain limited, but respiratory infections constitute a leading cause of paediatric hospitalisation within the public health network. The Ecuadorian Social Security Institute (IESS) and Ministry of Public Health together provide healthcare coverage to over 90% of the population through the integrated public network (RPIS), where paediatric ICU capacity constraints are recurrent during peak RSV seasons (May–August).

Palivizumab is the only approved immunoprophylaxis against RSV in high-risk infants. Its efficacy is well-established (IMPact-RSV; SENTINEL1), and cost-effectiveness has been demonstrated in the UK, Austria, Spain and Colombia — but **no local economic evidence exists for Ecuador**.

OBJECTIVE

To evaluate the cost-utility of palivizumab prophylaxis vs. no prophylaxis in preterm infants (≤35 wGA, ≤6 months) from the perspective of the Ecuadorian Public Health System as third-party payer, providing the first local economic evidence to inform national formulary and coverage decisions.

METHODS

Model:	Decision tree, 5-dose palivizumab vs. no prophylaxis; tracks RSV hospitalization, then recurrent wheezing over 6 years
Population:	Preterm infants ≤35 wGA and ≤6 months of age (highest-risk group)
Perspective:	The Ecuadorian Public Health System, as a third-party payer, is named the Integrated Public Health Network (RPIS)
Time horizon:	6 years; costs & outcomes discounted at 5% per year (national guidance)
Costs:	2024 USD; from official IESS Health Production Statistics; palivizumab at ceiling price with statutory 15% discount (Art. 163 LoH)
Uncertainty:	PSA with 1,000 Monte Carlo simulations; Beta (probabilities), log-normal (costs), gamma (utilities)
Threshold:	Per-capita GDP, Ecuador's national reference (national guidance)
Reporting:	Consolidated Health Economic Evaluation Reporting Standards — CHEERS 2022

EPIDEMIOLOGICAL & CLINICAL PARAMETERS

Parameter	Value	Source
RSV hospitalisation risk (no prophylaxis)	34.91%	SENTINEL1
Palivizumab efficacy — reduced hospitalisation	77.78%	IMPact-RSV trial
Palivizumab efficacy — reduced wheezing	46.41%	Blanken et al.
RSV hospitalisation frequency / year	2.52	Buendia et al.
Probability of wheezing after RSV infection	82.81%	Franco Looor et al.
Recurrent wheezing episodes / year	4.63 (95% CI: 3.70-5.78)	Rodriguez-Martinez
Discount rate (costs & outcomes)	5% annually	MSP Ecuador, 2022

HEALTHCARE SYSTEM CONTEXT

Ecuador's public health system operates through the Integrated Public Health Network (RPIS), with the IESS and Ministry of Public Health together covering over 90% of the population. Ecuador adopted the USD as its official currency in 2000, making cost estimates directly comparable to international data without currency conversion adjustments.

Drug pricing: Palivizumab's unit cost was extracted from Ecuador's national drug ceiling-price database (November 2025), with the statutory 15% discount applied per Article 163 of the Organic Health Law, the same discount applicable to all speciality biologics procured through public networks. This represents the maximum legally permitted price for MoH procurement.

Current formulary gap: As of the analysis date, no RSV-specific preventive intervention is routinely available for preterm infants within the Ecuadorian public health system. Palivizumab has not been included in the national formulary (Cuadro Nacional de Medicamentos Básicos), leaving the highest-risk neonatal population without access to the only evidence-based prophylactic option, a gap this analysis directly addresses.

RSV seasonality in Ecuador: RSV circulation in Ecuador peaks between May and August, coinciding with the rainy season on the coast and elevated humidity in inter-Andean valleys. This defined seasonal pattern allows for targeted prophylaxis planning; palivizumab can be administered strategically at the start of the season to maximise population-level protection during the highest-risk months.

DECISION-ANALYTIC MODEL

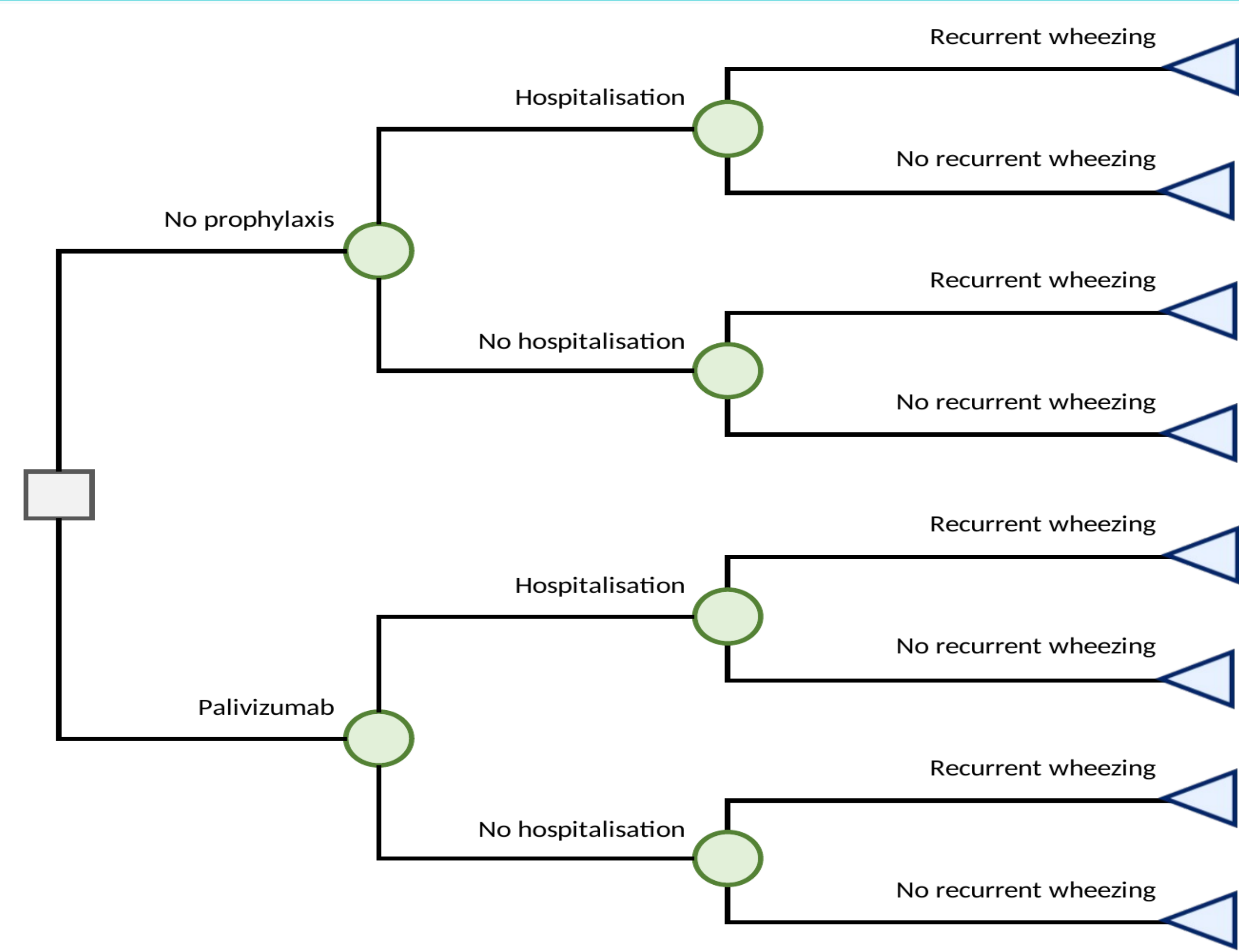


Figure 1. Decision tree comparing palivizumab (5-dose) vs. no prophylaxis. Each arm tracks RSV-related hospitalisation followed by recurrent wheezing.

COSTS, UTILITIES & DISUTILITY ESTIMATES

Item	Value / Source
COSTS	
RSV hospitalisation / episode (ICD J12.1)	USD 3,346.08 IESS AS400, 2023-24
Wheezing exacerbation / episode (ICD J45.9)	USD 282.57 IESS AS400, 2023
Palivizumab 5-dose regimen (15% statutory discount, Art. 163)	Ceiling price STFP-MSP, Nov 2025
UTILITIES	
No RSV infection (healthy)	1.000 Assumption
RSV, no hospitalisation	0.950 Nguyen et al. 2025
RSV — general ward	0.580 Nguyen et al. 2025
RSV — ICU/HDU	0.390 Nguyen et al. 2025
DISUTILITY	
Recurrent wheezing (per year, proxy: childhood asthma)	0.0830 Rodriguez-Martinez et al.

MODEL STRUCTURE & RATIONALE

Model selection: A decision tree framework was selected, given the short- to medium-term analytic horizon, the discrete nature of the clinical events modelled, and the absence of recurrent transitions beyond the initial RSV season and subsequent wheezing episodes. This structure avoids unnecessary assumptions required by state-transition models while remaining consistent with validated economic evaluations of palivizumab in LATAM settings.

Clinical inputs: The probability of RSV hospitalisation without prophylaxis was derived from the SENTINEL1 observational study, considered an upper-bound approximation for this high-risk population. In the absence of nationally representative Ecuadorian incidence data, hospitalisation frequency was informed by a Colombian cost study in neonates and infants, a methodologically sound regional comparator. The probability of recurrent wheezing after RSV infection was sourced from an observational study in Ecuadorian infants (Franco-Looor 2023).

Cost inputs: All unit costs are expressed in 2024 USD. Ecuador adopted the USD as its official currency in 2000, eliminating the need for currency conversion or purchasing power parity adjustments. The average cost per RSV hospitalisation episode (USD 3,346.08) was obtained from the IESS Health Production Statistics Viewer, based on 2023–2024 hospital discharge and billing records for ICD-10 code J12.1. Wheezing exacerbation costs (ICD-10 J45.9) were estimated at USD 282.57 per episode from the same source.

Probabilistic sensitivity analysis: To assess robustness and account for parameter uncertainty, a PSA was conducted using 1,000 Monte Carlo simulations. Key parameters varied simultaneously included: efficacy of palivizumab against RSV hospitalisation, efficacy against recurrent wheezing, probability of RSV-related hospitalisation in unexposed infants, cost per hospitalisation episode, cost per wheezing exacerbation, cost of the 5-dose regimen, and all health utility values.

BASE-CASE RESULTS



Strategy	Cost (USD)	QALYs
No prophylaxis	9,243.27	0.2900
Palivizumab	8,179.42	0.5360

COST-EFFECTIVENESS PLANE

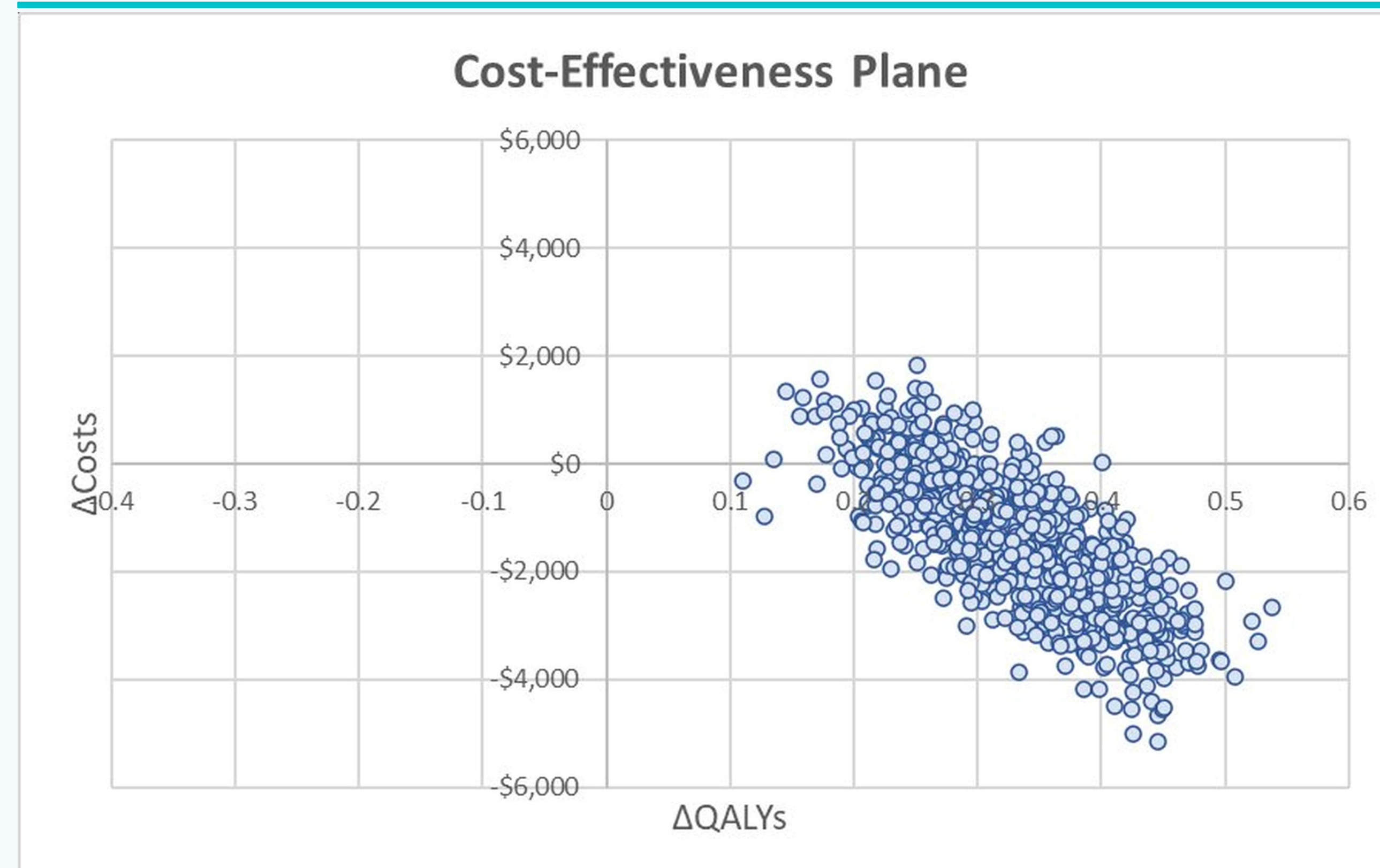


Figure 2. 1,000 Monte Carlo simulations — nearly all in the southeast quadrant (more effective, less costly), confirming dominant profile.

Key Results at a Glance

- 💰 **USD 1,063.85 saved** per infant (= 2.2× Ecuador minimum wage, USD 482)
- ➕ **+0.246 QALYs gained** (0.2900 → 0.5360 per patient)
- ✓ **>90% of 1,000 PSA simulations** in dominant SE quadrant (↑100% at any WTP)
- 🏠 **USD 3,346.08 avg hospitalisation cost avoided** per RSV episode

POLICY CONTEXT

Financial impact: Each high-risk preterm infant prevented from RSV hospitalisation avoids USD 3,346.08 in direct costs plus up to USD 1,309.93 in downstream wheezing exacerbation costs over the 6-year horizon. The 5-dose palivizumab regimen pays for itself within the NHS budget, with net savings of USD 1,063.85 per patient even before accounting for quality-of-life benefits.

Healthcare system context: The IESS and Ministry of Public Health cover >90% of Ecuador's population. Paediatric ICU capacity is recurrently strained during RSV peak season (May–August); bronchiolitis is among the leading diagnostic categories for paediatric emergency admissions nationally.

Formulary implications: Results support inclusion of palivizumab in Ecuador's national formulary for preterm infants ≤35 wGA. Net cost savings plus improved outcomes place this intervention in the highest evidence tier for health technology decisions under Ecuador's per-capita GDP threshold (CHEERS 2022; national guidance).

Future research: Emerging RSV prevention alternatives, maternal vaccination and long-acting monoclonal antibodies (nirsevimab), warrant head-to-head economic evaluation as locally relevant data become available in Ecuador.

COST-EFFECTIVENESS ACCEPTABILITY

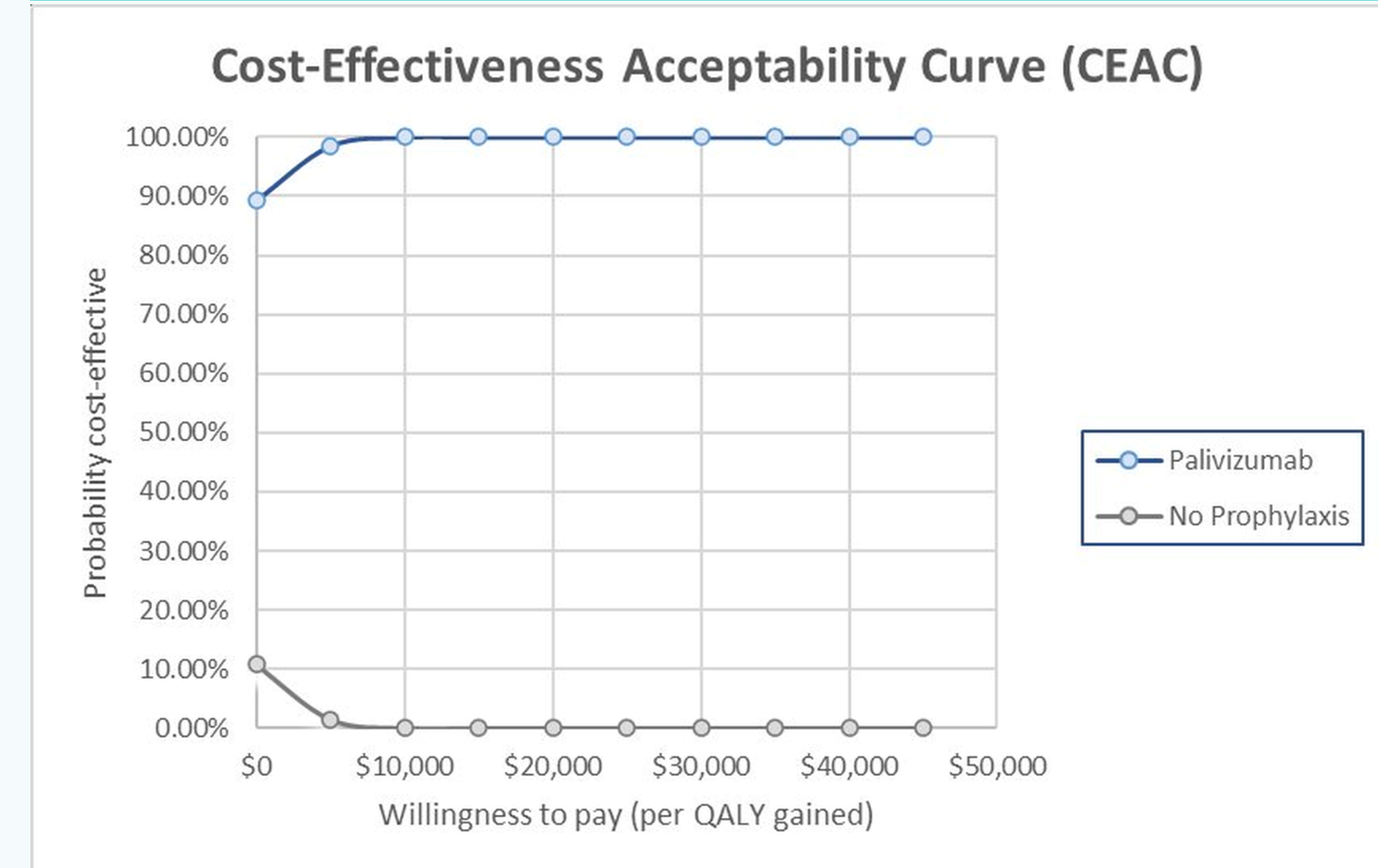


Figure 3. CEAC — palivizumab exceeds 90% probability of cost-effectiveness even at WTP = USD 0/QALY, approaching 100% at all higher thresholds.

DISCUSSION

Hospitalisation is the key driver: RSV hospitalisation (~USD 3,346/episode) is the costliest event. The 77.8% reduction achieved by palivizumab generates savings that more than offset the cost of prophylaxis, even before wheezing reductions.

Robust across all uncertainty: Dominance holds in >90% of 1,000 PSA simulations at WTP = USD 0, approaching 100% at all higher thresholds, robust even under wide parameter ranges from cross-country extrapolation.

Consistent with global evidence: Results align with evaluations from Austria, the UK, Spain and other LMIC settings. Most directly, the Colombian cost-utility analysis (Ordóñez & Huertas, BMC Infect Dis 2024) used the same validated model structure, capturing acute RSV hospitalisation and medium-term wheezing, and also found dominance, supporting cross-regional comparability.

Study strengths:

- Locally validated IESS cost data from official AS400 national databases
- Statutory 15% drug discount applied per Art. 163 Organic Health Law
- Full CHEERS 2022 compliance
- 1,000 Monte Carlo iterations
- First local economic evidence from the Ecuadorian public payer perspective
- Model structure validated against the Colombian precedent (Ordóñez & Huertas 2024)

Limitations: RSV incidence extrapolated from international data; 6-year horizon may underestimate lifetime wheezing burden; full adherence assumed; nirsevimab and maternal vaccine not modelled.

CONCLUSION

Palivizumab is a **dominant and cost-saving strategy**: it is **simultaneously less costly (–USD 1,063.85/patient) and more effective (+0.246 QALYs) than no prophylaxis in preterm infants in Ecuador**.

DOMINANT →

Greater than 90% probability of cost-effectiveness at WTP = USD 0/QALY, approaching 100% across all clinically relevant thresholds including Ecuador's national per-capita GDP reference.

ROBUST →

This analysis provides the first local economic evidence from the Ecuadorian public payer perspective, directly supporting inclusion of palivizumab in Ecuador's national formulary for preterm infants ≤35 wGA, filling a critical evidence gap for health decision-makers.

FIRST LOCAL EVIDENCE →

By reducing RSV hospitalisations and recurrent wheezing, palivizumab relieves paediatric ICU pressure during peak RSV season (May–Aug), while generating net savings of >2× the national monthly minimum wage per high-risk infant protected.

KEY REFERENCES

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FUNDING & DISCLOSURES

No specific funding received. The author declare no commercial or financial relationships with palivizumab manufacturers or any RSV prevention product for developing this study. Independent academic and consulting work conducted within Value Health Economics Group.

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ISPOR 2026 • EE393
Poster Session 4
Tue May 19 • 4:00–7:00 PM
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