

Cost-effectiveness Analysis of Bivalent Respiratory Syncytial Virus Prefusion F Vaccine for Adults 60 Years of Age and Older in Japan

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BACKGROUND

- Respiratory syncytial virus (RSV) can cause severe respiratory illness in older adults, similar to influenza, which contributes to morbidity, mortality, and increased healthcare burden.¹
- A bivalent RSV prefusion F protein-based (RSVpreF) vaccine was approved in 2024 in Japan²; however, it has not been included in the Japanese National Immunization Program (NIP) as of April 2025.

OBJECTIVE

To evaluate the cost-effectiveness of the RSVpreF adult vaccine compared with no vaccination in Japanese adults aged ≥60 years
from both the payer and societal perspectives.

METHODS

Model Overview

- A previously published population-based, multi-cohort, Markov-type model³ was adapted to estimate the economic and health impact of vaccination against RSV in a hypothetical Japanese population aged ≥60 years.
- Health and economic outcomes were projected based on age, comorbidity status, RSV incidence rates, general population mortality rates, RSV case-fatality rates (CFRs), vaccination status and time since vaccination, accounting for monthly variation in the timing of vaccination and rates of RSV illness.

Model Outcomes

- Health outcomes: RSV cases, stratified by care setting (hospitalization, emergency department (ED) visit, and outpatient visit), and RSV-related death.
- Economic outcomes: Medical care costs, vaccination costs, and costs related to productivity losses.

Model Inputs

- Population: Adults aged ≥60 years (Population Estimates 2023)⁴, stratified into four age groups (60–64, 65–74, 75–84, 85+), further categorized by comorbidity profile (high risk or low risk) (**Table 1**).
- RSV incidence rates were estimated based on methods by Mizukami et al.⁵ and Kurai et al.⁶ (Table 1).
- Vaccine effectiveness (VE) was based on the results of seasons 1 and 2 of the RENOIR trial and extrapolation up to 4 season⁷ (Figure 1).
- Other key model inputs were as shown in Table 1.

Figure 1. Vaccine effectiveness against RSV hospitalization/ED visit and RSV outpatient visit (base case)

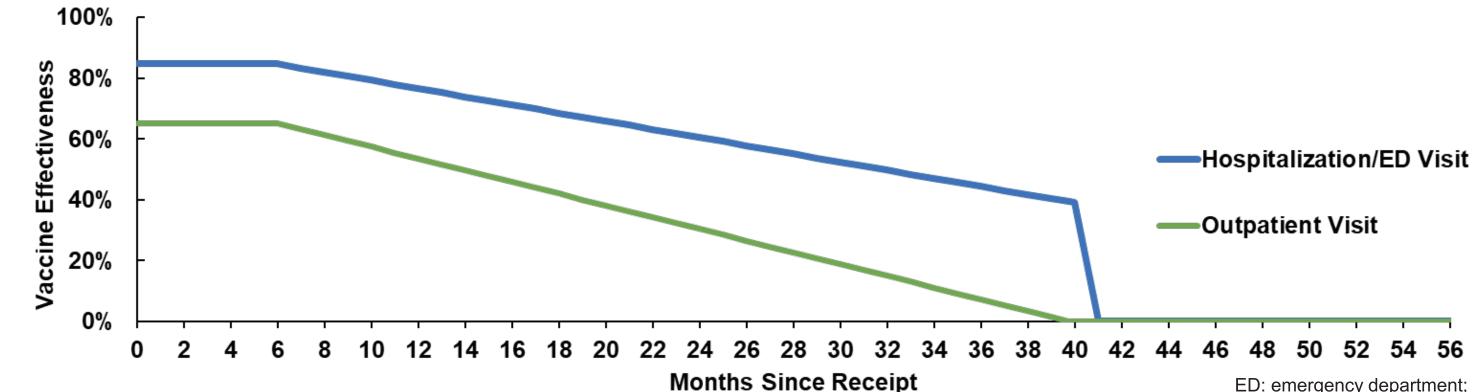


Table 1. Key model inputs

ED: emergency department; RSV: respiratory syncytial virus; VE: vaccine effectiveness.

	Age (years) and risk level							
	60–64		65–74		75–84		85+	
	Low	High	Low	High	Low	High	Low	High
Number of population	7,508,000		16,149,000		13,368,000		6,707,000	
Risk distribution (%) a, 8, 9, 10	88.8	11.2	76.4	23.6	76.4	23.6	76.4	23.6
RSV Incidence rates per 100,000 persons b, 5, 6, 11, 12, 13								
RSV hospitalization	33.2	555.1	45.9	776.4	134.1	2300.1	158.9	2786.1
RSV ED visit	175.7	441.8	201.8	572.9	130.7	400.1	143.2	470.8
RSV outpatient visit	1929.9	3341.5	1940.4	3732.1	1305.1	2714.8	1310.8	2954.2
Vaccination rate (%) 14	50.0							
Mortality rates per 100 persons								
Annual general population mortality 15	0.367		1.171		2.963		10.537	
RSV hospitalization-related CFR ¹⁶	1		3.6					
General population utilities ¹⁷	0.928		0.903		0.843		0.789	
Annual QALY losses 18		RS'	V hospitaliza	ntion: 0.20; R	SV ED/outpa	atient visits: (0.06	
Vaccine cost (JPY) 19	23,948							
Vaccine administration cost (JPY) 20	3,310							
Medical costs per episode (JPY) ¹¹	RSV hospitalization: 865,723; RSV ED visit: 11,307; RSV outpatient visit: 6,661							
Work losses: Patients		•	•	,	,	'	•	
Workforce participation rate (%) ²¹	8	1.8	4	2.2	1	1.4		0
Daily wage (JPY) ²²	13,889							
Number of work-loss days ^{23, 24}	RSV hospitalization ²³ : 30; RSV ED/outpatient visits ²⁴ : 5							
Work losses: Caregivers				,				
Workforce participation rate (%) ²¹				6	1.2			
Daily wage (JPY) ²²	13,889							
Number of work-loss days ^c	RSV hospitalization: 11; RSV ED/outpatient visits: 5							

CFR: case-fatality rate; ED: emergency department; JPY: Japanese yen; QALY: quality-adjusted life-year; RSV: respiratory syncytial virus.

a High-risk conditions include chronic lung, heart, renal, and liver disease; diabetes mellitus; cancer; organ transplantation; cerebrospinal fluid leakage; acquired immune deficiency syndrome; functional or anatomic asplenia; and alcoholism [8]. Risk distribution was calculated based on the data reported by Imai et al.[8], patient survey [9], and scale of hospitals data [10].

b The RSV incidence rates calculated based on Mizukami et al. [5] and Kurai et al. [6] were adjusted using Japanese population, proportions of people at low and high risk, and distribution of RSV incidence rates by care setting, age group, and risk group derived based on a recent study of adults in the United States [12, 13].

C Assumption.

Model Analyses

- Base case: Cost-effectiveness of a single dose of the vaccine versus no vaccination from the Japanese payer and societal perspectives over a lifetime horizon (i.e., maximum age of 99 years) at a 2% discount rate.
- Cost-effectiveness was based on incremental cost-effectiveness ratios (ICERs) of the RSVpreF vaccination versus no vaccination (cost-effectiveness threshold: Japanese yen [JPY] 5 million per quality-adjusted life-year [QALY]).
- Scenario analyses, one-way deterministic sensitivity analyses (DSA), and probabilistic sensitivity analyses (PSA) were performed to account for uncertainty associated with model parameters.

RESULTS

- The introduction of RSVpreF vaccine is anticipated to reduce 204,145 cases of RSV hospitalizations, 113,170 cases of RSV ED visits, 542,790 cases of RSV outpatient visits, and 27,764 RSV-related deaths compared with no vaccination (Table 2).
- These reductions resulted in a JPY 176,121 million drop in medical costs and a JPY 161,307 million drop in productivity losses (Table 2)
- The RSVpreF vaccination was found to be cost-effective compared with no vaccination, with an ICER of JPY 1,458,898/QALY from the payer perspective and JPY 903,263/QALY from the societal perspective (Table 3).
- Results from the scenario analyses (Table 4), DSA (Figure 2), and PSA (Figure 3) confirmed the robustness of the base-case results.

Table 2. Base case: Health and economic outcomes (N=43.732.000)

	No vaccine	RSV pre F	Difference
Health outcomes			
No. of cases			
RSV hospitalization	3,956,841	3,752,696	-204,145
RSV ED visit	1,573,082	1,459,912	-113,170
RSV outpatient visit	12,805,628	12,262,839	-542,790
Total	18,335,551	17,475,447	-860,105
No. of RSV-related deaths	538,130	510,367	-27,764
Costs (in millions, JPY) (per population)			
Medical costs	2,814,270	2,638,149	-176,121
Vaccination costs	0	599,656	599,656
Costs related to productivity losses	1,778,754	1,617,447	-161,307

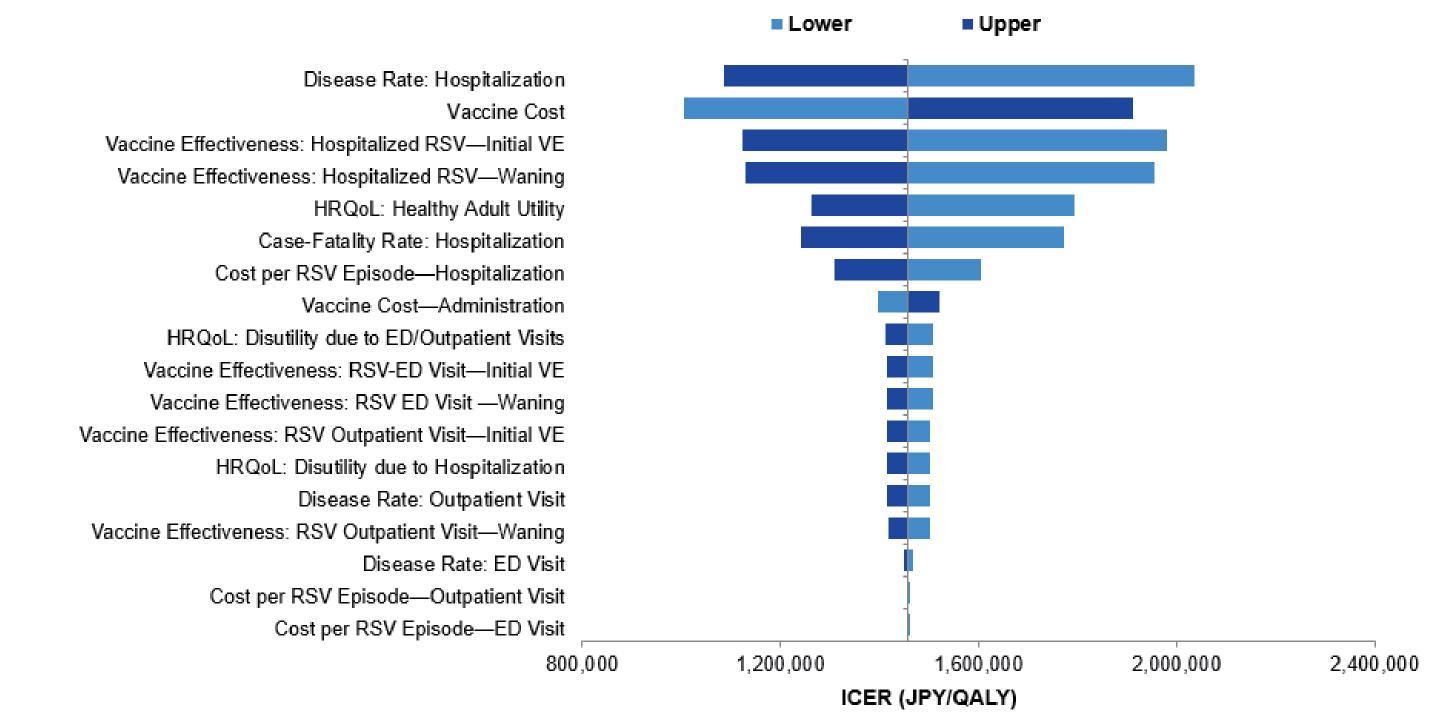
ED: emergency department; JPY: Japanese yen; RSV: respiratory syncytial virus; RSVpreF: RSV prefusion F protein-based.

Table 3. Base case: cost-effectiveness analysis results (N=43,732,000)

	No vaccine	RSVpreF	Difference
QALY (per population)	474,307,460	474,597,772	290,312
Costs (in millions, JPY) (per population)			
Medical costs + vaccination costs	2,814,270	3,237,805	423,535
Medical costs + vaccination costs + productivity losses	4,593,024	4,855,252	262,228
ICER (JPY/QALY gained)*			
Payer perspective			1,458,898
Societal perspective			903,263

^{*}The cost-effectiveness threshold was JPY 5 million/QALY.
ICER: incremental cost-effectiveness ratio; JPY: Japanese yen; QALY: quality-adjusted life-year; RSVpreF: RSV prefusion F protein-based

Figure 2. Tornado diagram of the RSVpreF vaccination vs. no vaccination (payer perspective)



± 25% of base-case values.

ED: emergency department; HRQoL: health-related quality of life; ICER: incremental cost-effectiveness ratio; JPY: Japanese yen; QALY: quality-adjusted life-year;

LIMITATIONS

- Epidemiological data on RSV incidence rates in Japan are limited.
- In the base-case analysis, the VE decline between seasons 1 and 2 was extended and conservatively truncated at the end of season 4 because the efficacy remained high in season 2 during the RENOIR trial ^{26, 27} (**Figure 1**). The exact duration and magnitude of VE require confirmation by ongoing real-world studies.
- The RSVpreF vaccine price is not officially determined in Japan.
- The model excludes other RSV-related complications and their costs.

REFERENCES

References can be accessed via this QR code:

RSV: respiratory syncytial virus; RSVpreF: RSV prefusion F protein-based; VE: vaccine effectiveness



Table 4. Scenario analysis results

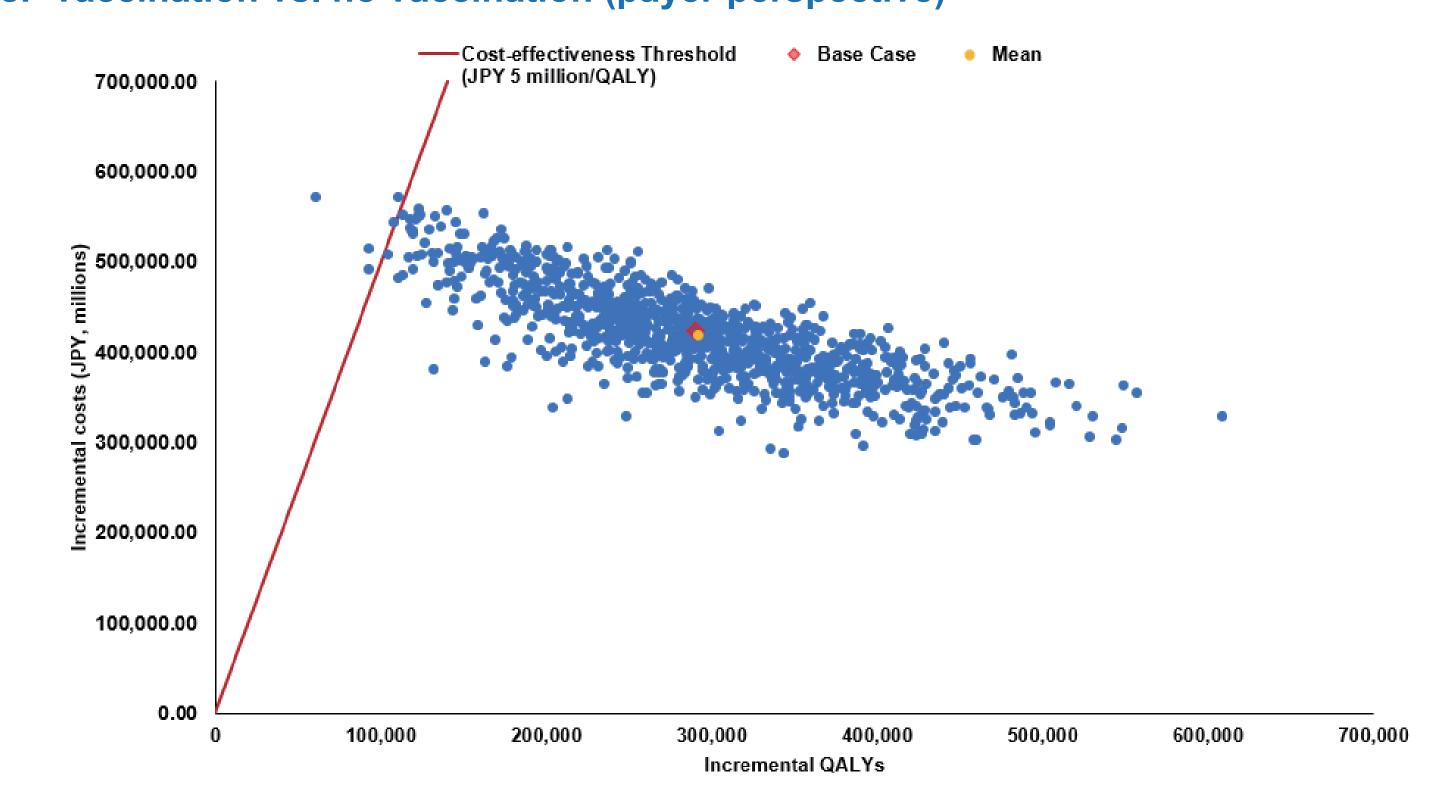
Scenario settings		Incremental v	ICERs (JPY/QALY)		
		Costs (n	_		
	QALYs	Medical costs + vaccination costs	Medical costs + vaccination costs + productivity losses	Payer	Societal
Base case	290,312	423,535	262,228	1,458,898	903,263
Age and risk group					
≥65 years	249,781	319,400	207,700	1,278,718	831,527
≥70 years	200,787	218,594	150,484	1,088,687	749,471
≥75 years	145,931	148,407	110,833	1,016,964	759,488
≥80 years	75,488	83,464	68,072	1,105,660	901,762
≥85 years	36,517	45,871	38,289	1,256,152	1,048,52
≥90 years	11,488	17,956	15,050	1,563,016	1,310,06
65 years and those aged 60–64 years at high risk	34,746	32,046	-7,829	922,303	Dominant
≥65 years and those aged 60–64 years at high risk	274,977	329,511	187,750	1,198,325	682,786
≥75 years and those aged 60–74 years at high risk	249,103	170,110	50,475	682,891	202,627
RSV incidence rate per Kurai et al. b, 25	99,567	557,638	480,207	5,600,615	4,822,93
RSV hospitalization-related CFR: 7.7% VE-values ^c	198,843	421,499	297,350	2,119,756	1,495,40
Conservative	244,387	454,135	314,612	1,858,262	1,287,35
Optimistic	331,839	394,375	215,377	1,188,451	649,041

b The RSV incidence rates based on Kurai et al. [25] were adjusted using Japanese population, proportions of people at low and high risk, and distribution of US-specific RSV incidence rates by care setting, age group, and risk group derived based on a recent study of adults in the United States [12, 13].

c In the conservative scenario, the rate of linear decline was assumed to persist through month 30 (end of season 3) and was truncated at month 31 (i.e., assumed to reach 0% by month 31). In to optimistic scenario, the observed slope between months 7 and 16 was assumed to persist until effectiveness reached 0% (for VE RSV hospitalization/RSV ED, month 70).

CFR: case-fatality rate; ED: emergency department; ICER: incremental cost-effectiveness ratio; JPY: Japanese yen; QALY: quality-adjusted life-year; RSV: respiratory syncytial virus; RSV prefix profession F protein-based: VE: vaccine effectiveness.

Figure 3. Probabilistic sensitivity analysis results for cost-effectiveness of the RSVpreF vaccination vs. no vaccination (payer perspective)



JPY: Japanese yen; QALY: quality-adjusted life-year; RSVpreF: RSV prefusion F protein-based.

CONCLUSIONS

- The RSVpreF vaccine is cost-effective compared to no vaccination for adults aged 60 years and older in Japan.
- The introduction of the RSVpreF vaccine has the potential to provide public health benefits by protecting older adults against RSV-related diseases and reducing healthcare burden.
- These findings will be valuable in informing policy decisions regarding the inclusion of the RSVpreF vaccine in the routine vaccination program.

DISCLOSURES

- The model was developed by Pfizer Inc., and this research was funded by Pfizer Japan Inc.
- Kosaku Komiya has received consultation fees and honoraria for delivering promotional lectures from Pfizer Japan Inc.
- IQVIA was paid by Pfizer Japan Inc. for conducting the study and medical writing support.

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