



April 4, 2023

[C2H2111] Summary of cost-effectiveness evaluation of remdesivir (Veklury®)

1. Indication

Coronavirus disease 2019 (COVID-19)

2. Price of the drug

Remdesivir has been reimbursed since August 2021 at JPY 63,342 (as of January 2023). The price is calculated based on the Cost Calculation Method. This product is designated as an H1 cost-effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

The scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below. This product is used to treat COVID-19. As the effectiveness of remdesivir for COVID-19 is not likely to be homogeneous and depends on the severity as per the Clinical Management of Patients with COVID-19 by the Ministry of Health, Labour and Welfare (MHLW), the population was divided into three parts.

Population	Adults with COVID-19 were categorized based on the severity* as follows: (a) Moderate I (93% < SpO ₂ < 96%; shortness of breath and pneumonia findings) (b) Moderate II (SpO ₂ ≤ 93%; oxygen administration required) (c) Severe (administration to ICU or mechanical ventilator required)
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	* The definition follows Clinical Management of Patients with COVID-19 by the MHLW
Comparator	(a)(b)(c): Standard of Care (SoC)

4. Evaluation of additional benefits

The manufacturer searched for randomized controlled trials (RCTs) and non-RCTs and then performed meta-analysis without distinguishing between RCTs and non-RCTs. The manufacturer insisted on the additional benefits of remdesivir over SoC in each population because the meta-analysis showed that remdesivir had statistically significant effectiveness or a superior tendency in recovery (discharge) and mortality compared to SoC. However, the academic group insisted that only RCTs be used to evaluate the additional benefits. Moreover, they insisted that the final SOLIDARITY trial report by the WHO should be considered in the evaluation of additional benefits because they identified the final report in the review process owing to the difference in the article search period. The results of the meta-analysis by the academic group are as below. The third ECCEE session concluded that the results of the academic group were more appropriate. Based on the discussion, remdesivir has additional benefits for populations (a) and (b), but not for population (c).

Population	Endpoint	Hazard ratio (95% confidence interval) [†]
(a) Moderate I	Recovery (Discharge)	1.05 (0.88 to 1.24)
	Mortality	0.76 (0.48 to 1.22)
(b) Moderate II	Recovery (Discharge)	1.15 (0.87 to 1.53)
	Mortality	0.70 (0.39 to 1.23)
(c) Severe	Recovery (Discharge)	0.93 (0.76 to 1.14)
	Mortality	1.13 (0.91 to 1.40)

[†]Hazard ratios for recovery (discharge) greater than 1 and for mortality less than 1, indicate that remdesivir is more effective than the comparator.

5. Results of the cost-effectiveness analysis

The manufacturer performed a cost-utility analysis for each population using decision tree and Markov models. The manufacturer used the results of the evaluation of additional benefits in the analysis. The academic group re-analyzed

using the results from the meta-analysis based on RCTs only (including the final SOLIDARITY trial report) for populations (a) and (b). For population (c), the academic group performed the cost-minimization analysis, as remdesivir did not show any additional benefits over SoC. The ECCEE accepted the following results.

Population	Comparator	ICER (JPY/QALY)
(a) Moderate I	SoC	14,555,045
(b) Moderate II	SoC	190,503
(c) Severe	SoC	Cost increase