

Multicriteria Health Technology Assessments for High-Cost Oncology Drugs in Peru: A Cross-Sectional Study of RENETSA Records, 2023-2024



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Introduction

- Cancer is a major global public health problem, with nearly 20 million new cases each year (1).
- New oncological treatments have improved survival and quality of life, but their high cost challenges the sustainability of health systems (2).
- In Peru, the 2021 National Cancer Law guarantees access to comprehensive oncological care (3).
- Its regulation requires that high-cost technologies not included in the National List of Essential Medicines (PNUME) undergo Health Technology Assessment (HTA) by RENETSA (4).
- In November 2022, a Technical Document was approved to guide HTA of high-cost oncological technologies using a multicriteria approach (HTA-MC), which considers disease burden, clinical need, efficacy, safety, innovation, equity, resources, and cost-effectiveness (5).

Objective

- To describe the characteristics of the assessments issued by RENETSA and to explore the relationship between each criterion and the final recommendation

Methods

- A cross-sectional study was conducted based on HTA reports published by RENETSA up to December 31, 2024. Clinical, methodological, and institutional variables, as well as those related to the assessment of health technologies in the evaluation process, were analyzed. The association between decision criteria and the final recommendation was examined using bivariate statistical tests (chi-square and Mann–Whitney U).

Table 1. Clinical characteristics of the evaluated indications and outcome of HTA–MC reports

Characteristic	Total n (%)	Favorable Recommendation n (%)	Unfavorable Recommendation n (%)	p-value*
Total	61 (100.0)	20 (32.8)	41 (67.2)	
<i>Type of cancer</i>				
Solid	39 (63.9)	10 (25.6)	29 (74.4)	0.113
Hematologic	22 (36.1)	10 (45.5)	12 (54.5)	
<i>Clinical scenario**</i>				
Early	6 (15.4)	1 (16.7)	5 (83.3)	0.969
Metastatic	33 (84.6)	9 (27.3)	24 (72.7)	
<i>Line of treatment</i>				
First line	19 (63.3)	7 (36.8)	12 (63.2)	1.000
Second line or higher	11 (36.7)	4 (36.4)	7 (63.6)	
Not applicable***	31	9	22	
<i>Median overall survival gain (months) †</i>				
Median (IQR)	6 (3.3–11.1)	8.6 (5.5–13.6)	3.9 (2.8–10.7)	0.229

IQR: interquartile range.

* Chi-square test was used for comparison of proportions.

** Only determined for solid tumors.

*** Early scenario and/or oncohematologic neoplasms. Not considered for statistical testing.

† Only 17 evaluations reported the median survival gain in months in the assessment reports. The Mann–Whitney U test was used to compare medians.

Discussion and conclusions

- During the analysis period, most HTA–MC reports on oncology drugs issued by RENETSA resulted in unfavorable recommendations (67.2%).
- According to RENETSA's 2022 Technical Document, favorable decisions should consider criteria such as lack of alternatives, desirable effects, fewer harms, positive balance of effects, moderate or high certainty of evidence, comparative advantage, potential to enhance equity, and cost-effectiveness. However, in this study, the criteria least aligned with favorable recommendations were certainty of evidence and level of innovation.
- In all cases where certainty of evidence was evaluated, it was rated as “very low.” This low certainty negatively influenced other criteria—particularly innovation and the estimation of effect size—often contributing to negative recommendations. The most frequent causes of diminished certainty, according to the GRADE approach, were risk of bias and imprecision.
- Several limitations must be noted. Data were sourced from RENETSA's public compendium, which may contain transcription or update errors affecting information integrity. The cross-sectional design also limited the ability to assess temporal trends in recommendations. Moreover, low-frequency categories required variable regrouping, reducing the depth of analysis.
- Overall, the most influential criteria linked to favorable decisions were clinical need, desirable effects, a favorable benefit-risk balance, and equity impact. The development of cancer-specific thresholds for effect sizes—validated through expert consensus—is recommended to guide future evaluations.

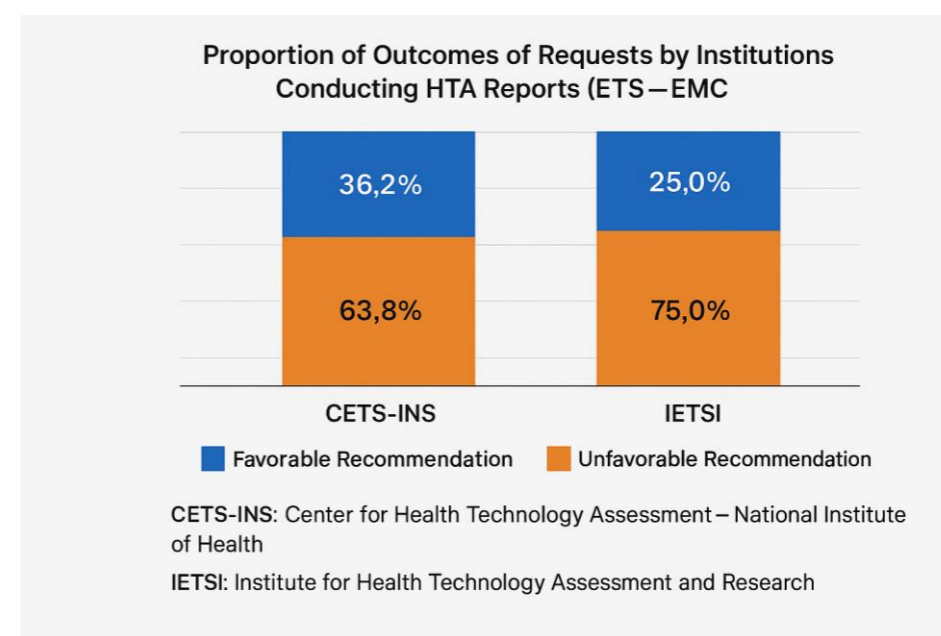
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Figure 1.



Results

- A total of 61 HTA–MC reports on oncology treatments were analyzed. Of these, 32.8% (n=20) received a favorable recommendation and 67.2% (n=41) an unfavorable one. The CETS at INS had the highest rate of favorable outcomes (36.2%), while IETSI issued the highest proportion of unfavorable recommendations (75.0%) (Figure 1).
- The median overall survival (OS) gain was 6.0 months (IQR: 3.3–11.1). Reports with favorable recommendations showed a median OS gain of 8.6 months (IQR: 5.5–13.6), compared to 3.9 months (IQR: 2.8–10.7) in the unfavorable group. These differences were not statistically significant (Table 1).
- Favorable recommendations were significantly more frequent in reports without available therapeutic alternatives (50.0% vs. 13.8%; p=0.003), and in those reporting moderate or large desirable effects (75.0% vs. 4.0%; p<0.001). Conversely, 96.0% of evaluations lacking desirable effects were unfavorable.
- Reports with trivial or small undesirable effects had more favorable outcomes compared to those with uncertain harms (56.5% vs. 15.4%; p=0.008). A favorable or probably favorable balance of effects was also strongly associated with favorable recommendations (81.0% vs. 4.3%; p<0.001).
- Equity impact played a significant role: 69.2% of reports likely to increase equity received a favorable recommendation, compared to just 11.8% with uncertain or reduced impact (p<0.001) (Table 2).

Table 2. Criteria evaluated and outcome of HTA–MC reports

Characteristic	Total n (%)	Favorable Recommendation n (%)	Unfavorable Recommendation n (%)	p-value**
Clinical need				
With Alternative	29 (47.5)	4 (13.8)	25 (86.2)	0.003
Without alternative	32 (52.5)	16 (50.0)	16 (50.0)	
Grouped desirable effects				
Don't know	25 (41.0)	1 (4.0)	24 (96.0)	<0.001
Trivial / Small	16 (26.3)	4 (25.0)	12 (75.0)	
Moderate / Large	20 (32.8)	15 (75.0)	5 (25.0)	
Grouped undesirable effects				
Don't know	26 (42.6)	4 (15.4)	22 (84.6)	0.008
Trivial / Small	23 (37.7)	13 (56.5)	10 (43.5)	
Moderate / Large	12 (19.7)	3 (25.0)	9 (75.0)	
Grouped certainty of evidence***				
Very low	47 (77.0)	17 (36.2)	30 (63.8)	0.320
Low / Moderate	4 (6.6)	3 (75.0)	1 (25.0)	
No study included	10 (16.4)	0	10	
Grouped balance of effects****				
Don't know	23 (37.7)	1 (4.3)	22 (95.7)	<0.001
Does not favor I nor C / Probably favors C	16 (26.2)	1 (6.3)	15 (93.8)	
Probably favors I / Favors I	21 (34.4)	17 (81.0)	4 (19.0)	
Varies	1 (1.6)	1	0	
Level of innovation				
Innovative	3 (4.9)	2 (66.7)	1 (33.3)	0.515
Not innovative	58 (95.1)	18 (31.0)	40 (69.0)	
Grouped equity				
Don't know	18 (29.5)	0 (0.0)	18 (100)	<0.001
Probably no impact / Probably reduced	17 (27.9)	2 (11.8)	15 (88.2)	
Probably increased / Increased	26 (42.6)	18 (69.2)	8 (30.8)	
Required resources				
Don't know	1 (1.6)	0 (0.0)	1 (100)	NE
Minimal costs and savings	3 (4.9)	2 (66.7)	1 (33.3)	
Moderate costs	8 (13.1)	3 (37.5)	5 (62.5)	
Moderate savings	1 (1.6)	0 (0.0)	1 (100)	
Extensive	48 (78.7)	15 (31.3)	33 (68.8)	
Cost-effectiveness				
No study included	53 (86.9)	17 (32.1)	36 (67.9)	NE
Probably favors C	4 (6.6)	1 (25.0)	3 (75.0)	
Favors C	3 (4.9)	1 (33.3)	2 (66.7)	
Probably favors I	1 (1.6)	1 (100)	0 (0.0)	
Favors I	0	0	0	

I: Intervention, C: Comparator, NE: Not Evaluated.

* The criteria are described in the Manual for Multicriteria Evaluation of High-Cost Oncology Drugs.

** Chi-square test was used for comparison of proportions.

*** The category 'no study included' was not included in the statistical test.

**** The category 'varies' was not included in the statistical test.