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Implementation of the National Cancer Law for health technology assessments of high-cost technologies for oncological diseases in a Latin American middle – income country: a descriptive analysis of regulations and assessment reports

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Research Article

Keywords: Health Technology Assessment, High-Cost Technology, Cancer, Health Policy, Decision Making (source: MeSH)

Posted Date: September 21st, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10866185/v1

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Additional Declarations: No competing interests reported.

Abstract

Background

In 2022, Peru approved the implementing Regulation of the National Cancer Law, establishing multicriteria health technology assessment (MC-HTA) through the national HTA network (RENETSA) to inform coverage decisions for high-cost oncological technologies. This study aimed to describe and assess the drafting quality of the regulatory provisions governing MC-HTA for high-cost oncological technologies in Peru and examine their implementation using RENETSA assessment reports published between 2022–2025 in addition to international multicriteria frameworks.

Methods

We conducted a descriptive study of regulatory provisions governing MC-HTA for high-cost oncology technologies in Peru. Provisions were analyzed across five dimensions (assessment requests, assessment criteria, stakeholder participation, timelines, and use of recommendations) and their drafting quality was assessed using Peruvian legislative drafting guidelines. Regulatory provisions were compared with RENETSA assessment reports and three international multicriteria frameworks (GRADE-EtD, WHO-INTEGRATE, and HTA Core Model). Report characteristics were summarized using descriptive measures.

Results

Six regulatory provisions and 106 MC-HTA reports were included. Drafting imprecisions were identified across all five dimensions. Ministry of Health-initiated requests represented 3.8% of assessments. The Regulation restricted eligible technologies to pharmaceutical products and medical devices, omitted other types of interventions and purposes beyond treatment, did not define “oncological disease”, and did not establish a high-cost threshold for medical devices. All reports assessed pharmaceutical products, 97.2% concerned treatment, and 91.5% addressed malignant neoplasms. The assessment criteria specified in the Regulation differed from those included in the reference multicriteria frameworks. Stakeholder participation definition was omitted; patient and physician participation was documented in 41.5% and 100% of reports, respectively. Median development time was 177 business days, compared with a regulatory limit of 45 business days for which the starting point was not specified. A transitional provision established a ‘binding opinion’ requirement only for the acquisition of pharmaceutical products.

Conclusions

The regulatory framework governing MC-HTA for high-cost oncology technologies in Peru contains definitional, technical, and procedural imprecisions, while its implementation shows differences between regulatory provisions and observed assessment practices. Clarifying the scope of eligible technologies, assessment criteria, stakeholder participation, timelines, and the use of recommendations could strengthen the consistency of the MC-HTA process.

Contributions to the literature

- Health technology assessment is used to guide public funding of high-cost cancer care, but less is known about how regulatory design is translated into practice.
- This study links Peru's cancer-law provisions with the assessment reports produced under that regulatory framework, connecting health policy design with real-world implementation.
- Combining legislative drafting analysis with health technology assessment provides a broader way to identify gaps between regulation and practice.
- This approach may inform countries about designing or revising policies for assessing and funding high-cost health technologies, particularly in Latin America and other middle-income settings.

Background

In 2021, the National Cancer Law was passed in Peru [1], to strengthen the prevention, diagnosis, treatment and coverage of oncological diseases. In 2022, its Regulation was approved, followed by amendments in 2023 [2] and 2024 [3].This regulatory framework established mechanisms for access to high-cost health technologies and incorporated multicriteria health technology assessments (MC-HTAs) as an instrument to inform evidence-based decisions regarding their use and funding. The development of these assessments was assigned to the Peruvian National Network for Health Technology Assessment (RENETSA, in Spanish), comprising three health technology assessment (HTA) agencies. To this end, in 2022 technical document [4] was approved establishing the methodology for developing MC-HTAs in accordance with the provisions of the Regulation of the cancer law; this document was updated in 2025 [5].

Nevertheless, the existence of a regulatory framework does not always guarantee its effective implementation [6]. Five years after the Law was passed, it is relevant to analyze how the provisions of the Regulation have been reflected in the practice of developing MC-HTAs in the country. In this context, the objective was to conduct a descriptive analysis of the regulatory language and to contrast it with the characteristics of MC-HTA reports developed under this framework and with international methodological references, to identify possible implications for policy implementation. The findings aim to contribute to the design and revision of regulatory frameworks that incorporate high-cost HTA into coverage decisions.

Methods

Study design

A descriptive study was conducted to characterize the regulatory provisions governing the request and conduct of high-cost HTA for oncological diseases in Peru, and to examine how these provisions were reflected in the characteristics of the MC-HTAs reports produced under this framework and with international multicriteria frameworks for HTA.

Selection, data extraction and analytical dimensions of the regulatory provisions of the Regulation

From the Regulation of the National Cancer Law and its amendments, provisions referring to RENETSA were selected and their content was extracted. The information was organized across five analytical dimensions: (1) MC-HTAs requests, (2) assessment multicriteria, (3) participants in the development process, (4) development deadlines, and (5) use recommendations.

From the technical documents approved under the regulatory framework [4, 5] to establish the assessment methodology, those used in the development of at least one of the included MC-HTAs reports were selected. Information corresponding to the “assessment multicriteria” and “participants in the development process’ dimensions was extracted from these documents.

Search, selection and data extraction of MC-HTAs reports

The official publication repository and the dynamic report on RENETSA’s official website (https://www.gob.pe/55329-red-nacional-de-evaluacion-de-tecnologias-sanitarias-renetsa) were searched in January 2026. MC-HTA reports on high-cost health technologies for the management of oncological diseases published between 2022 and 2025 and developed using at least one technical document approved under the regulatory framework, were included.

Two authors independently extracted information on: the requesting entities (entity of origin, health subsector, requesting institution, and region of origin); the characteristics of the assessed technologies and populations (type and number of technologies, annual cost per patient reported, purpose of use, age group, neoplastic or associated condition, type of neoplasm, anatomic extent and resectability status in solid neoplasms, prior treatment history, refractory status, and recurrence status); patients, caregivers, representatives of patient organizations and specialist physician participation during clinical question formulation, as well as the use of patient values and preferences data in the balance of effects criterion; and the type of use recommendation and year of publication.

Additionally, public information requests were submitted to RENETSA through the National Institute of Health in February and June 2026. Based on the responses received, we planned to describe reasons for

non-admissibility of requests and estimated development time in business days (excluding Saturdays, Sundays, and national public holidays) and calendar days.

Other sources of information

Non-systematic searches were conducted on official Peruvian government portals to include national regulations related to the regulation of the National Cancer Law, using keywords such as “pharmaceutical product”, “medical device”, “prioritization”, “health technology assessment” and “high cost”. In addition, the following reference multicriteria assessment frameworks were included to complement the descriptive analysis of the “assessment multicriteria” dimension: the Evidence to Decision (EtD) framework of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group [7], the World Health Organization’s WHO-INTEGRATE framework [8] and the HTA Core Model of the European Network for Health Technology Assessment (EUnetHTA) [9].

Statistical analysis

The database was imported into Stata version 19. Categorical variables were summarized using absolute and relative frequencies. Numerical variables were summarized using measures of central tendency and dispersion, selected according to the distribution of the data.

Analysis of the dimensions

First, the content of the included regulatory provisions was described. Then, the regulatory language of the content was analyzed by assessing compliance with four legislative drafting criteria established in the technical legislative guide that supports the development of regulations in Peru [10]. These criteria were: clarity, understood as the capacity for accessible comprehension; simplicity, defined as the omission of unnecessary or redundant elements; precision, aimed at ensuring textual accuracy and avoiding ambiguities; and conciseness, understood as limiting content to what is strictly necessary. Finally, the findings were contrasted with the characteristics of the published MC-HTAs reports and data submitted by RENETSA for the dimensions “MC-HTAs requests”, “participants in the development process”, “development timelines” and “use recommendations”. For the “assessment multicriteria” dimension, the comparison was made against the criteria proposed by the included standardized multicriteria assessment frameworks.

Use of generative artificial intelligence

ChatGPT (OpenAI, San Francisco, CA, USA) was used during manuscript preparation for language editing, improvement of clarity, and translation of selected text. It was not used for data extraction, statistical analysis, or interpretation of the findings. All AI-assisted text was reviewed and approved by the authors.

Results

Regarding the regulatory documents, six provisions of the Regulation of the Cancer Law and its amendments concerning the requests and assessments of high-cost health technologies for oncological diseases by RENETSA were included. In addition, a technical document approved in 2022 [4] was included, as it was the only one used to develop all included MC-HTAs, along with a national regulatory document on high-cost oncological pharmaceutical products [11].

Regarding the MC-HTAs reports, 125 reports on high-cost oncological health technologies published between 2022 and 2025 were identified; 19 were excluded because they had not been developed using any technical document. Finally, 106 reports were included.

Dimension: MC-HTA requests

The regulation stipulates that, at the individual patient level, requests for the assessment of pharmaceutical products not included in national formularies or medical devices for the treatment of oncological diseases must be submitted by the treating specialist physician to the pharmacotherapeutic committee (PTC) of the healthcare facility. If the cost exceeds the high-cost threshold defined by the National Health Authority (NHA), the PTC refers to the request to RENETSA for assessment. This process is subject to defined timelines. The regulation also establishes that the Ministry of Health, in its role as the NHA, may request the assessment of health technologies when a public health need exists [12].

Requesting entities

Unlike requests submitted by the treating physician on behalf of a specific patient, the regulation does not define an operational pathway applicable to requests initiated by the NHA, omitting reference to the actors involved, the referral mechanisms, and the applicable timelines. No other Peruvian regulatory documents were identified that provide guidance on the implementation of this provision for the NHA in the cancer regulatory framework context.

Definitions for determining technologies eligible for assessment

Assessment by RENETSA is restricted to high-cost pharmaceutical products or medical devices intended for the treatment of oncological diseases. However, the Regulation does not define ‘health technology’ or ‘high cost’, limits its scope to these two types of technologies, and omits purposed of use other than treatment. Furthermore, the high-cost threshold has only been defined in other Peruvian regulatory documents for pharmaceutical products [11], but not for medical devices. The Regulation also does not define “oncological disease”, does not specify the types or characteristics of the neoplasms covered, and does not explicitly state whether health conditions arising from disease-related complications or treatment-related adverse events fall within its scope.

Characteristics of requesting entities, assessed technologies, and oncological diseases evaluated in MC-HTAs reports

By entity of origin, 96.2% (n = 102) of requests originated from the PTC of a healthcare provider institution, predominantly located in Metropolitan Lima (Table 1). All assessed technologies were pharmaceutical products, with a therapeutic purpose in 97.2% (n = 103) of assessments. By health condition, 91.5% (n = 97) corresponded to malignant neoplasms and 8.5% (n = 9) to conditions associated with the neoplastic disease. By type of neoplasm, Leukemia (17.9%; n = 19) and breast cancer (15.1%; n = 16) were the most frequently assessed. Among solid neoplasms, 64.2% (n = 43) were metastatic and 46.3% (n = 31) were unresectable. Additionally, 49.1% (n = 52) of assessments included populations with one or more prior treatments and 41.5% (n = 44) included refractory, resistant, or non-responsive populations (Table 2). Data on reasons for request non-admissibility were not available.

Table 1
Requesting entities in RENETSA high-cost oncology MC-HTA reports, 2022–2025.

Characteristics	Total (N = 106) n (%)
Entity of origin	
Pharmacotherapeutic committee (PTC) of a health care provider institution	102 (96.2)
National Health Authority (Ministry of Health)	4 (3.8)
Requesting health subsector *	
Comprehensive Health Insurance - Ministry of Health	54 (50.9)
Social Health Insurance - EsSalud	53 (50.0)
Armed Forces (navy, army or air force) and National Police	0 (0)
Requesting institution	
National Institute of Neoplastic Diseases (INEN)	31 (29.3)
Regional Institute of Neoplastic Diseases of the Center (IREN-Center)	8 (7.6)
Regional Institute of Neoplastic Diseases of the North (IREN-North)	3 (2.8)
Regional Institute of Neoplastic Diseases of the South (IREN-South)	1 (0.9)
Other institutions	63 (59.4)
Region of origin of the request *	
Metropolitan Lima	86 (81.1)
Provinces	22 (20.8)

*A single report could include more than one requesting subsector or region. Therefore, categories were not mutually exclusive and percentages may exceed 100%.

Table 2
Characteristics high-cost health technologies and populations assessed in RENETSA oncology MC-HTA reports, 2022–2025.

Characteristics	Total (N = 106) n (%)
Type of high-cost health technology assessed	
Pharmaceutical product	106 (100)
Medical device	0 (0)
Number of high-cost technologies requested per assessment	
One high-cost health technology	94 (88.7)
Two high-cost health technologies	12 (11.3)
Annual cost of the technology per patient reported (USD) *	$ 63 954.3 (35 669.71 to 103 064.52)
Annual cost of the technology per patient reported (PEN) *	S/ 218 187 (121 691 to 351 615.5)
Purpose of use of the high-cost health technology assessed	
Treatment	103 (97.2)
Other purpose of use (pre-transplant conditioning)	3 (2.8)
Age group	
Adult population	86 (81.1)
Pediatric population	10 (9.4)
Adult and pediatric population	7 (6.6)
Not specified	3 (2.8)
Neoplastic condition or neoplasm-associated condition	
Solid malignant neoplasm	66 (62.3)
Malignant neoplasm of lymphatic or hematopoietic tissue	31 (29.2)
Health conditions arising from adverse events of neoplasm treatment †	6 (5.7)
Health conditions arising from complications of the neoplasm ‡	3 (2.8)
Type of neoplasm	
Leukemia	19 (17.9)

Characteristics	Total (N = 106) n (%)
Type of high-cost health technology assessed	
Breast cancer	16 (15.1)
Lymphoma	9 (8.5)
Colorectal cancer	8 (7.6)
Lung cancer	8 (7.6)
Renal cancer	7 (6.6)
Unspecified hematologic neoplastic condition	6 (5.7)
Prostate cancer	5 (4.7)
Skin cancer	5 (4.7)
Gastrointestinal cancer	4 (3.8)
Thyroid cancer	4 (3.8)
Urogenital cancer	3 (2.8)
Liver and biliary tract cancer	3 (2.8)
Multiple myeloma	3 (2.8)
Cervical cancer	2 (1.9)
Other neoplasms or neoplastic syndromes	4 (3.8)
Anatomical extent of solid neoplasms §	
Metastatic only	43 (64.2)
Locally advanced only	2 (3.0)
Localized only	1 (1.5)
Locally advanced or metastatic	9 (13.4)
Not specified	12 (17.9)
Resectability status of solid neoplasms §	
Unresectable	31 (46.3)
Resectable	1 (1.5)
Not specified	35 (52.2)
Prior treatments	

Characteristics	Total (N = 106) n (%)
Type of high-cost health technology assessed	
One or more prior treatments received	52 (49.1)
No prior treatment received	34 (32.1)
Not specified	20 (18.9)
Refractoriness status	
Refractory, resistant or non-responsive to treatment	44 (41.5)
Not refractory, not resistant or responsive to treatment	5 (4.7)
Not specified	57 (53.8)
Recurrence status	
Recurrent or relapsed neoplasm	21 (19.8)
Newly diagnosed (*de novo*) neoplasm	5 (4.7)
Not specified	80 (75.5)

* Median (interquartile range).

† Graft-versus-host disease (GVHD).

‡ Symptomatic anemia in people with a hematologic neoplastic syndrome, constitutional symptoms due to splenomegaly in people with a hematologic neoplasm, and carcinoid syndrome in people with a solid neoplasm.

§ The analysis of this variable was restricted to reports assessing health technologies directed at solid neoplasms. This group included 67 reports: 66 corresponding to solid neoplasms and one referring to carcinoid syndrome in people with a solid neoplasm.

Dimension: Assessment multicriteria

The Regulation stipulates that high-cost health technologies must be assessed using the following criteria: disease burden, therapeutic impact, safety profile, level of innovation, equity, unmet medical need, and socioeconomic impact. It also states that additional criteria may be incorporated.

Criteria by technology type and reference framework used

The Regulation establishes mandatory assessment criteria applicable to all types of health technologies but does not define them, nor does it specify mechanisms for modifying them or clarify the authority responsible for doing so. Subsequently, the 2022 technical document [4] defines and operationalizes these criteria using the GRADE EtD framework [7] as a reference.

Comparison with international multicriteria frameworks

When the criteria in the Regulation were compared with those proposed by GRADE [7], the WHO-INTEGRATE framework [8] and the HTA Core Model [9], discrepancies were identified. Although criteria such as “therapeutic impact” and “safety profile” relate to clinical effectiveness or benefits, safety or harm, and the benefit-risk balance, the regulation presents them separately, with other terminology and does not make the balance criteria explicit. Criteria such as “disease burden”, “unmet medical need”, “level of innovation”, and “socioeconomic impact” do not have a direct correspondence or are positioned as contextual elements in international frameworks. Finally, the Regulation omits cross-cutting criteria such as certainty of evidence, implementation feasibility, organizational implications, and ethical and legal aspects.

Dimension: Participants in the assessment process

The Regulation stipulates that RENETSA must request the participation of specialist physicians in oncology and invite representatives of oncology patient associations from civil society, in accordance with the regulations to be established for that purpose.

Definition of ‘participation’

The regulation does not define “participation”, delegating its conceptualization to the technical document published in 2022. That document also does not define the term but establishes that patients, family members, caregivers, or, in their absence, patient association representatives participate by providing information on their perspectives, values, and preferences during clinical question formulation and for the assessment of the balance of effects criterion. In contrast, it establishes that specialist physicians participate with voice and vote rights in the validation of the clinical question and in a deliberative dialogue to assess criteria, issue judgements, and formulate the use recommendation.

Stakeholder participation in MC-HTAs reports

Patient, family member, or caregiver participation during clinical question formulation was reported in 41.5% (n = 44) of assessments, and information on their values and preferences obtained through interviews was incorporated into the balance of effects criterion in 43.4% (n = 46) of assessments. Patient associations were not contacted for participation in clinical question formulation in 61.3% (n = 65) of reports. In contrast, specialist physicians participated in clinical question formulation in all assessments (Table 3).

Table 3
Patients, relatives, patient associations and medical specialists' participation in RENETSA oncology MC-HTA reports, 2022–2025.

Characteristics	Total (N = 106) n (%)
Participation of patients, relatives or caregivers during formulation of the clinical question	
At least one patient, relative or caregiver participated	44 (41.5)
Did not participate despite contact attempt *	14 (13.2)
Did not participate due to lack of consent	5 (4.7)
Did not participate for other reasons †	7 (6.6)
Not specified	36 (34.0)
Participation of patient association representatives during formulation of the clinical question	
At least one patient association representative participated	1 (0.9)
Did not participate despite contact attempt *	1 (0.9)
Did not participate because no patient associations were contacted ‡	65 (61.3)
Not specified	39 (36.8)
Participation of oncology medical specialists during formulation of the clinical question	
At least one oncology medical specialist participated	106 (100)
Source of information on patients' values and preferences for the balance of effects criterion	
Information from interviews with patients, relatives or caregivers was used	46 (43.4)
Information from interviews with patients, relatives or caregivers was not used	26 (24.5)
Not specified	34 (32.1)

* The category "Did not participate despite contact attempt" includes cases in which an attempt was made to contact patients, relatives, caregivers or patient associations, but no response was obtained, contact information was unavailable or contact details were not up to date.

† Other reasons include assessments requested by the National Health Authority, cases in which the patient was no longer eligible for the technology assessed, or death.

‡ The category "Did not participate because no contact was made" indicates that no contact attempt by the assessing entity was explicitly reported.

Dimension: Development deadline

The Regulation stipulates that RENETSA must submit to the corresponding healthcare payer the report containing the use recommendation within a maximum of 45 business days. However, it does not reference any other regulatory document justifying this timeline, nor does it specify the initial milestone from which it should be counted (receipt of request, admission, or assignment to a member HTA agency of the network). Furthermore, the Regulation does not include provisions on the suspension, extension, or exceptions to the established timeline.

Development times

The median time between receipt of the request and submission of the report to the healthcare payer was 177 business days (interquartile range [IQR]: 97 to 328) (Table 4). Data on the dates of assignment to the member HTA agencies of RENETSA were unavailable, preventing estimation of development times excluding administrative processes.

Table 4
Development times, use recommendations, and publication year in RENETSA oncology MC-HTA reports, 2022–2025.

Characteristics	**Total (N = 106)** **n (%)**
Time between the request and submission of the report to the relevant funding entity (business days) *	177 (97 to 328)
Time between the request and submission of the report to the relevant funding entity (calendar days) *	254 (141 to 472)
Type of use recommendation	
Against use	78 (73.6)
In favor of use	28 (26.4)
MC-HTA reports published by year	
2025	46 (43.4)
2024	43 (40.6)
2023	17 (16.0)

* Median (interquartile range). Time was counted from the day after receipt of the request to the date the report was submitted to the funding entity, considered by RENETSA as the publication date of the MC-HTA report. For calculation of business days, Saturdays, Sundays and holidays corresponding to the official Peruvian calendar were excluded.

Dimension: Use recommendations

The Regulation stipulates that the report containing the use recommendation for the assessed health technology will be submitted to the corresponding healthcare payer but does not specify whether this recommendation is binding for the coverage decision. A subsequent amendment incorporated the requirement to have a “binding opinion” from the report for the acquisition of pharmaceutical products, if the report exists. However, this provision was established as temporary and subject to an expiry period.

Types of recommendations formulated in MC-HTAs reports

Two types of recommendation were reported: “in favor” and “against”. Of the reports, 26.4% (n = 28) issued a recommendation in favor of the use of the assessed health technology, while 73.6% (n = 78) issued a recommendation against its use. Reports were published mainly in 2025 and 2024 (Table 4).

Discussion

Main findings

We identified that the regulatory provisions applicable to MC-HTAs present imprecisions in their regulatory language that can be grouped into those arising from definitional gaps; those of a technical, methodological and participatory nature; those related to the use recommendation; and those concerning the roles of the entities involved. This classification facilitates the interpretation of findings as limitations potentially affecting different stages of the assessment process, as well as the entities or actors involved.

Imprecisions arising from definitional gaps

Eligible technologies are limited to pharmaceutical products and medical devices; the high-cost threshold has only been defined for pharmaceutical products; and uses other than treatment were not explicitly stated. Consistently, all technologies assessed through 2025 were pharmaceutical products, and 97.2% had a therapeutic purpose. However, other Peruvian regulations [13, 14] as well as international HTA agencies [15] and organizations [16] adopt a broader definition of health technology, encompassing interventions, procedures, organizational systems, and uses such as diagnosis, prevention, and rehabilitation. Furthermore, Latin American experiences have established national high-cost thresholds not restricted to pharmaceutical products alone and subject to periodic updating [17]. Broadening the definition of health technology and establishing a more comprehensive high-cost threshold would enable the assessment of medical devices and other potentially useful technologies, aligning Peruvian scope with international standards.

The scope of the term “oncological disease” was not defined. In practice, 91.5% of assessments addressed malignant neoplasms, predominantly solid tumors, while a smaller proportion concerned neoplasm-associated conditions not directly related to its management. This may reflect the actual composition of demand or a restricted interpretation by requesting entities of the term as circumscribed

to malignant neoplasms. This study cannot distinguish between these explanations, as only published reports were analyzed and requests that were not submitted or not admitted were not available. In either case, the scope of the term was probably determined by practice rather than by regulation.

Delimiting this term is complex. Although accepted classification systems distinguish between malignant, *in situ*, benign and uncertain-behavior neoplasms [18], some aspects remain under debate, such as the malignant potential from which a lesion should be considered “cancer” [19]. This regulatory ambiguity could be reduced by defining the neoplasms covered through such a classification system and by explicitly stating whether characteristics such as malignant transformation potential and conditions associated with the neoplasm fall within the scope. Alternatively, as in another country in the region [17], a legal framework applicable to any condition requiring high-cost technologies could be adopted, in contrast to the Peruvian scheme, which only provides for certain diseases.

Technical, methodological and participation-related imprecisions

The Regulation establishes criteria that are not necessarily applicable to all types of health technologies [20, 21] and uses nomenclature that differs from those of international assessment multicriteria frameworks, which constrained the adoption of one of these frameworks in the technical document. Other countries also establish value dimensions or assessment criteria in their regulations using context-specific nomenclature [17, 22] although not all declare their origin or adopt a standardized reference multicriteria framework as Spain does [22]. Nevertheless, operationalizing these criteria is a common challenge, given variability in their definitions and assessment methods as well as the complexity of gathering the information required to evaluate them [23–28]. In this context, stating general value dimensions and delegating their definition and operationalization to technical bodies, grounded in standardized multicriteria frameworks and adapted to the type of technology, could promote consistency in the assessment process.

The term “participation” was not defined, and a differentiated degree of involvement was established between specialist physicians and patients. This contrasts with the lower participation of patients or their representatives, which was related to the staged design and limitations of the invitation for participation, patient-related reasons and lack of reporting. The findings suggest that although participation is provided for, the mechanisms to make it effective were insufficient. In this regard, it has been described that ‘participation’ is understood differently across contexts and that strategies exist to involve patients in decision-making processes [29, 30]. Therefore, defining the terms of participation, establishing roles, mechanisms, and points of engagement, including a regularly updated directory of patient associations, would strengthen the participation of these stakeholders.

The report development deadline was established at 45 business days. The observed median in the included reports was 177 business days, equivalent to 254 calendar days (approximately eight months), which exceeds the regulatory timeline. However, because the initial milestone was not clearly defined, the extent of non-compliance when measuring time from assignment to a member agency of RENETSA

remains unknown. The development time in the Peruvian context, although exceeding the deadline, is consistent with those reported by other HTA agencies, which development time frequently range from three to twelve months worldwide [31] and from six to ten months in Latin American contexts [32, 33] considering that extensions may be allowed. On this basis, the regulated timeline may be difficult to achieve for any comparable process. Specifying the starting milestone and the grounds for suspension or extension would enable the verification of compliance and enforceability.

Imprecisions related to the use recommendation

The Regulation does not specify whether the use recommendation is binding for the coverage decision. Although a transitional provision refers to the “binding opinion” of reports for the acquisition of pharmaceutical products, this provision has a time-limited validity and does not extend to medical devices. Literature distinguishes the assessment and recommendation of a technology from the coverage decision, which falls under a different institutional level [6]. An example is Chile, where the regulation explicitly differentiates between the entity that recommends and the entity that decides on coverage [17] This separation would allow space for negotiation, a mechanism currently absent in the Peruvian context.

Imprecisions concerning the roles of the entities involved

The distribution of requests suggests an uneven implementation of the pathways established for initiating assessments. Although the regulatory framework allows requests from the NHA, this pathway had scarce uptake, while requests originating from healthcare provider institutions predominated. Assessments frequently addressed advanced clinical scenarios, such as metastatic disease, refractory status, or the use of health technology after one or more prior treatments, which is consistent with the type of indications typically associated with high-cost oncological technologies [34–36]. However, some neoplasms with high disease burden or considered national priorities status during the study period, such as cervical, gastric, lung, and prostate cancer [37–39] were less represented among the requests, which may reflect the regulatory predominance of the individual-level pathway.

The absence of requests from certain regions or health subsectors may be explained by differences in oncological healthcare needs, knowledge of the regulatory and logistical process, operational capacity, or the referral of patients to other healthcare providers. In this scenario, a more clearly defined pathway from the NHA could complement local and individual-level requests through proactive identification of technologies linked to national oncological priorities, in line with international experiences in which requests often come from governmental entities or the pharmaceutical industry and are articulated with explicit prioritization processes [40–42] Furthermore, clarifying the distribution of responsibilities between regulatory and technical levels could contribute to the implementation of appropriate methodologies and multicriteria frameworks for assessing these technologies and reduce the risk of their modification or elimination without explicit technical justification, as has been requested in the national context [43].

Limitations and strengths

This study has limitations. It was based on published reports; therefore, categories recorded as 'not specified' do not necessarily reflect the absence of the attribute. In addition, data on non-admitted requests were unavailable, which prevented evaluation of admission consistency and actual MC-HTAs demand. Information on other specific clinical characteristics that could have allowed a more detailed characterization of the evaluated populations was not collected, because these characteristics vary substantially across and within oncological diseases and no standardized national classification was available. The analysis was descriptive and did not examine determinants of assessment duration or reasons for the non-participation of some requesting entities.

Among its strengths, the study integrated a regulatory language analysis of the provisions, based on nationally regulated criteria and carried out by specialists in legal and policy matters, and contrasted this with the characteristics of all assessment reports conducted under that framework. To the best of our knowledge, this is the first study with this objective, as it differs from a regional precedent that evaluated compliance of the high-cost HTA process with its regulatory framework without analyzing regulatory appropriate drafting or its implications [44]. Future research could evaluate reports produced under updated methodologies, assess participation mechanisms, conduct interviews with key stakeholders, and track coverage decisions following the issuance of recommendations.

Conclusion

Regulatory imprecisions were identified across eligible technologies, covered oncologic-related health conditions, assessment criteria, institutional roles, deadlines, stakeholder participation, and the distinction between recommendations and coverage decisions. In implementation, assessments focused exclusively on pharmaceutical products, mainly for therapeutic use and malignant neoplasms, with no medical device reports identified. NHA-initiated requests were scarce, development time exceeded the unanchored 45-business-day limit, documented participation differed between physicians and patients or their representatives, and the binding opinion requirement applied only to pharmaceutical product acquisition, suggesting limitations in translating regulatory design into effective implementation. These findings may inform revisions to Peru's regulatory framework for high-cost health technology assessment and may be relevant to other health systems seeking to align regulatory design with transparent and consistent coverage decision-making.

Abbreviations

EtD
Evidence to Decision
EUnetHTA
European Network for Health Technology Assessment
GRADE

Grading of Recommendations Assessment, Development and Evaluation

HTA

Health Technology Assessment

INS

National Institute of Health *(Instituto Nacional de Salud)*

MC-HTA

Multicriteria Health Technology Assessment

RENETSA

National Network for Health Technology Assessment *(Red Nacional de Evaluación de Tecnologías Sanitarias)*

UHC

Universal Health Coverage

WHO-INTEGRATE

World Health Organization INTEGRATE

Declarations

Acknowledgements

Not applicable.

Authors' contributions

SGL and GMC contributed to the conceptualization of the study. SGL, GMC, and VVQ contributed to the methodology. SGL and AZVC performed data curation. SGL, GMC, AZVC, MH, and VVQ contributed to the formal analysis and preparation of the original draft. All authors contributed to the review and editing of the manuscript. SGL supervised the study. All authors read and approved the final manuscript.

Funding

The study was self-funded by the authors.

Data availability

The multicriteria health technology assessment reports analyzed during the current study are publicly available through the official publication repository and the dynamic report on RENETSA's official (https://www.gob.pe/55329-red-nacional-de-evaluacion-de-tecnologias-sanitarias-renetsa). Additionally, public information requests were submitted to RENETSA through the National Institute of Health.

Ethics approval and consent to participate

The study was based on publicly available and publicly requestable documents. No personal data or sensitive information was used; therefore, approval by a research ethics committee and informed

consent to participate were not required.

Consent for publication

Not applicable. The manuscript does not contain identifiable data, images, videos, or other information relating to any individual person.

Competing interests

AZVC provided professional services to the Peruvian National Institute of Health until July 2025. SGL, GMC, and VVQ provided professional services to the Peruvian National Institute of Health until December 2025. MH is currently employed by the Peruvian National Institute of Health. The authors declare that these relationships did not influence the design, analysis, interpretation of the results, or preparation of the manuscript.

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SGL is a physician with expertise in evidence synthesis methodology and health technology assessment. GMC is a political science professional specializing in health policy. AZVC and MH are physicians with expertise in evidence synthesis methodology and health technology assessment. VVQ is a lawyer specializing in health law and health policy.

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