

# Trends in Medical Device reimbursement decisions in South Korea: A Novel and Comprehensive Analysis

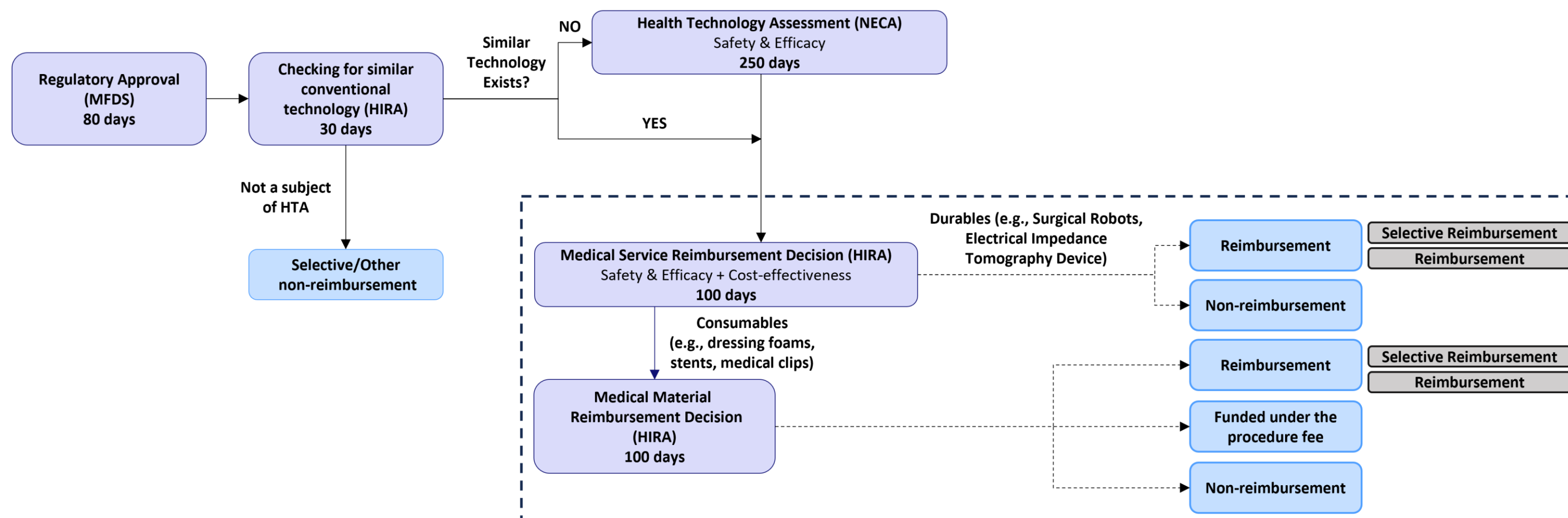
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## BACKGROUND

The Health Insurance Review and Assessment Service (HIRA) facilitates pharmaceutical and medical device reimbursement in South Korea.<sup>1</sup> Medical device reimbursement follows a complex pathway encompassing Medical Services (MS) and Medical Materials (MM).

Figure 1. Reimbursement Pathway of Medical Devices



## OBJECTIVES

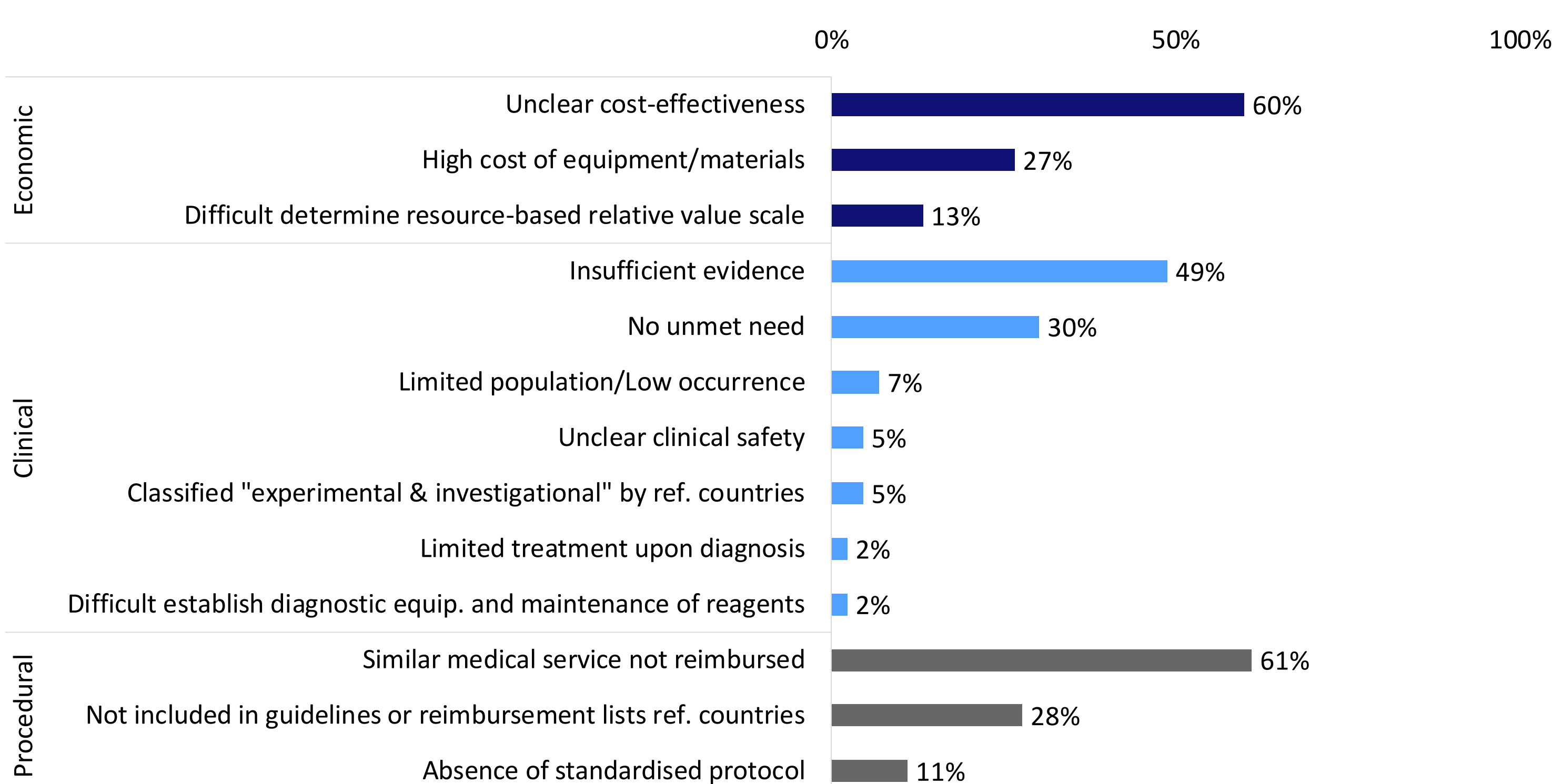
- To address gaps in literature around HIRA's decision outcomes regarding medical devices by evaluating HIRA's decision outcomes and key factors for rejections
- To help future applicants improve the quality of submissions and increase the probability of securing a reimbursement

## METHODS

- Publicly available data for the period between 2020 and 2023 was retrieved from Medical Service Assessment Reports and the Medical Material Assessment Reports on the HIRA website
- For the analysis of Medical Services, 117 out of 130 public documents published between 2020 and 2023 were analysed. These documents included Medical Service Assessment Reports, Medical Service and Medical Material Joint Assessment Reports. 13 documents were excluded from the analysis, as they solely represented reassessment results involving adjustments to the reimbursement limit without any changes to the reimbursement type. Each report provided the outcome of a single reimbursement decision, resulting in a total of 117 reimbursement decisions considered for Medical Services
- Regarding Medical Materials, a total of 125 public documents were published during the study period. We analysed 78 of these documents, which encompassed Medical Material Assessment Results, Independent Review Process (IRP), Reassessment, and Value Appraisal Assessment results involving changes to the reimbursement type. 47 documents were excluded from the analysis, as they solely represented reassessment results involving adjustments to the reimbursement limit without any changes to the reimbursement type. Since each public document for medical materials could contain multiple outcomes, we accounted for a total of 212 reimbursement decisions in this category
- Extracted data was analysed for decision outcomes. To identify key factors associated with non-reimbursement, submissions under "non-reimbursement" were further analysed. The key factors associated with non-reimbursement were categorised into three distinct classes - economic, clinical, and procedural
- Economic reasons were further subdivided into unclear cost-effectiveness, high cost of materials, and difficulty in determining resource-based relative scale
- Clinical reasons were divided into several subcategories, including insufficient evidence, safety concerns, limited population/occurrence, no unmet need, procedure classified as "experimental and investigational" by reference countries or AETNA, difficulties in establishment of diagnostic equipment/maintenance of reagents and limited treatment upon diagnosis
- Procedural reasons encompassed a variety of factors such as not included in international procedure guidelines or reimbursement lists of reference countries, related medical service not reimbursed, similar therapeutic material/medical service not reimbursed, and absence of standardised protocol

## RESULTS

Figure 2. Reasons for Medical Service Reimbursement Rejections



### Medical Services

Findings for MS showed, 54% with full reimbursement, 26% selective reimbursement and 20% non-reimbursement. Notably, full reimbursement rates declined from 2020-2022 (69% to 45%) while non-reimbursement rates increased (2% to 34%).

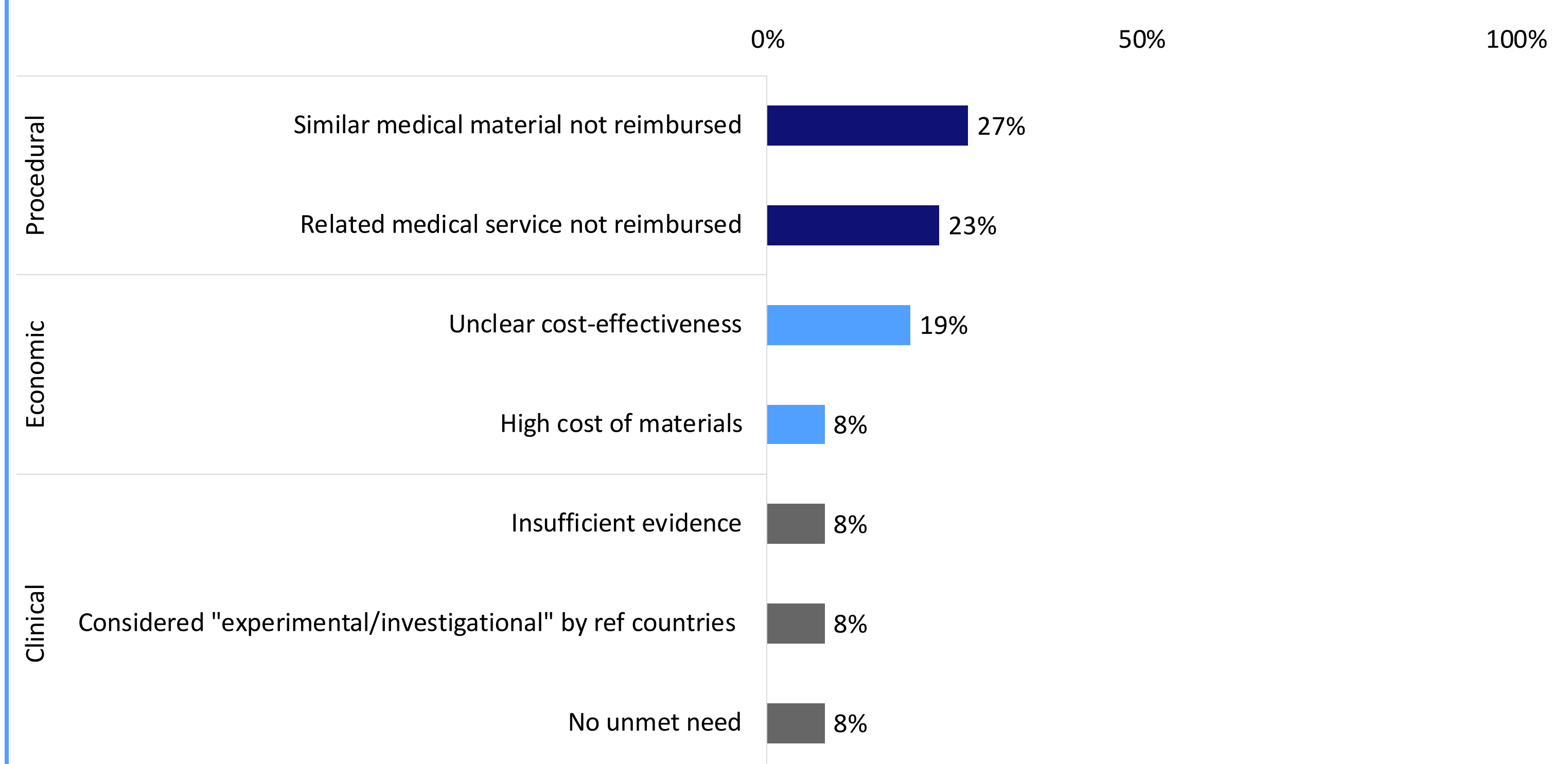
The analysis of reimbursement rejections of MS revealed that clinical reasons accounted for the highest percentage (57%), followed by procedural reasons (24%) and economic reasons (20%).

Within clinical reasons, it can be seen from Figure 2 that insufficient evidence together with no unmet need constituted more than three quarters of the rejections (49% and 30% respectively).

Regarding procedural reasons, the most prevalent reason was the non-reimbursement of similar medical services (61%), which implies that reimbursement decision outcome was heavily influenced by the absence of reimbursement coverage for comparable MS with similar intended use and target population.

For economic reasons, the primary contributing factor was unclear cost-effectiveness, accounting for 60%. Furthermore, a notable proportion of reimbursement rejections (27%) were attributed to the high cost of materials, implying that financial burden associated with the medical service, specifically the high cost of equipment or materials used during the procedure has a substantial impact on reimbursement decision outcomes.

Figure 3. Reasons for Medical Material Reimbursement Rejections



### Medical Materials

Findings for MM showed, 55% with full reimbursement, 16% selective reimbursement, 22% covered under procedure fee and 8% non-reimbursement. Additionally, MM are increasingly being funded "under procedure fee" rather than "non-reimbursement", which ensures its reimbursement specifically under the related MS while simultaneously preventing manufacturers from setting high prices. It is also interesting to note that a small percentage (3%) of Medical Materials applied under the "non-reimbursement" category received either full reimbursement (30%) or funded under procedure fee (70%).

Reimbursed Medical Services in South Korea often struggles to cover the full cost of medical devices due to the low reimbursement limit set by HIRA. Consequently, healthcare institutions compensate for this shortfall through imposing higher charges for non-reimbursed Medical Services.<sup>2</sup> Given this scenario, medical device companies occasionally seek application for non-reimbursement or oppose HIRA's decision for reimbursement. Such strategic approaches allow them to gain the flexibility to set their market prices freely and expand their business opportunities in the South Korean market. However, it's essential to approach this strategy with caution, as the increasing classification of medical materials as "funded under procedure fee" may impact the effectiveness of the non-reimbursement strategy. In this category, the costs of medical materials are not adequately reflected in the corresponding MS fee, leading to a significant disparity between the actual cost of the MM and the reimbursement received, which can hinder market access, and in some cases, encourage inappropriate reuse of the Medical Material.<sup>3,4</sup>

Procedural reasons emerged as major reasons for medical material reimbursement rejections with "similar" MM not reimbursed, accounting for 27% of the rejections and "related" MS not reimbursed" comprising 23%. These results imply that non-reimbursement of similar MM and related MS that the MM are registered under, play a crucial role in the reimbursement decision of MM.

Economic reasons also played a significant role, with unclear cost-effectiveness contributing to 19% of the reimbursement rejections and high cost of materials representing 8%.

Clinical reasons contributed to rejections the least, accounting for 24% of reimbursement rejections. Similar to MS reimbursement rejections, major clinical reasons for rejections included insufficient evidence, procedure considered as "experimental and investigational" by reference countries or AETNA, and no unmet need each accounting for 8%. Here, the procedure refers to the MS in which the MM is registered under.

## CONCLUSION

The analysis reveals HIRA's high reimbursement rate for medical devices and provides previously unpublished evidence on common reasons for rejections. To improve submission quality, manufacturers must effectively demonstrate the unmet need, clinical effectiveness in relevant patients and consider the potential impact of reimbursement status of related MS on their submissions. It should be noted that the public documents obtained from the HIRA website represent only a subset of the total reimbursement decisions made during the study period, and therefore, the exact number of reimbursement decisions remains unknown.

## REFERENCES

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