

A Recent Adoption of Cost-Effectiveness Thresholds in Brazil and Its Repercussions

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Introduction

The National Commission for Health Technology Incorporation (CONITEC) guides the Brazilian Ministry of Health in deciding which health technologies should be included or excluded in the list of services available to population. A recently (2022) approved law mandates the adoption of cost-effectiveness thresholds in technical appraisals, aiming to optimize resources and enhance the system efficiency. The adopted thresholds are fixed and linked to the GDP per capita (currently 46,155 BRL): 3 GDP per capita for rare diseases and 1 GDP per capita for non-rare diseases, sparking discussions about its impact on health system equity. Brazilian Ministry of Health emphasizes that it is not a cost containment strategy but a tool to assess efficiency and interpret ICER values.

Objectives

This study aims to discuss the impact of the thresholds' adoption in health technologies incorporation.

Methods

A survey was conducted on all recommendation reports for rare diseases issued by CONITEC between January 2012 and February 2022. Out of 35 recommendation reports published during this period, those for technology exclusion or expansion of use were excluded, along with reports lacking ICER values per QALY.

Results

The analysis of CONITEC's appraisals for 18 rare disease's health technologies incorporation found ICERs ranging from 22,468 BRL to 75,938,549 BRL per QALY (**Table 1**). With the recently adopted threshold, 90.9% of incorporated technologies would have surpassed it (**Figure 1**).

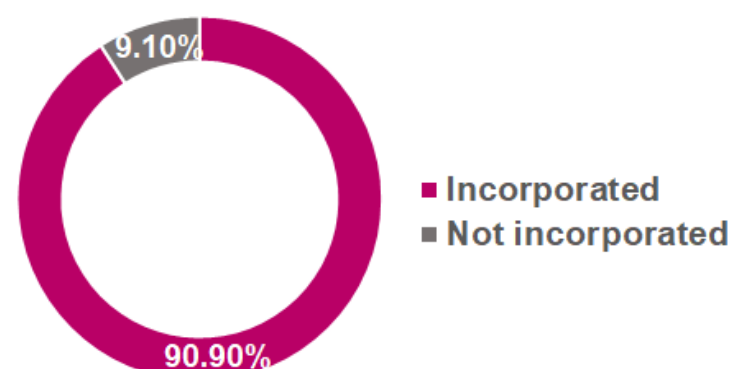


Figure 1. Technologies' incorporation status if the threshold was available.

Table 1. The 10 greatest ICER results and their respective incorporation decision.

Drug (#Technical Report)	Disorder	ICER (BRL)	Status	Decision
Ridisplam #709	SMA I	75,938,549	Above the Threshold	Incorporate
Migalast #632	Fabry's Disease	9,700,721	Above the Threshold	Do not incorporate
Aphacerliponase #706	Neuronal ceroid lipofuscinosis II	5,171,467	Above the Threshold	Incorporate
Beta-agalsidase #574	Fabry's Disease	4,699,570	Above the Threshold	Do not incorporate
Alfa-aglicosidase #617	Pompe's Disease	3,890,280	Above the Threshold	Do not incorporate
Givosirana #639	Acute hepatic porphyrias	2,892,086	Above the Threshold	Do not incorporate
Lumacaftor; ivacaftor #579	Cystic Fibrosis	2,258,270	Above the Threshold	Do not incorporate
Ivacaftor #581	Fibrose Cística	1,985,335	Above the Threshold	Incorporate
Vestronidase alfa #540	MPS VII	1,923,623	Above the Threshold	Incorporate
Nusinersena #595	SMA II	396,086	Above the Threshold	Incorporate

Also, Brazilian thresholds, when dollarized, seem low compared to other countries, highlighting a potential barrier to accessing treatments in Brazil, especially when considering the exchange rate and local purchasing power (**Figure 2**). These points raise concerns about the threshold becoming a barrier to population's access to new health technologies, questioning the threshold's pragmatic function.

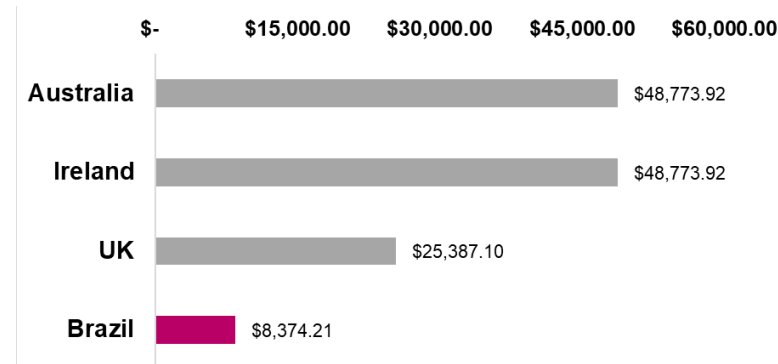


Figure 2. Comparison of cost-effectiveness thresholds*.

* Threshold estimated for Australia since its not public [1]. * NICE considers £20,000 per QALY gained to be cost effective [2-3].

Conclusion

Considering the exposed, adopting an internationally aligned cost-effectiveness threshold, tailored to rare diseases, is paramount. The disparity between the current threshold and historical ICERs, especially for rare diseases, is critical. Rectifying this not only reinforces system cohesion but also mitigates barriers to innovative treatment access.

References

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