

INTRODUCTION

- Budget Impact Analysis (BIA) is a mandatory component of health technology incorporation into the **Brazilian Private Health Insurance Coverage List**, regulated by the National Supplementary Health Agency (ANS).
- Since 2021, ANS has adopted a continuous review process for updating the coverage list.
- A critical parameter in BIA is the projected **market share** of the technology over time. Diffusion rate assumptions strongly influence projected costs or savings and may affect regulatory decisions.
- However, market share projections are inherently uncertain and frequently based on limited empirical evidence.

OBJECTIVE

- To compare market share assumptions used by proponents in BIA submissions with those adopted in ANS critical appraisal reports.

METHODS

- We conducted a retrospective mixed-methods document review of critical appraisal reports (RAC for the Portuguese acronym) of submissions from 2022 to November 2025, which are publicly in the ANS website.
- Quantitative analysis calculated absolute and relative diffusion rate differences (Year 1 and Year 5).
- Thematic qualitative analysis of RAC justifications followed the Braun & Clarke framework, identifying patterns in 52 RACs showing discordance between proponents and ANS critical appraisal.

- Among the 85 submissions available (Figure 1), differences in market share estimation were identified in 52 (61.2%) of the submissions, with market share increases in 25 cases and decreases in 27.

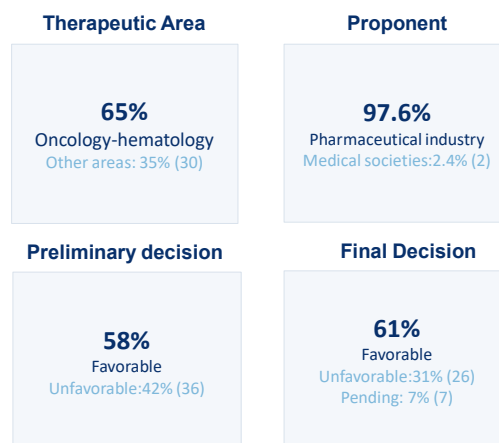


Figure 1. Characteristics of submissions to ANS

- In submissions with incremental budget impact (BI) (N=58), average absolute increase in market share in year 5 was 11.9%. In the subgroup where there was an increased market share (N=24) in the ANS reports, the absolute mean elevation was 37.3%.
- Among oncology/hematology submissions with positive BI (N=41), ANS-estimated Year 5 market share showed wide variation, from 15% to 100% (mean 62.2%, SD 27.9%).
- Thematic analysis identified 16 categories of justifications, with **“Therapeutic gap”** standing out as the primary justification for market share increase.

RESULTS

An **asymmetric pattern** was observed (Figure 2):

- when the budget impact (BI) estimated by the proponent was negative (cost savings), market share reduction predominated (51.8% of cases, versus only 3.7% cases with an increase), therefore reducing projected savings;
- when the BI estimated by the proponent was positive (increased spending), market share increase was frequent (41.4% of cases, versus 22.4% with a decrease), enlarging the recalculated budget impact. (Figure 2)

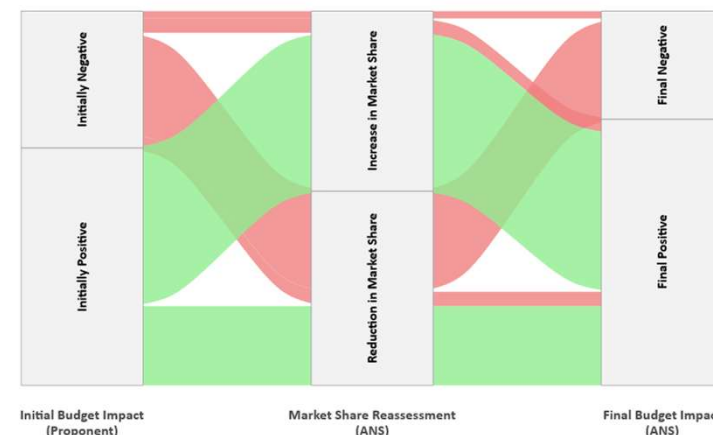


Figure 2. Flow of Budget Impact Assessment: From Proponent Submission Through Market Share Reassessment to Final ANS Determination

CONCLUSIONS

- ANS frequently increases the market share estimated by proponents, with substantial variability.
- Clearer guidance on market shares estimation in ANS submissions is warranted to enhance the predictability of the HTA submissions.