

Health economic decision models used in the cost-effectiveness analyses of innovative products submitted to the French National Authority for Health (HAS)

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OBJECTIVES

- In France, economic evaluation is used in the process of price negotiation of innovative health products. It is based on a modelling approach and requires the use of health economic decision models (HEDMs). Our objective was to review and analyse the use of HEDMs in cost-effectiveness analyses (CEAs) of innovative health products submitted by manufacturers.

METHODS

- We identified all published economic appraisals of CEAs from January 2016 to December 2022. The main aspects specifying the HEDM were independently extracted by two authors into a predefined grid (e.g., therapeutic area, HEDM type, health states). Disagreements were resolved through discussion.

RESULTS

- A total of 139 appraisals, including HEDMs from January 2016 to December 2022, were analysed. The majority of the CEAs focused on the first assessment of health products (drug or medical device) (**Figure 1**). Ninety percent (126/139) of the appraisals were for medical devices.
- The main therapeutic area was oncology (**Figure 2**). Twenty-two percent (31/139) of the CEAs were for orphan drugs.
- Most (53%, 73/139) of the CEAs were based on a partitioned survival model (PSM), while state transition models (STMs), such as Markov and semi-Markov models, were used in 33% (46/139) of CEAs. Microsimulation models were rarely used (3%, 4/139). Combined models (e.g., decision tree and Markov model) were implemented in 10% (14/139) of the CEAs (**Figure 3**).

- PSM was mainly used for CEAs of drugs, whereas STM (Markov or semi-Markov model) was mostly chosen in the case of medical devices (**Figures 4 & 5**).
- Regardless of the type of HEDM, the assumptions of the modelling structure were subject to limitations in almost a quarter of the appraisals in 2022 (e.g. lack of clinical plausibility related to HEDM assumptions).
- Three examples of CEAs in oncology reported 2 types of HEDMs. In the base case analysis, one type of HEDM (STM or PSM) was considered. An alternative type (PSM or STM) was explored via scenario sensibility analyses and induced a variation in the incremental cost-effectiveness ratio (ICER) of approximately +/-15%. However, this impact on the ICER was difficult to interpret without a full documentation on the structure of the two types of HEDM.

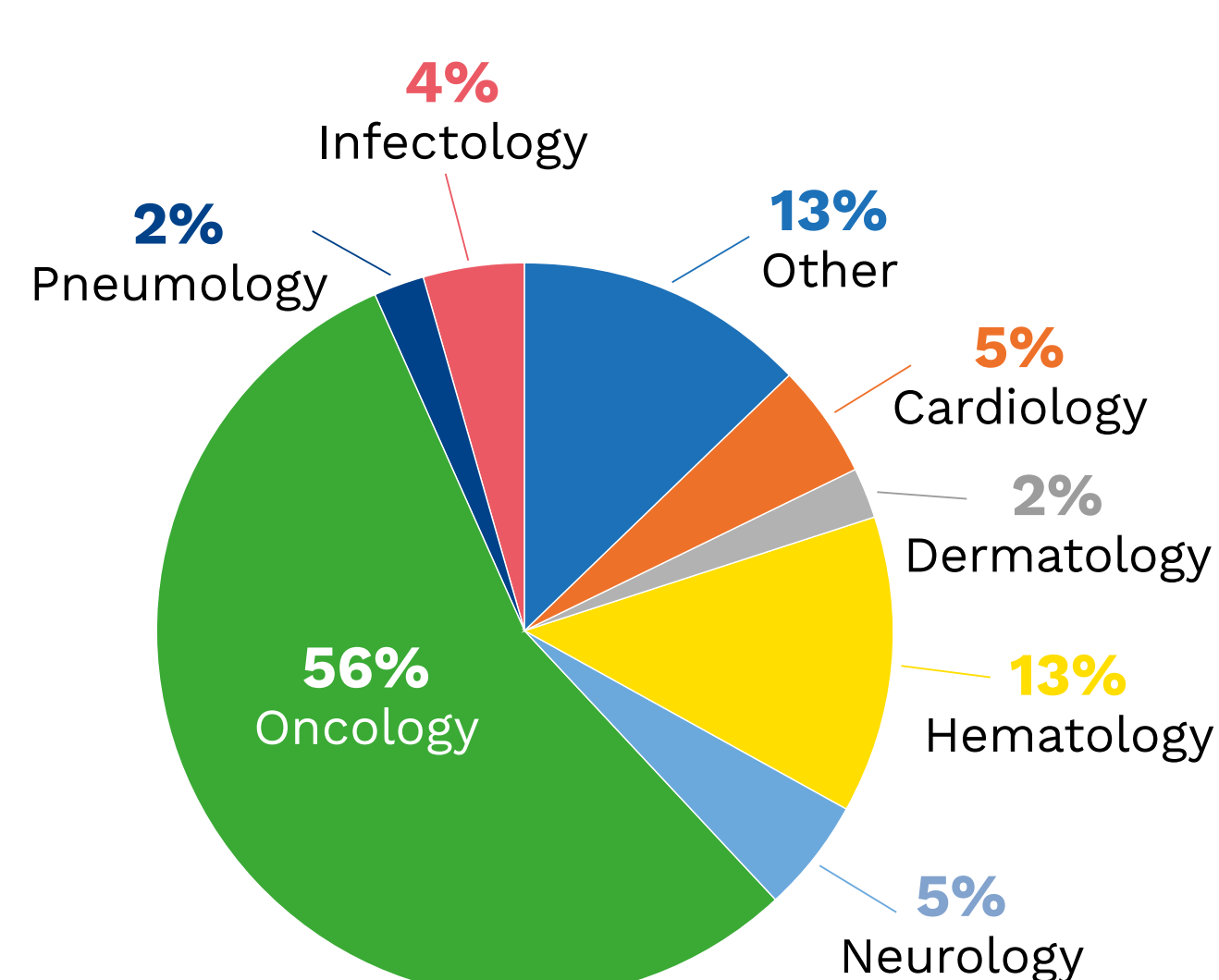


Figure 1. Breakdown by therapeutic area of the included appraisals (n=139)

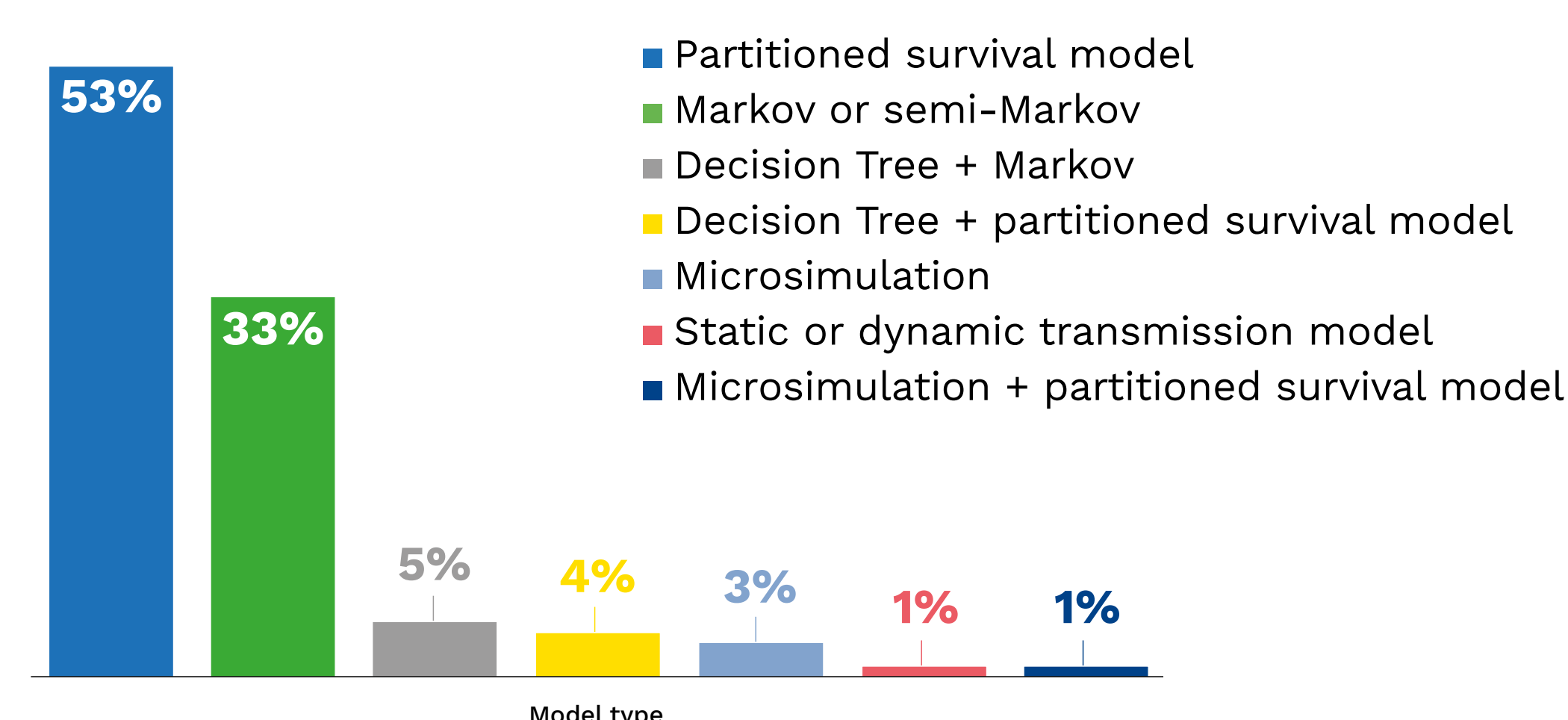


Figure 2. Breakdown by HEDM of the included appraisals (n=139)

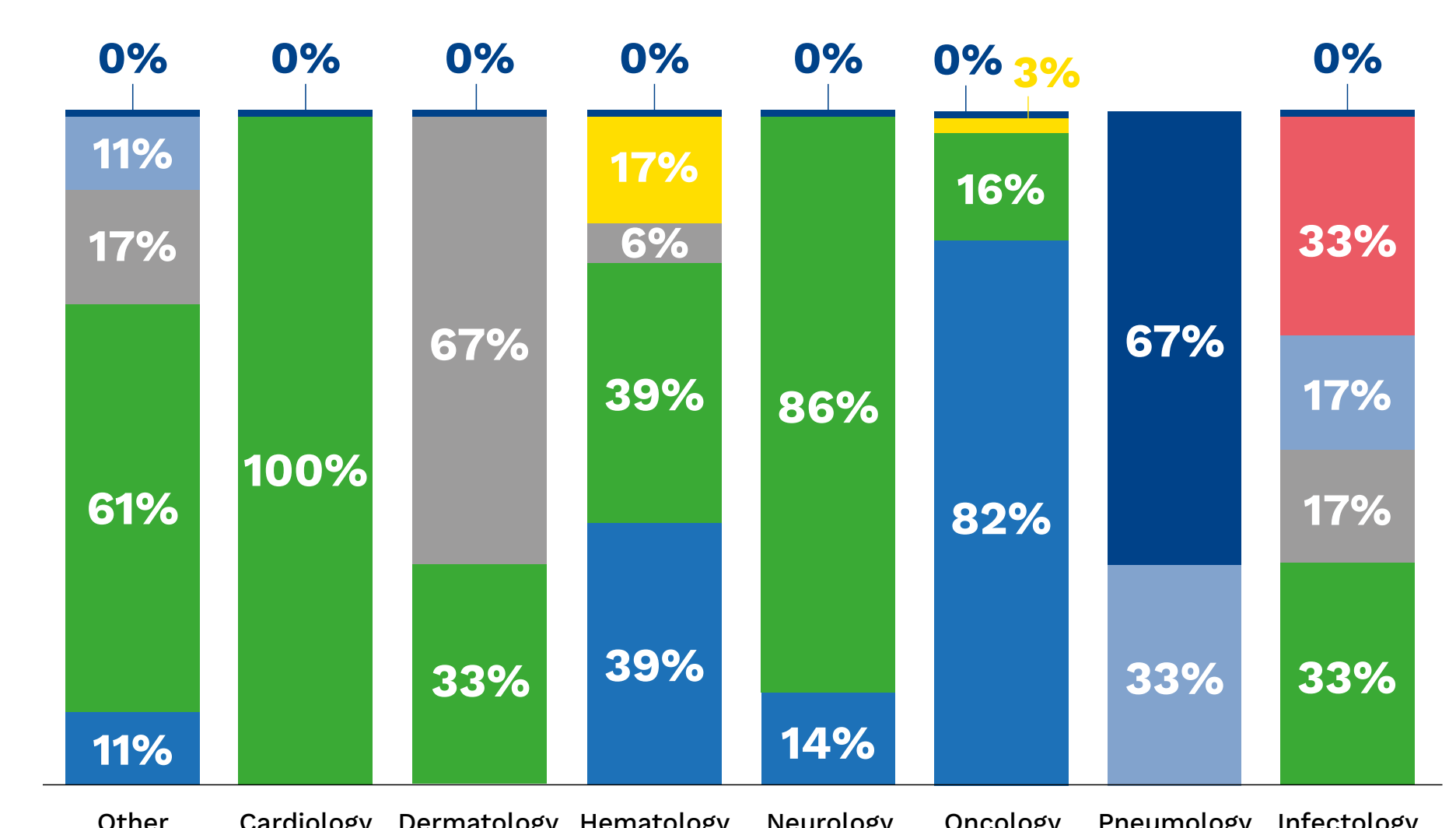
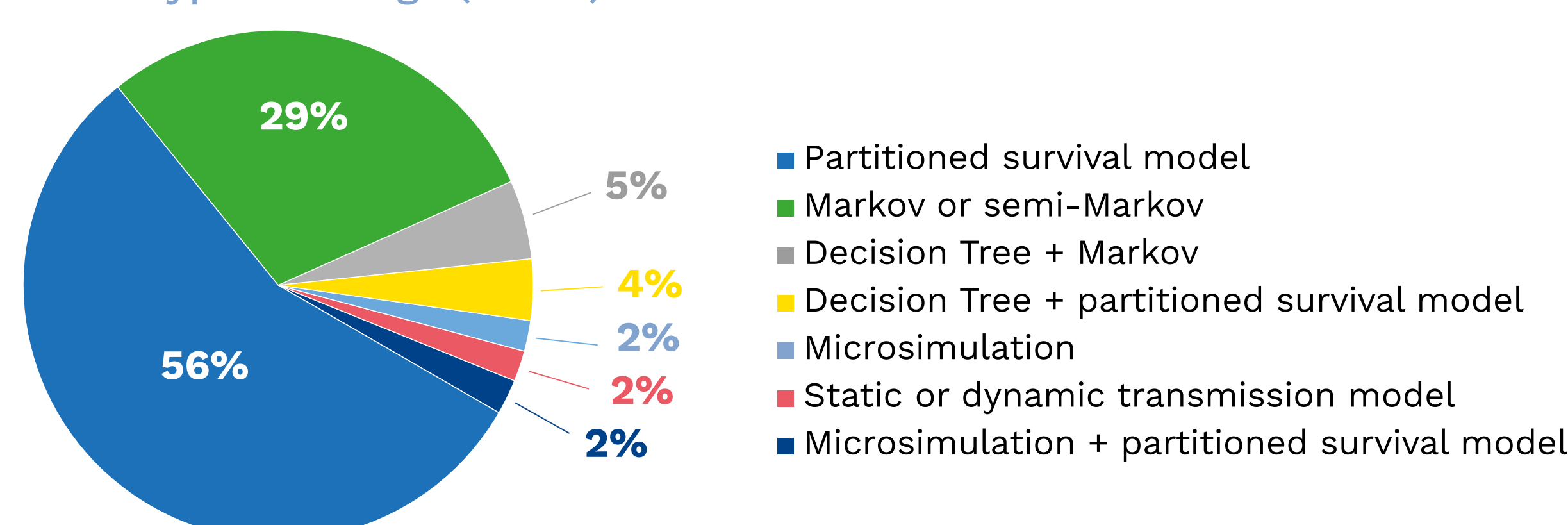
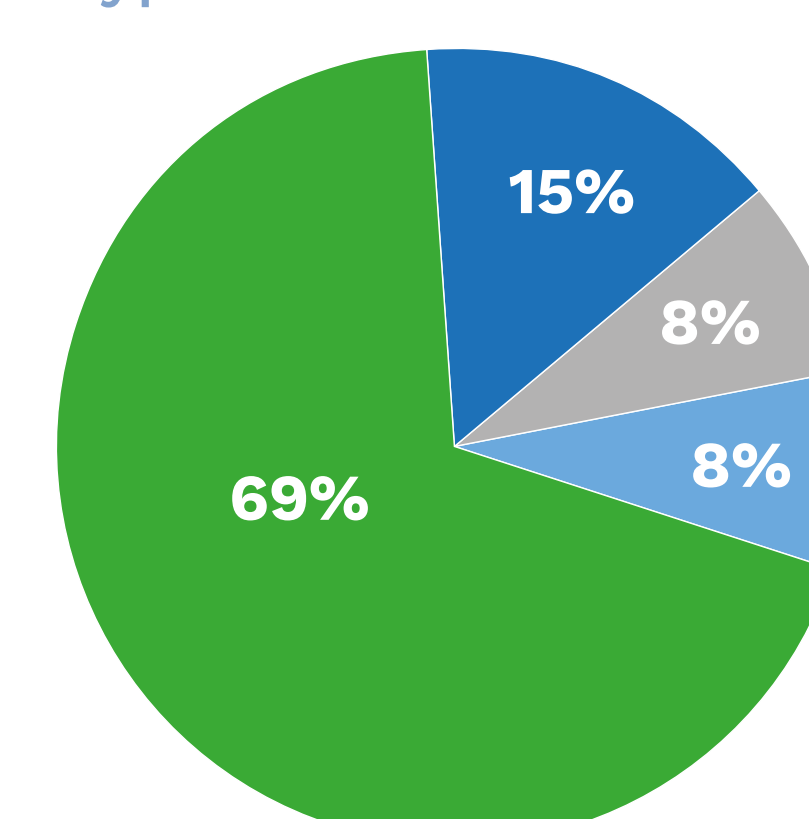


Figure 3. Breakdown of HEDM types by therapeutic area (n=139)

HEDM type for drugs (n=126)



HEDM type for medical devices (n=13)



Figures 4 & 5 : Breakdown of HEDM types by health technology (drugs or medical devices)

DISCUSSION

- Although a gradual improvement was seen regarding the global quality of CEAs submitted during the study period, PSMs lacked documentation on the plausibility of extrapolation of the survival curves.
- The HEDM choice itself was associated with structural uncertainty, which is difficult to explore.
- Treatment sequence models were rarely considered. In oncology CEAs, one of the main explanations was the lack of survival outcome data for the subsequent treatment lines.

CONCLUSIONS

This review showed that PSMs were frequently used, mainly because of their simplicity and the availability of survival data. We highlight two key messages:

- the main identified challenge was not often related to the choice of the HEDM itself but to the justification and plausibility of its related assumptions.
- in-depth documentation and adequate exploration of structural uncertainty related to model assumptions should be provided.