

BACKGROUND AND OBJECTIVE

- For healthcare products with moderate to major Clinical Added Value, a cost-effectiveness model is expected to be submitted to the CEESP as part of the market access reimbursement procedure in France.
- The CEESP doctrine, published in July 2021, aims to set out the general economic evaluation framework<sup>1</sup>.
- The objective of this analysis was to evaluate the impact of this doctrine on economic evaluation, by comparing pre- and post-doctrine CEESP opinions.

METHODS

- CEESP opinions published 18 months before (January 2020 – July 2021) and after (July 2021 - December 2022) the doctrine were selected from IQVIA internal and exhaustive database of published economic opinions and assessed using an extraction grid built on doctrine’s key insights :
  - Assessment of methodological conformity
  - Uncertainty qualification
  - CEESP’s position to guide public-decision making

RESULTS

- On the 79 economic opinions eligible, 36 opinions were published before and 43 after the doctrine publication. Most opinions were about drug evaluations.
- Before the publication, 50% of opinions were related to a first assessment. After publication, 60% was related to an extension of indication.
- The main therapeutic area was solid oncology-tumors with 49% of opinions published post-doctrine compared to 27% pre-doctrine.

Assessment of methodological conformity

- The CEESP doctrine defines the general framework elucidating the grading of methodological reservations. A major reservation designed an item deemed to fail to comply with the current recommendations which invalidates all or part of the economic evaluation.
- Similar proportion of opinions with major reservations were observed pre-and post-doctrine publication (33% versus 30%), the main driver being clinical data integration in the model (Figure 1).

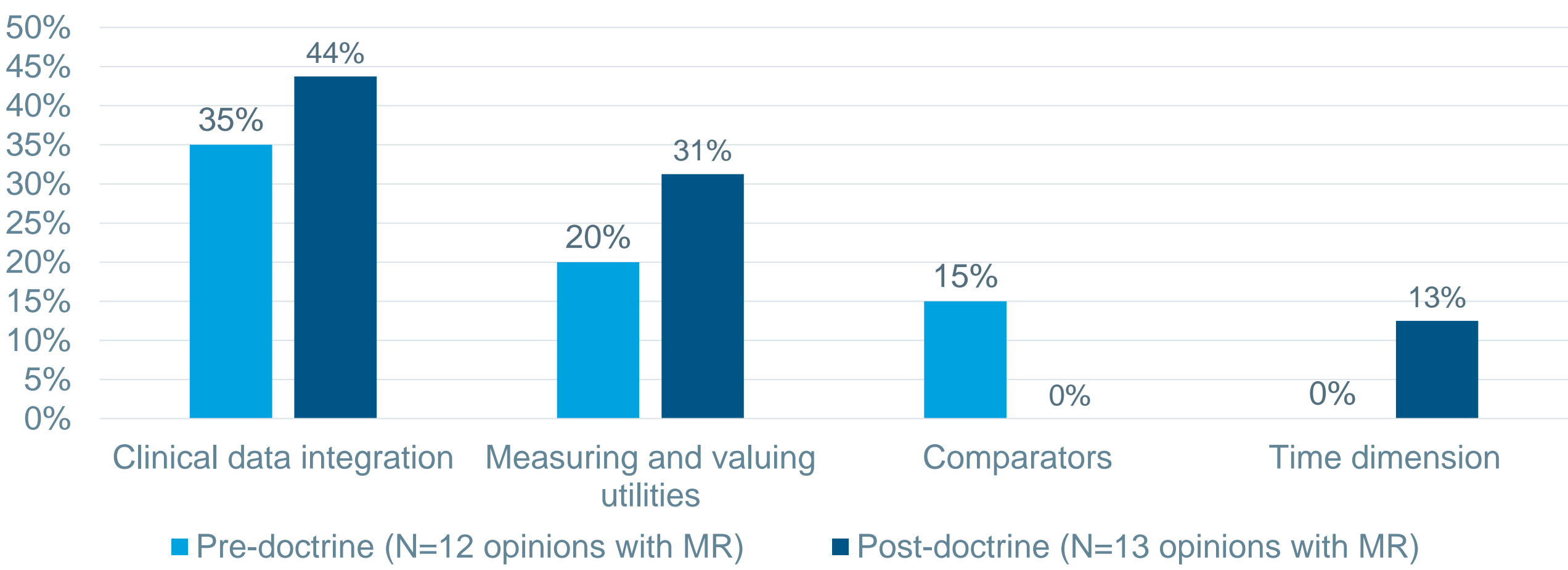


Figure 1 : Major reservations (MR) criteria

Uncertainty qualification

- The doctrine introduced the major overall uncertainty as a new criterion to qualify uncertainty in CEA, which invalidate the analysis.
- Among the post-doctrine opinions sample, 9 opinions received a major overall uncertainty.
- The reasons behind a major overall uncertainty can be multiple. Major overall uncertainty main drivers were the number of important reservations, in addition to uncertainty about key parameters estimation (Figure 2).

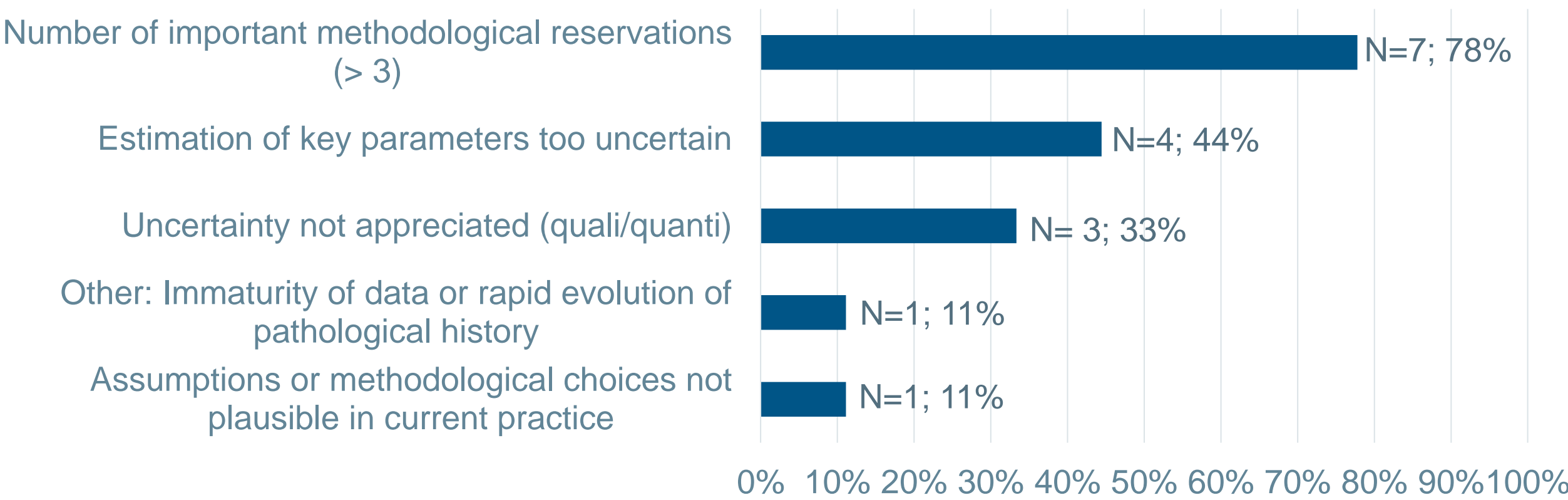


Figure 2 : Main major overall uncertainty drivers

- Scenario analyses were the main source of uncertainty, without a clear threshold to define the major overall uncertainty, since variations between 11% to 1000% of the ICER versus base case were observed (Figure 3).
- Economic opinions with a major overall uncertainty have a much higher average ICER’s variation in scenario analysis than economic opinions without (268% vs 124%). Uncertainty was greater in pre- than in post-doctrine overall opinions (Figure 4).

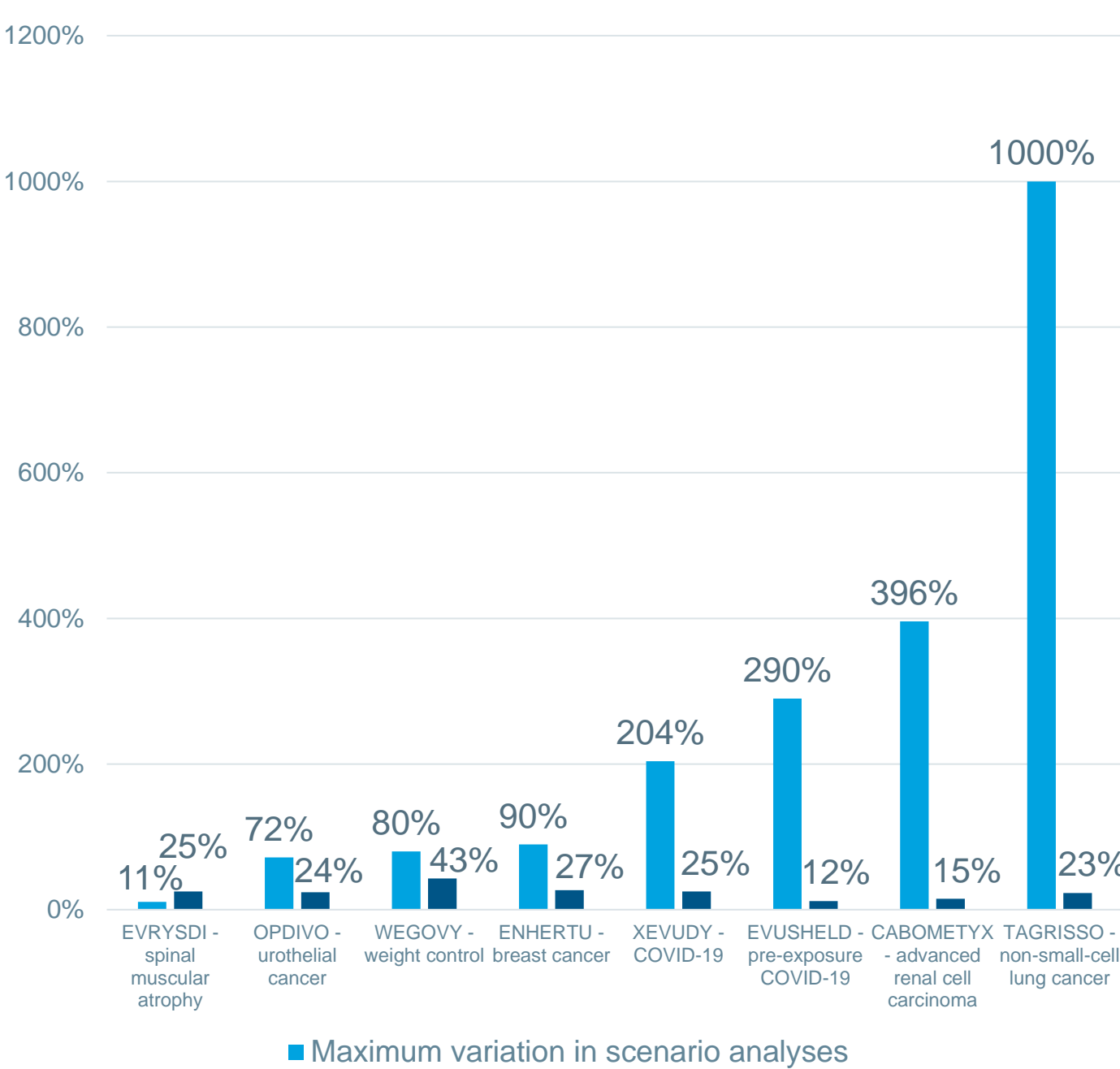


Figure 3 : ICER variations regarding scenario vs deterministic sensitivity analysis (DSA) – opinions with major overall uncertainty (n=9)

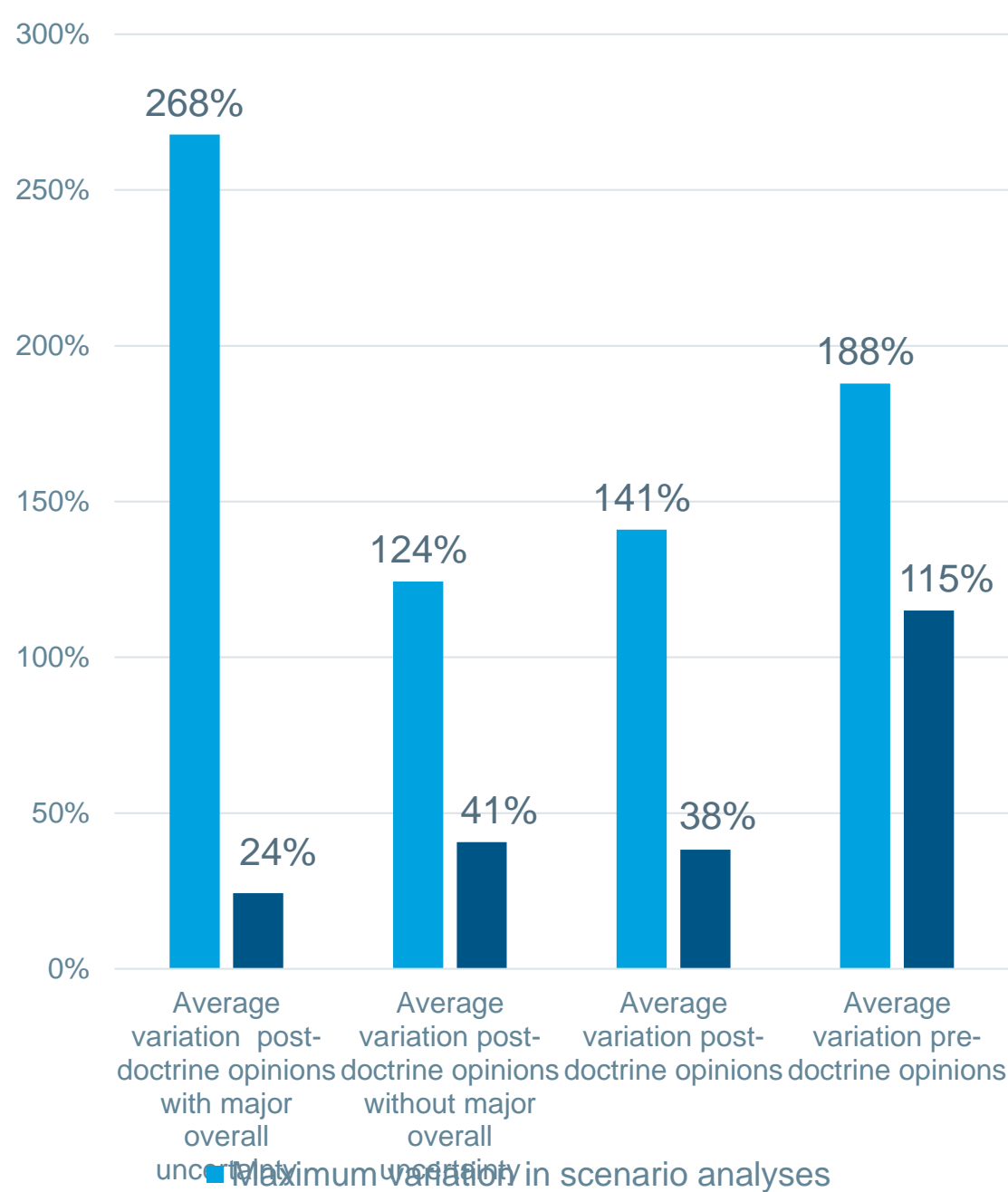


Figure 4 : ICER variations regarding scenario vs deterministic sensitivity analysis (DSA) – total sample (n=79)

CEESP’s position to guide public-decision making

- In France, public decision-makers do not regulate prices with reference to a particular ICER threshold. Nevertheless, the CEESP is entitled to deliver an opinion on the ICER level which can rank as high, very high, or extremely high.
- ICER qualification was more frequent in opinions published before the doctrine (Figure 5).
- Regarding the large ICER dispersion, no specific trend permits to determine a potential threshold at which the ICER is qualified as high or more (Figure 6).

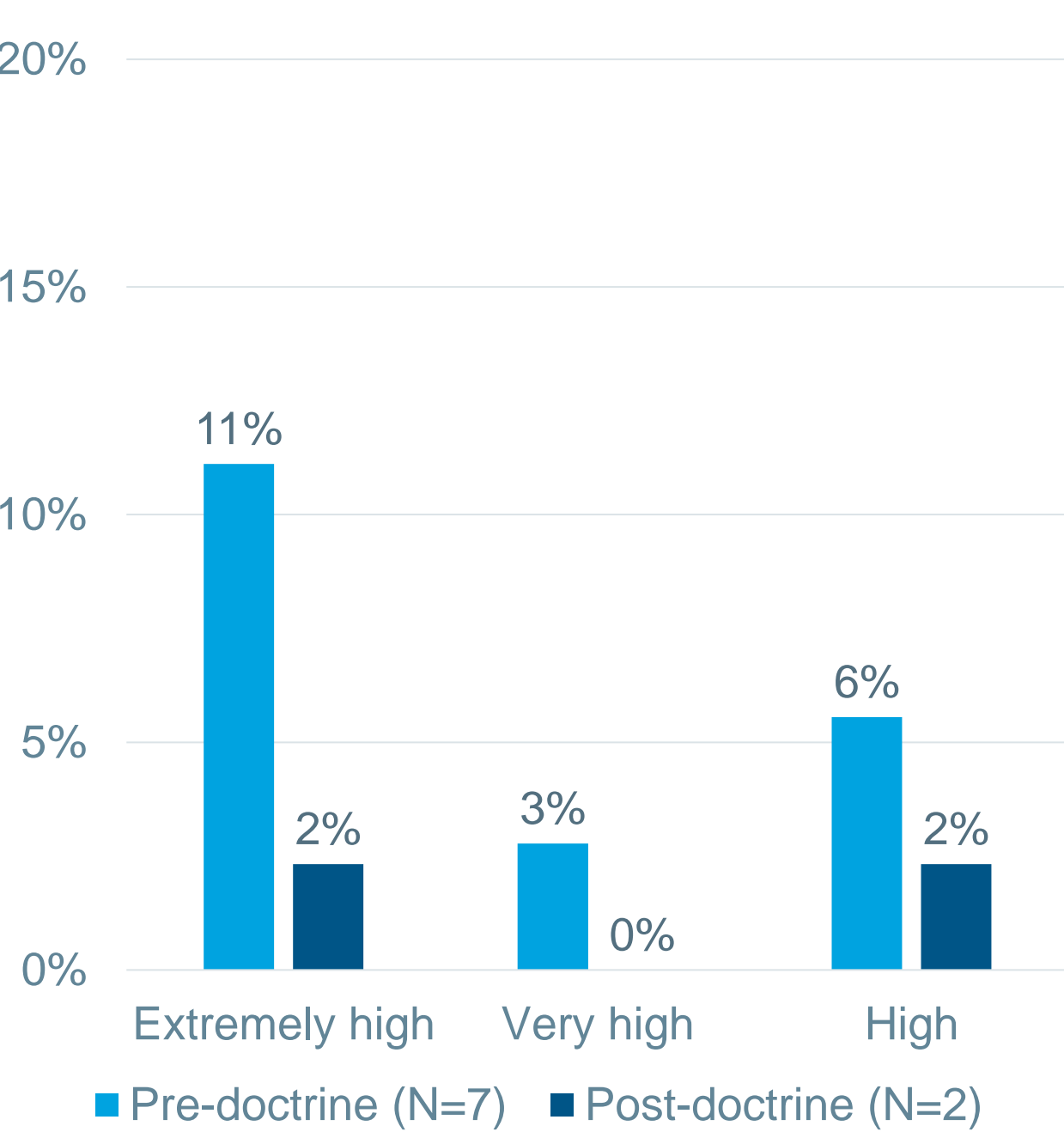


Figure 5 : Number of opinions with ICER qualification (among opinions without major reservations or a major overall uncertainty)

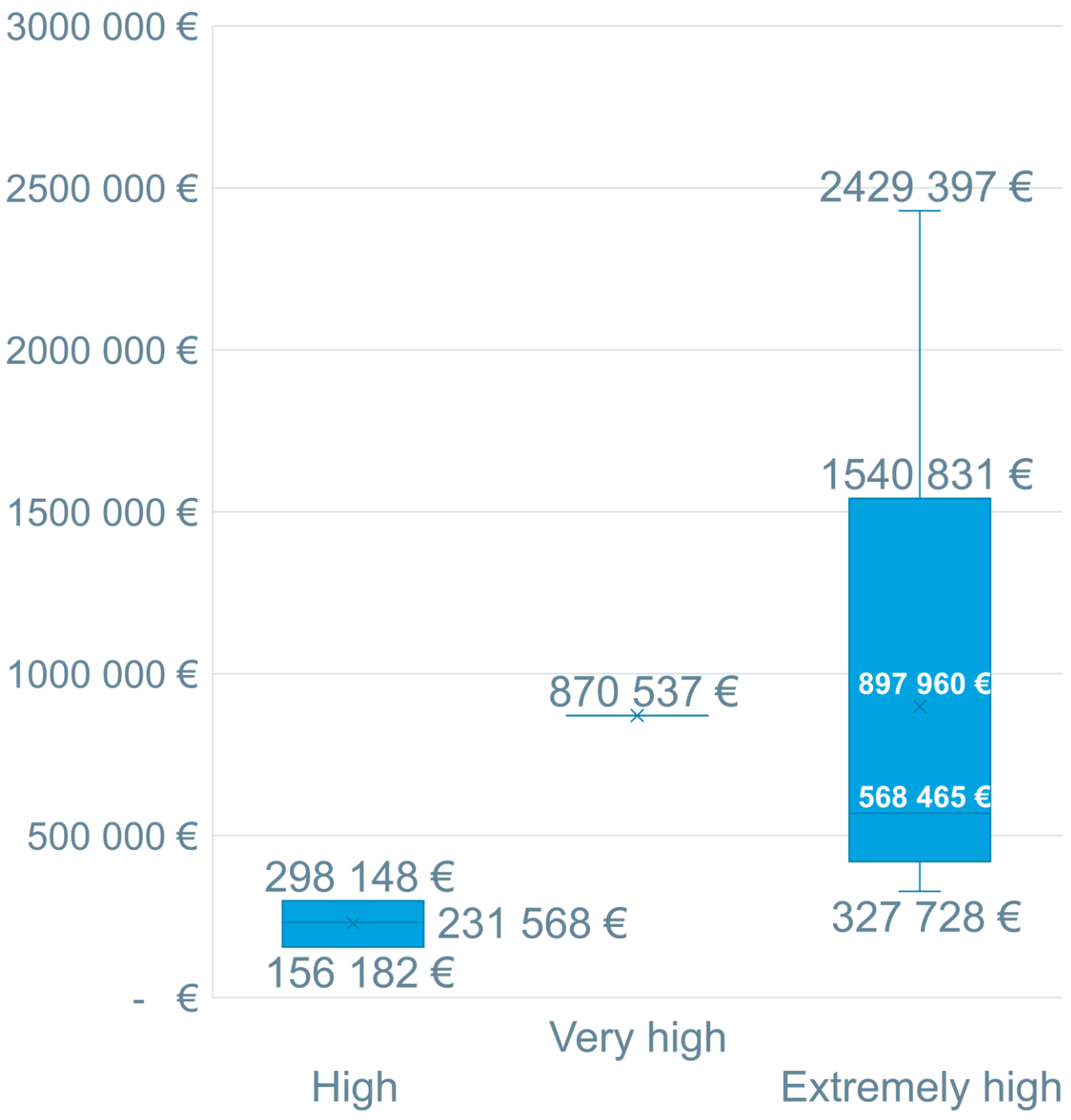


Figure 6 : ICER dispersion

CONCLUSION

Based on previous criteria used by the CEESP, the pre- and post-doctrine period do not seem to differ significantly: the doctrine’s publication impact seems limited. However, the introduction of the major overall uncertainty enables to integrate uncertainty as a determining factor for invalidating the cost-effectiveness analysis, in addition to the major reservation, both being potential challenges for price negotiation with the Economic Committee in France.

**Acronyms :** CEA : Cost-Effectiveness Analysis; CEESP : Commission for Economic and Public Health Evaluation; HAS : French National Authority for Health; ICER : Incremental Cost-Effectiveness Ratio; MR : major reservation

**Reference :** 1. Haute Autorité de Santé. Doctrine of the Commission for Economic and Public Health Evaluation. Saint-Denis La Plaine; HAS; 2021.

ISPOR – 26th Annual European Congress, November 2023 – Copenhagen, Denmark

Copyright© 2019 IQVIA. All rights reserved.

Copyright © 2018 IQVIA. All rights reserved.