Budget Impact Models in CEESP Opinions: A Decade of Insights

Putnam
Inizio Advisory

Olfa Doghri, MSc [1], Yosra Boukhris, PharmD [2], Marine Sivignon, PharmD [1], Romain Supiot[1], MSc [1], Rahma Sellami, PharmD[1], Nicolas Virely, MSc[1]
[1] Putnam, France, [2] Putnam, Tunisia

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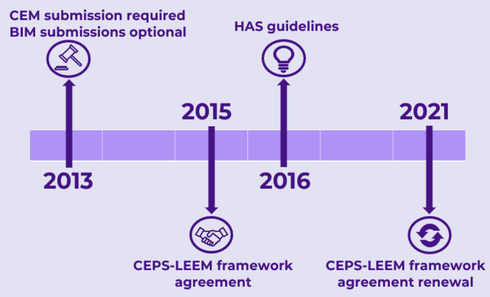
Introduction



- Since 2013, pharmaceutical and medical device (MD) companies in France have been required to submit cost-effectiveness analyses to the Haute Autorité de Santé (HAS) for innovative products. Budget impact model (BIM) submissions were optional.
- Under the 2015 CEPS-LEEM (Comité Economique des Produits de Santé – Les Entreprises du Médicament) framework agreement, BIMs became mandatory for drugs and MDs with a claim of (1) added therapeutic value (ASMR) I to III and (2) projected net sales exceeding €50 million in the second year.
- In 2016, HAS issued methodological guidelines detailing expectations on BIM.
- Subsequently, the 2021 CEPS-LEEM framework agreement between the same entities reaffirmed these requirements under Article 12d, maintaining the same BIM-submission conditions.

Objective and methods

- This study reviews HAS economic opinions (EOs) which included a BIM, focusing on methodological reservations (MRs) and their evolution following the 2015 framework agreement and its renewal in 2021, as well as the 2016 guidelines.
- EOs released by CEESP (Commission d'Evaluation Economique et de Santé Publique) between 2014 and 2024 were compiled into an internal database, "CEESPlorer". Data on BIM inclusion, submission type, therapeutic area, methodological reservations, and critical appraisal were extracted.
- Analyses were conducted by cluster years, corresponding to key policy milestones: **2014–2015**, **2016–2021** and **2022–2024**.

Results

① Overview

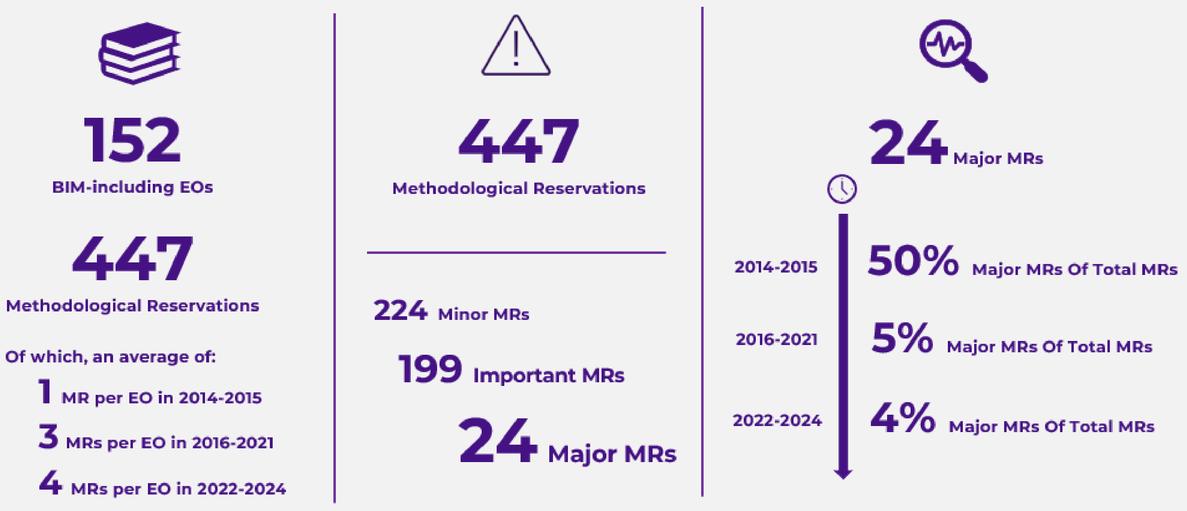
- Between 2014 and 2024, a total of **238 EOs** were published. Of these, **152 included a BIM**, representing **64%** of the total. Following the 2015 CEPS-LEEM framework agreement, there was a marked increase in BIM submissions: Only **17%** of EOs included a BIM in 2014–2015 versus **70%** in 2016–2021 and **77%** in 2022–2024.
- Overall, among these BIM-including EOs, 50% were submitted in the context of an extension of indication, while 42% sought initial reimbursement. Nearly half (47%) concerned medicines, 12% were associated with MDs, and 4% with vaccines.
- Across therapeutic areas, oncology accounted for 54% of BIM dossiers. Neurology and virology represented 7% each, while other areas were less represented (1% to 6%).
- In 2018, a unique case occurred: only one common BIM dossier was submitted for two separate cost-effectiveness model (CEM) dossiers corresponding to Ocrevus® (ocrelizumab) in both primary progressive and relapsing-remitting multiple sclerosis.

② Budget Impact Analysis Acceptability

- To assess the impact of the HAS-published BIM guidelines in 2016, BIM acceptability was compared between the pre-guideline period (2014–2016) and the post-guideline period (2017–2024). Of 152 BIM-including EOs, 15 were issued before 2016 and 137 after. In the earlier period, 27% of BIMs were not accepted versus 17% after 2016. Conversely, the proportion of accepted BIMs rose from 72% to 82%, reflecting improved compliance with the requirements (**Figure 1**).

Figure 1. BIM acceptability pre and post BIM guideline publication by HAS in 2016

③ Methodological Reservations



- Major MRs were mainly driven by clinical data and modeling assumptions (29% each), followed by cost measurement (13%) and comparators (8%) (**Figure 2**).

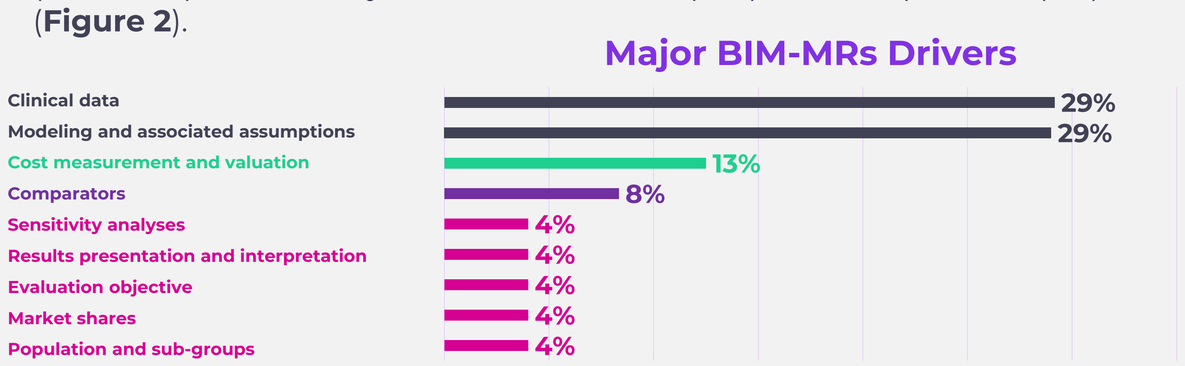


Figure 2. Key drivers of BIM-specific major methodological reservations

- Across 152 BIM-including EOs, 447 MRs were identified, with only 20 MR-free EOs. Of these, 8 MRs occurred in 2014–2015, 251 in 2016–2021, and 188 in 2022–2024. When relating the number of MRs to the number of BIM-including EOs, an increase is observed through the cluster years with an average of 1 MR per BIM-including EO in 2014–2015, 3 MRs per BIM-including EO in 2016–2021 and 4 MRs per EO in 2022–2024, suggesting a trend towards stricter assessments of BIMs.
- Of the 447 MRs identified, 224 were minor, 199 were important and only 24 were major. Major MRs, appeared in only 20 EOs, reducing from 50% (4 MRs) in 2014–2015 to 4% (11 MRs) in 2016–2021 and 5% (9 MRs) in 2022-2024.
- When major MRs were raised for both CEM and BIM in the CEM dossier, these were compared. The analysis revealed that only 9 of the 24 major MRs were BIM-specific, while the remaining 13 overlapped with CEM's (**Table 1**).

Table 1. BIM-specific major methodological reservations and their drivers

Health Product	Major BIM-specific MR driver	Major MR description
DEFITELIO® (defibrotide)	**Modeling & assumptions**	No distribution of patient management between arms
	Sensitivity analysis	No sensitivity analyses provided
TECENTRIQ® (atezolizumab)	**Cost measurement**	Underestimation of average treatment months and patient costs vs. nivolumab (–17%)
URGOSTART® (dressings)	**Modeling & assumptions**	Non-adapted modeling of resource use
	Cost measurement	Non-recommended approach for hospital costs
XTANDI® (enzalutamide)	**Evaluation objective**	No comparative scenario
	Comparators	Missing docetaxel as a comparator
TEGSEDI® (inotersen)	**Market shares**	Inconsistent scenario choices: patirisan arrival not accounted for → uninterpretable results
WEGOVY® (semaglutide)	**Modeling & assumptions**	Too high frequency of intervention estimated → major impact on results

Discussion & Conclusion

BIMs have become central to CEESP submissions as regulatory requirements evolve. Now included in most dossiers, where economic evaluation increasingly guides decisions, the complementary use of BIMs alongside cost-effectiveness analyses offers valuable insights for payers and authorities. Efficiency-specific major MRs often drive BIM-related ones, since BIMs are inherently dependent on efficiency analyses. Persistent methodological issues highlight the need to update BIM guidelines published nearly a decade ago. Harmonization remains essential for consistent and robust health technology assessments. The forthcoming 2026 CEPS-LEEM framework may either reinforce current practices or introduce significant changes.

Key Insights for a Successful BIM…

- **Ensure alignment with CEM to guarantee inter-dossier consistency: modeling assumptions, clinical data, structural choices and resource use.**
- **Include all relevant comparators.**
- **Apply comprehensive cost measurement following the recommended methodological approach.**
- **Avoid underestimating treatment durations.**
- **Conduct sensitivity analyses to assess the robustness of the BIM outputs.**
- **Design coherent market share scenarios, consistent with clinical practice, as they critically drive BIM outcomes.**

Contact
Marine Sivignon
Marine.sivignon@putassoc.com

Find out more at putassoc.com