EE752

WHAT ARE THE IMPACTS OF THE ABSENCE OF HEALTH ECONOMIC EVALUATIONS FOR DRUGS GRANTED AN ASMR IV RATING BY THE FRENCH NATIONAL AUTHORITY OF HEALTH (HAS)?

An Analysis of Medicines Assessed between May 2022 and May 2024.

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INTRODUCTION

In France, the French National Authority for Health (HAS) is responsible for assessing the clinical and economic value of medicines to inform public decisions on pricing and reimbursement.

Economic evaluations (EEs) are only required when specific criteria are met: the application concerns a first-time market access authorization or an extension of indication, the medicine claims an added clinical benefit (ASMR) rated between levels I and III, and a significant impact on public health expenditure or healthcare organization is expected.

As a result, medicines claiming a minor added clinical benefit (ASMR IV) are systematically excluded from the EE process.

This exclusion creates a gap in understanding their broader impact on the healthcare system, such as changes in care organization, patient adherence, or resource utilization.

The aim of this study is to provide an overview of medicines that initially claimed an ASMR I to III but were finally rated ASMR IV, and to discuss the consequences of excluding all ASMR IV medicines from economic evaluations in France.

METHOD

All medicine evaluations published by the French National Authority for Health (HAS) between May 2022 and May 2024 were extracted from the HAS website and compiled into a structured database.

For each evaluation, data were collected on the granted added clinical benefit (ASMR), the involvement of the HAS Economic and Public Health Evaluation Committee (CEESP), and the associated reimbursement mechanism. Only medicines that obtained an ASMR IV were included in the analysis. For these medicines, the study verified whether an economic assessment by the CEESP had been conducted and characterized the type of financing mechanism (e.g., retail or hospital with "liste en sus," retrocession, or diagnosis-related group (DRG)).

Descriptive and qualitative analyses were performed to identify patterns and gaps in the consideration of ASMR IV medicines within economic evaluations. The resulting dataset served as a basis to explore how the absence of systematic health economic evaluations may limit the consideration of broader organizational and financial effects in the HAS assessment process.

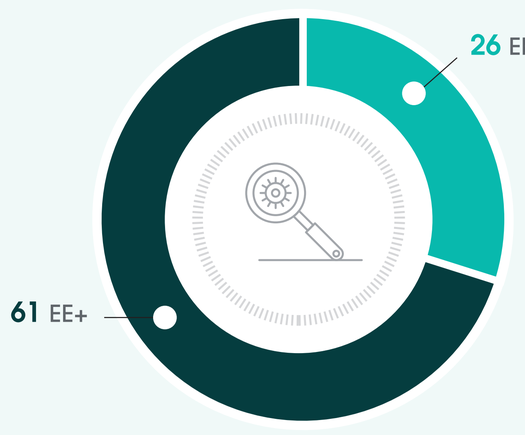
RESULTS

— Between May 2022 and May 2024, 87 medicines were granted a minor added clinical benefit (ASMR IV), representing nearly:

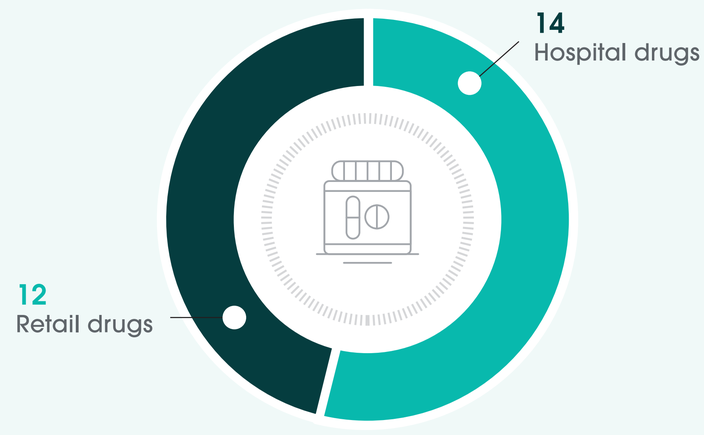
→ 20% of all HAS drug assessments.

A large majority of these medicines also received a major medical benefit rating (SMR important, n = 76).

ASMR IV MEDICINES:
WITH VS. WITHOUT ECONOMIC EVALUATION



ASMR IV MEDICINES WITHOUT EE:
RETAIL VS HOSPITAL MARKET



Among these 87 evaluations, only 26 were subject to a health economic assessment by the HAS as part of their market access procedure, representing 30% of ASMR IV medicines.

Most ASMR IV medicines have therefore not undergone a health economic evaluation, which could provide additional insights to complement the clinical assessment conducted by the HAS. However, beyond clinical efficacy, potential positive or negative externalities may exist for these products but are not considered in pricing and reimbursement decisions due to the lack of relevant data and structured assessment and pricing frameworks.

Beyfortus (nirsevimab) illustrates this situation. Indicated for the prevention of lower respiratory tract infections caused by respiratory syncytial virus (RSV), the medicine was associated with a substantial reduction in infant hospitalizations according to a study by Santé publique France. This analysis estimated that nirsevimab administration prevented approximately 5,800 hospitalizations for RSV-related bronchiolitis following emergency department visits (95% credible interval: 3,700–7,800), including 4,200 cases among infants aged 0–2 months, between September 15, 2023, and February 4, 2024, in France.

This represents a 23% reduction (16%–30%) in total RSV-related hospitalizations after emergency visits, and a 35% reduction (25%–44%) among infants aged 0–2 months, compared with the scenario without nirsevimab administration[(1)].

CONCLUSION

Among medicines rated ASMR IV, some may be associated with positive or negative externalities that extend beyond clinical efficacy alone. Considering these externalities through health economic evaluations could provide a more comprehensive understanding of a medicine's overall efficiency, by capturing its organizational, economic, or/and societal impacts. Such an approach would help inform public decision-making on pricing and reimbursement, strengthening the alignment between the clinical, economic, and social value of therapeutic innovations.

Reference
[1] https://www.santepubliquefrance.fr/presse/2024/bronchiolite-deux-etudes-francaises-demontrent-l-efficacite-du-beyfortus-R-dans-la-prevention-des-cas-graves-et-la-reduction-des-hospitalisations