A retrospective analysis of ESMO-MCBS and HTA Timelines in Ireland

HTA351

A.Wall, A. Henry
AstraZeneca Ireland

Introduction

The health budget in Ireland is finite, with an allocation of €30 million for new, life-enhancing medicines in Budget 2026 [1].

Given the constrained budget of the publicly funded health system, prioritising the allocation of limited financial resources with respect to new therapies is becoming increasingly important. This is especially true with respect to new cancer treatments.

The National Centre for Pharmacoeconomics (NCPE) conducts the health technology assessment (HTA) of pharmaceutical products for the Health Service Executive (HSE) in Ireland in collaboration with the HSE Corporate Pharmaceutical Unit (HSE-CPU). The NCPE makes recommendations at a national level for drugs.

Objective

The ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) was developed to facilitate improved decision-making regarding the value of anti-cancer therapies, promote the accessibility and reduce inequity of access to high value cancer treatments [2].

The ESMO-MCBS uses a scoring system that categorises cancer medicines into different levels of clinical benefit. In the non-curative setting, the focus of this study, the scale ranges from 1 to 5, with scores of 4 or 5 defined as high scores and indicating substantial additional clinical benefit relative to the standard of care. These are priority candidates for reimbursement, whereas scores of 1, 2 or 3 are considered low or average additional clinical benefit [3].

A 2024 LSE paper found that a high ESMO-MCBS score increased the likelihood of faster positive decisions from HTA agencies in England, Scotland, Australia, France and Canada [3].

The current reimbursement landscape in Ireland is challenging, and this project aims to determine whether the globally validated ESMO-MCBS has any correlation with timelines for reimbursement and access to treatments in the Irish setting. This research aims to explore whether a score of 4 or 5 increases time to positive HTA outcomes versus a score of less than 4 within the Irish context. We will also look at whether having a score of greater than 4 indicating a high clinical need always leads to reimbursement.

Method

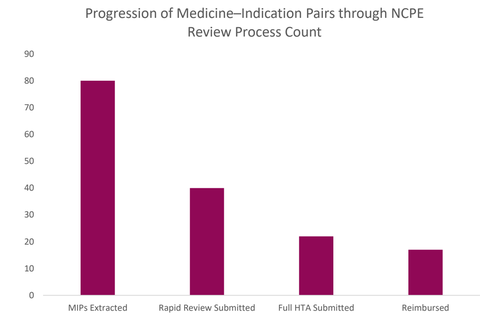
The study sample was limited to immunotherapies for treating solid tumours in a non-curative setting with published ESMO-MCBS scores that had been assessed by the NCPE between Jan 1, 2011, and Dec 31, 2023.

In this retrospective analysis, data were extracted from publicly available HTA reports, published clinical trial results, and publicly available HSE Drugs Group Minutes. The unit of measurement in the data extraction process was the medicine–indication pair (MIP) (i.e., a medicine for a specific indication).

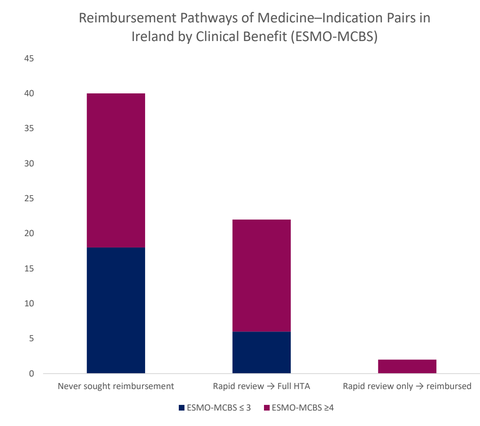
We analysed whether ESMO-MCBS was associated with the time between rapid review submission and reimbursement in Ireland, and factors associated with positive HTA outcomes.

Results

ESMO-MCBS scorecards encompassing 80 MIPs used in non-curative settings were extracted, totalling 40 rapid review submissions reviewed by the NCPE. Of these 40 MIPs, 22 full HTA submissions were reviewed by the NCPE, with 17 medicine–indication pairs receiving reimbursement.

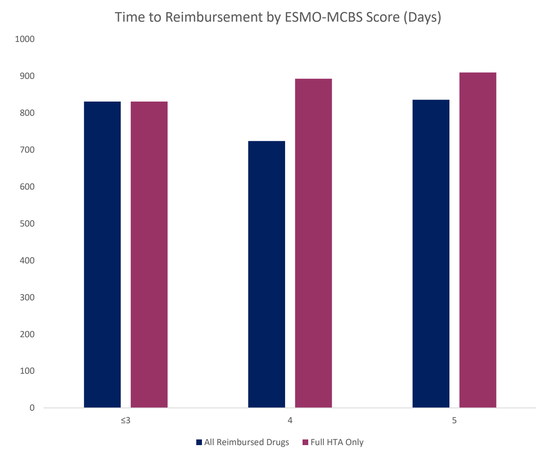


Of the 80 MIPs extracted, 50% never sought reimbursement in Ireland. 22 of these 40 MIPs had an ESMO-MCBS of either 4 or 5, indicating a substantial additional clinical benefit relative to the standard of care. Of the 40 MIPs that underwent a rapid review, only 22 underwent a full HTA. 2 MIPs received reimbursement with a rapid review only, both had ESMO-MCBS of 4.



7 MIPs that underwent a full HTA were not recommended for reimbursement. In 6 of the MIPs, this was on the basis of cost-effectiveness relative to existing treatments. 3 of these MIPs had an ESMO-MCBS of four or more. 1 MIP was not recommended for reimbursement based on clinical and cost-effectiveness. This MIP had an ESMO-MCBS of 5.

Time from rapid review submission to reimbursement of drugs with an ESMO-MCBS of three or less was an average of 831 days, while drugs with an ESMO-MCBS of 4 or 5 averaged 780 days. If we exclude drugs which were reimbursed with a rapid review only, including only MIPs that completed a full HTA, drugs with an ESMO-MCBS of 4 rises to 893 days from rapid review to reimbursement, and those with an ESMO-MCBS of 5 increases to 910 days.



Conclusion

High ESMO-MCBS scores were associated with a marginally reduced time between initial rapid review submission and reimbursement in Ireland.

However, when we consider only those drugs that completed a full HTA, medicine-indication pairs with a high ESMO-MCBS were associated with an increased time between initial rapid review submission and reimbursement.

50% of the medicine-indication pairs which were not recommended for reimbursement after a HTA had a high ESMO-MCBS, indicating that having a score of greater than 4 indicating a high clinical need does not always lead to reimbursement.

HTA decision making processes in Ireland could be improved by routine use of a standardised tool such as the ESMO-MCBS score in conjunction with other parameters of benefit in order to ensure oncology drugs with high clinical need get reimbursed.

References

1. Irish Pharmaceutical Healthcare Association, IPHA welcomes the Government's allocation of €30 million for new life-enhancing medicines in Budget 2026 improving patient outcomes. 2025.
2. European Society of Medical Oncology, About the ESMO-MCBS. 2025.
3. Kanavos, P.V., Erica; Angelis, Aris Use of the ESMO-Magnitude of Clinical Benefit Scale to guide HTA recommendations on coverage and reimbursement for cancer medicines: a retrospective analysis. Lancet Oncol 2024. 25: p. 1644-54.