

PROMOTING CLEAR AND EVIDENCE-BASED COMMUNICATION ABOUT THE BENEFIT OF CANCER TREATMENTS

Introduction

In 2015 the European Society for Medical Oncology (ESMO) launched the **ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS)** 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. Since value is based on considerations of the magnitude of clinical benefit as well as cost, and given the challenges to understanding the actual magnitude of the clinical benefit, the ESMO-MCBS was developed in 2015 as a validated and reproducible scale that is applicable across the full range of solid tumours and since 2023 in hematological malignancies. The latter has been developed in collaboration with the European Haematological Association (EHA).

The ESMO-MCBS incorporates a structured, rational and valid approach to data interpretation and analysis that reduces the tendency to have judgements affected by bias or uninformed and/or idiosyncratic data interpretation that has been developed in accordance with the public policy standard of “accountability for reasonableness”. It is a dynamic tool and its criteria are revised on a regular basis.

The ESMO-MCBS is an important first step to the critical public policy issue of value in cancer care, helping to frame the appropriate use of limited public and personal resources in the delivery of cancer care.

What is the potential use and accessibility of the ESMO-MCBS?

This structured and disciplined approach to deriving estimates of clinically meaningful benefit from published data can be used in a range of settings, including:

- 1. Public policy applications** – Grading derived from the ESMO-MCBS provides a backbone for value evaluations of cancer medicines and can help public policy-makers in the advancement of ‘accountability for reasonableness’ in resource allocation deliberations. It is being used as part of HTA processes in a growing number of countries.
- 2. Formulation of clinical guidelines** – For cancer therapies, the ESMO-MCBS scale provides a clear, well-structured and validated mechanism to indicate the magnitude of clinical benefit, in addition to the level of evidence, that can inform both national and international guidelines.
- 3. Clinical decision making** – The data enclosed in ESMO-MCBS scoring can help clinicians weigh the relative merits of competing relevant therapeutic options and may also be of benefit in explaining the relative merit of therapeutic options to patients and their families. This information may be especially helpful when treatments incorporate substantial out-of-pocket costs.
- 4. Editorial decisions and commentaries** – The ESMO-MCBS may be of use to editors, peer reviewers and commentators in considering the clinical significance of research findings from randomised clinical studies, cohort studies and meta-analyses with statistically significant positive findings.
- 5. Education** – The ESMO-MCBS is a powerful tool to teach a disciplined and validated approach to data interpretation. It is especially valuable for oncologists in training and for application in journal club discussion.

How is the ESMO-MCBS being used?

- It is incorporated in the ESMO Clinical Practice Guidelines and the Pan-Asian Adapted Guidelines, helping to provide patients with the best care options and setting the highest standards for cancer care.
- It has been acknowledged by the World Health Organisation as ‘a screening tool to identify cancer treatments that have potential therapeutic value that warrants full evaluation for the Essential Medicines List listing’¹.
- It is being used as part of HTA processes in a growing number of countries.
- It has been presented inside and outside Europe and in educational workshops for stakeholders, patient (advocates), pharma representatives and HTA bodies to increase knowledge sharing of the tool.
- It being used in oncology training programmes and journal club presentations, modelling a structured approach to data interpretation in the evaluation of clinical benefit.
- ESMO offers support to third parties wanting to use the scale.
- ESMO has developed searchable portals and online tools to facilitate the use of the ESMO-MCBS, such as the visualisations illustrating the score of a treatment together with the qualities that drive that score.

Filter by

Agent

Tumour

Score

✕ reset selection

Trastuzumab (2) ▾

Tumour type ▾

Curative setting ▾

Tumour sub-type ▾

Non-curative setting ▾

Tumour sub-group ▾

ESMO-MCBS V1.1 - Evaluation Forms

Evaluation form 1 ▾

Evaluation form 2a ▾

Evaluation form 2b ▾

Evaluation form 2c ▾

Evaluation form 3 ▾

Quality of Life Checklist ▾

Column view Table view Table with visualisation

✕	Tested Agent(s)	Combined Agent(s)	Control Arm	Treatment Setting	Tumour Sub-type	Ref.	Score	Scorecard
<input type="checkbox"/>	Trastuzumab	-	Chemotherapy	Patients with HER2-positive early breast cancer following surgery, ChT (neoadjuvant or adjuvant) and RT (if applicable) HERA	Early Breast Cancer	 	A	<div style="font-size: 8px; font-weight: bold;">PRELIMINARY SCORE CURATIVE</div> <div style="font-size: 8px; font-weight: bold;">DFS</div> <div style="width: 100%; height: 10px; background: linear-gradient(to right, #0070c0 80%, #ccc 80%); border: 1px solid #333; border-radius: 3px; margin-bottom: 5px;"></div> <div style="font-size: 8px; font-weight: bold;">ADJUSTMENTS</div> <div style="display: flex; justify-content: space-between; align-items: center; margin-top: 5px;"> </div> <div style="border: 1px solid #333; padding: 2px 5px; margin-top: 5px; background-color: #0070c0; color: white;"> <div style="font-size: 8px; font-weight: bold;">FINAL SCORE CURATIVE</div> <div style="font-size: 8px; font-weight: bold;">F1</div> <div style="width: 100%; height: 10px; background: linear-gradient(to right, #0070c0 90%, #ccc 90%); border: 1px solid #333; border-radius: 3px; display: flex; justify-content: flex-end; align-items: center; padding-right: 5px;"> A </div> </div>
<input type="checkbox"/>	Trastuzumab	Cisplatin and either capecitabine or 5-fluorouracil	ChT	HER2-positive metastatic adenocarcinoma of the stomach or gastroesophageal junction in patients who have not received prior anti-cancer treatment for their metastatic disease ToGA	Stomach or gastroesophageal junction cancer	 	3	<div style="font-size: 8px; font-weight: bold;">PRELIMINARY SCORE NON-CURATIVE</div> <div style="font-size: 8px; font-weight: bold;">OS</div> <div style="width: 100%; height: 10px; background: linear-gradient(to right, #70ad47 60%, #ccc 60%); border: 1px solid #333; border-radius: 3px; margin-bottom: 5px;"></div> <div style="font-size: 8px; font-weight: bold;">ADJUSTMENTS</div> <div style="display: flex; justify-content: space-between; align-items: center; margin-top: 5px;"> </div> <div style="border: 1px solid #333; padding: 2px 5px; margin-top: 5px; background-color: #70ad47; color: white;"> <div style="font-size: 8px; font-weight: bold;">FINAL SCORE NON-CURATIVE</div> <div style="font-size: 8px; font-weight: bold;">F2a</div> <div style="width: 100%; height: 10px; background: linear-gradient(to right, #70ad47 70%, #ccc 70%); border: 1px solid #333; border-radius: 3px; display: flex; justify-content: flex-end; align-items: center; padding-right: 5px;"> 3 </div> </div>

¹World Health Organisation. Executive Summary. The Selection and Use of Essential Medicines 2019. Report of the 22nd WHO Expert Committee on the Selection and Use of Essential Medicines, 1-5 April 2019.

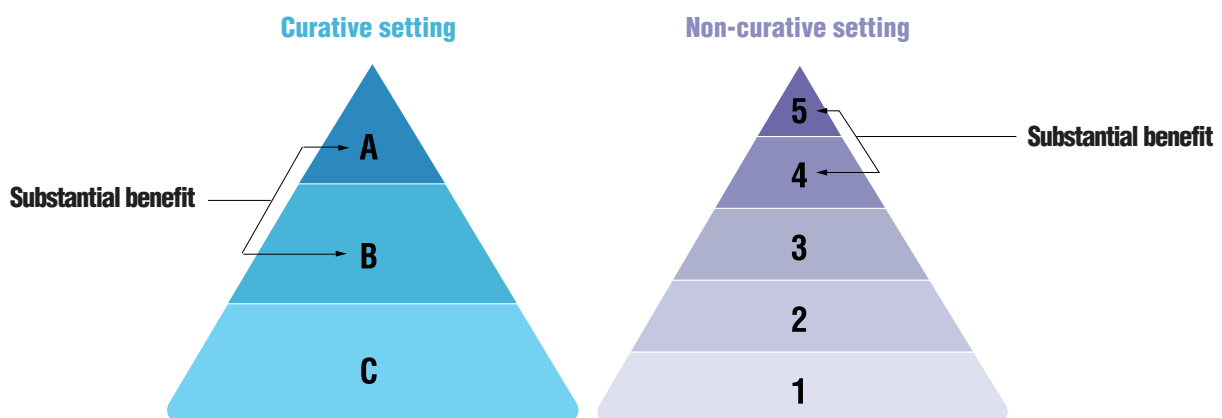
ESMO-MCBS: scoring criteria according to clinical settings

The scale considers overall survival, progression-free survival, disease free survival, hazard ratio, molecular response rate, quality of life, prognosis of the condition and toxicity. There are 5 evaluation forms plus a form to evaluate ESMO-MCBS score adjustments based on quality of life for ESMO-MCBS solid tumours and 6 evaluations form for ESMO-MCBS for haematological malignancies (ESMO-MCBS:H).

ESMO-MCBS in solid tumours

- **Quality of Life Checklist:** To evaluate ESMO-MCBS score adjustments based on quality of life
- **Evaluation form 1:** for new approaches to adjuvant therapy or new potentially curative therapies
- **Evaluation form 2a:** for therapies that are not likely to be curative with primary endpoint of overall survival (OS) with separate sheets for:
 - IF median OS with the standard treatment is ≤ 12 months
 - IF median OS with the standard treatment is $>12 - \leq 24$ months
 - IF median OS with the standard treatment is >24 months
- **Evaluation form 2b:** for therapies that are not likely to be curative with primary endpoint progression-free survival (PFS) with separate sheets for:
 - IF median PFS with standard treatment is ≤ 6 months
 - IF median PFS with standard treatment is >6 months
- **Evaluation form 2c:** for therapies that are not likely to be curative with primary endpoint other than OS or PFS or equivalent (non-inferiority) studies.
- **Evaluation form 3:** for single-arm studies in “orphan diseases” and for diseases with “high unmet need” when primary outcome is PFS or overall response rate (ORR).

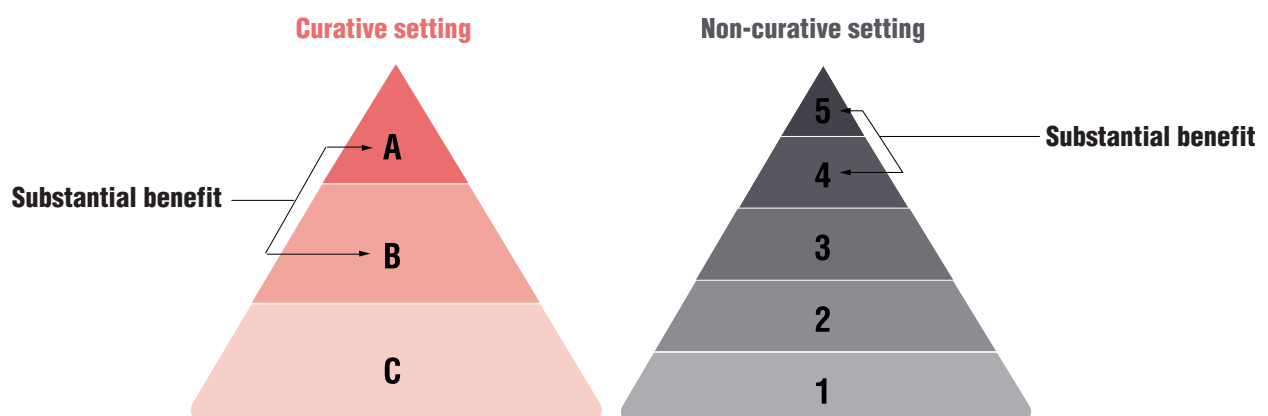
The highest grade of the ESMO-MCBS is A in the curative setting and this is restricted to new curative treatments with a grade B also to be considered to trigger rapid reimbursement. For non-curative indications 5 is the highest possible grade with 4 also to be considered to trigger rapid consideration for reimbursement.



ESMO-MCBS for haematological malignancies (ESMO-MCBS:H)

- **Evaluation form 1a:** for RCTs evaluating new approaches to new potentially curative therapies
- **Evaluation form 1b:** for single arm therapies with curative intent and de-escalation studies
- **Evaluation form 2a:** for therapies that are not likely to be curative with primary endpoint of OS with separate sheets for:
 - IF median OS with the standard treatment is <12 months
 - IF median OS with the standard treatment ≥ 12 - <24 months
 - IF median OS with the standard treatment ≥ 24 - <36 months
 - IF median OS with the standard treatment ≥ 36 months
- **Evaluation form 2b:** for therapies that are not likely to be curative with primary endpoint PFS with separate sheets for:
 - IF median PFS with standard treatment <6 months
 - IF median PFS with standard treatment ≥ 6 - <12 months
 - IF median PFS with standard treatment ≥ 12 months
- **Evaluation form 2c:** for therapies that are not likely to be curative with primary endpoint other than OS or PFS or equivalent (non-inferiority) studies.
- **Evaluation form 3:** for single-arm studies in “orphan diseases” and for diseases with “high unmet need” when primary outcome is PFS or ORR.

The highest grade of the ESMO-MCBS:H is A in the curative setting and this is restricted to new curative treatments with a grade B also to be considered to trigger rapid reimbursement. For non-curative indications 5 is the highest possible grade with 4 also to be considered to trigger rapid consideration for reimbursement.



For more information visit our website <https://www.esmo.org/Guidelines/ESMO-MCBS> where you can find, among other things, the scale evaluation forms, the ESMO-MCBS scorecards, the presentations at the ESMO Congresses, and the articles published in ESMO Journals – or contact us at mcbs@esmo.org.