

Linee Guida ESMO: etica, metodologia e risultati al servizio degli operatori e dei pazienti



In occasione della
GIORNATA NAZIONALE
del tumore mammario metastatico

2024
CARCINOMA
MAMMARIO METASTATICO:
QUALI NOVITÀ?

*Conoscere le novità per assicurare
il trattamento migliore a ogni paziente*

11 OTTOBRE 2024

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Orientale

DECLARATION OF INTERESTS

Alessandra Gennari, MD PhD

Consultancy/advisory role/speaker bureau: Astra Zeneca, Daichii-Sankyo, Eisai, Gentili, Gilead, Menarini Stemline, Pfizer, Novartis, Organon, Seagen, Lilly, Roche, MSD, Exact Science, Hikma

Non profit research support: AIRC, Italian Association for Cancer Research, MIUR Dept of Excellence, LILT, University of Piemonte Orientale, Italian Ministry of Health, EraNET Transcan – H2020, 2022 PRIN, 2023 PNRR Sanità

Scientific Board in BIG/IBCSG, Accademia Veronesi;
Membership/affiliation: LILT Novara, FUV

Outline

Scope

- The ESMO Clinical Practice Guidelines, prepared and reviewed by leading experts and based on the findings of **evidence-based medicine**, provide you with a set of recommendations to help patients with the best care options.



ESMO Guidelines Methodology

To assist those using and/or evaluating the ESMO Guidelines, download the methodology here

[Read more →](#)



Pocket Guidelines & Mobile App

Download the new version of our App with the latest Pocket Guidelines for oncology professionals

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Guidelines Slide Sets

The essential content of the guidelines in condensed slide format in PDF or PowerPoint. Summary format including algorithms, figures and tables for your presentations.

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ESMO PAGA
Pan-Asian Guidelines Adaptation



Pan-Asian Guidelines Adaptation (PAGA)

The PAGA project aims to adapt the ESMO Clinical Practice Guidelines by integrating Asian ethnic, scientific, socioeconomic, and local practice characteristics.

[Read more →](#)

Clinical Practice Guideline – Metastatic Breast Cancer

ESMO Clinical Practice Guideline for the diagnosis, staging and treatment of patients with metastatic breast cancer

Published in 2021 - Ann Oncol. 2021(32)

Authors: A. Gennari, F. André, C. H. Barrios, et al, on behalf of the ESMO Guidelines Committee

- This ESMO Clinical Practice Guideline provides key recommendations and algorithms for managing metastatic breast cancer.
- It covers diagnosis, staging, risk assessment, treatment, disease monitoring, palliative care and the patient perspective.
- ESMO-MCBS and ESCAT scores are given to describe the levels of evidence for treatment choices.
- The authors comprise an international expert group, with recommendations based on available evidence and expert opinion.
- In clinical practice, all recommendations provided need to be discussed with patients in a shared decision-making approach.

Living Guidelines

[ESMO Metastatic Breast Cancer Living Guidelines](#)

Related items

[Read full article](#)



[Download the PDF](#)





ESMO-MCBS Scorecards

[ESMO Scale for Clinical Actionability of molecular Targets \(ESCAT\)](#)

[Metastatic Breast Cancer: New ESMO Guideline With Evidence-Based Recommendations](#)

ESMO Clinical Practice Guidelines

- [Standard Operating Procedures](#) 
- [Author Responsibility and Acknowledgement Agreement](#) 



Updated October 2023

ESMO Clinical Practice Guidelines eUpdates

- [Standard Operating Procedures](#) 

Updated January 2022

ESMO Clinical Practice Living Guidelines

- [Standard Operating Procedures](#) 
- [Author Responsibility and Acknowledgement Agreement](#) 

Updated March 2022

ESMO Guidelines Methodology

- ❖ The **ESMO Guidelines Committee** (GLC) is responsible for the production and update of ESMO Clinical Practice Guidelines and related resources.
- ❖ In order to produce high-quality and well-formulated guidelines it is necessary to have strict procedures in place which provide clear instruction and are readily available to authors, editors and panel members.
- ❖ **To assist those using and/or evaluating the ESMO guidelines the GLC decided to openly publish the ESMO guidelines methodology here on the ESMO website.**

Authorship criteria

- The author group should consist of a minimum of 8 authors, including the SE as last author
- Each proposed author should have an internationally recognised profile in the field and a good reputation.
- The author group should be diverse, gender-balanced
- Inclusion of representative(s) of patient organisations or patient advocacy groups can be considered if appropriate, either as authors, if they meet the authorship criteria, or as reviewers.
- The lead author acts as the coordinating author and appears as first author, followed by the other co-authors and the SE as last author

EBM

- The following phrasing is recommended to aid communication of the strength of recommendation, based on advice from the **Grading of Recommendations, Assessment, Development and Evaluation Working Group (GRADE WG)**:10
 - Strong positive recommendations (grade A): ‘the authors recommend...’ or ‘clinicians should’ or ‘Do...’ - Strong negative etc
 - Recommendations should be accompanied by the proper LoE and GoR according to the adapted Infectious Diseases Society of America-United States Public Health Service Grading System⁵.
 - **Therefore, it is mandatory for all recommendations to be supported with an LoE and GoR.**

ESCAT criteria

The ESCAT score defines clinical evidence-based criteria for prioritising alterations from genomic-driven analyses for use as markers to select patients for targeted therapies. **The scale is comprised of six tiers** based on implications for patient management (Tier I-X). These tiers are sub-divided by level of clinical evidence. For pragmatic clinical guidance, the most relevant ESCAT tiers for CPGs are Tier I and II (targets ready for implementation in routine clinical decisions)

ESCAT

ESMO Scale for Clinical Actionability of Molecular Targets



Criteria for defining the ESCAT score for genomic alteration–drug matches

	ESCAT tier	Clinical value class	Clinical implication	Level of evidence	Overall ESCAT score
Ready for routine use	I: Alteration–drug match is associated with improved outcome in clinical trials	Drug administered to patients with the specific molecular alteration has led to improved clinical outcome in prospective clinical trial(s)	Access to the treatment should be considered standard of care	A: prospective, randomised clinical trials show the alteration–drug match in a specific tumour type results in a clinically meaningful improvement of a survival endpoint	I-A
				B: prospective, non-randomised clinical trials show that the alteration–drug match in a specific tumour type, results in clinically meaningful benefit as defined by ESMO-MCBS v1.1	I-B

ESMO-MCBS

- Where applicable, ESMO-MCBS calculations will be calculated and validated by the ESMO-MCBS Working Group and reviewed by the authors.

7.4.1.1 ESMO-MCBS table template

Supplementary Table SXX. ESMO-MCBS table for new therapies/indications in [Tumour type]

Therapy	Disease setting	Trial	Control	Absolute survival gain	HR (95% CI)	QoL/Toxicity	ESMO-MCBS Score ^a
Describe the new therapy	Describe the disease setting. Specify (Neo)adjuvant or advanced	Trial acronym (trial name if acronym is not available)[ref #] phase of trial, NCT number	Describe the control arm	Median, in months (state OS, PFS or both)	Median and 95% CI	Improved or Deteriorated or Similar or Not Available	Score X (Form X)

CI, confidence interval; EMA, European Medicines Agency; ESMO-MCBS, ESMO-Magnitude of Clinical Benefit Scale; HR, hazard ratio; OS, overall survival; PFS, progression-free survival; QoL, quality of life.

^a ESMO-MCBS v1.1.[ref ##] was used to calculate scores for new therapies/indications approved by the EMA or FDA. The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee (<https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms>).

ref # = include pivotal trial reference(s).

ref ## = Cherny NI, Dafni U, Bogaerts J et al. ESMO-Magnitude of Clinical Benefit Scale Version 1.1. Ann Oncol 2017; 28: 2340-2366.



ESMO Standard Operating Procedures (SOPs) for Clinical Practice Living Guidelines (Living GLs) Updates

ESMO Guidelines Committee (GLC)

Version	ESMO Living GLs SOP Version 1.0; January 2022
Approved	Giuseppe Curigliano, GLC Chair
Next review planned	After the next GLC meeting (in 2022, date to be confirmed); revisions can be made sooner as required

Note: this SOP only applies to ESMO Living GL updates. Please see the Clinical Practice Guideline (CPG) SOPs for full guidance on preparation of the original CPG publication, available here: <http://www.esmo.org/Guidelines/ESMO-Guidelines-Methodology>.

1 Definition and usage of Living GLs

A Living GL update is an online update of new CPGs or CPG updates. A simultaneous version is published on [esmo.org](http://www.esmo.org) when the CPG is published online that includes key recommendations, treatment algorithms and other details. The simultaneous version is then updated on a regular basis (every 3-12 months), with updates integrated into the online version. The Living GL updates are available on [esmo.org](http://www.esmo.org) and are linked to the original CPG on which the updates are based is published in an ESMO journal.

The Living GL version aims to produce interactive online GLs on the ESMO website ([esmo.org](http://www.esmo.org)) by summarising key recommendations, treatment algorithms and other details (e.g. ESMO-MCBS scorecards, references), in a user-friendly, interactive format. The Living GL will be based on the CPG treatment algorithms, without lengthy text, which is designed to be more user-friendly for busy practising clinicians.

2 Simultaneous CPG publication and Living GL publication (expected from July 2022)

The treatment algorithms from the published CPG are used to develop the first version of each 'Living GL,' referred to as the simultaneous Living GL update.

Once the project is fully operational (expected from July 2022), new CPGs/CPG updates will be published in an ESMO journal with a simultaneous Living GL version published on [esmo.org](http://www.esmo.org). CPG Chair, the lead author, Subject Editor (SE) and GLC Chair must approve the initial Living GL version.

The original CPG publication will include a note that the CPG will be supplemented by the Living GL version with a link to the CPG web page on [esmo.org](http://www.esmo.org).

3 Procedure for updates

In the case of a significant breakthrough that necessitates rapid communication as updated CPG content or in the case of a new European Medicines Agency (EMA) or Food and Drug Administration (FDA) indication bearing an ESMO-Magnitude of Clinical Benefit (ESMO-MCBS) score, the relevant ESMO SE will coordinate with the CPG authors to produce a Living GL update to the ESMO CPG (only for selected titles during 2022). This update will be published on the ESMO website linked to the appropriate CPG. Each Living GL will be named as follows: 'ESMO Clinical Practice Living Guideline, version 1, year 20XX' (i.e. version 1.2022, version 2.2022).

<https://www.esmo.org/living-guidelines/esmo-metastatic-breast-cancer-living-guideline>

Pan-Asian Guidelines Adaptation (PAGA)

ESMO PAGA

Pan-Asian Guidelines Adaptation



The Pan-Asian Guidelines Adaptation (PAGA) project aims to adapt the ESMO Clinical Practice Guidelines by integrating Asian ethnic, scientific, socioeconomic, and local practice characteristics.

The project provides a framework for the structured interaction of key opinion leaders in oncology from Asia and Europe.

Tailoring the ESMO Clinical Practice Guidelines to the local context results in a resource-efficient, valuable tool that can be used by health professionals and patients to harmonise optimal, evidence-based practice across Asia, focus on ethnic differences and potentially approach regulatory authorities.

Started in 2016 as a collaboration between ESMO and the Japanese Society of Medical Oncology (JSMO), the PAGA project has grown and flourished with the active collaboration of the oncology societies of China (CSCO), India (ISMPO), Indonesia (ISHMO), Japan (JSMO), South Korea (KSMO), Malaysia (MOS), Philippines (PSMO), Singapore (SSO), Taiwan (TOS), and Thailand (TSCO). Every year, Asian experts from these collaborating societies engage in productive scientific interactions with their European counterparts to build consensus towards Pan-Asian adaptation of three to four ESMO Clinical Practice Guidelines, which are then published in *ESMO Open* and presented at the ESMO Asia Congress.

Collaborating societies



SPECIAL ARTICLE

ESMO Clinical Practice Guideline for the diagnosis, staging and treatment of patients with metastatic breast cancer

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General principles of care

- ❖ For patients with MBC, **median OS is increasing with the introduction of new treatments** and patients are more likely to experience metastases in many areas of the body.
- ❖ As well as receiving the best available treatment, patients should be offered **optimal symptom control, psychological, social and spiritual support.**
- ❖
- ❖ **Shared decision making between the patient and health care professionals, as well as good communication and relationship building with the patient, family members and caregivers, is therefore paramount to ensure a mutual understanding of treatment expectations and goals.**
- ❖ The emotional toll of caring for patients who are dying also has an impact on health care staff, and processes should be in place to support their mental health, enabling them to continue to provide sensitive and effective care.

Section 7. Patient perspective

- Patient expectations of treatment and what 'clinical benefit' means for patients
- Patients very often emphasise that QoL is more important to them than PFS or OS. A healthy person would tend to ask why but a patient with cancer would agree.
- Hereby, the importance of psychosocial support comes to the forefront.
- For patients with MBC, it is not just treatment that is important since **they are also facing a lot of uncertainty and anxiety regarding their future in terms of what will happen next, how to organise their lives and what additional help they may need in the future.**

Patient perceptions of the ESMO-Magnitude of Clinical Benefit Scale

- The ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) is a highly appreciated tool for scoring the clinical benefit of treatments and is simple to use.⁶⁰ Given the fact that it is still not well-recognised among patients, patient-directed education regarding the ESMO-MCBS is needed.



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