

ENHERTU- New Indications – New Strategies for Oncology Practices

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Background

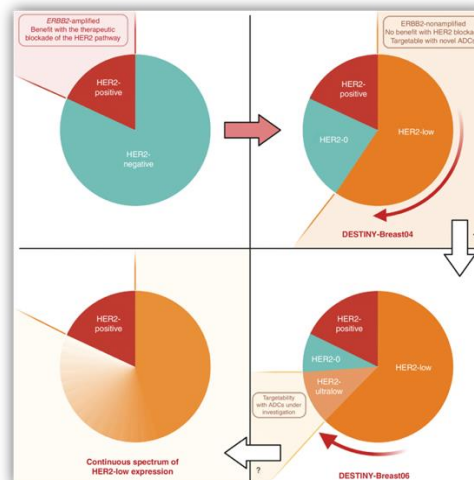
Since its original FDA approval for unresectable or metastatic HER2 positive breast cancer in 2019, ENHERTU has expanded its indications beyond breast cancer; the most recent approval in 2025 expands the use of ENHERTU into the HER2 ultra-low setting.

Objective(s)

With the approval of ENHERTU outside of the HER2 positive breast cancer setting, new treatment options are available for patients. Our question was how well these patients could be identified within the EMR systems, current guidelines and testing platforms.

Methods

We looked at the current guidelines for breast, lung, gastric and ovarian cancer to identify potential hurdles limiting treatment with ENHERTU. We assessed the inclusion of IHC testing by the major tumor profiling companies. We looked at the impact that our Texas Oncology Precision Medicine team has when processing orders for metastatic tumors.



Discussion

Not all current guidelines (NCCN, ASCO) are specifically identifying HER2 as an actionable target. For example, the ASCO-CAP guidelines on HER2 testing identify low levels of HER2 expression as HER2 negative. The 2023 update recommends the inclusion of a footnote on pathology reports to guide oncologist decision making for tumors with low levels of HER2 expression.

Traditionally, HER2 expression has been categorized in a binary way; however, a spectrum vs. binary approach might benefit patients across HER2 low tumors.

Results / Conclusion

HER2 testing is offered through all major tumor profiling companies. The Texas Oncology Precision Medicine team is guiding physicians to include the HER2 testing option as part of the panel for appropriate patients. The guidelines will be addressing new testing opportunities within their next update.

Reference(s)

ENHERTU prescribing information, revised 1/2025
Tarrantino et al, Cancer Discov (2022) 12 (9): 2026–2030

Disclosure

I have no financial or personal relationships to disclose that could influence the research or outcomes.