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Title **HER2 Testing**

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Reference Technology Review Report, 012/08.
http://medicaldev.moh.gov.my/uploads/12.her2.pdf

Aim

To determine the safety, effectiveness, and cost effectiveness of HER2 (human epidermal growth factor receptor 2) testing for breast cancer.

Conclusions and results

Immunohistochemistry (IHC) results show more variability (for IHC score of 2+) than fluorescence in situ hybridization (FISH) results, particularly in FISH-negative cases. The results of most studies indicate that a high-level HER2 amplification and an IHC score of 3+ will identify HER2-positive breast carcinoma; low level amplification and/or IHC of 2+ should be carefully interpreted. There is agreement that the most (cost) effective testing strategy is to screen all patients with IHC, followed by FISH/CISH for IHC of 2+ (or of 2+ and 3+) as recommended in the HER2-testing algorithm. The exclusive use of FISH for HER2 testing could lead to misdiagnosis in some cases.

Most of the retrievable evidence shows that concordance is high between FISH and chromogenic in situ hybridization (CISH). However, evidence suggests that CISH may be a viable and potential alternative to FISH for use in the HER2-testing algorithm.

Recommendations

Due to the consequential costs (nonmonetary costs/side effects of the therapy with trastuzumab and monetary costs) we recommend that all patients be screened with IHC, followed by FISH/CISH for IHC of 2+ (or of 2+ and 3+) as recommended in the HER2-testing algorithm.

Methods

The literature was systematically reviewed. PubMed, ProQuest, and MEDLINE via EBSCO were searched, as were websites for HTA agencies and relevant societies. Articles retrieved were cross-referenced according to topic. Eight diagnostic studies and two cost-effectiveness studies (one of which was a systematic review) were assessed in this review.

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