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Titel des Beitrags: Health economic impact of risk group selection according to ASCO-recommended biomarkers uPA/PAI-1 in node-negative primary breast cancer.

Abstract: Invasion factors uPA/PAI-1 are guideline-recommended (ASCO, AGO) biomarkers for decision support regarding adjuvant chemotherapy (CTX) in women with primary breast cancer. They define a high-risk group with strong benefit from adjuvant CTX and a low-risk group with uncertain benefit and excellent survival without CTX. In a target population (age>35/N0/G2/HR+/HER2-), administration of adjuvant CTX is not mandatory in Germany and other countries. Based on existing data, this economic model was developed to determine for the first time health economic impact of uPA/PAI-1 testing. Incremental cost-effectiveness ratio (ICER) resulting from uPA/PAI-1 testing was estimated for the target population by Markov modeling and sensitivity analysis. Survival data, CTX-uPA/PAI-1 interactions, and uPA/PAI-1 hazard ratios were derived from the Chemo N0 trial and other evidence. Incremental costs were computed from a payer's perspective appropriate to the German setting. Incremental effectiveness in life years (ly) was estimated taking into account age-adjusted life expectancy, disease-free survival (with/without CTX), and 2 years post-relapse survival. Sensitivity analysis was performed by varying residual
adjuvant CTX benefit in the low-risk group, denoted HR_CTX(LR), in range 0.8-0.99. All patients receive adjuvant endocrine therapy. Test is restricted to patients willing to forgo CTX if both markers are below specific cut-off values and to undergo CTX otherwise. For a typical 55-year-old patient, comparing to an "all-CTX" strategy without the test, ICER (all-CTX vs. test)>50,000 if HR_CTX(LR)>0.85, with savings of 18,500 per low-risk patient attributable to the test. The cost-effectiveness of forgoing CTX is very high as HR_CTX(LR) approaches one. Conversely, comparing to a "no-CTX" strategy (e.g., patients who initially refuse CTX) without the test, the test is very cost-effective at all ages in the target group if high-risk patients are willing to undergo CTX: ICER (test vs. no-CTX)6,000 at age 55 and even better at younger ages, remaining 25,000 up to age 75. The main determinants of cost utility are age and residual CTX benefit in low-uPA/PAI-1 patients. The uPA/PAI-1 test is cost-effective in the target group compared to either an "all-CTX" or a "no-CTX" scenario. This model thus lends health economic support to current guideline recommendations that uPA/PAI-1 testing is beneficial for BC patients with no lymph node involvement.