Effective Health Care

Gene Expression Profiling for Predicting Recurrence in Colon Cancer
Nomination Summary Document

Results of Topic Selection Process & Next Steps

■ Gene expression profiling for predicting recurrence in colon cancer is not feasible for a full systematic review due to the limited data available at this time; however, it will be considered for a potential technical brief by the Effective Health Care (EHC) Program.

- To see a description of a technical brief, please go to
  http://effectivehealthcare.ahrq.gov/index.cfm/research-for-policymakers-researchers-and-others/.

- If this topic is developed into a technical brief, key questions will be drafted and posted on the AHRQ Web site. To sign up for notification when this and other EHC Program topics are posted, please go to http://effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/.

Topic Description

Nominator: Organization

Nomination Summary: The nominator questions the comparative effectiveness of gene expression profiling (GEP) added to or in place of standard clinical and pathological risk factors to predict the risk of disease recurrence after surgery in adults with stage II colon cancer.

Staff-Generated PICO
Population(s): Adults with stage II colon cancer
Intervention(s): GEPs alone and with standard clinical and pathological risk factors
Comparator(s): Standard clinical and pathological risk factors without GEPs
Outcome(s): Estimates of risk, including laboratory performance measures (sensitivity, specificity, positive predictive value, and negative predictive value) for predicting recurrence; net balance of benefits versus harms from prescribing or not prescribing adjuvant chemotherapy including disease recurrence, disease-free survival, overall survival, quality of life and safety/adverse events

Key Questions from Nominator:
1. For patients with colon cancer, what is the comparative effectiveness of multi-parameter gene expression assays (e.g., Oncotype DX® colon cancer test) versus standard clinical and pathological risk factors for predicting disease recurrence and guiding decisions on adjuvant therapy?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/.)

- Uncertainty about the optimal prognostic indicator(s) for use in clinical settings currently exists and is an issue of importance to patients, health care providers, and health plan decision makers. Currently, many of these tests are entering the U.S. market without FDA review as laboratory developed tests. Although these tests are subject to analytical validation under CLIA regulations, they can be marketed without establishing clinical validity or utility. This gap indicates that a technical brief on this topic may be important and timely.