Washington State Health Care Authority

FINAL key questions and background

Gene expression profile testing of cancer tissue

Background

The lifetime risk of developing cancer is about 40%, and one in every five Americans will die from cancer.[1] Strategies for reducing the burden of cancer include preventing the disease, early diagnosis of cancer, and appropriate treatments of diagnosed cancers.[2] Common treatments for cancer include surgery, chemotherapy, radiation therapy, hormone therapy, and immunotherapy.[3] The most appropriate treatments for a particular cancer depend on the cancer's severity (e.g., cancer stage and grade), the patient's age and health status, response to previous treatments, and other factors.

In recent years, gene expression profile testing of cancer tissue has been used to help inform decisions on the most appropriate treatments. Gene expression profile testing identifies the genes in a cancer cell or tissue that are making messenger RNA, which carry the genetic information that cancer cells need to make proteins. Some gene expression profile tests are designed to increase the accuracy of the prognosis for a patient with cancer. If a test predicts that a cancer is slow growing or is unlikely to metastasize, then active surveillance of the cancer could be the most appropriate course. If a test predicts that a cancer is at high risk for progression and metastasis, then more aggressive treatments could be warranted.[4]

Policy context

There are a growing number of gene expression profile tests for cancer tissue designed to inform treatment decisions after diagnosis. Potential benefits of these tests are more appropriate treatment decisions and better patient outcomes, including avoiding treatment-related side effects and the potential cost savings from forgoing unnecessary treatments. This topic was selected for a health technology assessment because of medium concerns for the safety of these tests, medium/high concerns for efficacy, and high concerns for cost.

This evidence review will help to inform Washington's independent Health Technology Clinical Committee as the committee determines coverage regarding selected gene expression profile tests for patients with eligible breast, prostate, or colon cancers or multiple myeloma.

Proposed Scope

Population: Adults with breast, prostate, or colon cancers or multiple myeloma

Interventions: Gene expression profile testing of cancer tissue to inform treatment decisions, including the following tests by cancer type:

- Breast Cancer—Oncotype DX Breast Cancer Assay, EndoPredict, MammaPrint, Prosigna Breast Cancer Prognostic Gene Signature Assay (PAM50), Mammostrat, Breast Cancer Index (BCI)
- Prostate Cancer—Prolaris, Decipher, Oncotype DX Prostate Cancer Assay
- Colon Cancer—Oncotype DX Colon Cancer Assay, ColoPrint
- Multiple Myeloma—Myeloma Prognostic Risk Signature (MyPRS), SKY92-signature (formerly EMC92)

Comparators: Usual care without gene expression profile testing of cancer tissue, alternate gene expression profile tests (i.e., one test intervention listed above versus another)

Outcomes:

- Patient management decisions (including selection of active surveillance rather than active treatment)
- Clinical outcomes (e.g., morbidity, mortality, quality of life)
- Harms, such as consequences of false-positive or false-negative test results
- Cost-effectiveness and other economic outcomes

Time period for literature search: 2007 to 2017

Key Questions

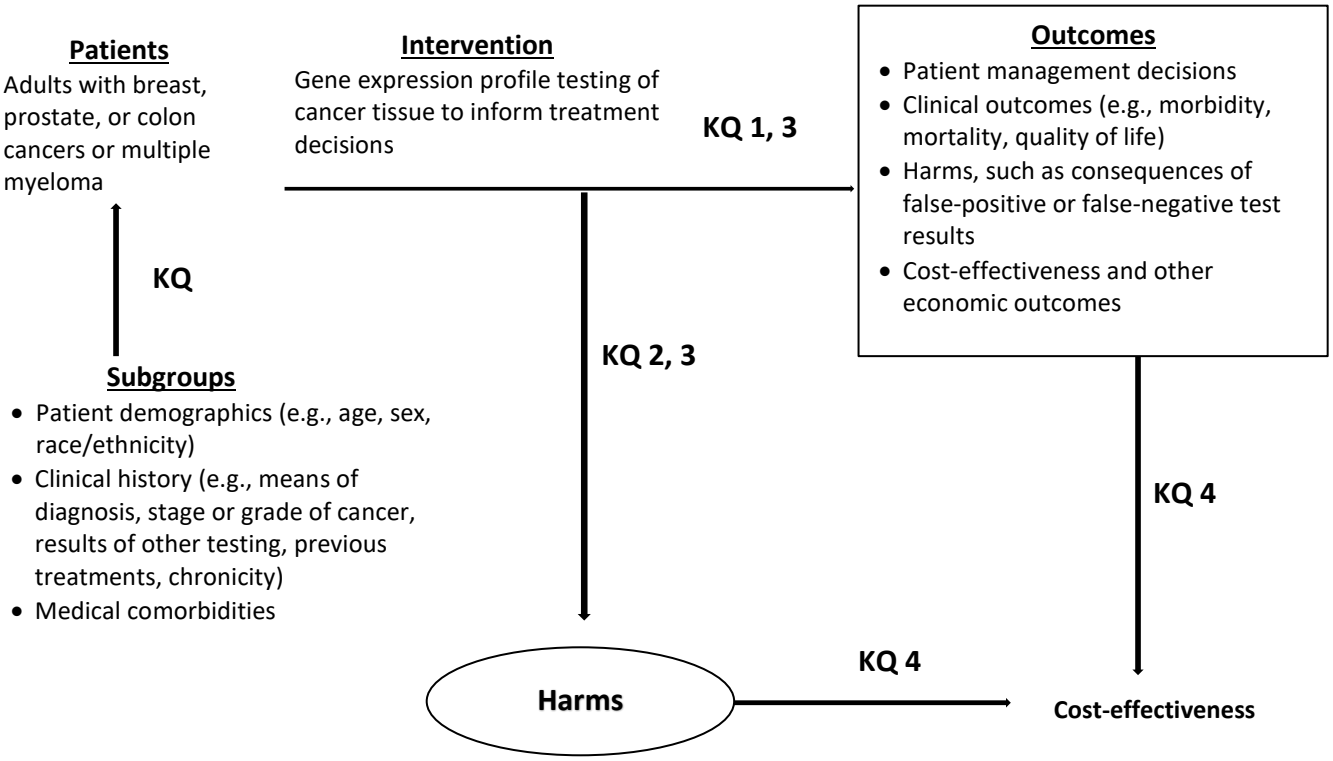
1. Effectiveness: What is the clinical utility of gene expression profile testing of cancer tissue to inform treatment decisions for patients with breast, prostate, and colon cancers and multiple myeloma?
    a. Is there evidence that test results affect treatment decisions?
    b. Do treatment decisions guided by gene expression profile testing of cancer tissue result in clinically meaningful improvements in patient outcomes?
2. Harms: What harms are associated with conducting gene expression profile testing of cancer tissue?
3. Special populations: Compared with usual care, do treatment decisions, patient outcomes, or harms after gene expression profile testing of cancer tissue vary by:
    a. Patient demographics (e.g., age, sex, race/ethnicity)?
    b. Clinical history (e.g., means of diagnosis, stage or grade of cancer, results of other testing, previous treatments, chronicity)?
    c. Medical comorbidities?
    d. Provider type or care setting?
4. What are the cost-effectiveness and other economic outcomes of gene expression profile testing used to inform treatment management decisions?

Eligible Studies

Randomized controlled trials, nonrandomized comparative studies, and systematic reviews of these two types of studies that assess clinical utility will be considered for Key Questions 1, 2, and 3. Cost-effectiveness studies and other comparative economic evaluations, along with systematic reviews of these types of studies, will be considered for Key Question 4.

Analytic framework

The analytic framework below will guide the selection, synthesis, and interpretation of available evidence.



References

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4. Meleth S, Reeder-Hayes K, Ashok M, et al. Technology assessment of molecular pathology testing for the estimation of prognosis for common cancers. In: *Technology Assessment of Molecular*

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5. Washington State Health Care Authority. Washington Apple Health (Medicaid) physician-related services/health care professional services billing guide. 2017; https://www.hca.wa.gov/assets/billers-and-providers/physician-related-services-bi-20170401.pdf.

Public comment and response

See Draft key questions: Comment and response document published separately.