



### What are gene expression profile tests?

Gene expression profile tests are sometimes used after breast cancer surgery to help doctors understand the risk of breast cancer returning (recurrence). Tumor tissue is tested for certain groups of genes associated with cancer. Based on the groups of genes found or “expressed,” a cancer recurrence rate is predicted (low, medium or high).

### How are gene expression profile tests used?

Test results may help you and your doctor decide whether or not to use chemotherapy in addition to other breast cancer treatments, such as radiation and hormone therapy.

### Why would you consider not having chemotherapy?

Chemotherapy is given to help decrease the risk of cancer recurrence, but it also has side effects. If you already know your risk for cancer recurrence is low, it is important to consider whether the side effects from chemotherapy outweigh the benefits.

### What are some of the side effects from chemotherapy?

Most side effects are temporary, such as hair loss, nausea and vomiting, but others can be more serious, such as heart damage and a weakened immune system.

### How is breast cancer recurrence risk usually determined?

Doctors use several standard risk assessment methods to evaluate breast cancer recurrence risk. These methods look at a combination of information such as family history, whether the cancer has spread to the lymph nodes and tumor size and cell characteristics.

### Why use gene expression profiles tests?

No assessment method used alone accurately predicts the risk of recurrence. Gene expression profile tests can be used in addition to other risk assessment methods. For some people with early stage breast cancer who are unclear about their risk of breast cancer recurrence they may provide additional information.

### Who might benefit from gene expression profile tests?

People with early stage I or II breast cancer who have an **unclear** risk of breast cancer recurrence based on standard risk assessment methods and who need to decide whether the benefits of chemotherapy outweigh the side effects.

### Who will not benefit from gene expression profile tests?

- People who are at **low** risk for breast cancer recurrence based on standard risk assessment methods and who have been told by their doctor that **chemotherapy is not recommended**.
- People who are at **high** risk for breast cancer recurrence based on standard risk assessment methods and who have been told by their doctor that **chemotherapy is recommended**.
- People who are choosing chemotherapy regardless of risk assessment results and chemotherapy side effects.

For these people, gene expression profile tests add additional cost without adding helpful information for making treatment decisions.

### **Have studies been completed using gene expression profile tests to make treatment decisions?**

No. There are no finished studies which used these tests to make decisions about chemotherapy and then followed patients over time to see if the right decision was made. There are at least two on-going studies testing whether gene expression profile tests can be used alone to guide treatment decisions.

### **What do national treatment guidelines say about gene expression tests?**

The National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology consider the Oncotype DX<sup>®</sup> gene expression test an option for certain patients with early stage breast cancer who have an unclear risk of breast cancer recurrence. The NCCN emphasizes that this test should only be used along with other risk assessment methods in making treatment decisions.

### **Is the Oncotype DX test covered by Regence?**

Yes, when criteria are met. You can find the criteria in the Regence Medical Policy as well as information on the effectiveness of gene expression profile tests for breast cancer at:

<http://blue.regence.com/trgmedpol/lab/lab42.html> .

### **What else should I know before making decisions about chemotherapy treatment?**

In addition to knowing your risk for breast cancer recurrence, talk to your doctor about your chemotherapy options, the potential side effects and the expected benefits.

### **THE BOTTOM LINE**

Gene expression profile tests should only be used if you have an unclear risk of breast cancer recurrence and you are trying to decide whether chemotherapy is right for you. These tests should not be used alone to make treatment decisions.

*Note: Regence physicians, nurses and pharmacists developed this summary to provide you with information about potential advantages and lack of advantages of gene expression profile testing. This summary was developed based upon an evaluation of information from the US Food and Drug Administration (FDA), scientific studies and input from practicing doctors and specialists*