

Reporter Backgrounder: Oncotype DX[®] For DCIS

Oncotype DX Breast DCIS Score[™] Represents Breakthrough in Personalizing Treatment of Pre-Invasive Cancer

Ductal carcinoma in situ (DCIS), or Stage 0 breast cancer, is a pre-invasive form of breast cancer in which the tumor cells are confined within the milk ducts. The incidence of DCIS in the U.S. now accounts for one out of every five new breast cancer cases¹. While most women with DCIS will have surgery—either a lumpectomy or a mastectomy—less than 20 percent of cases are estimated to recur or turn into an invasive breast cancer².

The majority of these women receive radiation following surgery, meaning that as many as **80 percent of women with DCIS may be receiving unnecessary treatment**, with the risks of therapy outweighing the benefits³. Oncotype DX for DCIS is the only genomic test validated to help physicians better understand a patient's individual tumor biology as they discuss individual treatment options after surgery.

What is the Oncotype DX Breast DCIS Score?

Oncotype DX for DCIS is a multi-gene test that has been shown to determine the likelihood of DCIS returning or the tumor returning as invasive breast cancer in the same location, also known as local recurrence. The test is performed on tumor tissue previously obtained during the original surgery and provides unique information based on the underlying tumor biology that can help individual patients and their doctors personalize their treatment plan.

The test includes an individualized DCIS Score result, which is a number between 0 and 100. The lower the score, the lower the chances are that a woman will have the tumor come back; the higher the DCIS score, the greater the chances that the tumor will come back either as DCIS or invasive cancer.

DCIS is a non-invasive cancer where abnormal cells are contained within the breast's milk ducts.



Ductal carcinoma in situ (DCIS) is a pre-invasive disease in which cancer is confined to the milk ducts.

Less than **20%**

of DCIS cases are estimated to recur or turn into invasive breast cancer,



Yet as many as **80%**

of women, or 40,000 patients each year, receive additional treatments that may not be needed at all.

¹ American Cancer Society, 2013

² Vernig, JNCI, 2013

³ Solin, JNCI, 2013

What is the Impact of the Oncotype DX Breast DCIS Score on Treatment Decisions?

- Published research has shown that 60-70 percent of DCIS patients have a low risk of recurrence at 10 years⁴. The test result predicts the risk of local recurrence (DCIS or invasive carcinoma) and helps inform decisions regarding the need for additional treatments, like radiation, following surgical removal of the tumor.
- The result, along with patient age, tumor size, tumor grade and medical history, is used to help patients and their doctors personalize their treatment plan. It is important to consider personal concerns such as work/life priorities and tolerance for risk of the disease coming back versus the side effects of treatment (i.e. radiation).
- The Oncotype DX Breast DCIS Score result enables women and their doctors to personalize their treatment decisions and potentially forgo unnecessary treatment, such as radiation, when they have a low score and a low risk of local recurrence. For others, the result confirms that they would indeed benefit from a more aggressive approach to treatment.



Is it Covered by Insurance?

- Medicare has established coverage for the Oncotype DX Breast DCIS Score for patients with DCIS, although coverage outside of Medicare will vary by insurance plan.

⁴ Rakovitch, BCRT, 2015