

**Contact:**

Mark Sands  
BCW  
+44 207 300 6411  
[mark.sands@bm.com](mailto:mark.sands@bm.com)



**NICE expands recommendation for the Oncotype DX<sup>®</sup> test to more patients with early-stage breast cancer**

- *Only test recommended based on its ability to predict chemotherapy benefit*
- *Recommendation expanded to include patients with micrometastatic disease*
- *Continues to be available on NHS for patients throughout the UK*

LONDON, UNITED KINGDOM, 19 December 2018 -- Genomic Health today announced that the National Institute for Health and Care Excellence (NICE) in the United Kingdom has issued its [updated guidance](#) once again recommending the Oncotype DX Breast Recurrence Score<sup>®</sup> test for use in clinical practice to guide adjuvant chemotherapy treatment decisions for certain patients with early-stage breast cancer. Further, NICE expanded its recommendation to include patients with micrometastases, indicating that some cancer cells have spread to the lymph nodes.

“Oncotype DX is the only test that provides specific information about an individual patient’s response to chemotherapy, correctly identifying the important minority of patients who will receive substantial treatment benefit and the majority of patients who will not benefit from chemotherapy,” said Simon D H Holt, Honorary Consultant Surgical Oncologist, Peony Breast Care Unit. “This test allows us to target treatment much more effectively and should be routinely used for all eligible patients.”

The recommendation of the Oncotype DX test in this updated guidance is based on its unique ability to predict who will benefit from chemotherapy and who will not. Importantly, NICE acknowledges Oncotype DX as the only test that reduces the overall number of patients who receive chemotherapy, as well as the only test supported by long-term patient outcomes evidence, including the recently published landmark [TAILORx study](#). Further, NICE also found the Oncotype DX test to be the most cost-effective tool in guiding chemotherapy treatment.

“Genomic Health is pleased that even more UK breast cancer patients will have access to this crucial test to help them decide whether to have chemotherapy. As the only test proven to predict who will benefit from chemotherapy and who will not, we believe Oncotype DX is the best option to help guide such an important treatment decision,” said Stephen Ogram, UK Managing Director, Genomic Health. “More than 22,000 women across the UK have already benefitted from the test. We will continue to work with physicians to ensure all eligible patients receive their Recurrence Score<sup>®</sup> result before deciding whether to have chemotherapy.”

Following the [2013 guidance](#), NICE also included Oncotype DX in the updated [Breast Cancer Quality Standard](#) in June 2016 and their [Breast Cancer Pathway](#) in September 2017 to encourage uptake of the

test within the National Health Service (NHS) as a high priority to improve breast cancer care. As a result, over 95% of NHS trusts have adopted Oncotype DX and helped more than 22,000 patients benefit from making personalised chemotherapy treatment decisions.

The predictive value of the Oncotype DX test was also recently acknowledged by Germany's health technology assessment body - the Institute for Quality and Efficiency in Health Care (IQWiG) - which [concluded](#) that only the Oncotype DX test has sufficient evidence to guide breast cancer adjuvant chemotherapy decisions based on the TAILORx study results.

Additionally, the US National Comprehensive Cancer Network (NCCN) categorised Oncotype DX as the only "preferred" test for chemotherapy treatment decision-making for node-negative, early stage breast cancer patients in its 2018 [updated treatment guidelines](#) for treatment. In the guidelines, Oncotype DX continues to be distinguished as the only genomic test predictive of chemotherapy benefit.

### ***About early-stage breast cancer and the Oncotype DX test***

Oncotype DX is the only genomic test validated for its ability to predict the likelihood of chemotherapy benefit as well as risk of recurrence in early-stage breast cancer. Breast cancer is the most common cancer in European women<sup>1</sup> and affects many of them during their years dedicated to working and raising a family. While chemotherapy is routinely offered, research shows that only a minority of patients with early-stage breast cancer actually benefit from it.<sup>2</sup>

The Oncotype DX test is designed to facilitate personalised clinical decisions by providing information about the biology of an individual breast cancer, with the potential to deliver financial benefits for healthcare systems. This is supported by substantial real-world evidence showing that the test can reduce the number of women undergoing unnecessary chemotherapy by up to 60 percent.<sup>3</sup>

To learn more about the Oncotype DX test, visit: [www.OncotypeIQ.co.uk](http://www.OncotypeIQ.co.uk)

### ***About Genomic Health***

Genomic Health, Inc. is the world's leading provider of genomic-based diagnostic tests that help optimise cancer care. With its Oncotype IQ<sup>®</sup> Genomic Intelligence Platform, the company is applying its state-of-the-art scientific and commercial expertise and infrastructure to translate significant amounts of genomic data into clinically-actionable results for treatment planning throughout the cancer patient's journey, from diagnosis to treatment selection and monitoring. The Oncotype IQ portfolio of genomic tests and services currently consists of the company's flagship line of Oncotype DX gene expression tests that have been used to guide treatment decisions for more than 950,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype DX<sup>®</sup> AR-V7 Nucleus Detect<sup>™</sup> test. The company is based in Redwood City, California with international headquarters in Geneva, Switzerland and a UK office in London. For more information, please visit, [www.GenomicHealth.co.uk](http://www.GenomicHealth.co.uk) and follow the company on Twitter: [@GenomicHealth](#), [Facebook](#), [YouTube](#) and [LinkedIn](#).

---

<sup>1</sup> Ferlay J et al, Eur J Cancer. 2013

<sup>2</sup> Paik et al. *J Clin Oncol*. 2006; Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. *Lancet*. 2012.

<sup>3</sup> Loncaster J et al, Eur J Surg Oncol 2017

*This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the belief that the Oncotype DX Breast Cancer test is unique in its ability to predict chemotherapy benefit in early stage breast cancer; the company's belief that the Oncotype DX Breast Cancer test is cost effective and can reduce the cost of treatment in the United Kingdom and in various other health systems around the world; that the recommendation by NICE will lead to increased use of the Oncotype DX Breast Cancer test in the United Kingdom; the applicability of study results to actual outcomes; and the ability of the company's tests to impact clinical practice. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the company's ability to increase usage of its tests; the company's ability to successfully commercialize its tests outside of the United States; the company's ability to compete against third parties; the risk that the company may not obtain or maintain sufficient levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop; the risks and uncertainties associated with regulation of the company's tests; the results of clinical studies; the applicability of clinical study results to actual outcomes; and the other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018. These forward- looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.*

*NOTE: The Genomic Health logo, Oncotype, Oncotype DX, Breast Recurrence Score, DCIS Score, Genomic Prostate Score, Oncotype DX AR-V7 Nucleus Detect, and Oncotype IQ are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.*

*###*