



NEWS RELEASE

Medicare Insurance Coverage for Breast Cancer Index™ Test Expanded to Include Node-Positive Breast Cancer

5/10/2021

-- More women gain access to a test that helps determine whether extended endocrine therapy is appropriate for them --

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that its subsidiary, Biotheranostics, Inc., has received broader Medicare coverage for its Breast Cancer Index™ test under an expanded Medicare Local Coverage Determination (LCD: L37822) effective today.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20210510005802/en/>

Under the new criteria, the Breast Cancer Index™ test is now covered for post-menopausal women diagnosed with early-stage node-positive (one to three axillary lymph nodes), non-relapsed, estrogen receptor (ER) and/or progesterone receptor (PR) positive, HER2 negative breast cancer to help physicians manage treatment of the patient. Previously, Medicare covered the test only for patients with node-negative, non-relapsed, ER and/or PR positive, HER2 negative breast cancer. Therefore, the expanded coverage increases the availability of Breast Cancer Index testing with no cost to Medicare beneficiaries who meet the LCD criteria.

“Expansion of Medicare coverage for the Breast Cancer Index test and its recent inclusion in National Comprehensive Cancer Network guidelines are major milestones toward making the test standard of care for all early-stage, HR+ breast cancer patients,” said Kevin Thornal, division president, Diagnostic Solutions at Hologic.

For hormone receptor positive (HR+) post-menopausal breast cancer patients on extended endocrine therapy, the



side effects and toxicities of treatment often have significant negative effects on health and quality of life, such as osteoporosis, bone fractures and joint pain. As a result, knowing when extended endocrine therapy will benefit a patient is as important as avoiding it when it will not make a difference. The Breast Cancer Index test can help personalize extended endocrine treatment for all HR+ early-stage patients.

The ratio of breast cancers diagnosed as node-negative or node-positive varies year to year, but according to data published by the National Cancer Institute¹ in 2021, approximately 85% of early-stage, HR+ breast cancers were node-negative and 15% were node-positive that year. This means that approximately 25,000 more women every year will be eligible for testing with Breast Cancer Index based on the expanded coverage.

About Breast Cancer Index

Breast Cancer Index™ is a molecular, gene expression-based test uniquely positioned to provide information to help physicians individualize treatment decisions for patients with early-stage, HR+ breast cancer. This breakthrough test helps oncologists and patients navigate the difficult trade-offs between taking steps to prevent recurrence of their disease and facing significant side effects and safety challenges related to unnecessary treatment. Breast Cancer Index has guideline designation from the American Joint Committee on Cancer for cancer staging based on molecular profile. ASCO, NCCN, the European Group on Tumor Markers (EGTM) and St. Gallen acknowledge Breast Cancer Index as a biomarker to inform the chemotherapy decision; ASCO, NCCN and EGTM to inform the extended endocrine treatment decision. It is the only validated, commercially available test that predicts benefit from extended endocrine therapy. Breast Cancer Index is intended for routine clinical use, and treatment decisions based on results are the responsibility of the physician. It is a laboratory developed test (LDT) performed in a CLIA-certified and CAP-accredited diagnostic laboratory and is not required to be cleared or approved by the US Food and Drug administration. For more information, visit www.breastcancerindex.com.

About Hologic

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit www.hologic.com.

Forward-Looking Statements

This press release may contain forward-looking information that involves risks and uncertainties, including statements about the use of the Breast Cancer Index test. There can be no assurance this test will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient. The actual effect of the use of the test can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. In addition, there can be no assurance that this test will be

commercially successful or achieve any expected level of sales based on the expanded Medicare coverage. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

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SOURCE: Hologic, Inc.

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Investor Contact

Michael Watts

Vice President, Investor Relations and Corporate Communications

(858) 410-8588

michael.watts@hologic.com

Media Contact

Jane Mazur

Vice President, Divisional Communications

(585) 355-5978

jane.mazur@hologic.com

Source: Hologic, Inc.