# Adaptive Biotechnologies Receives Updated Medicare Coverage for its Minimal Residual Disease (MRD) Assay, clonoSEQ® for Blood Cancer Patients

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- Local coverage determination (LCD) confirms access to the only FDA-cleared in vitro diagnostic to detect and monitor minimal residual disease (MRD) from bone marrow and blood sample types in certain blood cancers
- LCD supports the expansion of coverage for additional clonoSEQ indications, providing a clear pathway for Non-Hodgkin's Lymphoma (NHL) and other lymphoid cancers

SEATTLE, Nov. 11, 2021 (GLOBE NEWSWIRE) -- Adaptive Biotechnologies Corporation (Nasdaq: ADPT), a commercial stage biotechnology company that aims to translate the genetics of the adaptive immune system into clinical products to diagnose and treat disease, announced that Palmetto GBA's Molecular Diagnostics Program (MolDX) has finalized a local coverage determination (LCD) which supports the Medicare coverage for clonoSEQ® to detect and monitor minimal residual disease (MRD) in patients with B-cell acute lymphoblastic leukemia (ALL), multiple myeloma (MM) and chronic lymphocytic leukemia (CLL).

"We are pleased that MolDX finalized the LCD for next-generation sequencing (NGS) tests for MRD, solidifying patient access to the critical results that our clonoSEQ Assay provides across the continuum of care," said Lance Baldo, MD, Chief Medical Officer of Adaptive Biotechnologies. "This LCD provides a pathway for the continued expansion of clonoSEQ into routine clinical care to benefit the more than 700,000 patients living with lymphoid malignancies in the United States.[1] We look forward to our continued work with Medicare to help evolve coverage within this rapidly advancing field."

The final LCD is consistent with the draft posted by Medicare in September of 2020, which established coverage of MRD as a "series of assays" in a patient with cancer and outlined specific coverage criteria for MRD tests. The LCD states that MRD testing for cancer is a sensitive and specific way to measure relative amounts of cancer cells in the body and has demonstrated its ability to impact patient care. The LCD also mentions that MRD assessment with clonoSEQ in lymphoid cancers, including ALL, MM and CLL, is a well-established tool for physicians.

clonoSEQ is the first and only U.S. Food and Drug Administration (FDA)-cleared assay for MRD assessment in CLL, MM and ALL, and is widely available to clinicians and patients across the U.S. clonoSEQ leverages the power of NGS and offers an accurate and reliable way to assess how disease burden changes over time in response to treatment or during remission. When utilized as a series of tests throughout a patient's journey with cancer, the assay can help clinicians predict long-term outcomes, assess treatment response, monitor disease burden and detect potential relapse. clonoSEQ has broad coverage in the U.S., with over 240 million covered lives across both Medicare and commercial payers.

**About the clonoSEQ Assay**
The clonoSEQ Assay is the first and only FDA-cleared assay for MRD in chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and B-cell acute lymphoblastic leukemia (ALL). Minimal residual disease (MRD) refers to the small number of cancer cells that can stay in the body during and after treatment. clonoSEQ was initially granted De Novo designation and marketing authorization by the FDA for the detection and monitoring of MRD in patients with MM and ALL using DNA from bone marrow samples. In August 2020, clonoSEQ received additional clearance from the FDA to detect and monitor MRD in blood or bone marrow from patients with CLL.

The clonoSEQ Assay leverages Adaptive's proprietary immune medicine platform to identify and quantify specific DNA sequences found in malignant cells, allowing clinicians to assess and monitor MRD during and after treatment. The assay provides standardized, accurate and sensitive measurement of MRD that allows physicians to predict patient outcomes, assess response to therapy over time, monitor patients during remission and predict potential relapse. Clinical practice guidelines in hematological malignancies recognize that MRD status is a reliable indicator of clinical outcomes and response to therapy, and clinical outcomes have been shown to be strongly associated with MRD levels measured by the clonoSEQ Assay in patients diagnosed with CLL, MM and ALL.

The clonoSEQ Assay is a single-site test performed at Adaptive Biotechnologies. In addition to its FDA-cleared uses, clonoSEQ is also available as a CLIA-validated laboratory developed test (LDT) service for use in other lymphoid cancers and sample types. For important information about the FDA-cleared uses of clonoSEQ, including the full intended use, limitations, and detailed performance characteristics, please visit www.clonoSEQ.com/technical-summary.

**About Adaptive Biotechnologies**
Adaptive Biotechnologies is a commercial-stage biotechnology company focused on harnessing the inherent biology of the adaptive immune system to transform the diagnosis and treatment of disease. We believe the adaptive immune system is nature's most finely tuned diagnostic and therapeutic for most diseases, but the inability to decode it has prevented the medical community from fully leveraging its capabilities. Our proprietary immune medicine platform reveals and translates the massive genetics of the adaptive immune system with scale, precision and speed to develop products in life sciences research, clinical diagnostics and drug discovery. We have three commercial products and a robust clinical pipeline to diagnose, monitor and enable the treatment of diseases such as cancer, autoimmune conditions and infectious diseases. Our goal is to develop and commercialize immune-driven clinical products tailored to each individual patient. For more information, please visit adaptivebiotech.com and follow us on www.twitter.com/adaptivebiotech.

**Forward Looking Statements**
This press release contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize and achieve market acceptance of our current and planned products and services, our

research and development efforts, and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors are described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file with the Securities and Exchange Commission from time to time. We caution you that forward-looking statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent our views as of the date hereof. We undertake no obligation to update any forward-looking statements for any reason, except as required by law.

**References**


1. National Cancer Institute. Cancer Stat Facts: Non-Hodgkin Lymphoma. Accessed November 11, 2021. Available at: https://seer.cancer.gov/statfacts/html/nhl.html.


Source: Adaptive Biotechnologies