ABOUT MINIMAL RESIDUAL DISEASE (MRD)

MRD is increasingly being used to inform treatment decisions, making MRD test selection increasingly important.

- MRD refers to the small number of cancer cells that can remain in a patient's body during and after treatment, often causing no physical signs or symptoms, that may result in disease recurrence.
- With new treatment options that are becoming available for blood cancer patients, clinicians are eager to have as much information as possible to help them decide on the most appropriate course for each patient.
- What we are seeing is a shift in which MRD is replacing traditional primary endpoints such as progression-free survival (PFS) in clinical trials.
- As technologies for MRD detection have improved, physicians have been able to detect increasingly smaller amounts of disease, and in myeloma for example, controlled trials have shown that even these small amounts of disease matter when it comes to predicting a patient's long-term clinical outcomes.
- Selection of an appropriate MRD test becomes even more important when you consider clinicians now have access to an approved, MRD-directed therapy.

MRD testing is an essential component of clinical practice guidelines for lymphoid malignancies like multiple myeloma and acute lymphoblastic leukemia (ALL).

- For myeloma patients, the NCCN Guidelines and IMWG Consensus Criteria recommend MRD assessment using a validated assay after each treatment stage.
- For ALL patients, the NCCN Guidelines recommend MRD assessment after completion of initial induction and at additional time points depending on treatment regimen. The guidelines also call for baseline characterization of the leukemic clone to facilitate subsequent MRD analysis.

clonoSEQ
ABOUT THE CLONOSEQ ASSAY

clonoSEQ, a highly-accurate, sensitive, and standardized MRD test to help predict patient outcomes, assess treatment response, monitor disease burden over time, and detect signs of returning disease.

- clonoSEQ is a next-generation sequencing (NGS)-powered test that detects, quantifies, and monitors MRD in patients with lymphoid malignancies like multiple myeloma and B-cell ALL.
- Using the unique DNA sequences that are associated with lymphocyte receptors for a specific patient, clonoSEQ precisely identifies malignant cells, counts how many of those cells are present in a patient's bone marrow sample, and tracks those cancer cells over time.
- clonoSEQ testing is already being used at the majority of NCCN cancer centers (25 of 26) and usage is expanding to referral centers and community practices.

clonoSEQ is the first and only FDA-cleared test for MRD assessment in any lymphoid cancer.

- clonoSEQ is an FDA-cleared in vitro diagnostic (IVD) test service provided by Adaptive Biotechnologies for use in B-cell ALL and multiple myeloma patients to detect and monitor MRD in bone marrow samples. clonoSEQ is also available for use in other lymphoid cancers as a CLIA-regulated laboratory developed test (LDT) service.
- clonoSEQ results should always be used in combination with clinical examination, patient medical history, and other findings. Results may vary according to sample time within the course of disease or by sampling site location. For important info about the FDA-cleared uses of clonoSEQ, including test limitations, visit clonoSEQ.com/technical-summary.

clonoSEQ testing has been granted Medicare coverage for the assessment of MRD in bone marrow samples from patients with multiple myeloma or B-cell acute lymphoblastic leukemia (ALL).

- clonoSEQ testing is now covered by Medicare in alignment with the FDA-cleared uses of clonoSEQ for e.g. bone marrow samples from patients with myeloma or B-cell ALL and clinical practice guidelines in myeloma and ALL.
- This Medicare coverage policy is a recognition of the essential role of MRD testing in clinical patient management and supports the use of clonoSEQ testing throughout the continuum of care.
- Specific coverage criteria for clonoSEQ testing are outlined in the relevant Local Coverage Article (LCA). The Centers for Medicare & Medicaid Services (CMS) requires non-covered patients to complete an Advance Beneficiary Notice (ABN) prior to receiving testing services. More information and an ABN template are available at clonoSEQ.com/coverage.

Adaptive continues to actively pursue coverage for clonoSEQ with national and regional private payers, as well as expanded Medicare coverage for additional lymphoid cancers and sample types.