Submitted by: Audrey Demaree, Senior Manager, Medical Affairs
Name: Lance Baldo, Chief Medical Officer
Company/Organization: Adaptive Biotechnologies Corporation
Address: 1551 Eastlake Ave East, #200 Seattle, WA 98102
Phone: (206) 279-2414
Email: lbaldo@adaptivebiotech.com
Date of request: Tuesday, October 27, 2020
NCCN Guidelines Panel: Acute Lymphoblastic Leukemia (Adult)

On behalf of Adaptive Biotechnologies, we request that the NCCN Pediatric Acute Lymphoblastic Leukemia Guideline Panel review and consider the following modifications to the Guidelines.

Rationale

The clonoSEQ® Assay is cleared by the FDA for the assessment of minimal residual disease (MRD) in the bone marrow of patients with multiple myeloma and acute lymphoblastic leukemia and blood or bone marrow in patients with chronic lymphocytic leukemia.[1] clonoSEQ is the first and only test approved for MRD assessment in these malignancies. The FDA has publicly recognized the rigor of clonoSEQ validation and has restated the need for a standardized MRD tool to aid in clinical management.[2]

To ensure that all patient populations have access to this standardized and specific technology, Adaptive Biotechnologies has secured a positive coverage determination by Medicare and will continue to pursue private payer coverage policies, thus removing a patient access barrier.[3]

We would like to acknowledge the committee for including a comprehensive review of MRD testing methods, time points, and considerations within the current guidelines and would like to make the following minor recommendations.

Requested Modifications (based on Version 1.2020)

- Page 30 (ALL-F); Bullet 2; modify to align with Adult ALL Guidelines: MRD is an essential component of patient evaluation over the course of sequential therapy. ~~If patient is not treated in an academic center,~~ If a validated MRD assessment technology with appropriate sensitivity is not available locally, there are commercially available tests available that should be used for MRD assessment.

References

1. clonoSEQ®. Seattle, WA: Adaptive Biotechnologies Corporation; 2018. https://www.clonoseq.com/technical-summary
2. FDA authorizes first next generation sequencing-based test to detect very low levels of remaining cancer cells in patients with acute lymphoblastic leukemia or multiple myeloma [press release]. September 28, 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622004.htm
3. CMS. Local Coverage Article: Billing and Coding: MolDX: ClonoSEQ® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies (A56270). https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56270&ver=16&Cntrctr=374&ContrVer=1&CntrctrSelected=374*1&DocType=Active&s=48&bc=AhAAAAIAkAAA&. Updated January 1, 2020. Accessed October 27, 2020.