MEDICARE LOCAL COVERAGE DETERMINATION (LCD) POLICY

CLL COMPANION DIAGNOSTIC TESTING [POLICY A56009]

CPT: 88271, 88275, 88291, 88374, 88377

MEDICARE LOCAL COVERAGE DETERMINATION (LCD)

Noridian, the Medicare Administrative Contractor (MAC) for California, has issued a Medicare **local coverage determination (LCD) policy [A56009]** applicable to Chronic Lymphocytic Leukemia (CLL) Companion Diagnostic Testing, CPT Codes 88271, 88275, 88291, 88374 and 88377.

The full text of the LCD for CLL Testing is available online.

This Reference Guide sets forth excerpts of key information from the LCD, which PDL believes can assist providers to determine:

(1) whether CLL Testing is medically appropriate for your patient
(2) circumstances and diagnoses for which Noridian / Medicare will pay for CLL Testing
(3) when providers must secure a signed Advance Beneficiary Notice (ABN) from a Medicare patient

The list of ICD codes provided below consists of *commonly utilized diagnosis codes*.

- This is not a full list of ICD codes for this test. The complete CMS policy and full list of ICD codes can be found at the following website: https://www.cms.gov/
- To view the CMS Local Coverage Determination (LCD) for CCL Companion Diagnostic Testing visit the following website. Article - Billing and Coding: FDA Approved CLL Companion Diagnostic Test (A56009) (cms.gov).
- It is the responsibility of the ordering provider to ensure appropriate diagnostic coding for a test.
- If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advanced Beneficiary Notice (ABN) form is required.

COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY

Note: Providers should seek information related to National Coverage Determinations (NCD) and other Centers for Medicare & Medicaid Services (CMS) instructions in CMS Manuals. This LCD only pertains to the contractor's discretionary coverage related to this service.

Effective April 11, 2016, the FDA approved venetoclax (VENCLEXTA®/AbbVie), a new drug treatment for patients with B-cell chronic lymphocytic leukemia (CLL) with 17p deletion and at least one prior therapy, and a new indication for Vysis CLL FISH Probe Kit, a laboratory test to detect 17p deletion, as a companion diagnostic for venetoclax.

Venetoclax is an inhibitor that binds directly to the BCL-2 protein whose overexpression has been associated with resistance to chemotherapeutics. The 17p deletion is more frequently observed in treated patients than in patients who have received no treatment. Therefore, venetoclax has been approved for patients with previous treatment for CLL with the 17p deletion as detected by the Vysis CLL FISH Probe Kit. Vysis CLL FISH Probe Kit is not intended for monitoring of residual disease.

Noridian will only cover 17p deletion detection by FISH testing services when performed using validated assays. To date, Vysis CLL FISH Probe Kit is the only FDA validated and approved assay for the detection of the 17p deletion as the companion diagnostic for Venetoclax. Vysis CLL FISH Probe Kit services may only be billed by a CLIA certified lab. Vysis Fish Probe Kit by Abbott Molecular meets the reasonable and necessary criteria for Medicare reimbursement.

To report a Vysis FISH Probe kit service, please submit the following claim information:

1. When medically necessary and enumeration is performed, reviewed, and interpreted by a physician or pathologist:
   - Select the CPT® code 88374 or 88377 for your service as appropriate and enter 2 units of service (UOS)
2. When medically necessary and enumeration is performed and reviewed by a cytotechnologist
   - Select the CPT® code 88271 and 88275 for your service as appropriate and enter 4 units and 1 unit of service respectively (UOS)
   - Select the CPT® code 88291 with 1 unit of service for physician interpretation

Additional Information: To bill the PC component, the pathologist must read and interpret the raw data. Per Chapter 10, Version 16.3 in the NCCI Policy Manual for Medicare Services, physicians may not report the professional component provided by the technician or scientist.

Note: This billing and coding guideline ONLY applies to the UNMODIFIED, Vysis CLL FISH Probe Kit by Abbott for patients with CLL who have received at least one prior therapy and who are potential candidates for venetoclax.B-type natriuretic peptide (BNP) is a cardiac neurohormone produced mainly in the left ventricle. It is secreted in response to ventricular volume expansion and pressure overload, conditions often present in congestive heart failure (CHF). Used in conjunction with other clinical information, measurement of BNP levels (either total or N-terminal) is useful in rapidly establishing or excluding the diagnosis or worsening of CHF in patients with acute exacerbation of dyspnea. Also, BNP levels determined in the first few days after an acute coronary syndrome or event (ACS) may be useful in the prediction of longer-term cardiovascular risk but this risk assessment does not change the management of ACS and is non-covered by regulation.

REMINDER: The ordering provider is solely responsibility for assigning diagnosis (codes) for CLL Companion Diagnostic Testing. PDL does not – through this Reference Guide or otherwise – recommend any particular diagnosis codes. PDL will submit to Medicare only the diagnosis (codes) provided to PDL by the ordering provider and/or his/her authorized staff.

ICD-10-CM Codes commonly used for CLL Companion Diagnostic Testing

CPT: 88271, 88275, 88291, 88374, 88377

CODE	DESCRIPTION
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse