



## NHS MEDICAL POLICY

### MINIMAL RESIDUAL DISEASE (MRD) TESTING Procedure 2026-001

Minimal residual disease (MRD) analysis for solid tumors using cell free DNA with sufficient evidence of clinical utility and validity may be considered medically necessary when:

1	The identification of recurrent, refractory or progressive disease will require a change in management AND
2	The member is not undergoing concurrent molecular laboratory testing or surveillance or monitoring for recurrent, refractory or progressive disease AND
3	The member meets one of the following: <ul style="list-style-type: none"> <li>• The member is currently being treated for cancer AND</li> <li>• The test has not previously been done for this cancer diagnosis OR</li> <li>• There is a clinical suspicion that the molecular profile of the member’s tumor has changed OR</li> <li>• The members are not currently being treated for their cancer AND</li> <li>• There is a clinical suspicion for tumor recurrence AND</li> </ul>
4	The members meet one (1) of the following: <ul style="list-style-type: none"> <li>• The member is being tested via Guardant360 Response or Guardant Reveal and has one of the following: <ul style="list-style-type: none"> <li>• Metastatic colon cancer, OR</li> <li>• Colon cancer at any stage, and</li> <li>• The member is being monitored for response to immune checkpoint inhibitor therapy OR</li> </ul> </li> <li>• The member is being tested with Signatera and has one of the following: <ul style="list-style-type: none"> <li>• Metastatic colon cancer OR</li> <li>• Muscle invasive bladder cancer OR</li> <li>• Metastatic breast cancer OR</li> <li>• Any tumor, AND</li> </ul> </li> <li>• The member is being monitored for response to immune checkpoint inhibitor therapy (e.g. pembrolizumab [Keytruda], ipilimumab [Yervoy], nivolumab [Opdivo])</li> </ul>

5	<p>Frequency of testing does not exceed recommendations for monitoring noted in National Comprehensive Cancer Network (NCCN) guidelines for RECIST (Response Evaluation Criteria in Solid Tumors) for any of the following:</p> <ul style="list-style-type: none"> <li>• Initial testing within 4-6 weeks after surgery as a baseline and for adjuvant therapy decisions</li> <li>• Every 3-6 months for the first 2 years initially or with recurrence or progression (not to exceed 4 tests/year)</li> <li>• Every 6-12 months for the following 3 years (not to exceed 2 tests/year) for colorectal cancer (CRC), NSCLC (Non-Small Lung Cancer)</li> <li>• Annually for following 5 years (not to exceed 1 test/year)</li> <li>• As indicated thereafter, based on clinicopathologic features.</li> </ul>
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**SOURCES**

1. Blue Shield of California Medical Policy: Tumor-Confirmed Circulating Tumor DNA for Cancer Management Policy 2.0 Medicine Effective date: March 1, 2023
2. Blue Shield of California Medical Policy: Oncology: Molecular Analysis of Solid Tumors and Hematologic Malignancies; 2.0 Medicine. Page 13 Effective Date: May 1, 2025.
2. Center for Medicare & Medicaid Services, Medicare Coverage Database: Local Coverage Determination MoLDX: Minimal Residual Disease Testing (L38779). Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38779>.

**CODE REFERENCE (This may not be a comprehensive list of codes to apply to this policy.)**

0340U

**POLICY HISTORY/REVISION INFORMATION**

Date	Action/Description