

EVIDENCE-BASED SOLID TUMOR MINIMAL RESIDUAL DISEASE (MRD) TESTING

- I. Minimal residual disease (MRD) analysis for solid tumors using cell free DNA (0340U, 0422U, 81479) with sufficient evidence of clinical utility and validity is considered **medically necessary** when:
 - A. The identification of recurrent, refractory, or progressive disease will require a change in management, **AND**
 - B. The member is not undergoing concurrent molecular laboratory testing for surveillance or monitoring for recurrent, refractory, or progressive disease, **AND**
 - C. The member meets one of the following:
 1. The member is currently being treated for cancer, **AND**
 - a) The test has not previously been done for this cancer diagnosis, **OR**
 - b) There is a clinical suspicion that the molecular profile of the member's tumor has changed, **OR**
 2. The member is not currently being treated for their cancer, **AND**
 - a) The test has not been done in the past 12 months, **OR**
 - b) There is a clinical suspicion for tumor recurrence, **AND**
 - D. The member meets one of the following:
 1. The member is being tested via Guardant360 Response or Guardant Reveal and has one of the following:
 - a) Metastatic colon cancer, **OR**
 - b) Colon cancer at any stage, **AND**
 - (1) The member is being monitored for response to immune checkpoint inhibitor therapy, **OR**

2. The member is being tested via Signatera and has one of the following:
 - a) Metastatic colon cancer, **OR**
 - b) Muscle invasive bladder cancer, **OR**
 - c) Metastatic breast cancer, **OR**
 - d) Any solid tumor, **AND**
 - (1) The member is being monitored for response to immune checkpoint inhibitor therapy.
- II. Minimal residual disease (MRD) analysis (0340U, 0422U, 81479) with sufficient evidence of clinical utility and validity using solid tumor tissue is considered **investigational** for all other indications where clinical utility and validity have not been demonstrated.

REFERENCES

1. Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination. MoIDX: Minimal Residual Disease Testing for Cancer (L38779). Available at:
<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38779>
2. Centers for Medicare & Medicaid Services. Medicare Coverage Database: Billing and Coding: MoIDX: Minimal Residual Disease Testing for Solid Tumor Cancers (A58376). Available at:
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58376>