

Broad Molecular Profiling Panel Tests via Circulating Tumor DNA (ctDNA)

- I. Broad molecular profiling panel tests via circulating tumor DNA (liquid biopsy) (0239U, 0242U, 0326U, 81445, 81455) are considered **medically necessary** when:
 - A. The member has a diagnosis, progression, or recurrence of one of the following:
 1. Advanced (stage IIIb or higher) or metastatic lung adenocarcinoma, **OR**
 2. Advanced (stage IIIb or higher) or metastatic large cell lung carcinoma, **OR**
 3. Advanced (stage IIIb or higher) or metastatic squamous cell lung carcinoma, **OR**
 4. Advanced (stage IIIb or higher) or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS), **OR**
 5. Locally advanced/metastatic pancreatic adenocarcinoma, **OR**
 6. Gastric cancer, **OR**
 7. Esophageal or esophagogastric junction cancer, **OR**
 8. Metastatic prostate cancer, **OR**
 9. Advanced (stage III or higher) cutaneous melanoma, **OR**
 10. Metastatic colorectal cancer, **OR**
 11. Hormone receptor positive/HER2-negative recurrent unresectable or stage IV breast cancer, **AND**
 - B. At least one of the following:
 1. The member is medically unfit for invasive tissue sampling (biopsy), **OR**

2. Biopsy was performed, but material was insufficient for molecular analysis, **OR**
 3. Biopsy was performed, but molecular analysis was not able to be completely assessed on tissue due to availability of testing methodologies.
- II. Broad molecular profiling panel tests via circulating tumor DNA (liquid biopsy) (0239U, 0242U, 0326U, 81445, 81455) are considered **investigational** for all other indications.
 - III. Broad molecular profiling panel tests via circulating tumor DNA (liquid biopsy) (0239U, 0242U, 0326U, 81445, 81455) performed simultaneously with solid tumor tissue testing are considered **investigational**.

NOTES AND DEFINITIONS

1. **Cell-free circulating tumor DNA (ctDNA)** is fragmented, tumor-derived DNA circulating in the bloodstream that is not being carried in a cell. ctDNA derives either directly from the tumor or from circulating tumor cells.
2. **Circulating Tumor Cells (CTCs)** are intact cells that have shed into the bloodstream or lymphatic system from a primary tumor or a metastasis site, and are carried around the body by blood circulation.

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