

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, 0409U, 81445, 81455, 81462, 81463, 81464) are considered **medically necessary** when:
 - A. The member has a diagnosis, progression, or recurrence of one of the following:
 1. Stage IV or metastatic lung adenocarcinoma, **OR**
 2. Stage IV or metastatic large cell lung carcinoma, **OR**
 3. Stage IV or metastatic squamous cell lung carcinoma, **OR**
 4. Stage IV or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS), **OR**
 5. Locally advanced/metastatic pancreatic adenocarcinoma, **OR**
 6. Metastatic or advanced gastric cancer, **OR**
 7. Metastatic or advanced esophageal or esophagogastric junction cancer, **OR**
 8. Metastatic prostate cancer, **OR**
 9. Stage III or higher cutaneous melanoma, **OR**
 10. Metastatic colorectal cancer, **OR**
 11. Locally advanced or metastatic ampullary adenocarcinoma, **OR**
 12. Persistent or recurrent cervical cancer, **OR**
 13. Unresectable or metastatic biliary tract cancer, **OR**
 14. Suspected or confirmed histiocytic neoplasm, **OR**
 15. Locoregional unresectable or metastatic extrapulmonary poorly differentiated neuroendocrine carcinoma, **OR**

16. Locoregional unresectable or metastatic large or small cell carcinoma, **OR**
 17. Locoregional unresectable or metastatic mixed neuroendocrine-non-neuroendocrine neoplasm, **OR**
 18. Suspected metastatic malignancy of unknown primary with initial determination of histology, **OR**
 19. Recurrent ovarian, fallopian tube or primary peritoneal cancer, **OR**
 20. Recurrent or stage IV breast cancer, **AND**
- B. If a broad molecular profiling panel test via circulating tumor DNA is being performed simultaneously with solid tumor tissue testing, the member must have one of the following diagnoses:
1. Lung adenocarcinoma, **OR**
 2. Large cell lung carcinoma, **OR**
 3. Squamous cell lung carcinoma, **OR**
 4. Non-small cell lung cancer (NSCLC) not otherwise specified (NOS).
- II. Broad molecular profiling panel tests via circulating tumor DNA (liquid biopsy) (0239U, 0242U, 0326U, 81445, 81455, 81462, 81463, 81464) are considered **investigational** for all other indications, including being performed simultaneously with solid tumor tissue testing for tumor types other than those described above.

DEFINITIONS

1. **Circulating tumor DNA (ctDNA):** 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.

REFERENCES

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