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

- I. Broad molecular profiling panel tests via circulating tumor DNA (ctDNA) (liquid biopsy) are considered **medically necessary** when:
 - A. The member has a diagnosis, progression, or recurrence of one of the following:
 - 1. Metastatic lung adenocarcinoma, OR
 - 2. Metastatic large cell lung carcinoma, OR
 - 3. Metastatic squamous cell lung carcinoma, OR
 - 4. 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**



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- 16. Locoregional unresectable or metastatic large or small cell neuroendocrine 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 (ctDNA) 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 (ctDNA) 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. **Advanced** cancer (advanced stages or advanced tumor or advanced/metastatic): Cancer that is unlikely to be cured or controlled with treatment. The cancer may have spread from where it first started to nearby



©2025 Concert Proprietary tissue, lymph nodes, or distant parts of the body. Treatment may be given to help shrink the tumor, slow the growth of cancer cells, or relieve symptoms.

2. **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.

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