## Tumor-Type Agnostic Solid Tumor Molecular Profiling Panels

- I. Tumor-type agnostic solid tumor molecular profiling panels are considered **medically necessary** when:
  - A. The member meets both of the following:
    - 1. The member has a diagnosis of:
      - a) Recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer, **OR**
      - b) Histiocytosis, OR
      - c) Non-small cell lung cancer (NSCLC) regardless of stage, OR
      - d) Resectable or borderline resectable pancreatic adenocarcinoma, **OR**
      - e) Central nervous system tumor, AND
    - 2. The member is seeking further cancer treatment (e.g., therapeutic chemotherapy), **OR**
  - B. The member meets one of the following:
    - 1. The member is being evaluated for a suspected metastatic malignancy of unknown type, **OR**
    - 2. The member is undergoing initial evaluation for a known or suspected gastric cancer, **OR**
    - 3. The member has a diagnosis of uterine neoplasm, AND
      - a) The member is undergoing initial evaluation, OR
    - 4. The member undergoing initial evaluation for a known or suspected gastrointestinal stromal tumor (GIST), **AND** 
      - a) The tumor is negative for *KIT* and *PDGFRA* mutations.



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- II. Repeat testing via a tumor-type agnostic solid tumor molecular profiling panel is considered **medically necessary** when:
  - A. The member has progression of:
    - 1. Advanced or metastatic non-small cell lung cancer (NSCLC), OR
    - 2. Advanced or metastatic gastric adenocarcinoma, OR
    - 3. Metastatic prostate cancer.
- III. Tumor-type agnostic solid tumor molecular profiling panels are considered **investigational** for all other indications.

**NOTE**: Additional codes representing additional IHC and/or cytogenetics analyses may be billed alongside the PLA or GSP codes.

## DEFINITIONS

 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 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.

## REFERENCES

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 3.2025. https://www.nccn.org/professionals/physician\_gls/pdf/nscl.pdf



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- 2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Version 6.2024. http://www.nccn.org/professionals/physician\_gls/PDF/colon.pdf
- 3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 6.2024. https://www.nccn.org/professionals/physician\_gls/pdf/breast.pdf
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer, Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 3.2024. https://www.nccn.org/professionals/physician\_gls/pdf/ovarian.pdf
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma. Version 1.2025. https://www.nccn.org/professionals/physician\_gls/pdf/pancreatic.pdf
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors (GISTs). Version 2.2024. https://www.nccn.org/professionals/physician\_gls/pdf/gist.pdf
- 7. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Central Nervous System Cancers. Version 3.2024. https://www.nccn.org/professionals/physician\_gls/pdf/cns.pdf
- 8. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2025. https://www.nccn.org/professionals/physician\_gls/pdf/prostate.pdf
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer. Version 5.2024. https://www.nccn.org/professionals/physician\_gls/pdf/gastric.pdf
- 10. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Occult Primary (Cancer of Unknown Primary [CUP]). Version 2.2025. https://www.nccn.org/professionals/physician\_gls/pdf/occult.pdf
- 11. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Histiocytic Neoplasms. Version 3.2024 https://www.nccn.org/professionals/physician\_gls/pdf/histiocytic\_neoplasms.pdf
- 12. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma. Version 2.2025. https://www.nccn.org/professionals/physician\_gls/pdf/ampullary.pdf
- FoundationOne CDx Technical Information (PMA approval number: P170019). US Food and Drug Administration. Website: https://www.accessdata.fda.gov/cdrh\_docs/pdf17/P170019C.pdf. Accessed 08/12/2024.



Oncology Testing: Solid Tumor Molecular Diagnostics 2025.2

14. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Uterine Neoplasms. Version 2.2025. https://www.nccn.org/professionals/physician\_gls/pdf/uterine.pdf

