KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Next Generation Sequencing for Advanced Cancer (somatic/tissue testing)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Next Generation Sequencing (NGS) (90.2)
Local Coverage Determinations (LCD)	9/30/2015 - Noridian retired LCD for Genetic Testing (L24308). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L39232) (Guardant360®)
Local Coverage Article (LCA)	MolDX: Plasma-Based Genomic Profiling in Solid Tumors (A58975) (Guardant 360®)
Decision Memo	Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) ***FDA-approved tests*** *(not all-inclusive)* FoundationFocus™ CDxBRCA Assay (Foundation Medicine, Inc.) FoundationOne CDx (Foundation Medicine, Inc.) FoundationOne Liquid CDx (Foundation Medicine, Inc.) Guardant360® CDx (Guardant Health, Inc.) Oncomine™ Dx Target Test (Thermo Fisher Scientific, Inc.) Praxis™ Extended RAS Panel (Illumina, Inc.) MSK-IMPACT™ (Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets))

For Non-Medicare Members

I. Next Generation Sequencing can **only be covered for the following solid cancer types:**
   1. Stage III or IV non-small cell lung cancer
   2. stage IV pancreatic carcinoma

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3. stage IV colon carcinoma
4. stage IV prostate
5. stage IV ovarian
6. stage IV endometrial
7. stage IV biliary
8. stage IV gastric
9. stage IV esophageal (adeno and squamous) gastroesophageal
10. stage IV breast (ER or PR positive)

II. In addition, the member must meet **ALL of the following**:
1. The individual is a candidate for a targeted therapy associated with a specific tumor biomarker or disease site
2. Results of testing will directly impact clinical decision making
3. The testing method is considered to be scientifically valid and proven to have clinical utility based on prospective evidence
4. **EITHER** of the following:
   - Identification of the specific biomarker or risk assessment using a Gene Expression Classifier (GEC)/Next Generation Sequencing is required in order to initiate a related therapy and the therapy has been validated by the National Comprehensive Cancer Network™ (NCCN Guidelines™) as a category 1, 2A, or 2B recommendation for the individual's tumor type or disease site **OR**
   - Identification of the specific biomarker or use of a GEC/Next Generation Sequencing has been demonstrated in published peer-reviewed literature to improve diagnosis, management or clinical outcomes for the individual's condition being addressed

III. The following panels meet Kaiser Permanente coverage criteria in regard to actionable mutations —any of these three labs can be used:
- CellNetix SymGene Panel
- Oncoplex (University of Washington)
- Caris Life Sciences

NOTE: If the submission is for a different vendor, it will be redirected to one of the above preferred labs under section III for HMO. For POS and PPO, a similar narrow panel limited to the genes above can be considered on a case-by-case basis if labs A-D are unacceptable.

IV. Molecular testing for hematology-oncology indications is **considered experimental, investigational or unproven in the following situations:**
- there is insufficient evidence to support molecular testing for the specific tumor type or disease site
- the requested gene(s) or biomarker(s) are correlated with a known therapy, but that therapy has not been validated for the specific tumor type or disease site

Individual or targeted gene testing can be covered for specific, actionable mutations for cancer types that panel testing is not covered.

Please see the list of ***non-covered*** genetic panels on the KPWA criteria page – Genetic Panel Testing. This includes, but is not limited to:

- FoundationOne
- Guardant360

Repeat testing is non-covered.

If requesting this these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Symgene 79 NGS Cancer Panel:

CPT® or HCPC Codes	Description
88374 (x2)	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
88381	Microdissection (ie, sample preparation of microscopically identified target); manual
G0452	Molecular pathology procedure; physician interpretation and report

Symgene Focus- Targeted NGS Cancer Panel (Lung):

CPT® or HCPC Codes	Description
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
88374 (x2)	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure
88360	Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual
88381	Microdissection (ie, sample preparation of microscopically identified target); manual
G0452	Molecular pathology procedure; physician interpretation and report

Symgene Focus- Targeted NGS Cancer Panel (Colon):

CPT® or HCPC Codes	Description
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
88381	Microdissection (ie, sample preparation of microscopically identified target); manual
G0452	Molecular pathology procedure; physician interpretation and report

Caris Life Sciences

CPT® or HCPC Codes	Description
81479	Unlisted molecular pathology procedure

Oncoplex (University of Washington)

CPT® or HCPC Codes	Description
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS,

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	NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed

FoundationOne® (Foundation Medicine) –
Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare: Considered Not Medically Necessary, use preferred vendors above

CPT® or HCPC Codes	Description
0239U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations *FoundationOne® Liquid CDx*
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden *FoundationOne CDx™*

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/04/2020	08/04/2020 MPC, 08/03/2021 MPC, 08/02/2022MPC, 09/06/2022MPC, 08/01/2023MPC	11/13/2023

MPC Medical Policy Committee

Revision History	Description
08/04/2020	MPC approved to adopt new clinical criteria. Requires 60-day notice, effective date 01/01/2021.
11/13/2020	Added codes from CellNetix
09/06/2022	MPC approved to expand solid cancer types to include: stage IV prostate, stage IV ovarian , stage IV endometrial , stage IV biliary , stage IV gastric, stage IV esophageal (adeno and squamous) gastroesophageal, stage IV breast (ER or PR positive). Also approved Caris and Oncoplex as contracted lab vendors. 60-day notice required; effective 2/1/2023.
10/26/2022	Refiled 60 day notice. Adjusted effective dates for advanced cancers to 1/1/23 per RCW 48.43.810
01/24/2023	Added Applicable codes for FoundationOne® NGS testing
11/13/2023	Updated Medicare coverage article link

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