Test Specific Guidelines

Somatic Mutation Testing-Solid Tumors

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Introduction

Somatic mutation testing in solid tumors is addressed by this guideline.

Procedures Addressed

The inclusion of any procedure code in this table is provided for informational purposes and is not a guarantee of coverage nor an indication that prior authorization is required.

Procedures addressed by this guideline	Procedure codes
APC Sequencing	81201
BRAF V600 Targeted Mutation Analysis	81210
BRCA1/2 Sequencing	81163
BRCA1 Sequencing	81165
BRCA2 Sequencing	81216
EGFR Targeted Mutation Analysis	81235
FoundationOne CDx	0037U
Guardant360 TissueNext	0334U
KIT D816 Targeted Mutation Analysis	81273
KIT Targeted Sequence Analysis	81272
KRAS Exon 2 Targeted Mutation Analysis	81275
KRAS Targeted Mutation Analysis, Additional Variants	81276
MGMT Promoter Methylation Analysis	81287
MI Cancer Seek - NGS Analysis	0211U
MLH1 Sequencing	81292

Procedures addressed by this guideline	Procedure codes
Molecular Tumor Marker Test	81400 81401 81402 81403 81404 81405 81406 81407 81408 81479
Molecular Tumor Marker Test	88271
MSH2 Sequencing	81295
MSH6 Sequencing	81298
MSK-IMPACT	0048U
myChoice CDx	0172U
NRAS Exon 2 and Exon 3 Analysis	81311
NTRK1 Translocation Analysis	81191
NTRK2 Translocation Analysis	81192
NTRK3 Translocation Analysis	81193
NTRK Translocation Analysis	81194
Oncomine Dx Target Test	0022U
Oncotype MAP PanCancer Tissue Test	0244U
PALB2 Sequencing	81307
PDGFRA Targeted Sequence Analysis	81314
PGDx Elio Tissue Complete	0250U
PIK3CA Targeted Sequence Analysis	81309
PMS2 Sequencing	81317
Praxis Extended RAS Panel	0111U
PTEN Sequencing	81321

Procedures addressed by this guideline	Procedure codes
SF3B1 Common Variants (e.g. A672T, E622D, L833F, R625C, R625L)	81347
Solid Organ Neoplasm Molecular Profiling	81445
Solid Organ or Hematolymphoid Neoplasm Molecular Profiling - Expanded	81455
TERT Targeted Sequence Analysis	81345
therascreen FGFR RGQ RT-PCR Kit	0154U
therascreen PIK3CA RGQ PCR Kit	0155U
TP53 Sequencing	81351
TP53 Targeted Sequence Analysis	81352

What Are Somatic Mutation Tests?

Definition

Somatic mutation tests are broadly defined here as any test that measures changes in DNA, RNA, or chromosomes found in tumor tissue that is used to make cancer management decisions.

Somatic mutation tests are increasingly useful for therapy selection. Many cancer therapies are targeted at particular gene functions (therapeutic targets) and some require information about tumor genetics to use the therapies effectively (companion diagnostics). In these cases, NCCN as well as the FDA have outlined tumor testing that is recommended for specific cancers and the associated treatment implications.[1-5]

Test Information

Somatic Mutation Testing

The specific methodology used to identify somatic mutations is dependent upon the type of mutation being investigated.

DNA mutations are generally detected through direct analysis of individual mutations, portions of a gene, a whole gene, panels of genes, or the entire exome.

Chromosome abnormalities, such as translocations or deletions, may be detected through direct visualization of the chromosomes (karyotyping), in situ hybridization of probes (e.g., FISH) to detect deletions or duplications that are too

small to see directly, or by DNA-based methods (hybridization arrays or sequencing) that identify deletions or translocation breakpoints.

Gene expression profiling simultaneously measures the amount of RNA being made by many genes. Expression patterns may be used to predict the type of cancer present, the aggressiveness of the malignancy, and therapies that are likely to be effective.

The efficiency of next generation sequencing (NGS) has led to an increasing number of large, multi-gene somatic mutation panels. Given that malignancies can have multiple and unexpected genetic changes, these panels may provide physicians with information about therapeutic targets that would not otherwise be considered.

Tumor mutational burden (TMB) is a quantitative measure of the number of mutations in the genome of a tumor "sometimes defined as the total number of non-synonymous point mutations per coding area of a tumor genome".[6] High TMB is thought to be a useful marker in predicting tumor response to immune checkpoint inhibitor therapies and is often used as a type of biomarker.[6-8] "Panel sizes >667 Kb are necessary to maintain adequate PPA [positive percent agreement] and NPA [negative percent agreement] for calling TMB high versus TMB low across the range of cut-offs used in practice."[9]

Guidelines and Evidence

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) provided the following guidance:

NCCN Guidelines for Treatment of Cancer by Site provided detailed guidelines on the use of individual tumor markers for each cancer type addressed.[2,5,10-20]

NCCN made the following recommendations specifically for using multi-gene panels in the evaluation of non-small cell lung cancer (NSCLC): "The NCCN NSCLC Guidelines Panel strongly advises broader molecular profiling with the goal of identifying rare driver mutations for which effective drugs may already be available, or to appropriately counsel patients regarding the availability of clinical trials. Broad molecular profiling is defined as molecular testing that identifies all biomarkers identified in NSCL-19 [gene rearrangements in ALK, NTRK1/2/3, RET, and ROS1, BRAF V600E mutation, certain EGFR mutations, KRAS G12C mutation, and MET exon 14 skipping mutation], in either a single assay or a combination of a limited number of assays and optimally identifies emerging biomarkers. Tiered approaches based on low prevalence of co-occurring biomarkers are acceptable. Broad molecular profiling is a key component of the improvement of care of patients with NSCLC." [2]

NCCN made the following recommendations specifically for using multi-gene panels in the evaluation of metastatic colorectal cancer: "All patients with

metastatic colorectal cancer should have tumor tissue genotyped for RAS (KRAS and NRAS) and BRAF mutations individually or as part of an NGS panel."[10]

NCCN made the following recommendation for cutaneous melanoma: "For initial presentation of stage IV disease or clinical recurrence, obtain tissue to ascertain alterations in BRAF, and in the appropriate clinical setting, KIT from either biopsy of the metastasis (preferred) or archival material if the patient is being considered for targeted therapy. Broader genomic profiling (eg, larger NGS panels, BRAF non-V600 mutations) is recommended if feasible, especially if the test results might guide future treatment decisions of eligibility for participation in a clinical trial. If BRAF single-gene testing was the initial test performed, and is negative, clinicians should strongly consider larger NGS panels to identify other potential genetic targets (eg, KIT, BRAF non-V600)."[11]

NCCN made the following recommendation for epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer, prior to selection of systemic therapy for refractory or recurrent disease "Validated molecular testing should be performed in a CLIA-approved facility using the most recent available tumor tissue. Tumor molecular analysis is recommended to include, at a minimum, tests to identify potential benefit from targeted therapeutics that have tumor-specific or tumor-agnostic benefit including, but not limited to, BRCA1/2, HR status, MSI, TMB, NTRK if prior testing did not include these markers."[18]

NCCN made the following recommendation for ampullary adenocarcinoma: "Tumor/somatic molecular profiling is recommended for patients with locally advanced/metastatic disease who are candidates for anti-cancer therapy to identify uncommon mutations. Consider specifically testing for potentially actionable somatic findings including, but not limited to: fusions (ALK, NRG1, NTRK, ROS1, FGFR2, RET), mutations (BRAF, BRCA1/2, KRAS, PALB2), amplifications (HER2), microsatellite instability (MSI) and/or mismatch repair (MMR) deficiency."[19]

NCCN made the following recommendation for distantly metastatic salivary gland tumors: "Targeted systemic therapy is increasingly becoming an option for patients with distantly metastatic salivary gland tumors. NGS and other biomarker tests should be used to evaluate AR, NTRK, HRAS, PIK3CA, TMB, and HER2 status."[20]

NCCN made the following recommendation for locally advanced/metastatic pancreatic adenocarcinoma: "Tumor/somatic molecular profiling is recommended for patients with locally advanced/metastatic disease who are candidates for anti-cancer therapy to identify uncommon mutations. Consider specifically testing for potentially actionable somatic findings including, but not limited to: fusions (ALK, NRG1, NTRK, ROS1, FGFR2, RET), mutations (BRAF, BRCA1/2, KRAS, PALB2), amplifications (HER2), microsatellite instability (MSI), and/or mismatch repair (MMR) deficiency. Testing of tumor tissue is preferred; however, cell-free DNA can be considered it tumor tissue testing is not feasible."[14]

U.S. Food and Drug Administration

Some FDA labels require results from biomarker tests to effectively or safely use the therapy for a specific cancer type.[3] A list of all Pharmacogenomic Biomarkers included in FDA labeling and associated implications can be found here. While these tumor marker tests generally consist of a single biomarker, some larger panels of biomarkers are also included in the FDA labeling.

In 2017, the FDA approved FoundationOne CDx panel testing, which includes 324 genes, for particular individuals with NSCLC, melanoma, breast cancer, colorectal cancer, or ovarian cancer. See FDA document here.[21] A list of cleared or approved companion diagnostic devices, including FoundationOne CDx can be found here.[22]

In 2016, the FDA approved Oncomine Dx Target Test for individuals with non-small cell lung cancer (NSCLC). "The Oncomine™ Dx Target Test is a qualitative in vitro diagnostic test that uses targeted high throughput, parallel-sequencing technology to detect single nucleotide variants (SNVs) and deletions in 23 genes from DNA and fusions in ROS1 from RNA isolated from formalin fixed, paraffin-embedded (FFPE) tumor tissue samples from patients with non-small cell lung cancer (NSCLC) using the Ion PGM™ Dx System."[23]

Criteria

This guideline applies to all molecular somatic mutation testing intended for use in solid tumors.

Medical necessity criteria differ based on the type of testing being performed (i.e., tests for individual genes separately chosen based on the cancer type, versus pre-defined panels of genes) and how that testing will be billed (one or more individual gene-specific procedure codes, specific panel procedure codes, or unlisted procedure codes).

Note **This guideline addresses molecular markers only. It is intended to address DNA and RNA markers that are detected by next generation sequencing technology and those that are present on NGS panels. It does not address microsatellite instability (MSI), immunohistochemistry (IHC), or other markers that may be detected through other methods such as FISH, chromosomal microarray, routine chromosome analysis, etc.**

Individual Tumor Markers

When separate procedure codes will be billed for individual tumor markers (e.g., Tier 1 MoPath codes 81200-81355 or Tier 2 MoPath codes 81400-81408), each individually billed tumor marker test will be evaluated separately for medical necessity. The following criteria will be applied:

The member has a tumor type that will benefit from information provided by the requested tumor marker test based on at least one of the following:

All criteria are met from a test-specific guideline if one is available, or

An oncology therapy FDA label requires results from the tumor marker test to effectively or safely use the therapy for the member's cancer type (See *Common cancer types and associated tumor markers* table below for examples of currently recognized companion diagnostics), or

NCCN guidelines include the tumor marker test in the management algorithm for that particular cancer type and all other requirements are met (specific pathology findings, staging, etc.); however, the tumor marker must be explicitly included in the guidelines and not simply included in a footnote as an intervention that may be considered (See *Common cancer types and associated tumor markers* table below for examples of currently recommended gene tests)

Note **If five or more individually billed tumor marker tests are under review together (a "panel") and the member either has non-small cell lung cancer, metastatic colorectal cancer, or stage IV cutaneous melanoma OR meets criteria for 5 or more individual tumor markers, the panel will be approved. However, the laboratory will be redirected to use a panel CPT code for billing purposes (e.g. 81445 or 81455).**

Companion Diagnostic (CDx) Tumor Marker Panels

Solid tumor marker companion diagnostic assay panels are considered medically necessary when the member meets ALL of the following criteria:

Member has a diagnosis of cancer, AND

Treatment with a medication for which there is an FDA-approved companion diagnostic assay is being considered, AND

FDA approval for the CDx being requested must include the member's specific cancer type as an approved indication, AND

FDA label for the drug and indication being considered states companion diagnostic testing is necessary for patient selection (See *Common cancer types and associated tumor markers* table below for examples of currently recognized companion diagnostics for available therapies), AND

Member has not had previous somatic and/or germline testing that would have identified the genetic change required to prescribe medication under consideration, AND

Family History:

Member does not have a close (1st or 2nd degree) biological relative with a known germline mutation in a gene that is a target of the requested companion

diagnostic test (e.g. known familial mutation in BRCA1/2 and requested test is myChoice CDx), or

Member has a close (1st or 2nd degree) biological relative with a known germline mutation in a gene that is a target of the requested companion diagnostic test (e.g. known familial mutation in BRCA1/2 and requested test is myChoice CDx), and the member's germline test was negative, AND

Rendering laboratory is a qualified provider of service per the Health Plan policy.

Tumor Marker Panels

When a multi-gene panel is being requested and will be billed with a single panel CPT code (e.g. 81445 or 81455), the panel will be considered medically necessary when the following criteria are met:

The member has a diagnosis of one of the following cancers:

Locally advanced or metastatic ampullary adenocarcinoma

Metastatic colorectal cancer

Stage IV cutaneous melanoma

Non-small cell lung cancer

Locally advanced, metastatic, or recurrent pancreatic cancer

Recurrent or relapsed epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer

Recurrent, unresectable, or metastatic salivary gland tumors, OR

The member has a diagnosis of one of the following cancers, when the panel includes at least five of the genes associated with that cancer type listed in the below table *Common cancer types and associated tumor markers*:

Gastrointestinal Stromal Tumor (GIST)

Adult low-grade (WHO Grade 1 or 2) glioma

Anaplastic gliomas/glioblastoma

Malignant peripheral nerve sheath tumor

Regional or metastatic prostate cancer

Metastatic urothelial bladder cancer that has progressed following at least one line of prior platinum-containing chemotherapy

Metastatic or unresectable uveal melanoma that has progressed following all available treatments, OR

The member does not have one of the cancers listed in the section above, but at least 5 tumor markers included in the panel individually meet criteria for the member’s tumor type based on one of the following:

All criteria are met from a test-specific guideline if one is available, or

NCCN guidelines include the tumor marker test in the management algorithm for that particular cancer type and all other requirements are met (specific pathology findings, staging, etc.); however, the tumor marker must be explicitly included in the guidelines and not simply included in a footnote as an intervention that may be considered.

Note **If the member meets criteria for less than 5 of the individual tumor markers in the panel, the panel will not be reimbursed. The laboratory will be redirected to billing for individual tests for which the member meets criteria.**

Billing and Reimbursement Considerations

Multigene panels, when medically necessary, will only be considered for reimbursement when billed with an appropriate panel CPT code.

Only one tumor biomarker panel will be considered for reimbursement per occurrence of cancer.

If multiple CDx biomarker panels are ordered simultaneously based on FDA label requirements, only one panel will be considered for reimbursement. Additional unique biomarkers from the second panel may be considered for reimbursement if appropriate single marker or single gene procedure codes are billed.

If a biomarker panel was previously performed and an additional panel is being requested, only testing for the medically necessary, previously untested biomarkers will be reimbursable. Therefore, only the most appropriate procedure codes will be considered for reimbursement.

Other Considerations

For information on somatic mutation testing for hematological malignancies, please refer to the guideline *Somatic Mutation Testing - Hematological Malignancies*, as this testing is not addressed here.

For information on tumors markers assayed by liquid biopsy, please refer to the guideline *Liquid Biopsy Testing*, as this testing is not addressed here.

For information on testing for germline (inherited) mutations in genes related to hereditary cancer syndromes (e.g. Hereditary Breast and Ovarian Cancer, Lynch syndrome, etc), please refer to the appropriate test-specific guideline, as this testing is not addressed here. Although some of the same genes may be tested for inherited or acquired (somatic) mutations, this guideline addresses only testing for acquired mutations from hematological malignancies

Common Cancer Types and Associated Tumor Markers

This list not all inclusive.

Common Cancer Types and Associated Tumor Markers

Cancer Type	Tumor Marker	CPT	Indication for Test	Associated Treatments**
Colorectal (Metastatic, stage IV. Prognostic purposes only.)	BRAF variants	81210	Prognostic	N/A
Colorectal (Metastatic)	KRAS	81275, 81276	Pharmacogenomics	cetuximab[10], panitumumab[10]
Colorectal (Metastatic)	NRAS	81311	Pharmacogenomics	cetuximab[10], panitumumab[10]
Gastrointestinal Stromal Tumor (GIST)	BRAF sequencing	81406	Diagnostic, Predictive	N/A
Gastrointestinal Stromal Tumor (GIST)	KIT	81272	Diagnostic, Predictive	N/A
Gastrointestinal Stromal Tumor (GIST)	NF1	81408	Diagnostic	N/A
Gastrointestinal Stromal Tumor (GIST)	NTRK 1/2/3 (fusion)	81194	Diagnostic, Predictive	N/A
Gastrointestinal Stromal Tumor (GIST)	PDGFRA	81314	Diagnostic, Predictive	N/A
Gastrointestinal Stromal Tumor (GIST)	SDHB	81405	Diagnostic, Predictive	N/A
Glioma (Adult Low-Grade (WHO Grade 1 or 2))	ATRX	81479	Diagnostic	N/A
Glioma (Adult Low-Grade (WHO Grade 1 or 2))	BRAF variants	81210	Diagnostic	N/A

Cancer Type	Tumor Marker	CPT	Indication for Test	Associated Treatments**
Glioma (Adult Low-Grade (WHO Grade 1 or 2))	H3F3A	81479	Diagnostic	N/A
Glioma (Adult Low-Grade (WHO Grade 1 or 2))	HIST1H3B	81479	Diagnostic	N/A
Glioma (Adult Low-Grade (WHO Grade 1 or 2))	IDH1/2	81120, 81121	Diagnostic, Predictive, Prognostic	N/A
Glioma (Adult Low-Grade (WHO Grade 1 or 2))	NTRK1/2/3 (fusion)	81194	Pharmacogenomics	Larotrectinib sulfate[24]
Glioma (Adult Low-Grade (WHO Grade 1 or 2))	TERT (promoter)	81345	Diagnostic	N/A
Anaplastic Glioma/Glioblastoma	ATRX	81479	Diagnostic	N/A
Anaplastic Glioma/Glioblastoma	BRAF variants	81210	Diagnostic	N/A
Anaplastic Glioma/Glioblastoma	H3F3A	81479	Diagnostic	N/A
Anaplastic Glioma/Glioblastoma	HIST1H3B	81479	Diagnostic	N/A
Anaplastic Glioma/Glioblastoma	IDH1/2	81120, 81121	Diagnostic, Predictive, Prognostic	N/A
Anaplastic Glioma/Glioblastoma	MGMT promoter methylation	81287	Predictive, Prognostic	N/A
Anaplastic Glioma/Glioblastoma	NTRK1/2/3 (fusion)	81194	Pharmacogenomics	Larotrectinib sulfate[24]

Cancer Type	Tumor Marker	CPT	Indication for Test	Associated Treatments**
Anaplastic Glioma/Glioblastoma	TERT (promoter)	81345	Diagnostic	N/A
Melanoma (Metastatic)	BRAF variants	81210	Pharmacogenomics	vemurafenib[11], dabrafenib[11], trametinib/dabrafenib[11], vemurafenib/cobimetinib[11]
Non-small cell lung	EGFR	81235	Pharmacogenomics	erlotinib[2], afatinib[2], dacomitinib[2], gefitinib[2], osimertinib[2] (T790M)
Non-small cell lung	ALK/NPM1 fusion	81401	Pharmacogenomics	crizotinib[2], ceritinib[2], alectinib[2]
Non-small cell lung	ALK other fusions	81479	Pharmacogenomics	crizotinib[2], ceritinib[2], alectinib[2]
Peripheral Nerve Sheath Tumor (Malignant)	CDKN2A	81404	Diagnostic	N/A
Peripheral Nerve Sheath Tumor (Malignant)	EED	81479	Diagnostic	N/A
Peripheral Nerve Sheath Tumor (Malignant)	NF1	81408	Diagnostic	N/A
Peripheral Nerve Sheath Tumor (Malignant)	NTRK1/2/3 (fusion)	81194	Diagnostic	N/A
Peripheral Nerve Sheath Tumor (Malignant)	SUZ12	81479	Diagnostic	N/A
Prostate (Metastatic)	ATM	81408	Treatment Guidance	N/A
Prostate (Metastatic)	BRCA1/2	81162	Treatment Guidance	N/A
Prostate (Metastatic)	CDK12	81479	Treatment Guidance	N/A

Cancer Type	Tumor Marker	CPT	Indication for Test	Associated Treatments**
Prostate (Metastatic)	CHEK2	81479	Treatment Guidance	N/A
Prostate (Metastatic)	FANCA	81479	Treatment Guidance	N/A
Prostate (Metastatic)	PALB2	81307	Treatment Guidance	N/A
Urothelial Bladder (Metastatic)	FGFR2	81479	Pharmacogenomics	Erdafitinib[25]
Urothelial Bladder (Metastatic)	FGFR3	81479	Pharmacogenomics	Erdafitinib[25]
Urothelial Bladder (Metastatic)	NTRK1/2/3 (fusion)	81194	Pharmacogenomics	Larotrectinib sulfate[24]
Uveal Melanoma (Metastatic and/or Unresectable)	BAP1	81479	Risk Stratification	N/A
Uveal Melanoma (Metastatic and/or Unresectable)	EIF1AX	81479	Risk Stratification	N/A
Uveal Melanoma (Metastatic and/or Unresectable)	NTRK1/2/3 (fusion)	81194	Pharmacogenomics	Larotrectinib sulfate[24]
Uveal Melanoma (Metastatic and/or Unresectable)	PRAME	81401	Risk Stratification	N/A
Uveal Melanoma (Metastatic and/or Unresectable)	SF3B1	81347	Risk Stratification	N/A

Note **** In general, when there is an associated treatment, results from the referenced tumor marker are necessary for the safe or effective use of that therapy (companion diagnostics). The therapies and tumor markers are only included for cancer types approved for treatment according to FDA labeling.**

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