Molecular Profiling (Somatic Testing) Panels for Solid Cancer Tumors and Hematologic Malignancies

Policy Number: PG0438
Last Review: 05/02/2023

PARAMOUNT

HMO & PPO
MARKETPLACE
MEDICARE – ELITE, MAP

GUIDELINES

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE

X Professional
X Facility

DESCRIPTION

Clinical laboratory diagnostic tests can include tests that predict the risk associated with one or more genetic variations within a cancer or tumor (i.e. somatic mutations). Somatic mutation testing may be used to diagnose and subtype cancer, predict prognosis, make therapeutic decisions, and monitor disease progression. In addition, *in vitro* companion diagnostic laboratory tests provide a report of test results of genetic variations that are essential for the safe and effective use of a corresponding therapeutic product.

Somatic testing (molecular profiling) 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). Patients with advanced cancer can have recurrent, metastatic, and/or stage IV disease. Some genetic variations (companion diagnostics) in a patient's cancer can, in concert with clinical factors, predict how each individual responds to specific treatments. In these cases, National Comprehensive Cancer Network (NCCN) as well as the Food and Drug Administration (FDA) have outlined tumor testing that is recommended for specific cancers and the associated treatment implications. In application, molecular profiling panels test that measure changes in DNA, RNA, or chromosomes found in tumor tissue can contribute to predicting a patient's response to a given drug: good, bad, or none at all. Applications of molecular profiling panels to predict a patient's response to treatment occurs ideally prior to initiation of the drug.

Next Generation Sequencing (NGS) is one technique that can detect genetic variations within a cancer or tumor. Other techniques that could be utilized include (but are not limited to): Sanger sequencing, multiplex ligation-dependent probe amplification (MLPA), quantitative real-time PCR (polymerase chain reaction), allele specific PCR, and fluorescence in situ hybridization (FISH).

The specific methodology used to identify somatic mutations is dependent upon the type of mutation being investigated. Additionally, with the efficiency of next generation sequencing (NGS) of DNA and RNA has led to an increasing number of large, multi-gene somatic mutation panels.
Examples of FDA approved companion diagnostic tests for use include (but are not limited to) the following:

- FoundationOne®CDx test (F1CDx)

    - Manufacturer: Foundation Medicine
    - Tumor Type: Solid
    - Technology: NGS
- Oncomine DX Target Test
    - Manufacturer: Thermo Fisher Scientific
    - Tumor Type: Non-small cell lung cancer
    - Technology: NGS

An up-to-date listing of FDA Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) can be found here: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

POLICY

Paramount Commercial Plans, Medicare Advantage Plans and Paramount Medicaid Advantage

- **Refer to medical policy Genetic Testing, PG0041 for specific procedure-to-product line coverage determination.**
- **When the procedure code is covered, for a specific Molecular Profiling (Somatic Testing) Panel a prior authorization is required.**

If the servicing laboratory selects to use multiple CPT codes (i.e. unbundled or stacked version) for billing purposes, and the medical necessity criteria are met below for a panel, the laboratory will be strongly encouraged to use an applicable panel CPT code.

COVERAGE CRITERIA

Paramount Commercial Plans, Medicare Advantage Plans and Paramount Medicaid Advantage

Genomic profiling (somatic testing) of a **solid tumor for advanced cancer** is considered medically necessary when the following criteria are met:

1. The test is performed in a CLIA-certified laboratory and is ordered by a treating physician

2. Patient has:
   a. either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and
   b. either not been previously tested using the same test for the same primary diagnosis of cancer or repeat testing using the same test only when a new primary cancer diagnosis is made by the treating physician; and
   c. decided to seek further cancer treatment (e.g., therapeutic chemotherapy).

3. The diagnostic laboratory test must have:
   a. the results of testing will directly impact clinical decision making; and
   b. identification of the specific biomarker has been demonstrated in published peer-reviewed literature to improve diagnosis, management or clinical outcomes for the individual's condition being addressed; and
   c. FDA approval or clearance as a companion in vitro diagnostic; and
   d. an FDA approved or cleared indication for use in that patient's cancer; and
   e. results provided to the treating physician for management of the patient using a report template to specify treatment options.
   OR
   f. the test has satisfactorily completed a TA by MolDX for the stated indications of the test; and
   g. the assay performed includes at least the minimum genes and genomic positions required for the identification of all FDA-approved therapies with a companion diagnostic biomarker for its intended use that can be reasonably detected by the test. Because these genes and variants will change as the literature and drug indications evolve, they are listed separately in an associated Coverage Article, as well as in the MolDX TA forms.

Hematological Cancer

Molecular profiling using Chromosomal Microarray analysis (e.g., Oncoscan, Reveal SNP-Oncology, CGH or SNP

array) is proven and medically necessary for individuals with acute leukemia.

Use of a Next Generation Sequencing profile test to assess minimal residual disease (e.g., ClonoSeq) is proven and medically necessary when the following criteria are met:

- Individual has acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL) and testing is being performed within 3 months of completing a course of therapy and there is no clinical evidence of disease; or
- Individual has multiple myeloma and testing is being performed within three months of an allogenic or autologous bone marrow transplant; and there is no clinical evidence of disease

The following must be present for coverage eligibility:

- For tests that are specifically indicated in patients whom are known to have a myeloid malignancy at the time of testing, NCD 90.2 applies.
- The patient has a diagnosis of AML, MDS, or MPN. AML, MDS, and MPN are herein classified as refractory and/or metastatic cancers and fulfil the NCD 90.2 criteria.
- The test has satisfactorily completed a TA by MolDX® for the stated indications of the test.
- The assay performed includes *at least* the minimum genes and positions indicated for its intended use, as described in an associated coverage Article or found in the TA forms.
- For patients that do not have a diagnosis of a myeloid malignancy, where one is suspected, the patient must have an undefined cytopenia for greater than 4 months, other possible causes have been reasonably excluded.
- Testing is performed on bone marrow biopsies, bone marrow aspirates, bone marrow clots, peripheral blood samples, or extramedullary sites suspected of harboring a myeloid malignancy.

Situations in which Test should not be used or coverage is denied:

The test in question will be non-covered if:

- A TA has not been satisfactorily completed by MolDX®. For tests that are currently covered but a TA submission has not been made, providers must submit completed TA materials by February 10th, 2020 or coverage will be denied.
- Another NGS test was performed on the same surgical specimen/ blood draw (specimen obtained on the same date of service).
- Testing falls within scope of NCD 90.2 and has been tested with the same test for the same genetic content.

Paramount Related/Referenced Policies, listing may not be all-inclusive:

- Medical Policy - Genetic Testing, PG0041
- Medical Policy - Gene Expression Profiling of Melanomas, PG0119
- Medical Policy - Comparative Genomic Hybridization (CGH)/Chromosomal Microarray Analysis (CMA), PG0296
- Medical Policy - Molecular Markers in Fine Needle Aspirates of Thyroid Nodules, PG0298
- Medical Policy - Genetic Expression Assays for Breast Cancer Prognosis, PG0301
- Medical Policy - Gene Expression Profiling for Colorectal Cancer, PG0357
- Medical Policy - Gene Expression Profiling for Cancers of Unknown Primary Site, PG0364
- Medical Policy - Genetic and Protein Biomarkers for Diagnosis and Risk Assessment of Prostate Cancer, PG0367
- Medical Policy - Germline Multi-Gene Panel Testing, PG0453
- Medical Policy - Whole Exome Sequencing (WES) and Whole Genome Sequencing (WGS), PG0468
- Medical Policy - Liquid Biopsy, PG0500
- **https://www.paramounthealthcare.com/services/providers/prior-authorization-criteria/**
- **https://www.paramounthealthcare.com/services/providers/prior-authorization-criteria/specialty-drug-prior-authorization-criteria-library**
  https://www.paramounthealthcare.com/medicare/2021/current-members/prior-authorization

CODING/BILLING INFORMATION

The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only. Not an all-inclusive listing

Codes that are covered may have selection criteria that must be met.

CPT CODES	
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., bacterial artificial chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81277	Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-of-heterozygosity variants for chromosomal abnormalities
81425	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis
81426	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (e.g., parents, siblings) (List separately in addition to code for primary procedure)
81427	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (e.g., updated knowledge or unrelated condition/syndrome)
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),
81449	Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZHA, FLT3, IHD1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed
81451	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81456	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis
81479	Unlisted molecular pathology procedure
81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy
81519	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalinfixed paraffin embedded tissue, algorithm reported as recurrence score

81520	Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score
81521	Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis
81522	Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score
81525	Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score
81529	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis
81540	Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalinfixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype
81541	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a diseasespecific mortality risk score
81542	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalinfixed paraffin-embedded tissue, algorithm reported as metastasis risk score
81545	Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)
81546	Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (e.g., benign or suspicious)
81551	Oncology (prostate), promoter methylation profiling by real-time PCR of 3 genes (GSTP1, APC, RASSF1), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a likelihood of prostate cancer detection on repeat biopsy
81552	Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
86152	Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood);
86153	Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); physician interpretation and report, when required
81599	Unlisted multianalyte assay with algorithmic analysis
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score
0013U	Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)
0014U	Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome nextgeneration sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)
0018U	Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy
0019U	Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents
0021U	Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTRRopporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score

0022U	Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider
0026U	Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result (“Positive, high probability of malignancy” or “Negative, low probability of malignancy”)
0036U	Exome (i.e., somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses
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
0045U	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score
0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score
0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancerassociated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)
0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements
0056U	Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)
0069U	Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffinembedded tissue, algorithm reported as an expression score
0089U	Oncology (melanoma) gene expression profiling by RTqPCR PRAME and LINC00518, superficial collection using adhesive patch(es)
0090U	Oncology (cutaneous melanoma) mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, malignant)
0091U	Oncology (colorectal) screening, cell enumeration of circulating tumor cells, utilizing whole blood, algorithm, for the presence of adenoma or cancer, reported as a positive or negative result
0113U	Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as risk score
0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome nextgeneration sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cellfree DNA
0153U	Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement
0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence
0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)
0204U	Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including BRAF, RAS, RET, PAX8, and NTRK) for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected
0208U	Oncology (medullary thyroid carcinoma), mRNA, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma

0211U	Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffinembedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association
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
0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements
0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for singlenucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumormutational burden and microsatellite instability, utilizing formalin-fixed paraffin-embedded tumor tissue
0245U	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage
0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden
0262U	Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways (ER, AR, PI3K, MAPK, HH, TGFB, Notch), formalin-fixed paraffin-embedded (FFPE), algorithm reported as gene pathway activity score
0329U	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations
0334U	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
0364U	Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate
0379U	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by next generation sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden
0391U	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splicesite variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score [Effective 07/01/2023]

REVISION HISTORY EXPLANATION
ORIGINAL EFFECTIVE DATE: 05/24/2018

Date	Explanation & Changes
05/24/18	• Effective 03/16/18 Next Generation Sequencing (NGS) tests for advanced cancer [i.e., FoundationOne CDx™ (F1CDx) [0037U], Oncomine™ Dx Target Test (81455)] may be covered with prior authorization for Elite per CMS guidelines • Next Generation Sequencing (NGS) tests for advanced cancer are non-covered for HMO, PPO, Individual Marketplace & Advantage • Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)

09/27/18	• Added code 0022U as covered with prior authorization for Elite per CMS guidelines and non-covered for HMO, PPO, Individual Marketplace & Advantage • Code 81445 should be billed for Oncomine™ Dx Target Test for DOS 06/22/2017-09/30/2017 • Code 0022U should be billed for Oncomine™ Dx Target Test for DOS after 10/01/2017 • Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
8/14/19	• Policy name changed/updated from NGS for Advanced Cancer to Molecular Profiling (Somatic Testing) Panels for Cancer • Policy reviewed and updated to reflect the most current clinical evidence per National Comprehensive Cancer Network®. Molecular profiling for advanced colorectal, breast, ovarian, melanoma, and non-small cell cancer when criteria are met is now covered for HMO, PPO, Individual Marketplace and Advantage • Criteria were added for InvisionFirst™, Guardant360®, and molecular profiling related to AML
12/28/2020	• Medical policy placed on the new Paramount Medical policy format
11/08/2021	• Policy updated to reflect most current clinical evidence • Changed title name from Molecular Profiling (Somatic testing) Panels for Cancer to Molecular Profiling (Somatic Testing) Panels for Solid Cancer Tumors and Hematologic Malignancies • This policy applies to all molecular profiling for use in solid tumors and hematologic malignancies • This policy does not apply to molecular profiling found by liquid biopsy
03/02/2022	• Updated coverage for procedure codes 0005U, 0037U, 0047U, 0179U, 0239U, 0242U, 0244U
08/08/2022	• Added procedure 0329U, new code effective 7/1/2022, non-covered, all product lines • Added procedure 0334U, new code effective 7/1/2022, prior authorization required, all product lines
01/23/2023	• Paramount added new 2023 procedure codes 0364U and 0379U – non-Covered, effective 01/01/2023 • Paramount added new 2023 procedure codes 81449, 81451 and 81456 – requiring a prior authorization, effective 01/01/2023
03/03/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
05/02/2023	• Added new 2023 procedure code 0391U, effective 07/01/2023 – non-covered for Paramount Commercial Insurance Plans and covered with a prior authorization for Medicare Advantage Plans
05/25/2023	• Clarified the allowed coverage, specific to the genetic procedure code o Refer to medical policy Genetic Testing, PG0041 for specific procedure-to-product line coverage determination. o When the procedure code is covered, for a specific Molecular Profiling (Somatic Testing) Panel a prior authorization is required.

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/services/providers/medical-policies/ .

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Ohio Department of Medicaid

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets

U.S. Preventive Services Task Force, http://www.uspreventiveservicestaskforce.org/
Industry Standard Review

Hayes, Inc.

Industry Standard Review

U.S. Food & Drug Administration, List of Cleared or Approved Diagnostic Devices (In Vitro and Imaging Tools) National Comprehensive Cancer Network® (NCCN) Guidelines, Acute Myeloid Leukemia, Version 3.2019.