Pharmacogenomics and Companion Diagnostics

Humana®

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Medical Coverage Policy

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Description

Pharmacogenomics and companion diagnostics tests are laboratory studies that use an individual's unique genetic makeup to help determine response to a specific medication. Companion diagnostics differ from pharmacogenomics testing because they are co-developed with a specific drug to help evaluate response or nonresponse to the drug. Companion diagnostics are often approved by the US Food & Drug Administration (FDA) corresponding with a specific pharmacotherapy. Both types of tests are used to guide management for cancers (eg, non-small cell lung cancer [NSCLC], breast, colorectal cancer [CRC]) and in noncancer indications.

Multigene (or expanded) panels analyze a broad set of genes simultaneously (as opposed to single gene testing that searches for variants in one specific gene) and have been proposed to evaluate the DNA of an individual with a personal and/or family history of more than one hereditary condition or syndrome. Panels often include medically actionable genes but may also include those with unclear medical management.

Coverage Determination

Any state mandates for pharmacogenomics and companion diagnostics testing take precedence over this medical coverage policy.

Genetic testing may be excluded by certificate. Please consult the member's individual certificate regarding plan coverage.

Apply General Criteria for Genetic and Pharmacogenomics Tests when disease- or gene-specific criteria are not available on a medical coverage policy. For information regarding General Criteria for Genetic and Pharmacogenomics Tests, please refer to Genetic Testing Medical Coverage Policy.

Adeno-Associated Virus Serotype 5 (AAV5) Antibody Testing

Humana members may be eligible under the Plan for **AAV5 antibody testing (eg, AAV5 DetectCDx)** when the following criteria are met:

- Individual diagnosed with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity less than 1 IU/dL); **AND**
- Testing performed using an FDA-approved test **(AAV5 DetectCDx)** prior to initiation of treatment with valoctocogene roxaparvovec-rvox (Roctavian)

***ALK* Mutation Testing**

Humana members may be eligible under the Plan for ***ALK* mutation testing (eg, VENTANA *ALK* [D5F3] CDx Assay)** when the following criteria are met:

- Individual diagnosed with advanced, recurrent or metastatic NSCLC; **AND**
- Testing performed prior to initiation of treatment with alectinib (Alecensa), brigatinib (Alunbrig), ceritinib (Zykadia), crizotinib (Xalkori) or lorlatinib (Lorbrena)

***BRCA* COMPANION DIAGNOSTIC TEST**

Humana members may be eligible under the Plan for ***BRCA* companion diagnostic testing (eg, BRACAnalysis CDx)** when the following criteria are met:

Breast Cancer

- Individual diagnosed with locally advanced or metastatic *HER2*-negative breast cancer; **AND**
  - Testing performed prior to initiation of treatment with talazoparib (Talzenna); **OR**
- Individual diagnosed with high-risk early onset, recurrent or metastatic *HER2*-negative breast cancer; **AND**
  - Treated with prior chemotherapy and/or endocrine therapy; **AND**

- Testing performed using an FDA-approved test **(BRACAnalysis CDx)** prior to initiation of treatment with olaparib (Lynparza)

Ovarian, Fallopian Tube or Primary Peritoneal Cancer

- Individual diagnosed with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer; **AND**
- Individual in a complete or partial response to platinum-based chemotherapy; **AND**
  - Testing performed using an FDA-approved test prior to initiation of maintenance treatment with olaparib (Lynparza); **OR**
  - Testing performed prior to initiation of maintenance treatment with rucaparib (Rubraca)

Pancreatic Cancer

- Individual diagnosed with metastatic pancreatic cancer; **AND**
- Treated with first-line platinum-based chemotherapy regimen for at least 16 weeks without cancer progression; **AND**
- Testing performed prior to initiation of treatment with olaparib (Lynparza)

For information regarding **germline *BRCA1* and *BRCA2* susceptibility testing for breast, ovarian and pancreatic cancer**, please refer to Genetic Testing for Heredtiary Breast, Ovarian, Pancreatic and Prostate Cancer Medical Coverage Policy.

***EZH2* Mutation Test**

Humana members may be eligible under the plan for ***EZH2* mutation testing (81236, 81237)** using an FDA-approved test **(cobas *EZH2* Mutation Test)** to predict benefit from tazemetostat (Tazverik) for an individual diagnosed with follicular lymphoma.

***FGFR* MUTATION TEST**

Humana members may be eligible under the Plan for ***FGFR* mutation testing (eg, therascreen *FGFR [0154U]*) *(FGFR2* and *FGFR3* genes)** when the following criteria are met:

Cholangiocarcinoma

- Individual diagnosed with unresectable locally advanced or metastatic cholangiocarcinoma, received prior treatment; **AND**
- Testing performed using an FDA-approved test **(FoundationOne CDx [0037U])** prior to initiation of treatment with infigratinib (Truseltiq) or pemigatinib (Pemazyre)

Intrahepatic Cholangiocarcinoma

- Individual diagnosed with unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma and has received prior treatment; **AND**

- Testing performed prior to initiation of treatment with futibatinib (Lytgobi)

Urothelial Cancer

- Individual diagnosed with advanced or metastatic urothelial cancer that has progressed on at least 1 line of prior platinum-containing chemotherapy; **AND**

- Testing performed prior to initiation of treatment with erdafitinib (Balversa)

Folate Receptor Alpha Test

Humana members may be eligible under the Plan for **Folate Receptor Alpha (FRα) testing (eg, Ventana FOLR1)** when the following criteria are met:

- Individual diagnosed with platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer; **AND**

- Individual has received at least 1 to 3 prior systemic treatment regimens; **AND**

- Testing performed prior to initiation of treatment with mirvetuximab soravtansine-gynx (Elahere)

Homologous Recombination Deficiency (HRD) Test

Humana members may be eligible under the Plan for **HRD testing** when the following criteria are met:

- Testing performed using an FDA-approved test **(MyChoice CDx [0172U])** for the management of advanced, persistent or recurrent platinum sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer; **AND**

- Prior to the initiation of combination treatment with bevacizumab (Avastin) and olaparib (Lynparza)

Human Leukocyte Antigens (*HLA*) Allele Testing

Humana members may be eligible under the Plan for ***HLA-A* typing** when the following criteria are met[110,138,150,187,219]:

- 18 years of age or older; **AND**
- Individual diagnosed with unresectable or metastatic synovial sarcoma; **AND**
- Testing performed prior to initiation of treatment with afamitresgene autoleucel (Tecelra)

Humana members may be eligible under the Plan for ***HLA-A* 02:01** testing when the following criteria are met:

- Individual diagnosed with unresectable or metastatic uveal melanoma; **AND**
- Testing performed prior to initiation of treatment with tebentafusp-tebn (Kimmtrak)

MAGE-A4 IHC Testing

Humana members may be eligible under the Plan for **MAGE-A4 IHC testing** when the following criteria are met[138,187,198,219]:

- 18 years of age or older; **AND**
- Individual diagnosed with unresectable or metastatic synovial sarcoma; **AND**
- Testing performed prior to initiation of treatment with afamitresgene autoleucel (Tecelra)

***MET* Gene Test**

Humana members may be eligible under the Plan for ***MET* gene testing** when the following criteria are met:

- Individual diagnosed with metastatic NSCLC; **AND**
- Testing performed prior to initiation of treatment with capmatinib (Tabrecta) or tepotinib (Tepmetko)

Microsatellite Instability and/or Mismatch Repair Testing

Humana members may be eligible under the Plan for **microsatellite instability (MSI)** and/or **mismatch repair deficient/ proficient testing (dMMR/pMMR)** when the following criteria are met:

- Individual diagnosed with an unresectable or metastatic solid tumor***** that has progressed on prior therapy with no alternatives; **AND**

- Testing performed prior to initiation of treatment with dostarlimab-gxly (Jemperli); **OR**

- Testing performed prior to initiation of treatment with pembrolizumab (Keytruda), excluding pediatric patients with central nervous system cancers

For information regarding coverage determination/limitations for **MSI/MMR testing in Lynch syndrome**, please refer to Genetic Testing for Hereditary Colorectal and Uterine Cancer Medical Coverage Policy.

***NTRK* Test**

Humana members may be eligible under the Plan for ***NTRK1*, *NTRK2* and *NTRK3* gene testing (81191-81194)** when the following criteria are met:

- Individual diagnosed with a solid tumor that is either:

  - Advanced or metastatic; **OR**
  - Not a candidate for surgical resection; **AND**

- No alternative systemic therapy options; **AND**
- Testing performed prior to initiation of treatment with entrectinib (Rozlytrek) or larotrectinib (Vitrakvi)

***PD-L1* TESTING**

Humana members may be eligible under the Plan for ***PD-L1* testing** when the following criteria are met:

Breast Cancer

- Individual diagnosed with locally recurrent unresectable or metastatic triple negative breast cancer; **AND**

- Testing performed using an FDA-approved test **(PD-L1 IHC 22C3 pharmDx)** prior to initiation of treatment with pembrolizumab (Keytruda)

Cervical Cancer

- Individual diagnosed with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy; **AND**

- Testing performed using an FDA-approved test **(PD-L1 IHC 22C3 pharmDx)** prior to initiation of treatment with pembrolizumab (Keytruda)

Esophageal Cancer

- Individual diagnosed with locally advanced or metastatic squamous cell carcinoma of the esophagus; **AND**

- Testing performed using an FDA-approved test **(PD-L1 IHC 22C3 pharmDx)** prior to initiation of treatment with pembrolizumab (Keytruda)

Head and Neck

- Individual diagnosed with recurrent, unresectable or metastatic head and neck squamous cell carcinoma; **AND**

- Testing performed using an FDA-approved test **(PD-L1 IHC 22C3 pharmDx)** prior to initiation of treatment with pembrolizumab (Keytruda)

NSCLC

- Individual diagnosed with NSCLC; **AND**

    - Individual is post complete surgical resection and adjuvant platinum-based chemotherapy; **AND**

    - Testing performed using an FDA-approved test **(VENTANA PD-L1 Assay)** prior to initiation of **adjuvant** treatment with atezolizumab (Tecentriq); **OR**

- Individual diagnosed with advanced or metastatic NSCLC; **AND** any of the following:

- Testing performed using an FDA-approved test **(PD-L1 IHC 22C3 pharmDx)** prior to initiation of treatment with cemiplimab-rwlc (Libtayo) or pembrolizumab (Keytruda); **OR**

- Testing performed using an FDA-approved test **(PD-L1 IHC 28-8 pharmDx)** prior to initiation of treatment with ipilimumab (Yervoy)and nivolumab (Opdivo); **OR**

- Testing performed using an FDA-approved test **(VENTANA PD-L1 Assay)** prior to initiation of treatment with atezolizumab (Tecentriq)

PIK3CA Gene Test

Humana members may be eligible under the Plan for ***PIK3CA* gene testing** when the following criteria are met:

- Individual diagnosed with metastatic breast cancer or breast cancer that has advanced on or after endocrine-based therapy; **AND**

- *HR*-positive and *HER2*-negative breast cancer; **AND**

- Testing performed using an FDA-approved test **(Therascreen *PIK3CA* RGQ PCR Kit [0155U])** prior to initiation of treatment with alpelisib (Piqray) and fulvestrant (Faslodex)

PIK3CA/AKTI/PTEN Testing

Humana members may be eligible under the Plan for ***PIK3CA/AKTI/PTEN* testing** when the following criteria are met:

- Individual diagnosed with *HR*-positive, *HER2*-negative breast cancer that is locally advanced or metastatic; **AND**

- Individual has progressed on at least one prior endocrine-based therapy and has been treated in the metastatic setting or reoccurred within 12 months of completing adjuvant therapy; **AND**

- Testing performed using an FDA-approved test **(FoundationOne CDx [0037U])** prior to initiation of treatment with capivasertib (Truqap)

RAS MUTATION ASSAY

Humana members may be eligible under the Plan for ***RAS* (*KRAS* and *NRAS*) mutation assay (eg, cobas KRAS Mutation Test)** when the following criteria are met:

Colon Cancer

- Individual diagnosed with CRC; **AND**
- Testing performed prior to the initiation of anti-*EGFR* antibody therapies cetuximab (Erbitux) or panitumumab (Vectibix)

NSCLC

- Individual diagnosed with advanced or metastatic NSCLC; **AND**
- Disease progression on prior therapy; **AND**
- Testing performed prior to initiation of treatment with adagrasib (Krazati) or sotorasib (Lumakras)

***RET* Mutation Assay**

Humana members may be eligible under the Plan for ***RET* mutation assay** when the following criteria are met:

- Individual diagnosed with metastatic NSCLC; **AND**
    - Testing performed prior to the initiation of treatment with pralsetinib (Gavreto) or selpercatinib (Retevmo); **OR**
- Individual diagnosed with advanced or metastatic solid tumors that progressed on prior systemic treatment or has no satisfactory alternative treatment options; **AND**
    - Testing performed prior to the initiation of treatment with selpercatinib (Retevmo)

***ROS1* Proto-Oncogene Receptor Tyrosine Kinase Rearrangements**

Humana members may be eligible under the Plan for ***ROS1* proto-oncogene receptor tyrosine kinase rearrangement testing** when the following criteria are met:

- Individual diagnosed with locally advanced, recurrent or metastatic NSCLC; **AND**
- Testing performed prior to initiation of treatment with crizotinib (Xalkori), entrectinib (Rozlytrek), lorlatinib (Lorbrena) or repotrectinib (Augtyro)

Tumor Mutation Burden Test

Humana members may be eligible under the Plan for **tumor mutation burden (TMB) testing** when the following criteria are met:

- Individual diagnosed with metastatic or unresectable solid tumor (excluding pediatric individuals with central nervous system cancers) that has progressed on prior therapy with no alternatives; **AND**
- Testing performed prior to initiation of treatment with pembrolizumab (Keytruda)

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **pharmacogenomics and companion diagnostics testing** for any indications other than those listed above including, but may not be limited to:

- *BTK* gene analysis (eg, chronic lymphocytic leukemia [81233]); **OR**
- Diagnosis for which pharmacologic therapy is not indicated and the drug(s) under consideration are not indicated for the treatment of the individual's diagnosis; **OR**
- Dihydropyrimidine dehydrogenase (DPYD) (81232), TYMS (81346) gene testing (eg, TheraGuide 5-FU) to predict response to fluorouracil or capecitabine (Xeloda) chemotherapy (excluding DPYD testing in instances of signs and symptoms of severe toxicity); **OR**
- Diseases for which the individual is not currently seeking treatment; **OR**
- *ERCC1* genetic testing to predict benefit from adjuvant platinum-based chemotherapy (eg, carboplatin [Paraplatin], cisplatin [Platinol], oxaliplatin [Eloxatin]); **OR**
- Evaluation of DNA conformational structures in the immune cells to assess the likelihood of response to immune checkpoint inhibitor (ICI) therapy targeting PD-L1 (eg, Episwitch CiRT [0332U]); **OR**
- *FGFR2/FGFR3* testing for any indications other than those listed above; **OR**
- HRD testing for any indication other than those listed above; **OR**
- MET testing for any indication other than those listed above; **OR**
- Multigene panels unless **ALL** genes in the panel meet disease- or gene-specific criteria (refer to Coverage Determination section). Examples include, but may not be limited to:
    - Targeted genomic sequence analysis panel, of 5-50 genes for solid organ neoplasm (81445); **OR**
    - Targeted genomic sequence analysis panel of 51 or more genes for solid organ or hematolymphoid neoplasm (81455) (eg, Tempus xT [0473U]); **OR**
- *PIK3CA* gene testing for any indication other than those listed above; **OR**
- *PLCG2* gene analysis (eg, chronic lymphocytic leukemia [81320]); **OR**
- *RAS* mutation testing for any indication other than those listed above; **OR**
- Reverse phase protein array, a semiquantitative analysis of 32 phosphoproteins and protein analytes (eg, Theralink [0249U]); **OR**
- Targeted KRAS and NRAS gene analysis formalin-fixed paraffin-embedded tissue (eg, Praxis extended *RAS* panel [0111U])

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for the following **pharmacogenomics and companion diagnostics testing:**

- *UGT1A1* molecular assay to predict dosing of Camptosar (irinotecan) in the treatment of colorectal and lung cancers (81350)

This is considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **FoundationOne CDx (0037U)** for any indications other than those listed above. Humana considers FoundationOne CDx not medically necessary for assessing candidacy of an individual in other cancers since there is no proven advantage of the FoundationOne CDx gene panel over targeted gene testing or small targeted panels.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
81191	NTRK1 (neurotrophic receptor tyrosine kinase 1) (eg, solid tumors) translocation analysis	
81192	NTRK2 (neurotrophic receptor tyrosine kinase 2) (eg, solid tumors) translocation analysis	
81193	NTRK3 (neurotrophic receptor tyrosine kinase 3) (eg, solid tumors) translocation analysis	
81194	NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (eg, solid tumors) translocation analysis	
81232	DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism), gene analysis, common variant(s) (eg, *2A, *4, *5, *6)	**Not Covered if used to report any test outlined in Coverage Limitations section**
81233	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)	**Not Covered**

81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence	
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)	
81275	KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; variants in exon 2 (eg, codons 12 and 13)	**Not Covered if used to report any test outlined in Coverage Limitations section**
81276	KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)	**Not Covered if used to report any test outlined in Coverage Limitations Section**
81301	Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed	
81309	PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20)	
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)	**Not Covered**
81346	TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism), gene analysis, common variant(s) (eg, tandem repeat variant)	**Not Covered**
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, drug metabolism, hereditary unconjugated hyperbilirubinemia [Gilbert syndrome]) gene analysis, common variants (eg, *28, *36, *37)	**Not Covered**
81378	HLA Class I and II typing, high resolution (ie, alleles or allele groups), HLA-A, -B, -C, and -DRB1	
81379	HLA Class I typing, high resolution (ie, alleles or allele groups); complete (ie, HLA-A, -B, and -C)	
81380	HLA Class I typing, high resolution (ie, alleles or allele groups); one locus (eg, HLA-A, -B, or -C), each	

81381	HLA Class I typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, B*57:01P), each	
81400	MOLECULAR PATHOLOGY PROCEDURE LEVEL 1	**Not Covered if used to report any test outlined in Coverage Limitations section**
81401	MOLECULAR PATHOLOGY PROCEDURE LEVEL 2	
81403	MOLECULAR PATHOLOGY PROCEDURE LEVEL 4	
81404	MOLECULAR PATHOLOGY PROCEDURE LEVEL 5	
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	**Not Covered if used to report any test outlined in Coverage Limitations section**
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	**Not Covered if used to report any test outlined in Coverage Limitations section**
81479	Unlisted molecular pathology procedure	**Not Covered if used to report any test outlined in Coverage Limitations section**
84999	Unlisted chemistry procedure	**Not Covered if used to report any test outlined in Coverage Limitations section**
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)	
88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure	**Not Covered if used to report any test outlined in Coverage Limitations section**
88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody 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	
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	
0111U	Oncology (colon cancer), targeted KRAS (codons 12, 13, and 61) and NRAS (codons 12, 13, and 61) gene analysis utilizing formalin-fixed paraffin-embedded tissue	**Not Covered**
0154U	Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3) utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status	
0155U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y), utilizing formalin-fixed paraffin-embedded breast tumor tissue, reported as PIK3CA gene mutation status	
0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report	**Not Covered**
0332U	Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint–inhibitor therapy	**Not Covered**
0471U	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalin-fixed paraffin-embedded (FFPE), predictive, identification of detected mutations	**New Code Effective 07/01/2024**

0473U	Oncology (solid tumor), next-generation sequencing (NGS) of DNA from formalin-fixed paraffin-embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden	**Not Covered** **New Code Effective 07/01/2024**
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

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Change Summary

01/25/2024 Update, Coverage Change. Updated Coding Information.
02/29/2024 Update, Coverage Change.
06/27/2024 Updated Coding Information.
09/26/2024 Update, Coverage Change.