Genetic Testing: Molecular Profiling Assays for Cancer Management

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

Administrative Process

Prior authorization is required for molecular profiling assays for cancer management.

For genetic testing for predisposition to cancer, see the Genetic Testing for Cancer Predisposition policy.

For germline pharmacogenetic testing, see the Genetic Testing: Pharmacogenetics policy.

Coverage

Indications that are covered

Somatic genetic testing using single-gene analysis, microsatellite instability (MSI) analysis, mismatch repair (MMR) analysis, tumor karyotyping, and fluorescence in situ hybridization (FISH) for cancer management is covered when criteria 1 and 2 listed below are met:

1. The test is ordered by a board-certified pathologist; endocrinologist; geneticist; oncologist; hematologist; or advanced-practice nurse in endocrinology; genetics, oncology, or hematology who is not affiliated with the commercial testing laboratory, if applicable.
2. The test is expected to directly impact management of one of the following specific conditions:
   • Breast cancer (excluding ductal carcinoma in situ [DCIS] of the breast)
   • Colorectal cancer
   • Esophageal cancer
   • Ewing sarcoma
   • Gastrointestinal stromal tumor (GIST)
   • Glioblastoma multiforme
   • Lung cancer
   • Leukemias/Lymphomas
   • Melanoma
   • Thyroid Carcinoma
   • Other hematological malignancies, lymphoproliferative disorders, and myelodysplastic/myeloproliferative conditions

Somatic multiple-gene molecular profiling panels and gene expression classifiers using the specific assays listed below, if any, are covered when criteria 1 and 2 listed below are met and any additional condition-specific criteria listed below are also met:

1. The test is ordered by a board-certified pathologist; endocrinologist; geneticist; oncologist; hematologist; or advanced-practice nurse in endocrinology; genetics, oncology, or hematology who is not affiliated with the commercial testing laboratory, if applicable.
2. The test is expected to directly impact management of one of the following specific conditions:
   • Breast Cancer
     A. EndoPredict (Myriad Genetics) is covered once per histologically-distinct tumor when all of the following criteria are met for each tumor that will be tested:
        i. The tumor is estrogen receptor positive
        ii. The tumor is human epidermal growth factor receptor 2 (HER2) negative
        iii. Axillary lymph nodes are negative
        iv. The member is a candidate for adjuvant chemotherapy
        v. Test results will directly impact chemotherapy-related decisions
     B. MammaPrint 70-gene Breast Cancer Recurrence Assay (Agendia) is covered once per histologically-distinct tumor when all of the following criteria are met for each tumor that will be tested:
        i. The tumor is estrogen receptor positive
        ii. The tumor is human epidermal growth factor receptor 2 (HER2) negative
        iii. The tumor is between 0.5 cm and 2.0 cm in diameter
Indications that are not covered

Criteria 1-2 listed below are met:

1. Short tandem repeat (STR) analysis
2. Criteria 1-2 listed below are met:
   - The test will be performed on fresh frozen tumor tissue rather than on formalin-fixed, paraffin-embedded tumor tissue
   - The test results will directly impact chemotherapy-related decisions
   - The test will be used in the management of a member who has received a hematopoietic stem cell transplant, transfusion of donor lymphocytes, administration of immunomodulatory cytokines, or other cellular therapy or is planning to receive one of these therapies in the immediate future.
   - The member is a candidate for hormone therapy and adjuvant chemotherapy

C. Oncotype DX Breast (Genomic Health) is covered once per histologically-distinct tumor when all of the following criteria are met for each tumor that will be tested:
   - The tumor is estrogen receptor or progesterone receptor positive
   - The tumor is HER2 positive with a diameter no larger than 1cm
   - Axillary lymph nodes are negative or there are up to three positive axillary lymph nodes
   - There is no evidence of distant metastasis

v. There is no evidence of distant metastasis

v. The member is a candidate for hormone therapy and adjuvant chemotherapy

D. Covered DNA Specimen Provenance Assay (DSPA) (Strand Diagnostics) or any other assay that will not be used in direct clinical management.

E. Definitions who has established a direct patient care relationship with the member to be tested.

v. The test is ordered by a board-certified pathologist; geneticist; oncologist; hematologist; immunologist; or advanced-practice nurse in genetics, oncology, hematology, or immunology who is not affiliated with the commercial testing laboratory, if applicable.

2. The test is expected to directly impact management of a member who has received a hematopoietic stem cell transplantation, transfusion of donor lymphocytes, administration of immunomodulatory cytokines, or other cellular therapy or is planning to receive one of these therapies in the immediate future.

Indications that are not covered

1. Molecular profiling assays are not covered and are considered not medically necessary when test results will not directly impact the treatment or management of a condition or provide a unifying diagnosis for a previously unidentified condition because the testing is not expected to restore or maintain the member’s health, prevent deterioration of the member’s condition, nor prevent the reasonably likely onset of a health problem or detect an incipient problem.

2. The following services are not covered and are considered not medically necessary because they are not within the practice parameters of the general medical community:
   - Comparative analysis using short tandem repeat (STR) markers, using the know error® DNA Specimen Provenance Assay (DSPA) (Strand Diagnostics) or any other assay to confirm specimen provenance or for any other indication except as described under Indications that are Covered, is considered integral to the primary procedure and ineligible for separate coverage.
   - Direct-to-consumer genetic testing.
   - Genetic testing for acquired disorders (those of non-genetic etiology, such as a condition caused by an identified environmental factor).
   - Genetic testing which was not ordered by a licensed healthcare provider or physician (see Definitions) who has established a direct patient care relationship with the member to be tested.
   - Genetic testing that is provided solely to satisfy data collection and analysis needs and that will not be used in direct clinical management.

3. Repeat testing of a histologically-distinct tumor, whether at the same site or a different site, using the same or a similar molecular profiling assay or gene expression classifier, is not covered and is considered not medically necessary because it is not considered an appropriate frequency of care.

4. Multiple-gene panels which include genes not associated with the specific condition, features, characteristics, or symptoms under evaluation, or including genes not associated with conditions within the ordering provider’s differential diagnosis list for the affected member, are not covered and are considered not medically necessary because they are not considered an appropriate type of service for the member’s condition.

5. Molecular profiling assays for management of any of the following indications are considered

- • Colorectal Cancer: Targeted molecular profiling panels limited to analysis of BRAF, KRAS, and/or NRAS gene mutations are covered for members with metastatic colorectal cancer.
- • Gastrointestinal Stromal Tumor (GIST): Targeted molecular profiling panels limited to analysis of BRAF, KIT, PDGFRA, and/or SDH gene mutations are covered for members with GIST.
- • Non-Small Cell Lung Cancer (NSCLC): Targeted molecular profiling panels limited to analysis of ALK, EGFR, and/or KRAS gene mutations are covered for members with NSCLC.
- • Melanoma: Targeted molecular profiling panels limited to analysis of BRAF and KIT gene mutations are covered for members with metastatic melanoma.
- • Thyroid Carcinoma: Afirma® Thyroid FNA Analysis (Veracyte) is covered for adults with cytologically-indeterminate thyroid nodules >1 cm in diameter.
experimental/investigational because reliable evidence does not permit conclusions concerning safety, effectiveness, or effect on health outcomes:

A. Anal carcinoma
B. Basal cell carcinoma
C. Bladder cancer
D. Bone cancers other than Ewing sarcoma
E. Cancer of unknown primary site
F. Cervical cancer
G. Ductal carcinoma in situ (DCIS) of the breast
H. Hepatocellular carcinoma
I. Lung cancer other than non-small cell lung cancer (NSCLC)
J. Multiple myeloma
K. Ovarian cancer
L. Penile cancer
M. Prostate cancer
N. Renal cancer
O. Soft tissue sarcomas other than gastrointestinal stromal tumor (GIST)
P. Squamous cell carcinoma of the skin
Q. Testicular cancer
R. Tracheal cancer

6. All other molecular profiling assays for cancer management are considered experimental/investigational because reliable evidence does not permit conclusions concerning safety, effectiveness, or effect on health outcomes. These services include, but are not limited to:

- Analysis of proteomic patterns/proteomic profiling
- Detection and/or analysis of cell-free DNA or circulating tumor cells
- Genomic microarray testing for hematological malignancies
- Liquid biopsy
- MicroRNA analysis
- Single nucleotide polymorphism (SNP) analysis except as specified under Indications that are Covered:
  - Topographic genotyping
  - Whole exome and whole genome sequencing
  - 50SEQ (med fusion)
  - BluePrint Molecular Subtyping Profile (Agenda)
  - Breast Cancer Index (BCI) (Biotheranostics)
  - CancerIntercept Detect (Pathway Genomics)
  - CancerIntercept Monitor (Pathway Genomics)
  - CancerTYPE ID (Biotheranostics)
  - clonoSEQ (Adaptive Biotechnologies)
  - ColonSentry (Innovative Diagnostic Laboratory)
  - ColonSEQ (med fusion)
  - ColonSEQPlus (med fusion)
  - ColoPrint (Agenda)
  - ColoVantage
  - ConfirmMDx (MDxHealth)
  - Cxbladder (Pacific Edge)
  - Decipher Prostate Cancer Classifier (GenomeDx Biosciences)
  - DecisionDX-Melanoma (Castle Biosciences)
  - DecisionDX-UM (Castle Biosciences)
  - Epi proColon (Epigenomics)
  - FoundationOne (Foundation Medicine)
  - FoundationOne Heme (Foundation Medicine)
  - GeneKey
  - GeneStrat (biodesix)
  - Guardant360 (Guardant Health)
  - Lung Molecular Profile (Genoptix)
  - LungSEQ (med fusion)
  - Lymphoid Molecular Profile (Genoptix)
  - Melanoma Molecular Profile (Genoptix)
  - MelanomaSEQ (med fusion)
  - Molecular Intelligence (Caris Life Sciences)
  - Myeloid Molecular Profile (Genoptix)
  - myPath Melanoma (Myriad Genetics)
• MyPRS (Signal Genetics)
• NeoType tumor profiles (NeoGenomics Laboratories)
• NexCourse Complete (Genoptix)
• NexCourse Solid (Genoptix)
• Omnisseq Comprehensive (OmniSeq)
• Oncofocus (Oncologia)
• OncoGxLung (Rosetta Genomics)
• OncoGxOne (Rosetta Genomics)
• OncotypeDX™ Colon Cancer Assay (Genomic Health, Inc.)
• OncotypeDX™ DCIS Breast Cancer Assay (Genomic Health, Inc.)
• OncotypeDX™ Prostate Score (GPS) Assay (Genomic Health, Inc.)
• PancraGEN (Interpace Diagnostics)
• Paradigm Cancer Diagnostic (PCDx) (Paradigm)
• Prolaris (Myriad Genetics)
• ProstaVysion (Bostwick Laboratories)
• ResponseDX Colon (Response Genetics, Inc.)
• ResponseDX Tissue of Origin (Response Genetics, Inc.)
• RosettaGX Cancer Origin and CORE Cancer Origin Reflex (Rosetta Genomics)
• RosettaGX Reveal (Rosetta Genomics)
• RosettaGxBladder (Rosetta Genomics)
• RosettaGxKidney (Rosetta Genomics)
• RosettaGxLung (Rosetta Genomics)
• RosettaGxProstate (Rosetta Genomics)
• SelectMDx (MDxHealth)
• TheraLink HER Family Assay (Theranostics Health)
• ThyGenX (Interpace Diagnostics)
• ThyraMIR (Interpace Diagnostics)
• ThyroSeq (CBLPath)
• UroGenRA Kidney Array CGH (Cancer Genetics)
• Urovysion
• Veristrat Proteomic Testing (biodesix)
• Xpresys Lung (Integrated Diagnostics)

Definitions

Healthcare provider is any licensed non-physician (excluding naturopathic providers).

Molecular profiling analyzes samples of tissue or fluid to detect somatic mutations.

Physician is a licensed medical doctor or doctor of osteopathy.

Codes

If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

<table>
<thead>
<tr>
<th>Code(s)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0005U</td>
<td>Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score</td>
</tr>
<tr>
<td>0006M</td>
<td>Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier</td>
</tr>
<tr>
<td>0007M</td>
<td>Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index</td>
</tr>
<tr>
<td>0009U</td>
<td>Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin-fixed paraffin-embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified</td>
</tr>
<tr>
<td>0011M</td>
<td>Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>0012 M</td>
<td>Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma</td>
</tr>
<tr>
<td>0013 M</td>
<td>Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma</td>
</tr>
<tr>
<td>0013U</td>
<td>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)</td>
</tr>
<tr>
<td>0014U</td>
<td>Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)</td>
</tr>
<tr>
<td>0016U</td>
<td>Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation</td>
</tr>
<tr>
<td>0017U</td>
<td>Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected</td>
</tr>
<tr>
<td>0018U</td>
<td>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</td>
</tr>
<tr>
<td>0019U</td>
<td>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</td>
</tr>
<tr>
<td>0022U</td>
<td>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</td>
</tr>
<tr>
<td>0023U</td>
<td>Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or nondetection of FLT3 mutation and indication for or against the use of midostaurin</td>
</tr>
<tr>
<td>0026U</td>
<td>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”)</td>
</tr>
<tr>
<td>0027U</td>
<td>JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15</td>
</tr>
<tr>
<td>0036U</td>
<td>Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses</td>
</tr>
<tr>
<td>0037U</td>
<td>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</td>
</tr>
<tr>
<td>0040U</td>
<td>BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative</td>
</tr>
<tr>
<td>0045U</td>
<td>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</td>
</tr>
<tr>
<td>0046U</td>
<td>FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative</td>
</tr>
<tr>
<td>0047U</td>
<td>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</td>
</tr>
<tr>
<td>0048U</td>
<td>Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated 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)</td>
</tr>
<tr>
<td>0049U</td>
<td>NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative</td>
</tr>
<tr>
<td>0050U</td>
<td>Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements</td>
</tr>
<tr>
<td>0053U</td>
<td>Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade</td>
</tr>
<tr>
<td>0056U</td>
<td>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)</td>
</tr>
<tr>
<td>0057U</td>
<td>Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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</tr>
<tr>
<td>0069U</td>
<td>Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score</td>
</tr>
<tr>
<td>8120</td>
<td>IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)</td>
</tr>
<tr>
<td>8121</td>
<td>IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)</td>
</tr>
<tr>
<td>81207</td>
<td>ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain</td>
</tr>
<tr>
<td>81208</td>
<td>ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence</td>
</tr>
<tr>
<td>81209</td>
<td>ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; targeted sequence analysis (eg, exon 12)</td>
</tr>
<tr>
<td>81201</td>
<td>APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence</td>
</tr>
<tr>
<td>81203</td>
<td>APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants</td>
</tr>
<tr>
<td>81202</td>
<td>BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative</td>
</tr>
<tr>
<td>81203</td>
<td>BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative</td>
</tr>
<tr>
<td>81204</td>
<td>BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative</td>
</tr>
<tr>
<td>81210</td>
<td>BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant</td>
</tr>
<tr>
<td>81218</td>
<td>CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence</td>
</tr>
<tr>
<td>81219</td>
<td>CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9</td>
</tr>
<tr>
<td>81228</td>
<td>Cyto genetic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, bacterial artificial chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)</td>
</tr>
<tr>
<td>81229</td>
<td>Cyto genetic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities</td>
</tr>
<tr>
<td>81235</td>
<td>EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)</td>
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<tr>
<td>81245</td>
<td>FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15)</td>
</tr>
<tr>
<td>81246</td>
<td>FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (eg, D835, I836)</td>
</tr>
<tr>
<td>81261</td>
<td>IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology (eg, polymerase chain reaction)</td>
</tr>
<tr>
<td>81262</td>
<td>IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); direct probe methodology (eg, Southern blot)</td>
</tr>
<tr>
<td>81263</td>
<td>IGH@ (Immunoglobulin heavy chain locus) (eg, leukemia and lymphoma, B-cell), variable region somatic mutation analysis</td>
</tr>
<tr>
<td>81264</td>
<td>IGK@ (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma, B-cell), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)</td>
</tr>
<tr>
<td>81265</td>
<td>Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [eg, buccal swab or other germline tissue sample] and donor testing, twin zygoty testing, or maternal cell contamination of fetal cells)</td>
</tr>
<tr>
<td>81266</td>
<td>Comparative analysis using Short Tandem Repeat (STR) markers; each additional specimen (eg, additional cord blood donor, additional fetal samples from different cultures, or additional zygosity in multiple birth pregnancies) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>81267</td>
<td>Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; without cell selection</td>
</tr>
<tr>
<td>81268</td>
<td>Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; with cell selection (eg, CD3, CD33), each cell type</td>
</tr>
<tr>
<td>81270</td>
<td>JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant</td>
</tr>
</tbody>
</table>
| 81272  | KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (eg, exons 8,
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81273</td>
<td>KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, mastocytosis), gene analysis, D816 variant(s)</td>
</tr>
<tr>
<td>81275</td>
<td>KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13</td>
</tr>
<tr>
<td>81276</td>
<td>KRAS (Kirsten rat sarcom viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)</td>
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<tr>
<td>81287</td>
<td>MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme), methylation analysis</td>
</tr>
<tr>
<td>81288</td>
<td>MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis</td>
</tr>
<tr>
<td>81292</td>
<td>MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis</td>
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<tr>
<td>81294</td>
<td>MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants</td>
</tr>
<tr>
<td>81295</td>
<td>MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants</td>
</tr>
<tr>
<td>81297</td>
<td>MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis</td>
</tr>
<tr>
<td>81298</td>
<td>MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis</td>
</tr>
<tr>
<td>81300</td>
<td>MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants</td>
</tr>
<tr>
<td>81301</td>
<td>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</td>
</tr>
<tr>
<td>81310</td>
<td>NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants</td>
</tr>
<tr>
<td>81311</td>
<td>NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg,</td>
</tr>
<tr>
<td>81313</td>
<td>PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kalikrein-related peptidase 3 [prostate specific antigen]) ratio (eg, prostate cancer)</td>
</tr>
<tr>
<td>81314</td>
<td>PDGFRα (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]) gene analysis, targeted sequence analysis (eg, exons 12, 18)</td>
</tr>
<tr>
<td>81315</td>
<td>PML/RARα, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative</td>
</tr>
<tr>
<td>81316</td>
<td>PML/RARα, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative</td>
</tr>
<tr>
<td>81317</td>
<td>PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis</td>
</tr>
<tr>
<td>81319</td>
<td>PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants</td>
</tr>
<tr>
<td>81321</td>
<td>PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis</td>
</tr>
<tr>
<td>81323</td>
<td>PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant</td>
</tr>
<tr>
<td>81327</td>
<td>SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis</td>
</tr>
<tr>
<td>81334</td>
<td>RUNX1 (run related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis (eg, exons 3-8)</td>
</tr>
<tr>
<td>81340</td>
<td>TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (eg, polymerase chain reaction)</td>
</tr>
<tr>
<td>81341</td>
<td>TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using direct probe methodology (eg, Southern blot)</td>
</tr>
<tr>
<td>81342</td>
<td>TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)</td>
</tr>
</tbody>
</table>

**MOLECULAR PATHOLOGY PROCEDURE LEVEL 1**

**MOLECULAR PATHOLOGY PROCEDURE LEVEL 2**

**MOLECULAR PATHOLOGY PROCEDURE LEVEL 3**

**MOLECULAR PATHOLOGY PROCEDURE LEVEL 4**

**MOLECULAR PATHOLOGY PROCEDURE LEVEL 5**

**MOLECULAR PATHOLOGY PROCEDURE LEVEL 6**
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81406</td>
<td>MOLECULAR PATHOLOGY PROCEDURE LEVEL 7</td>
</tr>
<tr>
<td>81407</td>
<td>MOLECULAR PATHOLOGY PROCEDURE LEVEL 8</td>
</tr>
<tr>
<td>81408</td>
<td>MOLECULAR PATHOLOGY PROCEDURE LEVEL 9</td>
</tr>
<tr>
<td>81445</td>
<td>Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (e.g., 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</td>
</tr>
<tr>
<td>81450</td>
<td>Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (e.g., BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, if performed</td>
</tr>
<tr>
<td>81455</td>
<td>Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA and RNA analysis when performed, 51 or greater genes (e.g., ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed</td>
</tr>
<tr>
<td>81504</td>
<td>Oncology (tissue of origin), microarray gene expression profiling of &gt; 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores</td>
</tr>
<tr>
<td>81519</td>
<td>Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score</td>
</tr>
<tr>
<td>81520</td>
<td>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</td>
</tr>
<tr>
<td>81521</td>
<td>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</td>
</tr>
<tr>
<td>81525</td>
<td>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</td>
</tr>
<tr>
<td>81540</td>
<td>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 formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype</td>
</tr>
<tr>
<td>81541</td>
<td>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 disease-specific mortality risk score</td>
</tr>
<tr>
<td>81545</td>
<td>Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (e.g., benign or suspicious)</td>
</tr>
<tr>
<td>81551</td>
<td>Oncology (prostate), promoter methylation analysis by real-time RT-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</td>
</tr>
<tr>
<td>81599</td>
<td>Unlisted multianalyte assay with algorithmic analysis</td>
</tr>
<tr>
<td>88120</td>
<td>Cytopathology, in situ hybridization (e.g., FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual</td>
</tr>
<tr>
<td>88121</td>
<td>Cytopathology, in situ hybridization (e.g., FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology</td>
</tr>
<tr>
<td>88182</td>
<td>Flow cytometry, cell cycle or DNA analysis</td>
</tr>
<tr>
<td>88245</td>
<td>Chromosome analysis for breakage syndrome; baseline Sister Chromatic Exchange (SCE), 20-25 cells</td>
</tr>
<tr>
<td>88248</td>
<td>Chromosome analysis for breakage syndromes; baseline breakage, score 50-100 cells, count 20 cells, 2 karyotypes (e.g., for ataxia telangiectasia, Fanconi anemia, fragile X)</td>
</tr>
<tr>
<td>88249</td>
<td>Chromosome analysis for breakage syndromes; score 100 cells, clastogen stress (e.g., diepoxybutane, mitomycin C, ionizing radiation, UV radiation)</td>
</tr>
<tr>
<td>88261</td>
<td>Chromosome analysis; count 5 cells, 1 karyotype, with banding</td>
</tr>
<tr>
<td>88262</td>
<td>Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding</td>
</tr>
<tr>
<td>88263</td>
<td>Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding</td>
</tr>
<tr>
<td>88264</td>
<td>Chromosome analysis, analyze 20-25 cells</td>
</tr>
<tr>
<td>88271</td>
<td>Molecular cytogenetics; DNA probe, each (e.g., FISH)</td>
</tr>
<tr>
<td>88272</td>
<td>Molecular cytogenetics; chromosomal in situ hybridization, analyze 3-5 cells (e.g., for derivatives and markers)</td>
</tr>
<tr>
<td>88273</td>
<td>Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells (e.g., for microdeletions)</td>
</tr>
<tr>
<td>88274</td>
<td>Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells</td>
</tr>
</tbody>
</table>
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References

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metastatic solid tumor patients. 

Jegadeesh Issa second- or third-line treatment for advanced non-small cell lung cancer: Extended analysis of the PROSE trial. 

on overall survival of patients with advanced ovarian cancer. Oncotarget, 7, 19840-19849. 


