DeanHealthPlan
A member of SSM Health

Coverage of any medical intervention discussed in a Dean Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

Genetic Testing for Somatic Tumor Markers MP9486

Covered Service: Yes

Prior Authorization Required: No

Additional Information: Genetic testing is covered for a Dean Health Plan member if the test results provide a direct medical benefit or guides reproductive decision-making for the Dean Health Plan member. See Genetic Testing MP9012 for additional information.

A first-degree relative is defined as an individual's parents, full siblings, and children.

A second-degree relative is defined as an individual's grandparents, grandchildren, aunts, uncles, nephews, nieces and half-siblings.

A third-degree relative is defined as first cousins, great-aunts, great-uncles, great-grandchildren, or great-grandparents.

Medicare Policy: Prior authorization is dependent on the member's Medicare coverage. Prior authorization is not required for Medicare Cost (Dean Care Gold) and Medicare Supplement (Select) when this service is provided by participating providers. Prior authorization is required if a member has Medicare primary and Dean Health Plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

BadgerCare Plus Policy: Dean Health Plan covers when BadgerCare Plus also covers the benefit.

Dean Health Plan Medical Policy:

General Criteria for Somatic Mutation Genetic Testing

1.0 Tumor biomarker or gene expression classifier (GEC) tests are considered medically necessary when **ALL** of the following criteria are met:

1.1 The individual is a candidate for a targeted therapy associated with a specific tumor biomarker(s) or disease site; **AND**

1.2 Results of testing will directly impact clinical decision making; **AND**

1.3 The testing method is considered to be scientifically valid to identify the specific tumor biomarker; **AND**

1.4 **Either** of the following:

1.4.1 Identification of the specific gene or biomarker is required in order to initiate a related therapy and the therapy has been validated by the National Comprehensive Cancer Network™ (NCCN Guidelines™) as a category 1, 2A, or 2B recommendation for the individual's tumor type or disease site; **OR**

1.4.2 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.

2.0 Multi-gene panels to direct proven therapy or management changes for hematology-oncology indications when **ALL** of the following criteria are met:

2.1 Sequential testing of individual genes or biomarkers is not practical (e.g. limited tissue available, urgent treatment decisions pending); **AND**

2.1.1 Identification of the genes or biomarkers on the panel has been demonstrated in published peer-reviewed literature to improve diagnosis, management, or clinical outcomes for the individual's tumor type or disease site; **AND**

2.1.2 The panel is targeted and limited to genes or biomarkers that are associated with the specific tumor type or disease site.

2.2 Use of multi-gene panel is validated by the NCCN Guidelines™ as category 1, 2A, or 2B recommendation for the individual's tumor type or disease site.

3.0 Molecular testing for hematology-oncology indications and are considered experimental and investigational, and therefore considered not medically necessary for the following situations:

3.1 There is insufficient evidence to support molecular testing for the specific tumor type or disease site and/or not recommended by NCCN Guidelines™;

3.2 The requested gene(s) or biomarker(s) are correlated with a known therapy, but that therapy has not been validated for the specific tumor type or disease site.

4.0 Genetic testing for the following tumor types are medically necessary when an individual meets the testing criteria outline in the relevant NCCN Guidelines™.

4.1 **Acute Lymphoblastic Leukemia** – **BCR-ABL1 Fusion gene** testing may be indicated when **1 or more** of the following:

4.1.1 Initial diagnosis of acute lymphoblastic leukemia, and need for risk stratification or treatment planning;

4.1.2 Philadelphia chromosome-positive acute lymphoblastic leukemia, and for assessment of minimal residual disease, as indicated by **1 or more** of the following:

4.1.2.1 Following completion of initial induction therapy;

4.1.2.2 Following complete remission;

4.1.2.3 Prior to and following stem cell transplant.

4.1.3 Need for BCR-ABL1 kinase domain mutation analysis in member treated with tyrosine kinase inhibitors as indicated by **1 or more** of the following:

4.1.3.1 During the first-line tyrosine kinase inhibitor therapy, as indicated by **EITHER** of the following:

4.1.3.1.1. Suboptimal treatment response;

4.1.3.1.2. Treatment failure

4.1.3.2 During second-line tyrosine kinase therapy, when there is hematologic or cytogenic failure.

4.2 **Acute Promyelocytic Leukemia – PML-RARA Fusion** gene testing may be indicated for **1 or more** of the following:

4.2.1 Confirmation of diagnosis of acute promyelocytic leukemia;

4.2.2 Documentation of molecular remission following consolidation therapy;

4.2.3 Documentation of molecular remission following therapy for relapse.

4.3 **Chronic Eosinophilic Leukemia/Hypereosinophilic Syndrome FIP1L1-PDGFRA**-positive fusion gene testing may be indicated for:

4.3.1 Confirmation of FIP1L1-PDGFRA

4.4 **Chronic Myelogenous Leukemia** – **BCR-ALB1 Fusion** gene testing may be indicated when **1 or more** of the following are present:

4.4.1 Confirmation of diagnosis of chronic myelogenous leukemia;

4.4.2 Need for BCR-ABL1 kinase domain mutation analysis in member treated with tyrosine kinase inhibitors, as indicated by **1 or more** of the following:

4.4.2.1 At diagnosis for member in advanced phase of disease (e.g. accelerated phase, blast phase);

4.4.2.2 During first-line tyrosine kinase inhibitor therapy as indicated by **1 or more** of the following:

4.4.2.2.1. Loss of major molecular response associated with increase in BCR-ABL1 transcript levels (e.g. BCR-ALB1 levels no longer ≤ 0.1%);

4.4.2.2.2. Suboptimal treatment response;

4.4.2.2.3. Treatment failure.

4.4.2.3 During second-line tyrosine kinase inhibitor therapy, when there is hematologic or cytogenetic failure;

4.4.2.4 Failure to achieve major molecular response (e.g. BCR-ABL1 transcript levels of ≤ to 0.1%) within 3 months of resumption of tyrosine kinase inhibitor therapy after loss of major molecular response associated with prior tyrosine kinase inhibitor discontinuation.

4.4.3 Monitoring response to therapy.

5.0 **Lynch Syndrome Colorectal Tumor Analysis** tumor analysis is medically necessary for **ANY** of the following:

5.1 Tumor testing for the gene BRAF V600E and MLH1 promoter hypermethylation of an individual with colon cancer when IHC tumor screening identified a loss of MLH1 expression;

5.2 Microsatellite instability (MSI) testing of endometrial tumor tissue as an initial screen in an individual with colorectal and/or endometrial cancer or colorectal adenomas (when malignant tissue is not available) for **ANY** of the following indications:

5.2.1 Individual with colorectal or endometrial cancer, or colorectal adenomas whose family meets **ANY** of the following:

5.2.1.1 Endometrial cancer diagnosis prior to age 50 years;

5.2.1.2 The Amsterdam II criteria are met, which includes at least three relatives with a Lynch syndrome related cancer and **ALL** of the following:

5.2.1.2.1. One must be a 1st-degree relative of the other two; **AND**

5.2.1.2.2. At least two successive generations must be affected; **AND**

5.2.1.2.3. No history of FAP in the colorectal cancer cases (if any)

5.2.1.3 The revised Bethesda guidelines are met which includes **ANY** of the following:

5.2.1.3.1. Colorectal cancer diagnosed younger than age 50 years;

5.2.1.3.2. Presence of synchronous, metachronous colorectal, or other Lynch syndrome related cancer, regardless of age;

5.2.1.3.3. Colorectal cancer with the MSI-I histology diagnosed in an individual younger than 60 years;

5.2.1.3.4. Colorectal cancer diagnosed with one or more 1st – degree relatives with a Lynch syndrome related cancer, with one or the cancers diagnosed under age 50;

5.2.1.3.5. Colorectal cancer diagnosed in two or more 1st or 2nd degree relatives with a Lynch syndrome related cancer, regardless of age.

6.0 Metastatic colorectal tumor genetic testing - **KRAS and NRAS or BRAF V600E** is medically necessary for **ANY** of the following:

6.1 KRAS and NRAS gene testing may be indicated when **ALL** of the following are present:

6.1.1 Metastatic colorectal cancer; **AND**

6.1.2 Anti-epidermal growth factor receptor (EGFR) therapy is being considered

6.2 BRAF V600E targeted mutation testing may be indicated when **ALL** of the following are present:

6.2.1 Colorectal cancer newly diagnosed and untreated; **AND**

6.2.2 Need to screen for Lynch syndrome, as indicated by **1 or more** of the following:

6.2.2.1 Tumor immunochemistry abnormal for MLH1 protein expression;

6.2.2.2 Tumor with micro satellite instability (MSI-high)

7.0 The following Colon Cancer genetic tests are considered experimental and investigational, and therefore are considered not medically necessary (including but not limited to) the following:

7.1 Oncotype DX Colon Cancer Assay for risk stratification in colorectal cancer stage II and III A/B

7.2 Oncotype DX Recurrence Score test

7.3 Colon Cancer Gene Expression Assay – GeneFx Colon

8.0 **Melanoma** – Gene expression profiling is considered experimental and investigational and therefore is not medically necessary.

8.1 Cutaneous Melanoma: Gene expression profiling is considered experimental and investigational and therefore is not medically necessary (e.g. DecisionDx-Melanoma, myPath Melanoma)

8.2 Uveal Melanoma: Gene expression profiling is considered medically necessary for risk stratification in members with localized uveal melanoma (eg. DecisionDx-UM)

9.0 **Malignant Melanoma in Tumor BRAF V600** genetic testing is considered medically necessary when **ANY** of the following criteria are met:

9.1 Melanoma (metastatic or unresectable);

9.2 Systemic therapy is being considered, as indicated by **ANY** of the following:

9.2.1 BRAF inhibitor (e.g. dabrafenib, vemurafenib);

9.2.2 PD1 inhibitor (e.g. nivolumab, pembrolizumab)

10.0 **Myelodysplastic Syndrome (MDS)** genetic testing including TET2, DNMT3A, TP53, SF3B1, SRSF2, U2AF1, ZRSR2, ASXL1, RUNX1, EZH2, NRAS, CBL, JAK2, SETBP1, IDH1, IDH2, ETV6 is considered medically necessary when **ANY** of the following criteria are met:

10.1 MDS will bone-marrow biopsy confirmed intermediate risk using the IPSS, the WPSS, or the IPSS-R classification methods;

10.2 Member was treated on a lower-risk scale but did not experience a response to treatment.

11.0 **Myeloproliferative Neoplasms - Janus Kinase 2 (JAK2)** mutation genetic testing is considered medically necessary for confirmation of **ANY** of the following:

11.1 **Polycythemia Vera (PV)** Janus Kinase 2 (JAK2) V617F for **ANY** of the following:

11.1.1 Hemoglobin >16,5 g/dL in men, >16.0 g/dL in women;

11.1.2 Hematocrit >49% in men, >48% in women;

11.1.3 Increased red cell mass (RCM) more than 25% above mean normal predicted value

11.2 **Polycythemia Vera (PV)** Janus Kinase 2 exon 12 mutation testing is considered medically necessary for the diagnosis of when **ALL** of the following criteria are met:

11.2.1 Individual meets criteria for JAK2 V617F; **AND**

11.2.2 JAK2 V617F mutation analysis was previously completed and was negative

11.3 **Essential Thrombocythemia (ET) or Thrombocytosis** when **ANY** of the following criteria are met:

11.3.1 Platelet count ≥ 450 X 10^9/L;

11.3.2 Bone marrow biopsy showing proliferation mainly on the megakaryocyte lineage with increased numbers of enlarged, mature megakaryocytes with hyperlobulated nuclei. No significant increase or left shift in neutrophil granulopoiessis or erythropoiese and very rarely minor (grade 1) increase in reticulin fibers.

11.4 **Primary Myelofibrosis** (PMF) is suspected but not confirmed based on results of conventional testing

12.0 **Myeloprolifertaive Neoplasms CALR and MPL gene exon 9** mutations analysis considered medically necessary for the following when JAK2V617F mutation-testing has been performed and was negative:

12.1 Essential Thrombocythemia or Thrombocytosis (ET);

12.2 Primary myelofibrosis (PMF) is suspected but not confirmed based on results of conventional testing

13.0 **Breast Cancer Gene Expression Assay**

13.1 Gene expression assays to guide adjuvant chemotherapy in the treatment of breast cancer such as Oncotype DX Breast Cancer or Prosigna Breast Cancer Prognostic Gene Signature Assay are medically necessary for newly diagnosed breast cancer to assess the need for adjuvant chemotherapy in a member when **ALL** of the following criteria are met:

13.1.1 Histology demonstrates ductal, lobular, mixed, NST or micropapillary carcinoma; **AND**

13.1.2 Recently diagnosed pathologic stage I or stage II; **AND**

13.1.3 Primary tumor is hormone receptor-positive; **AND**

13.1.4 Primary tumor is HER2-receptor-negative; **AND**

13.1.5 No axillary node metastasis, or ≤ 2 mm axillary node metastasis; **AND**

13.1.6 Up to three positive axillary nodes.

13.2 Oncotype DX Breast Recurrence Score is considered medically necessary in members with HR-positive, HER-2 negative tumors to predict recurrence after treatment with endocrine therapy; **OR** to predict the benefit of adding adjuvant chemotherapy.

13.3 EndoPredict is considered medically necessary to assess the necessity of adjuvant chemotherapy in members with HR-positive, HER2-negative nonmetastatic tumors.

13.4 Oncotype DX Breast DCIS Score is considered experimental and investigational and therefore not medically necessary

13.5 .myChoice is considered experimental and investigational and therefore not medically necessary.

14.0 **Mammaprint 70-Gene Breast Cancer Recurrence Assay and Mammaprint Microarray Test** is medically necessary for a woman with Stage I or II invasive breast cancer being considered for adjuvant systematic therapy when **ALL** of the following criteria are met:

14.1 High clinical risk of recurrence; **AND**

14.2 Estrogen receptor (ER)-positive/progesterone receptor (PR)-positive; **AND**

14.3 Human epidermal growth factor receptor 2 (HER2)-negative; **AND**

14.4 Up to three (3) positive nodes

15.0 **Non-Small Cell Lung Cancer (NSCLC)** the following tests are medically necessary for the diagnosis and management of non-small cell lung adenocarcinoma:

15.1 ALK gene rearrangements

15.2 NTRK*1/2/3* gene fusions

15.3 PD-L1 expression

15.4 EGFR targeted gene analysis

15.5 KRAS targeted gene analysis

15.6 HER2 (ERBB2) targeted gene analysis

15.7 BRAF V600E point targeted mutation testing

15.8 ROS1 gene rearrangements

15.9 RET gene rearrangements

15.10 MET amplification

15.11 The following genes expression tests are considered experimental and investigational, and therefore not medically necessary: PTEN, CHGA, WT-1, CFL1, EML4-ALK

15.12 Guardant360 a circulating tumor DNA liquid biopsy test is considered medically necessary to identify somatic variants for recurrent or metastatic non-small cell lung cancer. All other liquid biopsy tests for any other indication are considered experimental/investigational

16.0 The following prostate cancer molecular tumor tests are considered medically necessary:

16.1 Oncotype DX Genomic Prostate Score Assay

16.2 Decipher Prostate Cancer Classifier Assay

16.3 Prolaris Biopsy Test

16.4 ProMark Proteomic Prognostic Test (Prostate)

17.0 **Prostate Cancer** Molecular tumor testing of confirmed **prostate cancer** is experimental and investigational, and therefore is considered not medically necessary (including but not limited to) the following:

17.1 MicroDNA Detection - Cancer

17.2 Prostate Cancer – Genetic Profiles

18.0 **Prostate Cancer** screening and prognostic genetic tests are considered medically necessary for prostate cancer when results will impact management and **ALL** of the following criteria are met:

18.1 ExoDxProstate/ExosomeDxProstate, SelectMDx (Intelliscore), Progensa PCA 3 Assay, 4K score, Prostate Health Index (PHI), IsoPSA Test and ConfirmMDx for prostate cancer medically necessary if **EITHER** of the following criteria are met:

18.1.1 PSA > 3.0 ng/ml and previous benign prostate biopsy or focal high grade prostatic interepithelial neoplasia (PIN); **OR**

18.1.2 PSA > 2.0 ng/ml and test will be used in place of either initial or repeat prostate biopsy

18.2 All other prostate cancer screening and prognostic genetic tests are considered experimental and investigational and therefore not medically necessary (including but not limited to the following):

18.2.1 CK5, CK14, and Racemase P504S testing

18.2.2 C-Met expression for predicting prognosis in person with advanced NSCLC and colorectal cancer, and other indications

18.2.3 Mi-Prostate Score

19.0 **Thyroid Nodule Gene Expression Testing** (Afirma Thyroid FNA Analysis, Affirma GSC, ThyraMir or Interpace ThyGenX Oncogene Panel) may be medically necessary when **ALL** of the following are present:

19.1 Age 21 years or older; **AND**

19.2 Thyroid nodule, as indicated by **ALL** of the following:

19.2.1 Diameter of 1 cm or greater on ultrasound; **AND**

19.2.2 Indeterminate cytology on fine needle aspirate, as indicated by **ANY** of the following:

19.2.2.1 Atypia of undetermined significance;

19.2.2.2 Follicular lesion of undetermined significance;

19.2.2.3 Follicular neoplasm or suspicious for follicular neoplasm

20.0 **Tumor Analysis or Gene Expression Profiling** for **ANY** of the following solid tumor types is considered experimental and investigational, and therefore is not medically necessary:

20.1 Anal carcinoma

20.2 Basal cell carcinoma

20.3 Bone cancer

20.4 Cancer of unknown origin/unknown primary

20.5 Cervical cancer

20.6 Head and neck cancer

20.7 Hepatobiliary cancer

20.8 Hodgkin lymphoma

20.9 Malignant mesothelioma

20.10 Penile cancer

20.11 Testicular cancer

20.12 Tracheal cancer

20.13 Esophageal cancer

20.14 Squamous cell carcinoma of the skin

20.15 Renal/kidney cancer

20.16 , FoundationOneHeme; Molecular Intelligence

20.17 Liquid biopsy (e.g. Cancerintercept, Colvera, GeneStrat) for any indication, including, but not limited to, breast cancer, colorectal cancer, lung cancer, melanoma, or ovarian cancer are considered experimental and investigational with the exception of:

20.17.1 Guardant360, a circulating tumor DNA liquid biopsy test, is considered medically necessary to identify somatic variants for recurrent or metastatic non-small cell lung cancer. See (15.9)

20.17.2 FoundationOne CDX is considered medically necessary for the indications listed in Genetic Testing for Pharmacogenetics MP9479

21.0 Other **Tumor Profile Testing** is considered experimental and investigational as indicated (not an all-inclusive list) for **ANY** the following:

21.1 Molecular testing for detection of or circulating tumor cells (e.g. Oncotype DX ARVR Nucleus Detect) for any hematology/oncology indication because it is considered experimental and investigational and therefore is not medically necessary.

21.2 Topographic genotyping (e.g. PancraGen) for an indication is not covered because it is considered experimental and investigational and therefore is not medically necessary.

21.3 Multi-gene cell-free tumor DNA assays or molecular testing of circulating tumor cells for a hematology/oncology indications are considered experimental and investigational and therefore are not medically necessary.

21.4 Affirma Xpression Atlas, Percepta Bronchial Genomic Classifier and Envisa Genomic Classifier

21.5 Cxbladder urine test for bladder cancer screening or detection

21.6 In vitro chemosensitivity and chemoresistance assays (chemoresponse assays) (e.g. ChemoFx Assay, Correct Chemo)

21.7 Lung cancer algorithmic tests (e.g. Biodsix)

21.8 Barrett's esophagus risk stratification testing (e.g. TissueCypher Barrett's Esophagus Assay)

21.9 Ductal carcinoma in situ risk stratification testing (e.g. DCISionRT, PreludeDx)

CPT/HCPCS Codes Related to MP9486

* The list of codes (and their descriptors, if any) is provided for informational purposes only and may not be all inclusive or current. Listing of a code in this medical policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with Dean Health Plan. Inclusion of a code above does not imply any right to reimbursement or guarantee claim payment. Other medical policies may also apply.

CPT Code	Description
81120	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)
81121	IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (i.e., detection of large gene
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (e. g, detection of large gene rearrangements)
81165	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81167	RCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)

CPT Code	Description
81168	CCND1/IGH (t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed
81170	ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (e.g., acquired imatinib tyrosine kinase inhibitor resistance), gene analysis
81175	ASXL1 (additional sex combs like 1, transcriptional regulator) (e.g., myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence
81176	ASXL1 (additional sex combs like 1, transcriptional regulator) (e.g., myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; targeted sequence analysis (e.g., exon 12)
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
81202	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; known familial variants
81203	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants
81206	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative
81207	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative
81208	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative
81210	BRAF (B-Raf proto-oncogene, serine/threonine kinase) (e.g., colon cancer, melanoma), gene analysis, V600 variant(s)
81212	BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
81215	BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; k812nown familial variant

CPT Code	Description
81216	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81218	EBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence
81219	CALR (calreticulin) (e.g., myeloproliferative disorders), gene analysis, common variants in exon 9
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
81233	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)
81235	EGFR (epidermal growth factor receptor) (e.g., non-small cell lung cancer) gene analysis, common variants (e.g., exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q) (e.g. cobas Mutation Test v2, OncoBeam Lung1: EGFR, therascreen EGFR)
81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (e.g., myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (e.g., diffuse large B-cell lymphoma) gene analysis, common variant(s)
81242	FANCC (Fanconi anemia, complementation group C) (eg, Fanconi anemia, type C) gene analysis, common variant (eg, IVS4+4A>T)
81245	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15)
81246	LT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (eg, D835, I836)
81261	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)

CPT Code	Description
81262	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)
81263	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemia and lymphoma, B-cell), variable region somatic mutation analysis
81264	IGK@ (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma, B-cell), gene rearrangement analysis, evaluation
81267	Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; without cell selection
81268	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
81270	JAK2 (Janus kinase 2) (e.g., myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant
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, 11, 13, 17, 18)
81273	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, 11, 13, 17, 18)
81275	KRAS (Kirsten rat sarcoma viral oncogene homolog) (e.g., carcinoma) gene analysis; variants in exon 2 (e.g., codons 12 and 13)
81276	KRAS (Kirsten rat sarcoma viral oncogene homolog) (e.g., carcinoma) gene analysis; additional variant(s) (e.g., codon 61, codon 146)
81277	Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-of-heterozygosity variants for chromosomal abnormalities
81278	IGH@/BCL2 (t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative
81279	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)
81287	MGMT (O-6-methylguanine-DNA methyltransferase) (e.g., glioblastoma multiforme), methylation analysis

CPT Code	Description
81288	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter
81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81293	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
81295	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81298	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81299	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary nonpolyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81301	Microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (e.g., BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed
81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant
81307	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence
81308	ALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; known familial variant
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)
81310	NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, exon 12 variants
81311	NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (e.g., colorectal carcinoma), gene analysis, variants in exon 2 (e.g., codons 12 and 13) and exon 3 (e.g., codon 61)

CPT Code	Description
81313	PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (e.g., prostate cancer)
81314	PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18)
81315	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (e.g., promyelocytic leukemia) translocation analysis; common breakpoints (e.g., intron 3 and intron 6), qualitative or quantitative
81316	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (e.g., promyelocytic leukemia) translocation analysis; single breakpoint (e.g., intron 3, intron 6 or exon 6), qualitative or quantitative
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)
81321	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis
81322	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant
81323	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant
81327	SEPT9 (Septin9) (eg, colorectal cancer) promoter methylation analysis
81334	RUNX1 (runt related transcription factor 1) (e.g. acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis
81338	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)
81339	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10
81340	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)
81341	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)

CPT Code	Description
81342	TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)
81347	SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)
81348	SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L)
81351	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; full gene sequence
81352	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; targeted sequence analysis (eg, 4 oncology)
81353	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; known familial variant
81357	U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)
81360	ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs)
81401	Molecular pathology procedure, Level 2
81402	Molecular Pathology Procedure Level 3
81403	Molecular Pathology Procedure Level 4
81404	Molecular Pathology Procedure Level 5
81405	Molecular Pathology Procedure Level 6
81406	Molecular pathology Level 7
81407	Molecular pathology procedure, Level 9
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
81426	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)

CPT Code	Description
81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)
81432	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, and TP53
81433	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11
81435	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11
81436	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11
81445	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 (e.g. Quest Diagnostic Thyroid Cancer Mutation Panel, OncoVantage)
81450	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, or isoform expression or mRNA expression levels, if performed
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, 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, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA,

CPT Code	Description
	PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81479	Unlisted molecular pathology procedure (e.g. SelectMDx)
81500	Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score
81503	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score
81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores
81514	Oncology (breast), mRNA, gene expression profiling by real-hyphentime RT-hyphenPCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-hyphenfixed paraffin-hyphen embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy (e.g. Oncotype Dx)
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 formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score (e.g. Oncotype Dx)
81520	Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (e.g. PAM50 Prosigna Breast Cancer Prognostic Gene Signature Assay)
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 (e.g. Mammaprint 70-Gene Breast Cancer Recurrence Assay)
81522	Oncology (breast), mRNA, gene expression profiling by RT-hyphenPCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-hyphenfixed paraffin-hyphenembedded tissue, algorithm reported as recurrence risk score (e.g. Endopredict)

CPT Code	Description
81523	Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis (e.g. Mammaprint)
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
81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result
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
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival (e.g. VeriStrat)
81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score
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 formalin-fixed 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 disease-specific mortality risk score (e.g. Prolaris)
81542	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-hyphenfixed paraffin-hyphenembedded tissue, algorithm reported as metastasis risk score (e.g. Decipher)
81545	Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (e.g., benign or suspicious) (e.g. Afirma Thyroid FNA analysis)

CPT Code	Description
81546	Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, 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 (e.g. ConfirmMDx)
81552	Oncology (uveal melanoma), mRNA, gene expression profiling by real-hyphentime RT-hyphenPCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-hyphenfixed paraffin-hyphenembedded tissue, algorithm reported as risk of metastasis (e.g. DecisionDx-UM)
81554	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP]) (e.g. Envisia Genomic Classifier)
81599	Unlisted multianalyte assay with algorithmic analysis (e.g. EndoPredict Risk Score
81652	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood);
81653	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required
83950	Oncoprotein; HER-2/neu
88271	Molecular cytogenetics; DNA probe, each (eg, FISH)
88274	Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells
88275	Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells
88291	Cytogenetics and molecular cytogenetics, interpretation and report
88360	Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual
88361	Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or

CPT Code	Description
	semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology
88374	Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells
88377	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure
0008M	Oncology (breast), mRNA analysis of 58 genes using hybrid capture, on formalin-fixed paraffin-embedded (FFPE) tissue, prognostic algorithm reported as a risk score (e.g. PAM50 Prosigna Breast Cancer Prognostic Gene Signature Assay)
0011M	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 (e.g. Liquid biopsy – CancerIntercept, GeneStrat, Colvera, Neolab Prostate)
0012M	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 urothelial carcinoma (e.g. Cxbladder test)
0013M	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 (e.g. Cxbladder test)
0015M	Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy
0016M	Oncology (bladder), mRNA, microarray gene expression profiling of 209 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like)
0017M	Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin-embedded tissue, algorithm reported as cell of origin
0003U	Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score (e.g. ExosomeDx, Prostate (IntelliScore)

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CPT Code	Description
0009U	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
0016U	Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts
0017U	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
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 (e.g. Thyroseq, ThiraMIR)
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 (e.g. OncoTarget/OncoTreat)
0021U	Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTR-Ropporin, 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 neoplasiz, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements (e.g. Oncomine Dx Target Test)
0023U	Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication for or against the use of midostaurin (e.g. LeukoStrat CDx FLT3 Mutation Assay)
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") (e.g. Thyroseq)
0027U	JAK2 (Janus kinase 2) (e.g., myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15
0036U	Exome (ie, 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

CPT Code	Description
	number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden (e.g. FoundationOne CDx)
0040U	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative
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 (e.g. Oncotype DX Breast DCIS Score Test)
0046U	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative
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 (e.g. Oncotype DX Genomic Prostate Score)
0048U	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) (e.g. MSK-IMPACT)
0049U	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative
0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements
0053U	Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade (e.g. Prostate Cancer Risk Panel – Mayo Clinic)
0059U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative
0067U	Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [MMP-1], carcinoembryonic antigen-related cell adhesion molecule 6 [CEACAM6], hyaluronoglucosaminidase [HYAL1], highly expressed in cancer protein [HEC1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score

CPT Code	Description
0069U	Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin fixed paraffin-embedded tissue, algorithm reported as an expression score (e.g. miR-31now)
0080U	Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy (e.g. Biodesix®)
0083U	Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations
0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es) (e.g. Pigmented Lesion Assay)
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) (e.g. myPath Melanoma)
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
0092U	Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy
0101U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])
0103U	Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])
0108U	Gastroenterology (Barrett's esophagus), whole slide-digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-

CPT Code	Description
	embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer (e.g. TissueCypher® Barrett's Esophagus Assay)
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 (e.g. Praxis Extended RAS Panel)
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 (MiPS Mi-Prostate Score)
0114U	Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus
0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA
0120U	Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter
0129U	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)
0130U	Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), targeted mRNA sequence analysis panel (APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, and TP53)
0131U	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes)
0132U	Hereditary ovarian cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes)
0133U	Hereditary prostate cancer-related disorders, targeted mRNA sequence analysis panel (11 genes) (List separately in addition to code for primary procedure) (e.g. RNA Insight for ProstateNext)

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CPT Code	Description
0134U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes)
0135U	Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes)
0137U	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) mRNA sequence analysis
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
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 (e.g. therascreen FGFR RGQ RT-PCR Kit)
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 (e.g. therascreen PIK3CA RGQ PCR Kit)
0158U	MLH1 (mutL homolog 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
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
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 (e.g. myChoice CDx)
0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm

CPT Code	Description
	reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents
0177U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status (e.g. therascreen PIK3CA RGQ PCR Kit)
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) (e.g. Resolution ctDx Lung)
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 (e.g. Afirma Xpression Atlas)
0205U	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 (e.g. PGDx elio tissue complete)
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
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities
0211U	Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association (e.g. MI Cancer Seek – NGS Analysis)
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score
0228U	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer

CPT Code	Description
0229U	BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis (e.g. Colvera)
0235U	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions (e.g. Genomic Unity PTEN Analysis)
0238U	Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions (e.g. Genomic Unity Lynch Syndrome Analysis)
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 (e.g. FoundationOne Liquid CDx)
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 (e.g. Guardant360)
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 (e.g. ThyGeNEXT)
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 (e.g. PGDx elioTM tissue complete)
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 (e.g., Guardant360 Tissue Next)
0339U	Oncology (prostate), mRNA expression profiling of HOXC6 and DLX1, reverse transcription polymerase chain reaction (RT-PCR), first-void urine following digital rectal examination, algorithm reported as probability of high-grade cancer (e.g. SelectMDx)

Coverage of any medical intervention discussed in a Dean Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

CPT Code	Description
S3854	Gene expression profiling panel for use in the management of breast cancer treatment (e.g. MammaPrint or the Breast Cancer Index)

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