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 Pharmacogenetics MP9479

Covered Service: Yes

Prior Authorization Required: Yes, except for tests indicated in 3.0 and 4.0.

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.

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:

1.0 Pharmacogenetics testing **requires prior authorization** through the Health Services Division and is medically necessary when **ALL** of the following criteria have been met:

- 1.1 The individual is a candidate for a targeted drug therapy associated with a specific gene biomarker or gene mutation; **AND**
- 1.2 The results of the pharmacogenetics test will directly impact clinical decision-making and clinical outcome for the member; **AND**
- 1.3 The testing method is considered to be scientifically valid to identify the specific gene biomarkers or gene mutation; **AND**
- 1.4 Identification of the specific gene or biomarker for use with a specific drug target has demonstrated to improve clinical outcomes for the member's condition being addressed and variant is required prior to initiating therapy with the target drug as noted by the U.S. Food and Drug Administration (FDA) approved prescribing label.

2.0 Multi-gene pharmacogenetics genotyping assays that do not meet the above criteria

are considered experimental and investigational, and therefore are not medically necessary.

3.0 Targeted genetic testing for drug therapy (excludes cancer related drugs) **does not** require prior authorization and is considered medically necessary when the criteria in 1.0 is met:

3.1 TPMT gene mutation or TPMT phenotypic assays are considered medically necessary prior to initiation of 6-mercaptopurine or azathioprine therapy

3.1.1 Only 1 genotypic or phenotypic assay of TPMT activity is necessary per member per lifetime

3.1.2 TPMT gene mutation assays and TPMT phenotypic assays are considered experimental and investigational for all other indications because their effectiveness for indications

3.2 HLA-B*5701 for persons who are infected with HIV-1 before starting treatment with ZIAGEN (abacavir)

3.3 Genotyping for HLA-B*1502 for persons with Asian ancestry before starting treatment with TEGRETOL (carbamazepine) or DILANTIN (phenytoin)

3.4 Genotyping for HLA-B*58:01 in Asian persons prior to starting allopurinol therapy

3.5 CFTR Cystic Fibrosis mutation test:G551D, G1244E, G1349D, G178R, G551S, R117H, S1255P, S549N, or S549R mutation gene testing for persons with cystic fibrosis who are being considered for treatment with KALYDECO (ivacaftor)

3.6 CFTR gene test to detect F508del mutation for persons with cystic fibrosis being considered for treatment with ORKAMBI (ivacaftor/lumacaftor)

3.7 GALA/GLA variant gene testing for person with Fabry disease who are being considered for treatment with GALAFOLD (migalastat) or FABRAZYME (agalsidase beta)

3.8 PCK9 Inhibitors gene testing for LDLR, ApoB, PCSK9 for person with heterozygous familial hypercholesterolemia prior to starting PCSK9 Inhibitors REPATHA (evolocumab))

3.9 G6PD gene testing prior to starting therapy with ELITEK (rasburicase)

3.10 PHEX gene testing for person with X-Linked Hypophosphatemia (XLH) prior to starting therapy with CRYSVITA (burosumab)

3.11 IDUA gene testing for person suspected of having mucopolysaccharidosis 1 (MPS1) prior to starting therapy with ALDURAZYME (laronidase)

3.12 IDS gene testing for person suspected of having mucopolysaccharidosis II prior to starting therapy with ELAPRASE (idursulfase)

3.13 ARSB gene testing for person with mucopolysaccharidosis VI prior to starting therapy with NAGLAZYME (galsulfase)

3.14 GALNS gene testing for person with mucopolysacchardosis IV type A prior to starting therapy with VIMIZIM (elosulfase)

3.15 SMN1 gene testing for person with spinal muscular atrophy prior to starting EVRYSDI (risdiplam)

3.16 FECH gene testing for person with Erythropoientic Protoporphyria prior to starting SCENESSE (afamelanotide)

3.17 SMN1 and SMN2 gene testing for person with SMA prior to starting SPRINRAZA (nusinersen)

3.18 TTR gene testing for person with peripheral nerve disease caused by hereditary transthyretin-mediated amyloidosis prior to starting ONPATTRO (patisiran)

3.19 GAA gene testing for person with Pompe Disease prior to starting LUMIZYME (alglucodase alfa)

3.20 LDLR, ApoB, PCSK9, LDLRAP1 gene testing prior to starting EVKEEZA (evinacumab) for homozygous familial hypercholesteremia

3.21 AGXT gene testing prior to starting OXLUMO (lumasiran) for treatment of Primary Hyperoxaluria Type 1

3.22 Molybdenum cofactor synthesis gene 1 (MOSC1) testing prior to starting NULIBRY (fosdenopterin) for treatment of molybdenum cofactor deficiency

3.23 SMN1 and SMN2 gene testing prior to starting ZOLGENSMA (onasemnogene abeparvovec-xioi) IV

3.24 RPE65 mutation testing for treatment of retinal dystrophy prior to starting treatment with LUXTURNA (voretigene neparvovec-rzyl)

4.0 The following discrete targeted genetic tests for drug therapy (cancer related drugs) **do not** require prior authorization and are considered medically necessary when the criteria in 1.0 is met (not an all-inclusive list):

4.1 Anaplastic lymphoma kinase (ALK) fusion gene (e.g. the Vysis ALK Break Apart FISH Probe Kit; Ventana ALK (D5F3) CDx Assay)) for persons who are considering XALKORI (crizotinib), ALECENSA (alectinib) or ZYKADIA (ceritinib) for the treatment of non-small cell lung cancer (NSCLC)

4.2 BRAF gene (V600E or V00K) in persons with unresectable or metastatic melanoma who are being considered for treatment with ZELBORAF

(vemurafenib), TAFINLAR (dabrafenib), COTELLIC (cobimetinib) or BRAFTOVI (encorafenib)

4.3 EGFR T790 mutation (e.g. cobas EGFR Mutation Test v2) testing for persons with non-small cell lung cancer being considered for treatment with TAGRISSO (osimertinib)

4.4 EGFR exon 19 deletions or exon 21 (L858R) substitution mutations (e.g. cobas EGFR Mutation Test, Therascreen EGFR RGQ PCR Kit) testing for persons with non-small cell lung cancer being considered for treatment with erlotinib or GILOTRIF (afatinib)

4.5 PD-L1 expression (e.g. PD-L1 IHC 22C3 pharmDx) testing for persons with non-small cell lung cancer, cervical cancer (recurrent or metastatic), esophageal, gastric or gastroesophageal junction cancer, squamous cell, unresectable or recurrent head and neck cancer, triple-negative breast cancer locally recurrent unresectable or metastatic and metastatic squamous cell carcinoma of the esophagus being considered for treatment with KEYTRUDA (pembrolizumab)

4.6 PD-1/PD-L1 expression (e.g. Ventana PD-L1 (SP263) Assay) testing for persons with urothelial carcinoma or non-small cell lung cancer who are being considered for treatment with IMFINZI (durvalumab)

4.7 PD-L1 expression (e.g. Ventana PD-L1 (SP142) Assay) for persons with triple-negative breast carcinoma, non-small cell lung cancer, metastatic non-small cell lung cancer and urothelial carcinoma who are being considered for treatment with TECENTRIQ (atezolizumab)

4.8 Platelet-derived growth factor receptor-beta (PDGFRß) gene rearrangements (e.g. PDGFRB FISH) testing for persons with chronic myelomonocytic leukemia and myelodysplastic syndrome/myeloproliferative disease being considered for treatment with GLEEVEC (imatinib mesylate)

4.9 c-KIT testing medically necessary for persons with gastrointestinal stromal tumors (e.g. Dako EGFR pharmDx Kit) or aggressive systemic mastocytosis (KIT D816V Mutation Detection by PCR) being considered for treatment with GLEEVAC (imatinib mesylate)

4.10 del(17p)/TP53 mutation (e.g. Vysis CLL FISH Probe Kit) medically necessary for persons with chronic lymphocytic leukemia/small lymphocytic lymphoma being considered for treatment with VENCLEXTA (venetoclax)

4.11 BCR/ABL mutations (e.g. MRDx BCR-ABL Test) medically necessary for persons with chronic myeloid leukemia being considered for treatment with TASIGNA (nilotinib)

4.12 FTL3 mutation assay (e.g. LeukoStrat CDx FLT Mutation Assay) testing for persons with acute myeloid leukemia (AML) being considered for treatment

with RYDAPT (midostaurin) or XOSPATA (gilternib)

4.13 Extended RAS Panel (Illumina, San Diego, CA) testing for persons with metastatic colorectal cancer being considered for VECTIBIX (panitumumab).

4.13.1 In persons with recurrent or metastatic non-small cell lung cancer who are being considered for treatment with TAFINLAR (dabrafenib), KEYTRUDA (pembrolizumab), or ZELBORAF (vemurafenib)

4.13.2 Persons with thyroid carcinoma who are being considered for treatment with TAFINLAR (dabrafenib) or ZELBORAF (vemurafenib)

4.14 Measurement of microsatellite instability and mismatch repair medically necessary for persons with unresectable or metastatic solid tumors being considered for treatment with KEYTRUDA (pembrolizumab)

4.15 BRAF and NRAS mutations (e.g. cobas KRAS Mutation Test; Therascreen KRAS RGQ PCR Kit, Dako EGFR pharmDx Kit) for persons with colorectal cancer being considered for treatment with ERBITUX (cetuximab) or VECTIBIX (panitumumab)

4.16 Praxis Extended RAS Panel medically necessary for persons with colorectal cancer who do not have mutations in RAS gene and NRAS who are being considered for treatment with ERBITUX (cetuximab) or VECTIBIX (panitumumab)

4.17 BRCA testing (e.g. BRACAnalysis CDx) for women with advanced epithelial ovarian cancer, fallopian tube or primary peritoneal cancer who have been treated with three or more lines of chemotherapy and are being considered for LYNPARZA (olaparib), and for women with advanced epithelial ovarian cancer, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum based chemotherapy and are being considered for maintenance treatment with LYNPARZA (olaparib)

4.18 BRCA testing (e.g. BRACAnalysis CDx) for women with metastatic, human epidermal growth factor receptor 2 (HER2)-negative breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting (regardless of family history) and are being considered for LYNPARZA (olaparib)

4.19 BRAF V600E mutation (the cobas 4800 BRAF mutation test) for person who are considering ZELBORAF (vemurafenib) for the treatment of unresectable or metastatic melanoma

4.20 BRAF gene (V600E or V600K) (e.g. THxID BRAF test of cobas 4800 BRAF mutation test) for persons who are considering COTELLIC (cobimetinib), MEKINIST (trametinib), and TAFINLAR (dabrafenib)

4.21 MGMT (O(6)-methylguanine-DNA methyltransferase) gene methylation assay

for predicting response to TEMODAR (temozolom) in persons with glioblastoma

4.22 Isocitrate dehydrogenase – 1 (IDH1) or isocitrate dehydrogenase- 2 (IDH2) gene testing for persons with acute myeloid leukemia who are considering IDHIFA (enasidenib) or TIBSOVO (ivosidenib)

4.23 BRCA testing medically necessary for women with advanced ovarian cancer, fallopian tube or primary peritoneal cancer who have been treated with three or more prior lines of chemotherapy and are being considered for ZEJULA (niraparib)

4.24 RAS Panel gene testing for persons with colon cancer prior to starting ERBITUX (cetuximab)

4.25 KRAS and NRAS gene testing for persons with metastatic colorectal cancer who are considering VECTIBIX (panitumumab)

4.26 EGFR or ALK genomic markers testing for persons with non-small cell lung cancer metastatic prior to receiving OPDIVO (nivolumab)

4.27 EGRF exon 20 insertion mutations genet testing prior to starting RYBREVANT (amivantamab-vmjw)

4.28 EGFR mutation testing for persons being considered for treatment with PERJETA (Pertuzumab) for colorectal cancer

4.29 FoundationOne CDx is considered medically necessary for the following:

4.29.1 Men with advanced, recurrent or metastatic prostate cancer who have been treated with androgen-receptor directed therapy and a taxane-based chemotherapy and are being considered for treatment with RUBRACA (rucaparib)

4.29.2 To identify advanced cancer in members with solid tumors that are tumor mutational burden-high (TMB greater than or equal to 10 mutations per megabase) and appropriate for treatment with KEYTRUDA (pembrolizumab)

4.29.3 For adult members with previously treated, locally advanced or metastatic cholangiocarcinoma with FGFR2 fusions or select rearrangements being considered for treatment with (permigatinib) PEMAZYRE

4.29.4 For members with locally advanced or metastatic METex14 mutated non-small cell lung cancer being considered for treatment with (capmatinib) TABRECTA

4.29.5 For members with metastatic castrate-resistant prostate cancer with homologous recombination repair (HRR) gene alterations being

considered for treatment with (olaparib) LYNPARZA

4.29.6 For adult and pediatric members with solid tumors that have a neutrophic receptor tyrosine kinase (NTKR) gene fusion being considered for treatment with (larotrectinib) VITRAKVI

4.29.7 For the treatment of postmenopausal women and men with hormone receptor (HR)-positive, human epidermal growth factor receptor-2 (HER2) negative, PIK3CA mutated advanced or metastatic breast cancer following progression on or after an endocrine-based regimen being considered for treatment with (alpelisib) PIQRAY in combination with (fulvestrant) FASLODEX

4.30 FoundationOne Liquid CDX is considered not medically necessary and therefore not covered for the following

4.30.1 Assessing candidacy of persons with non-small cell lung cancer for treatment with TAGRISSO (osimertinib) or IRESSA (gefitinib) because there is no proven advantage of the FoundationOne Liquid CDx over targeted EGFR mutation testing or small targeted panels for this indication

4.30.2 For persons with prostate cancer being considered for treatment with RUBARCA (rucaparib)

5.0 EGFR exon 19 deletion or exon 21 (L858R) substitution mutations for person who is considering VIZIMPRO (dacomitinib), IRESSA (gefitinib), GILOTRIF (afatinib) for the treatment of metastatic non-small cell lung cancer

6.0 Germline BRCA-mutated, HER2-negative for person who is considering TALZENNA (talazoparib) for locally advanced or metastatic breast cancer diagnosis

7.0 EGFR or ALK genomic tumor aberrations testing prior to receiving CYRAMZA (ramucirumab)

8.0 AlloMap gene expression profile **does not** require prior authorization and is medically necessary for monitoring rejection in members 15 years of age and older who are heart transplant recipients and who are more than six (6) months post-heart transplant.

9.0 The following pharmacogenetic tests **require prior authorization** and are considered medically necessary when the criteria in 1.0 is met (not an all-inclusive list):

9.1 One genotyping for CYP2C19 polymorphisms for persons who have been prescribed PLAVIX (clopidogrel). Repeat CYP2C19 genotyping has no proven value

9.2 One genotyping for CYP2D6 polymorphisms for persons who have been prescribed doses of XENAZINE (tetrabenazine) greater than 50 mg per day.

Repeat CYP2D6 genotyping has unproven value

9.3 One genotyping for CYP2D6 polymorphisms for persons with Gaucher disease type 1 who are being considered for treatment with CERDELGA (eliglustat). Repeat CYP2D6 genotyping has no proven value

9.4 NS3 Q80K polymorphism testing for the presence of the virus for persons with hepatitis C virus (HCV) genotype 1a infection being considered for treatment with OLYSIO (simeprevir);

9.5 NS5A Q80K polymorphism medically necessary for persons **with hepatitis C** virus genotype 1a infection being considered for treatment with OLYSIO (simperevir)

9.6 NS5A testing for presence of virus with NS5A resistance-associated polymorphisms medically necessary for persons with hepatitis C virus genotype 1, 3, and 4 infections being considered for treatment with DAKLINZA (daclatasvir) or elbasvir and ZEPATIER (grazoprevir)

9.7 Warfarin Pharmacogenetics - CYP2C9, CYP4F2, and VKORC1 gene testing may be indicated when **ALL** of the following are present

9.7.1 Age 18 years and older **AND**

9.7.2 Venous thromboembolism prophylaxis with warfarin planned for elective hip or knee arthroplasty **AND**

9.7.3 No known bleeding disorder or thrombophilia

10.0 Pharmacogenetic screening in the general population is considered not medically necessary.

11.0 The following tests are considered experimental and investigational, and therefore not medically necessary:

11.1 CYP2D6 genotyping for predicting response to beta blockers

11.2 CYP2D6 genotyping for predicting response to TAMOXIFEN (tamoxifen citrate)

11.3 CYP2D6 genotyping for individual's with Alzheimer's disease with different clinical response to ARICEPT (donepezil)

11.4 CYP2C9 genotype-guided dosing of coumarin derivatives

11.5 ComplyRx urine test for drug monitoring

11.6 OncoyticAssuranceRx for adherence monitoring to oral anticancer medications

11.7 Snapshot Oral Fluid Compliance for adherence monitoring to prescription drugs

11.8 Genotyping for other cytochrome P450 polymorphisms – 3A4/3A5

11.9 UGT1A1 molecular assay

11.10 Genotyping for VKORC1 polymorphism

11.11 Apolipoprotein E (ApoE) for determining therapeutic response to lipid-lowering medications

11.12 Genotyping for methylenetetrahydrofolate reductase (MTHFR) for determining therapeutic response to antifolate chemotherapy and for guiding antidepressant therapy

11.13 Measurement of thromboxane metabolites in urine (e.g. AspirinWorks) to evaluate aspirin resistance

11.14 rs3798220 allele genetic testing for selecting persons for chronic aspirin therapy or other indications

11.15 DPYD, MTHFR, and TYMS gene testing to allow area under the curve (AUC)-targeted 5-fluorouracil dosing (e.g. Myriad Genetics OnDose)

11.16 Genetic polymorphisms of dihydropyrimidine dehydrogenase and thymidylate synthase to predict 5-fluorouracil toxicity

11.17 IL28B polymorphism genotyping for interferon therapy for hepatitis C

11.18 Psychotropic Medication Pharmacogenetics – Gene Panels CYP450 Polymorphisms (e.g. GeneSight Psychotropic, Genecept Assay, Neuropharmagen, CNSDose); HLA Typing

11.19 ABCB1, ADRA2A, BDNF, COMT, DRD, FKBP5, GNB3, HTR, MC4R, OGFRL1, SLC6A4, SPTA1, and TPH1 genes - Psychotropic medication pharmacogenetics

11.20 Platelet reactivity/function testing (VerifyNow P2Y12 Assay, Ultegra System Rapid Platelet Function Assay-ASA) for individuals who have undergone percutaneous coronary intervention

11.21 Genecept Assay (Genomind)

11.22 Methotrexate polyglutamates (Avise PG test) for evaluating response to methotrexate therapy in rheumatoid arthritis or other conditions.

11.23 Beta adrenergic receptor genotyping for evaluating persons with treatment resistant asthma and for all other indications

11.24 Millenium PGT (Millennium Laboratories)

11.25 PersonaGene Genetic Panels (AlBioTech)

11.26 A1555G genotyping before prescribing aminoglycosides

11.27 Proove Profiles - Proove Narcotic Risk Panel and the Proove Drug Metabolism Panel

11.28 DPYD genes

11.29 TYMS genes

11.30 Attention-Deficit Hyperactivity Disorder ADRA2A, COMT, CYP2B6 and CYP2D6 genes

11.31 GRIK4 gene – Citalopram pharmacogenetics

11.32 IFNL3 and IFNL4 – Hepatitis C

11.33 OPRM1 gene – Naltrexone pharmacogenetics

11.34 SLCO1B1 gene for Statin dosing or selection

11.35 CYP2C19 polymorphisms testing for fluoxetine

11.36 Genotyping for A1555G before prescribing aminoglycosides

11.37 Amerigene PGT testing panels

11.38 Aegis Drug-Drug Interaction Test

11.39 Interferon-lambda 3 (IFNL3) for prediction of virological response to pegylated-interferon-alpha and ribavirin combination therapy

11.40 PGxOnePlus genetic testing for anxiety and gastroesophageal reflux disease

11.41 UrSure tenofovir quantification test for adherence monitoring to pre-exposure prophylaxis

11.42 Naltrexone Pharmacogenetics – OPRM1 Gene

11.43 Selective Serotonin Reuptake Inhibitors (SSRIs) – Cytochrome P450 polymorphism

11.44 Irinotecan Pharmacogenetics – UGT1A1 molecular assay for the proper dosage of irinotecan for persons with colorectal cancer or other types of cancer;

11.45 Hepatitis C Medication Pharmacogenetics – IFNL3 and IFNL4 Genes

11.46 Citalopram Pharmacogenetics – GRIK4 Gene

11.47 Genotyping for VKORC1 polymorphism

11.48 Opioid Pharmacogenetics – CYP450 Polymorphisms, OPRM1 Gene and GeneSight Analgesic Panel

11.49 AVISE MTX – Methotrexate polyglutamates test

11.50 myTAIHEART for evaluating graft rejection following heart transplant and all other indications

11.51 Multi-gene pharmacogenetic panels including but not limited to the following: Genecept Assay, GeneSightRx, GeneSight ADHD, GeneSight Analgesic, GeneSight MTHFR and GeneSight Psychotropic testing, Millenium PGT,

PersonaGene Genetic Panels, Proove Profiles, rxSEEK Epilepsy Drug Metabolism, OneOme RightMed Pharmacogenomic Test, SureGene Test, Pain Medication Insights, PharmacoDx, INFINITI Neural Response Panel, and IDgenetix

11.52 Methotrexate pharmacogenetics – MTHFR gene

CPT/HCPCS Codes Related to MP9479

* 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) (e.g. glioma), common variants (e.g. R140W, R172M)
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g. hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (e.g. detection of large gene rearrangements)
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated)
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)
81166	BRCA1 (BRCA1, DNA repair associated) (e.g. hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (e.g. detection of large gene rearrangements)
81167	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)
81210	BRAF (B-Raf proto-oncogene, serine/threonine kinase) (e.g., colon cancer, melanoma), gene analysis, V600 variant(s)
81212	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA

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CPT Code	Description
	repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis
81213	IFNL3 (interferon, lambda 3) (e.g. drug response), gene analysis, rs12979860 variant
81215	BRCA1 (BRCA1, DNA repair associated) (e.g. hereditary breast and ovarian cancer) gene analysis
81216	BRCA2 (BRCA2, DNA repair associated) (e.g. hereditary breast and ovarian cancer) gene analysis
81217	BRCA2 (BRCA2, DNA repair associated) (e.g. hereditary breast and ovarian cancer) gene analysis
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g. cystic fibrosis) gene analysis; common variants (e.g. ACMG/ACOG guidelines)
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g. cystic fibrosis) gene analysis; known familial variants
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g. cystic fibrosis) gene analysis; duplication/deletion variants
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g. cystic fibrosis) gene analysis; full gene sequence
81224	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g. cystic fibrosis) gene analysis; intron 8 poly-T analysis (e.g. male infertility)
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (e.g. drug metabolism), gene analysis, common variants
81226	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g. drug metabolism), gene analysis, common variants
81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (e.g. drug metabolism), gene analysis, common variants
81230	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (e.g. drug metabolism), gene analysis, common variant(s) (e.g. *2, *22)
81231	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (e.g. drug metabolism), gene analysis, common variants (e.g. *2, *3, *4, *5, *6, *7)
81232	DPYD (dihydropyrimidine dehydrogenase) (e.g. 5-fluorouracil/5-FU and capecitabine drug metabolism), gene analysis, common variant(s) (e.g. *2A, *4, *5, *6)
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)
81240	F2 (prothrombin, coagulation factor II) (e.g. hereditary

CPT Code	Description
	hypercoagulability) gene analysis, 20210G>A variant
81241	F5 (coagulation factor V) (e.g. hereditary hypercoagulability) gene analysis, Leiden variant
81245	FLT3 (fms-hyphenrelated tyrosine kinase 3) (e.g. acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (e.g. exons 14, 15)
81246	tyrosine kinase domain (TKD) variants (e.g. D835, I836)
81247	G6PD (glucose-6-phosphate dehydrogenase) (e.g., hemolytic anemia, jaundice), gene analysis; common variant(s)
81248	G6PD (glucose-6-phosphate dehydrogenase) (e.g. hemolytic anemia, jaundice), gene analysis; known familial variant(s)
81249	G6PD (glucose-6-phosphate dehydrogenase) (e.g. hemolytic anemia, jaundice), gene analysis; full gene sequence
81272	KIT (v-hyphenkit Hardy-hyphenZuckerman 4 feline sarcoma viral oncogene homolog) (e.g. gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (e.g. exons 8, 11, 13, 17, 18)
81273	KIT (v-hyphenkit Hardy-hyphenZuckerman 4 feline sarcoma viral oncogene homolog) (e.g. mastocytosis), gene analysis, D816 variant(s)
81275	(Kirsten rat sarcoma viral oncogene homolog) (e.g. carcinoma) gene analysis
81276	KRAS (Kirsten rat sarcoma viral oncogene homolog) (e.g. carcinoma) gene analysis
81283	IFNL3 (e.g. drug response) gene analysis
81287	MGMT (O-6-methylguanine-DNA methyltransferase) (e.g. glioblastoma multiforme), methylation analysis
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (e.g. hereditary hypercoagulability) gene analysis, common variants
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)
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)
81314	PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18)
81328	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (e.g., adverse drug reaction), gene analysis, common variant(s) (e.g. *5)
81335	TPMT (thiopurine S-methyltransferase) (e.g., drug metabolism),

CPT Code	Description
	gene analysis, common variants (e.g. *2, *3)
81346	TYMS (thymidylate synthetase) (e.g. 5-fluorouracil/5-FU drug metabolism), gene analysis, common variant(s) (e.g. tandem repeat variant)
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (e.g. irinotecan metabolism), gene analysis, common variants
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (e.g. warfarin metabolism), gene analysis, common variant(s)
81370	HLA Class I and II typing, low resolution (e.g. antigen equivalents); HLA-A, -B, -C, -DRB1/3/4/5, and -DQB1
81371	HLA Class I and II typing, low resolution (e.g., antigen equivalents); HLA-A, -B, and -DRB1 (e.g. verification typing)
81372	HLA Class I typing, low resolution (e.g. antigen equivalents); complete
81373	HLA Class I typing, low resolution (e.g. antigen equivalents); one locus, each
81374	HLA Class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, B*27), each
81375	HLA Class II typing, low resolution (e.g. antigen equivalents); HLA-DRB1/3/4/5 and -DQB1
81376	HLA Class II typing, low resolution (e.g. antigen equivalents); one locus (e.g., HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
81377	HLA Class II typing, low resolution (e.g. antigen equivalents); one antigen equivalent, each
81378	HLA Class I and II typing, high resolution (e.g. alleles or allele groups), HLA-A, -B, -C, and -DRB1
81379	HLA Class I typing, high resolution (e.g. alleles or allele groups); complete (i.e., HLA-A, -B, and -C)
81380	HLA Class I typing, high resolution (e.g. alleles or allele groups); one locus (e.g. HLA-A, -B, or -C), each
81381	HLA Class I typing, high resolution (i.e., alleles or allele groups); one allele or allele group (e.g. B*57:01P), each
81382	HLA Class II typing, high resolution (e.g. alleles or allele groups); one locus (e.g., HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
81383	HLA Class II typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, HLA-DQB1*06:02P), each
81400	Molecular Pathology Procedure Level 1
81401	Molecular Pathology Procedure Level 2
81403	Molecular Pathology Procedure Level 4

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CPT Code	Description
81405	Molecular Pathology Procedure Level 6
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
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, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81479	Unlisted molecular pathology procedure
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination
83950	Oncoprotein; HER-2/neu
84431	Thromboxane metabolite(s), including thromboxane if performed, urine
87900	Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics
87902	Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis C virus
87903	Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; first through 10 drugs tested
87904	Infectious agent phenotype analysis by nucleic acid (DNA or RNA)

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CPT Code	Description
	with drug resistance tissue culture analysis, HIV 1; each additional drug tested (List separately in addition to code for primary procedure)
88271	Molecular cytogenetics; DNA probe, each (e.g. FISH)
88274	Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells
88275	Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells
88360	Morphometric analysis, tumor immunohistochemistry (e.g. Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual
88361	Morphometric analysis, tumor immunohistochemistry (e.g. Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology
88374	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure
88377	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure
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
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)
0029U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (e.g. Focused Pharmacogenomics Panel – Mayo Clinic)
0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (e.g. CYP2C9, CYP4F2, VKORC1, rs12777823) (e.g. Warfarin Response Genotype)
0031U	Drug metabolism targeted sequence analysis (e.g. CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1, and rs12777823
0032U	COMT (drug metabolism) gene analysis

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CPT Code	Description
0033U	HTR1A gene analysis (e.g. citalopram metabolism)
0034U	TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma
0070U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g. drug metabolism) gene analysis, common and select rare variants
0071U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g. drug metabolism) gene analysis, full gene sequence
0072U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g. drug metabolism) gene analysis, targeted sequence analysis
0073U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g. drug metabolism) gene analysis, targeted sequence analysis
0074U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, targeted sequence analysis (e.g. non-duplicated gene when duplication/multiplication is trans)
0075U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g. drug metabolism) gene analysis, targeted sequence analysis (e.g. 5' gene duplication/multiplication)
0076U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g. drug metabolism) gene analysis, targeted sequence analysis (e.g. 3' gene duplication/multiplication)
0078U	Pain management (opioid-use disorder) genotyping panel, 16 common variants (buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder (e.g. INFINITI Neural Response Panel)
0079U	Comparative DNA analysis using multiple selected single-nucleotide polymorphisms (SNPs), urine and buccal DNA, for specimen identity verification
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
0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score

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CPT Code	Description
0110U	Prescription drug monitoring, one or more oral oncology drug(s) and substances, definitive tandem mass spectrometry with chromatography, serum or plasma from capillary blood or venous blood, quantitative report with steady-state range for the prescribed drug(s) when detected
0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes (e.g. Psych HealthPGx Panel)
0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes (e.g. Genomind Professional PGx Express)
0219U	Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility
0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug (e.g. PredictGlioma)
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report (e.g. Theralink)
0345U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6 (e.g., GeneSight® Psychotropic)
0347U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 16 gene report, with variant analysis and reported phenotypes (e.g., RightMed® PGx16 Test) OneOme®,
0348U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes (e.g., RightMedOne Ome)
0349U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis, including reported phenotypes and impacted gene-drug interactions (e.g., RightMedOne Ome)
0350U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes (e.g., RightMedOne Ome)

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CPT Code	Description
G9143	Warfarin responsiveness testing by genetic technique using any method
S3722	Dose optimization by area under the curve (auc) analysis, for infusional 5-fluorouracil

	Committee/Source	Date(s)
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