MEDICAL POLICY	Genetic Testing: Pharmacogenetic Testing (Medicare Only)
Effective Date: 9/1/2021  9/1/2021 Medical Officer Date	Medical Policy Number: 217 Medical Policy Committee Approved Date: 8/18; 12/18; 3/19; 6/19; 9/19; 11/19; 07/2020; 12/2020; 7/2021

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Notes:

- This policy does not address genetic tests to determine drug therapy for the following indications:
  - TPMT testing for inflammatory bowel disease.
  - Non-small cell lung cancer targeted therapies (e.g., EGFR, ALK, ROS1, RET genes).
  - BCR-ABL1 fusion gene testing, which may be considered medically necessary.

  Please see Medical Policy Cross References section below for medical policies that may apply to these pharmacogenetic tests.
- This policy does not address multigene pharmacogenetic panel tests for selecting medications or doses of medication, which are considered **investigational and not covered**. Please see the *Genetic Testing: Non-covered Genetic Panel Tests (Medicare Only)* Medical Policy for examples of pharmacogenetic panel tests which are considered investigational.
- This policy does not address genetic testing of mutations in the MTHFR, CYP450, or VKORC1 genes (See Medical Policy Cross References section below for relevant policy information).

Service	Medicare Guidelines
Next Generation Sequencing (e.g. FoundationOne® CDx)	National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2)[1] • *Note*: Please refer to the following list of FDA-approved companion diagnostics.[2] Please note that criteria from NCD 90.2 must still be met.
BCR-ABL1 Genetic Testing	• Local Coverage Determination (LCD): MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36186)[3] • Local Coverage Article: Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (A57422)[4] • Local Coverage Article: Billing and Coding: MolDX: BCR-ABL (A55600)[5] • Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6] • Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)[7]
BRAF Genetic Testing	• Local Coverage Article: Billing and Coding: MolDX: FDA-Approved BRAF Tests (A54420)[8] • Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6] • Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)[7]
BRCA1 and BRCA2 Genetic Testing	• National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2)[1] • Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36163)[9] • Local Coverage Article: Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing (A57355)[10]
BRACAnalysis CDx® Test	• Local Coverage Article: Billing and Coding: MolDX: Myriad's BRACAnalysis CDx® (A55295)[11] • Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6] • Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)[7]
BRAF Genetic Testing	• Local Coverage Article: Billing and Coding: MolDX: FDA-Approved BRAF Tests (A54420)[8] • Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6]

	• Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)[7]
CFTR Genetic Testing	• Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6] • Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)[7] • Local Coverage Determination (LCD): MolDX: Pharmacogenomics Testing (L38337)[12] • Local Coverage Article: Billing and Coding: MolDX: Pharmacogenomics Testing (A57385)[13]
FLT3 Genetic Testing	• Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36163)[9] • Local Coverage Article: Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing (A57355)[10] • Local Coverage Article: Billing and Coding: MolDX: BCR-ABL (A55600)[5] • Local Coverage Article: Billing and Coding: MolDX: Genetic Testing for Lynch Syndrome (A54996)[14] • Local Coverage Article: Billing and Coding: MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (A57892)[15] • Local Coverage Article: Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer (A56518)[16]
KRAS Genetic Testing	• Local Coverage Article: Billing and Coding: MolDX: FDA-Approved KRAS Tests (A54500)[17] • Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6] • Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)[7]
*HLA -B*15:02 Genotyping*	• Local Coverage Determination (LCD): MolDX: Pharmacogenomics Testing (L38337)[12] • Local Coverage Article: Billing and Coding: MolDX: Pharmacogenomics Testing (A57385)[13]
NRAS Genetic Testing	• Local Coverage Determination (LCD): MolDX: NRAS Genetic Testing (L36339)[18] • Local Coverage Article: Billing and Coding: MolDX: NRAS Genetic Testing (A57487)[19]
PDGFRß Genetic Testing	• Local Coverage Determination (LCD): MolDX: Genetic Testing for Lynch Syndrome (L36374)[20]

	• Local Coverage Article: Billing and Coding: MolDX: Genetic Testing for Lynch Syndrome (A54996)[14] • Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36163)[9] • Local Coverage Article: Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing (A57355)[10]
PIK3CA Genetic Testing	Local Coverage Article: Billing and Coding: MolDX: PIK3CA Gene Tests (A55602)[21]
SULT4A1 Genetic Testing	Local Coverage Article: Billing and Coding: MolDX: SULT4A1 Genetic Testing (A55601)[22]
SLC6A4 (also known as HTTLPR) Genetic Testing	Local Coverage Article: Billing and Coding: MolDX: HTTLPR Gene Testing (A55265)[23]
TPP1 Genetic Testing	• Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6] • Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)[7]
DMD, DPYD, SMN1, SLCO1B1 or TYMS Genetic Testing	• Local Coverage Determination (LCD): MolDX: Pharmacogenomics Testing (L38337)[12] • Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6] • Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)[7]
NUDT15, TPMT, or UGT1A1 Genetic Testing	• Local Coverage Determination (LCD): MolDX: Pharmacogenomics Testing (L38337)[12] • Local Coverage Article: Billing and Coding: MolDX: Pharmacogenomics Testing (A57385)[13]
VEGFR2 Genetic Testing	Local Coverage Article: Billing and Coding: MolDX: VEGFR2 Tests (A55469)[24]
MMACHC Genetic Testing	Local Coverage Article: Billing and Coding: MolDX: MMACHC Test (A55289)[24]
KIF6 Genetic Testing	Local Coverage Article: Billing and Coding: MolDX: KIF6 Genotype (A55273)[25]
IDH2 Genetic Testing	• Local Coverage Article: Billing and Coding: MolDX: Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia (AML) (A55712)[26] • Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6]

FGFR3 Genetic Testing	• Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256)[6] • Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)[7] • Local Coverage Determination (LCD): MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (L38684)[27] • Local Coverage Article: Billing and Coding: MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (A58211)[28]

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
0111U	Oncology (colon cancer), targeted KRAS (codons 12, 13, and 61) and NRAS (codons 12, 13, and 61) gene analysis, utilizing formalin-fixed paraffin-embedded tissue
0154U	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)
0155U	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)
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
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
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
81161	DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed
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 (ie, detection of large gene rearrangements)

81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81232	DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism), gene analysis, common variant(s) (eg, *2A, *4, *5, *6)
81233	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)
81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)
81283	IFNL3 (interferon, lambda 3) (eg, drug response), gene analysis, rs12979860 variant
81287	MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme), methylation analysis
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)
81311	NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61)
81315	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative
81316	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative
81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed
81335	TPMT (thiopurine S-methyltransferase) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3)
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)
81346	TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism), gene analysis, common variant(s) (eg, tandem repeat variant)
81400	Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
81401	Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)

81402	Molecular pathology procedure, Level 3 (eg, >10 SNPs, 2-10 methylated variants, or 2-10 somatic variants [typically using non-sequencing target variant analysis], immunoglobulin and T-cell receptor gene rearrangements, duplication/deletion variants of 1 exon, loss of heterozygosity [LOH], uniparental disomy [UPD])
81403	Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)
81404	Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)
81405	Molecular pathology procedure, Level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array analysis)
81406	Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)
81407	Molecular pathology procedure, Level 8 (eg, analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of >50 exons, sequence analysis of multiple genes on one platform)
81408	Molecular pathology procedure, Level 9 (eg, analysis of >50 exons in a single gene by DNA sequence analysis)
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, 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 (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
G9143	Warfarin responsiveness testing by genetic technique using any method, any number of specimen(s)
No Prior Authorization Required	
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

0034U	TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(eg, thiopurine metabolism) gene analysis, common variants (ie, TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5)
0046U	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative
81121	IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81210	BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; known familial variants
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; full gene sequence
81224	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; intron 8 poly-T analysis (eg, male infertility)
81245	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15)
81246	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (eg, D835, I836)
81275	KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; variants in exon 2 (eg, codons 12 and 13)
81276	KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)
81301	Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)
81328	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (eg, adverse drug reaction), gene analysis, common variant(s) (eg, *5)
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, *28, *36, *37)

81379	HLA Class I typing, high resolution (ie, alleles or allele groups); complete (ie, HLA-A, -B, and -C)
81380	HLA Class I typing, high resolution (ie, alleles or allele groups); one locus (eg, HLA-A, -B, or -C), each
81381	HLA Class I typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, B*57:01P), each
88271	Molecular cytogenetics; DNA probe, each (eg, FISH)
88272	Molecular cytogenetics; chromosomal in situ hybridization, analyze 3-5 cells (eg, for derivatives and markers)
88273	Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells (eg, for microdeletions)
88274	Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells
88275	Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells
Not Covered	
0032U	COMT (catechol-O-methyltransferase)(drug metabolism) gene analysis, c.472G>A (rs4680) variant
0033U	HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G])
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
81479	Unlisted Molecular pathology procedure
81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry procedure

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

Providence Health Plans Medical Policies

- Genetic Studies and Counseling
- Genetic Testing: Cytochrome P450 and VKORC1 Polymorphisms (Medicare Only)
- Genetic Testing: Hereditary Breast and Ovarian Cancer (Medicare Only)
- Genetic Testing: Inherited Susceptibility to Colorectal Cancer (Medicare Only)
- Genetic Testing: MTHFR (Medicare Only)
- Genetic Testing: Non-covered Genetic Panel Tests (Medicare Only)
- Inflammatory Bowel Disease (IBD) Serologic Testing and Therapeutic Monitoring
- Non-Small Cell Lung Cancer: Molecular Testing for Targeted Therapy (Medicare Only)

REFERENCES

1. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2). 2020; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372. Accessed 6/30/2021.
2. U.S. Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). 2021; https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools. Accessed 7/2/2021.
3. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36186). 2019; https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36186. Accessed 6/30/2021.
4. Centers for Medicare and Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (A57422). 2021; https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=57422. Accessed 6/30/2021.

5. Centers for Medicare and Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: BCR-ABL (A55600). 2019; https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=55600. Accessed 6/30/2021.
6. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256). 2019; https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36256. Accessed 6/30/2021.
7. Centers for Medicare and Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527). 2019; https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=57527. Accessed 6/30/2021.
8. Centers for Medicare and Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: FDA-Approved BRAF Tests (A54420). 2019; https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=54420. Accessed 6/30/2021.
9. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36163). 2019; https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36163. Accessed 6/30/2021.
10. Centers for Medicare and Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing (A57355). 2020; https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=57355. Accessed 6/30/2021.
11. Centers for Medicare and Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: Myriad's BRACAnalysis CDx® (A55295). 2020; https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=55295. Accessed 6/30/2021.
12. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): MolDX: Pharmacogenomics Testing (L38337). 2020; https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=38337. Accessed 6/30/2021.
13. Centers for Medicare and Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: Pharmacogenomics Testing (A57385). 2020; https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=57385. Accessed 6/30/2021.
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16. Centers for Medicare and Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer (A56518). 2021; https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=56518. Accessed 6/30/2021.
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