


<b>MEDICAL POLICY</b>	<b>Genetic Testing: Non-Covered Genetic Panel Tests (Medicare Only)</b>
<b>Effective Date: 10/1/2021</b>	Medical Policy Number: 214
 10/1/2021	Medical Policy Committee Approved Date: 4/18; 8/18; 12/18; 3/19; 4/19; 6/19; 9/19; 11/19; 07/2020; 9/2020; 1/2021; 3/2021; 5/2021; 6/2021; 8/2021; 10/2021
Medical Officer                      Date	

**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

**DOCUMENTATION REQUIREMENTS**

In order to determine the clinical utility of a genetic panel test, the following documentation must be provided at the time of the request:

- Name of the panel test OR the name of the gene(s) and/or components of the test
- Name of laboratory that performed or is performing the test
- Clinical notes should include the following:
  - Reason for performing test, including the suspected condition
  - Signs/symptoms/test results related to reason for genetic testing
  - Family history, if applicable
  - How test results will impact clinical decision making
- CPT codes billed

**POLICY CRITERIA**

**Notes:**

- This policy does not address the following:
  - Whole exome or genome sequencing.
  - Genetic tests related to reproductive planning or prenatal testing.
  - The GeneSight® Psychotropic (AssureRx Health, Inc.) genetic panel, as this test may be considered medically necessary when the Medicare LCD ([L36325](#)) criteria are met.

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- The list of not medically reasonable or necessary panels addressed in this policy is not all-inclusive.
- Due to the rapidly changing field of genetic testing; panel names, genes included, and coding may change subsequent to the last update of this policy.
- Other Medical Policies may apply:
  - Please see [Cross References](#) section below for medical policies which may apply to specific hereditary or oncologic conditions.
  - If available, condition- or test-specific policies should be used to review single gene or genetic panel tests. For example, genetic panel testing for hereditary colorectal cancer is addressed in the *Genetic Testing: Inherited Susceptibility to Colorectal Cancer* medical policies.
  - Please refer to the PHP *Genetic Studies and Counseling* medical policy for genetic panel medical necessity criteria not addressed in more specific medical policies.

**Policy Criteria Links**

- Not Medically Necessary Genetic Tests:
  - [Statutorily Excluded Genes](#)
  - [Statutorily Excluded Conditions](#)
  - [Genetic Panel Tests](#)
- [Not Medically Reasonable or Necessary Genetic Panel Tests](#)

This policy is based on several Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCDs) and Local Coverage Articles (LCAs). This CMS guidance was identified as of the last policy review date on 2/25/2018.

**Statutorily Excluded Genes**

- I. Inclusion of one or more of the following genes in a genetic panel test, for any indication, will be considered **not medically necessary and not covered**.<sup>1-38</sup>

<b>ACRVL1*</b>	<b>ASPA</b>	<b>ATP7B</b>	<b>BCKDHB</b>	<b>BLM</b>	CFTR
CYP2B6	ENG*	FANCC	GBA	HAX1	HBB
HEXA	IKBKAP	MCOLN1	MECP2	MMACHC	NSD1
SMPD1	SULT4A1	VEGFR2			

**EXCEPTIONS**

\* ACRVL1/ENG Gene Testing: For patients with “suspected” hereditary hemorrhagic telangiectasia (HHT) in which diagnosis confirmation would demonstrate an improved outcome, approval of panels containing ACRVL1 and/or ENG gene(s) will be made on a case-by-case basis through the appeal process.<sup>1,2</sup>

**Statutorily Excluded Conditions**

- II. Genetic panel tests for the evaluation of arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) are considered **not medically necessary and are not covered.**<sup>39,40</sup>

**Not Medically Necessary Genetic Panel Tests**

- III. Genetic panel tests which include one or more of the statutorily excluded genes and conditions addressed in the above criteria I. and II., are considered **not medically necessary and not covered**, including but not limited to:

Proprietary Test Name	Laboratory
Arrhythmia Panel	GeneDx
Breast/Gyn Cancer Panel	GeneDx
Copper Metabolism Disorders Panel	Invitae
Colorectal Cancer Panel	GeneDx
Personalized Medicine Panel	Alpha Genomix
Genecept™ Assay	Genomind
GenoMind Professional PGx Express (includes CORE Anxiety & Depression Report [15 Genes] and/or FULL Mental Health Report [24 Genes])	Genomind
GeneSight® Analgesic Panel	AssureRx Health, Inc.
GeneTrails® GIST Genotyping Panel	OHSU Knight Diagnostic Laboratories
Megalencephaly Panel	Seattle Children's Hospital
OvaNext	Ambry Genetics
Pain Medication DNA Insight™	Pathway Genomics®
Pain Panel	Alpha Genomix
PGxOne™ Plus Pharmacogenomics Test	Admera Health
Retinal Dystrophy Panel	Blueprint Genetics
RightMed Comprehensive Test	OneOme
Riscover Hereditary Cancer Panel	Progenity
UW-OncoPlex - Cancer Gene Panel	University of Washington
VistaSeq Colorectal Cancer	LabCorp / Integrated Genetics / Integrated Oncology

The Providence Health Plan (PHP) CMS Medical Policy Manual (UM382) hierarchy of coverage indicates that in the absence of an NCD, LCD, LCA, or other coverage guideline, CMS allows coverage determinations to be based on an objective, evidenced-based process. Therefore, the PHP commercial medical policy criteria have been applied to some of the panel tests listed, in the absence of Medicare coverage guidance:

**Not Medically Reasonable or Necessary Genetic Panel Tests**

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IV. Genetic panel testing\* is considered **not medically reasonable or necessary** when there is insufficient evidence that ALL of the genes and/or components in the panel have proven clinical utility. To establish clinical utility, **both** of the following criteria (A. and B) must be met for each gene and/or component of the panel test:

- A. Testing allows for a definitive diagnosis or risk classification and **either** of the following are met:
  - 1. Other clinical and/or laboratory tests were inconclusive; **or**
  - 2. Testing avoids a more invasive diagnostic testing (i.e., muscle biopsy); **and**
- B. Testing results will guide decision(s) in clinical management (predictive, diagnostic, prognostic, or therapeutic).

Genetic panel tests that include one or more genes for which clinical utility has not been established are considered **not medically reasonable or necessary** under *Social Security Act, §1862(a)(1)(A)* for Medicare members, including but not limited to the following tests: (Please see Policy Guidelines below for definition of panel testing.)

Proprietary Test Name	Laboratory
Ataxia Comprehensive Evaluation Panel	Athena Diagnostics
Cardiomyopathy Panel	GeneDx
CNGnome™	PerkinElmer Genomics
CxBladder Detect	Pacific Edge, Ltd.
CxBladder Monitor	Pacific Edge, Ltd.
CxBladder Triage	Pacific Edge, Ltd.
DCMNext	Ambry Genetics
ERA® (Endometrial Receptivity Analysis)	Igenomix®
Focused Pharmacogenomics Panel	Mayo Clinic, Mayo Medical Laboratories
GeneSight® ADHD	Assurex Health, Inc.
GeneTrails® Hematologic Malignancies 76 Gene Panel	OHSU Knight Diagnostic Laboratories
Genomic Unity® Ataxia Repeat Expansion Analysis	Varietyx Inc
Genomic Unity® Comprehensive Ataxia Repeat Expansion and Sequence Analysis	Varietyx Inc
Genomic Unity® DMD Analysis	Varietyx Inc
GPS Cancer®	NantHealth
GYNPlus®	Ambry Genetics
HCMNext	Ambry Genetics
Hemiplegic Migraine Panels	GeneDx
Infantile Epilepsy Panel	GeneDx
Lymph3Cx Lymphoma Molecular Subtyping Assay	Mayo Clinic
Macula Risk PGx	ArcticDX Inc. / Arctic Medical Laboratories

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<b>myTAIHEART</b>	TAI Diagnostics, Inc.
<b>Nervous System/Brain Cancer</b>	Invitae
<b>NextStep DX Plus</b>	Lineagen
<b>OmniSeq Advance<sup>SM</sup></b>	OmniSeq <sup>®</sup> Corporation
<b>OmniSeq Comprehensive<sup>®</sup></b>	OmniSeq <sup>®</sup> Corporation
<b>OtoGenome<sup>™</sup></b>	Laboratory for Molecular Medicine / Partners HealthCare
<b>OtoSCOPE<sup>®</sup> Panel</b>	University of Iowa
<b>OvaNext<sup>®</sup></b>	Ambry Genetics
<b>Polypharmacy Panel</b>	Genelex Corporation
<b>Polypharmacy Comprehensive Panel</b>	Genelex Corporation
<b>Psychiatry/ADHD Panel</b>	Alpha Genomix
<b>Skeletal Dysplasias Core Panel</b>	BluePrint Genetics
<b>SureGene Test for Antipsychotic and Antidepressant Response (STA2R)</b>	SureGene LLC
<b>Tissue of Origin<sup>®</sup> (TOO<sup>®</sup>) - Endometrial</b>	Cancer Genetics Inc.
<b>Tissue of Origin<sup>®</sup> (TOO<sup>®</sup>) – Head &amp; Neck</b>	Cancer Genetics Inc.
<b>Vita Risk<sup>®</sup></b>	Arctic Medical Laboratories
<b>Warfarin Response Genotype</b>	Mayo Clinic, Mayo Medical Laboratories

**POLICY GUIDELINES**

Centers for Medicare & Medicaid Services [\(CMS\) Guidance on Genetic Screening Tests](#)

According to the Medicare Claims Processing Manual, Chapter 16:<sup>41</sup>

“Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are **not covered** except when there is a statutory provision that explicitly covers tests for screening as described.

If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test. A/B MACs (A) and (B) have discretionary authority to make reasonable and necessary scope of benefit determinations.”

Statutorily Excluded Tests

Benefits not addressed in Title XVIII of the Social Security Act (i.e. the Act) are known as being “statutorily excluded,” meaning, Medicare is not authorized to pay for them under the Act.<sup>42</sup> Section Sec. 1862 (1)(A) of the act indicated that statutorily excluded services are deemed “not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”.<sup>43</sup>

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Molecular Diagnostic Services (MoIDX) Program

The Oregon Medicare contractor (MAC) has adopted the Molecular Diagnostic Services (MoIDX) program guidelines for their service area.”

According to the Noridian website regarding the MoIDX Program:<sup>44</sup>

“The MoIDX Program was developed by Palmetto GBA in 2011 to identify and establish coverage and reimbursement for molecular diagnostic tests. This program performs the following functions:

- Facilitates detailed and unique identification through registration of molecular diagnostic tests to facilitate claims processing and to track utilization.
- Establishes clinical utility expectations.
- Completes technical assessments of published test data to determine clinical utility and coverage.
- Establishes reimbursement.

The MoIDX Program has determined certain gene tests do not meet Medicare’s medical necessary requirements and have therefore been deemed as statutory exclusions. Inclusion of one or more of these genes in a genetic panel test for any indication will result in an entire panel to be denied.

General Centers for Medicare & Medicaid Services (CMS) Coverage Guidance Documents

In addition to the gene/condition specific CMS coverage guidance addressed in the criteria above, there are several CMS coverage guidance documents available that are more general in scope, and do not specifically address genetic testing for reproductive purposes or in the prenatal setting, but may list CPT codes, genes or genetic tests that may be applicable to this policy. These general CMS documents are:

- Centers for Medicare & Medicaid Services Local Coverage Determinations (LCDs): L36256<sup>45</sup> and L36807<sup>46</sup>, MoIDX: Molecular Diagnostic Tests (MDT)

Genetic Panel Testing

\*For the purposes of this policy, a genetic panel test is defined as a test that simultaneously evaluates 3 or more genes using one of three methodologies:

- next-generation sequencing (NGS)
- chromosomal microarray analysis (CMA)
- gene expression profiling (GEP)

Genetic panel tests may be used for a number of indications. This policy only addresses genetic panel tests that may be used for diagnosis or risk assessment of hereditary conditions and oncologic indications.

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Genetic panel tests may be either be proprietary, “off-the-shelf”, tests with a set number of genes (subject to change without notice), or they may be customized, “a la cart”, tests with genes selected by the ordering provider or genetic counselor based on a patient’s symptoms.

**BILLING GUIDELINES**

Some, but not all, panel tests may have a specific CPT or HCPCS code assigned (81410-81471). However, many panels may be billed with unlisted codes (e.g., 81479 or 81599) or multiple gene-specific (81200-81355) and/or molecular pathology procedure codes (81400-81408).

**CPT/HCPCS CODES**

Note: Codes addressed by this policy, may include, but are not limited to, the following:

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<b>Prior Authorization Required</b>	
0028U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, copy number variants, common variants with reflex to targeted sequence analysis
0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2, VKORC1, rs12777823)
81105	Human Platelet Antigen 1 genotyping (HPA-1), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-1a/b (L33P)
81106	Human Platelet Antigen 2 genotyping (HPA-2), GP1BA (glycoprotein Ib [platelet], alpha polypeptide [GPIba]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-2a/b (T145M)
81107	Human Platelet Antigen 3 genotyping (HPA-3), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex], antigen CD41 [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-3a/b (I843S)

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81108	Human Platelet Antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-4a/b (R143Q)
81109	Human Platelet Antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant (eg, HPA-5a/b (K505E))
81110	Human Platelet Antigen 6 genotyping (HPA-6w), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa, antigen CD61] [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-6a/b (R489Q)
81111	Human Platelet Antigen 9 genotyping (HPA-9w), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex, antigen CD41] [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-9a/b (V837M)
81112	Human Platelet Antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-15a/b (S682Y)
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)
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
81171	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81172	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)
81173	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence
81174	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant
81175	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence
81176	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; targeted sequence analysis (eg, exon 12)
81177	ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81178	ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles



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81179	ATXN2 (ataxin 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81180	ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81181	ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81183	ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence
81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant
81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81188	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81189	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; full gene sequence
81190	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; known familial variant(s)
81204	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)
81219	CALR (calreticulin)(eg myeloproliferative disorders, gene analysis, common variants in exon 9)
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)
81226	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)
81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic common variants regions for copy number variants (e.g. Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization[CGH] microarray analysis)
81230	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis, common variant(s) (eg, *2, *22)
81231	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *7)

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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)
81234	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles
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)
81238	F9 (coagulation factor IX) (eg, hemophilia B), full gene sequence
81239	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)
81247	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-)
81248	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s)
81249	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; full gene sequence
81250	G6PC (glucose-6-phosphatase, catalytic subunit) (e.g., Glycogen storage disease, type 1a, von Gierke disease) gene analysis, common variants (e.g., R83C, Q347X)
81256	HFE (hemochromatosis) (e.g. hereditary hemochromatosis) gene analysis, common variants (e.g. C282Y, H63D)
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2)(e.g. alpha thalassaemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (e.g., Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha20.5, and Constant Spring)
81258	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant
81259	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence
81269	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants
81271	HTT (huntingtin) (eg, Huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81274	HTT (huntingtin) (eg, Huntington disease) gene analysis; characterization of alleles (eg, expanded size)
81284	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles
81285	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)
81286	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence
81289	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; known familial variant(s)

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81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2 (eg hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81295	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, 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
81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant
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)
81312	PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81317	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81321	PTEN (phosphatase and tensin)(e.g., Cowden Syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis
81322	PTEN (phosphatase and tensin)(e.g., Cowden Syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant
81323	PTEN (phosphatase and tensin)(e.g., Cowden Syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant
81324	PMP22 (peripheral myelin protein 22)(e.g., Charcot-Marie-Tooth hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis
81325	PMP22 (peripheral myelin protein 22)(e.g., Charcot-Marie-Tooth hereditary neuropathy with liability to pressure palsies) gene analysis; full sequence
81326	PMP22 (peripheral myelin protein 22) (e.g., Charcot-Marie-Tooth hereditary neuropathy with liability to pressure palsies) gene analysis; know familial variant
81327	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis
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
81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and Ubiquitin protein ligase E3A) (e.g., Prader-Willi syndrome and/or Angelman syndrome methylation analysis
81332	SERPINA 1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase variants (e.g., *S and *Z)
81333	TGFB1 (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)
81334	RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis (eg, exons 3-8)
81335	TPMT (thiopurine S-methyltransferase) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3)

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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)
81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81344	TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)
81346	TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism), gene analysis, common variant(s) (eg, tandem repeat variant)
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variant(s) (eg, -1639G>A, c.173+1000C>T)
81400	Molecular pathology procedure, Level 1 (e.g., identification of single germline variant [e.g., SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
81401	Molecular pathology procedure, Level 2 (e.g., 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 (e.g., >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 1 exon)
81403	Molecular pathology procedure, level 4 (e.g. 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 (e.g., 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 (e.g., analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons)
81406	Molecular pathology procedure, Level 7 (e.g., 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 (e.g., 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, level 9 (e.g., analysis of >50 exons in a single gene by DNA sequence analysis)
81413	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A

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81414	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
81416	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (List separately in addition to code for primary procedure)
81417	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)
81430	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel, must include sequencing of at least 60 genes, including CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3, USH1C, USH1G, USH2A, and WFS1
81431	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); duplication/deletion analysis panel, must include copy number analyses for STRC and DFNB1 deletions in GJB2 and GJB6 genes
81434	Hereditary retinal disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, and USH2A
81437	Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL
81438	Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL
81439	Hereditary cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy), genomic sequence analysis panel, must include sequencing of at least 5 cardiomyopathy-related genes (eg, DSG2, MYBPC3, MYH7, PKP2, TTN)
81442	Noonan spectrum disorders (eg, Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, and SOS1
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

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81448	Hereditary peripheral neuropathies (eg, Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include sequencing of at least 5 peripheral neuropathy-related genes (eg, BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, SPTLC1)
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)
S3870	Comparative genomic hybridization (cgh) microarray testing for developmental delay, autism spectrum disorder and/or intellectual disability

**No Prior Authorization Required**

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
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(v-raf murine sarcoma viral oncogene homolog B1) (e.g. Colon Cancer) gene analysis, V600E variant
81218	CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81235	EGFR (Epidermal growth factor receptor)(EG, non-small cell lung cancer) gene analysis, common variants (EG, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)
81252	GJB2 (gap junction protein, beta 2, 26kDa, connexin 26) (eg, nonsyndromic hearing loss) gene analysis; full gene sequence



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81253	GJB2 (gap junction protein, beta 2, 26kDa, connexin 26) (eg, nonsyndromic hearing loss) gene analysis; known familial variants
81254	GJB6 (gap junction protein, beta 6, 30kDa, connexin 30) (eg, nonsyndromic hearing loss) gene analysis, common variants (eg, 309kb [del(GJB6-D13S1830)] and 232kb [del(GJB6-D13S1854)])
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, mastocytosis), gene analysis, D816 variant(s)
81275	KRAS ((V-KI-RAS2 Kirsten Rat Sarcoma Viral Oncogene)( EG carcinoma) gene analysis, variants in 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 (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
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)
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) (eg, adverse drug reaction), gene analysis, common variant(s) (eg, *5)
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
81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores
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
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
S3844	DNA analysis of the connexin 26 gene (GJB2) for susceptibility to congenital, profound deafness

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Not Covered	
0012M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma
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
0029U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie, CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and rs12777823)
0031U	CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7)
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])
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)
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)
0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma
0057U	Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank
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
0130U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis), targeted mRNA sequence analysis panel (APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, and TP53) (List separately in addition to code for primary procedure)
0131U	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes) (List separately in addition to code for primary procedure)



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0134U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes) (List separately in addition to code for primary procedure)
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
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes
0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes
0205U	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities
0216U	Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
0217U	Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
0218U	Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)
81205	BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (e.g., Maple syrup urine disease) gene analysis, common variants (e.g., R183P, G278s, E422X)
81209	BLM (Bloom syndrome, RecQ helicase-like) (e.g., Bloom syndrome) gene analysis 2281 del6ins7 variant
81242	FANCC (Fanconi anemia, complementation group C) (e.g., Fanconi Anemia, type C) gene analysis, common variant (e.g., IVS4=4A>T)
81243	FMR1 (Fragile X mental retardation 1) (e.g., fragile x mental retardation) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles
81244	FMR1 (Fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis; characterization of alleles (e.g., expanded size and methylation status)

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81251	GBA (glucosidase, beta, acid) (e.g., Gaucher disease) gene analysis, common variants (e.g., N370S, 84GG, L444P, IVS2=1G>A)
81255	HEXA (hexosaminidase A [alpha polypeptide]) (e.g. Tay-Sachs disease) gene analysis common variants (e.g., 1278insTATC, 1421+1G>C, G269S)
81260	IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein)(e.g. familial dysautonomia) gene analysis, common variants
81290	MCOLN1 (mucopolin 1 ) (e.g., Mucopolidosis, Type IV) gene analysis, common variants (e.g. IVS3-2A>G, del6.4b)
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (e.g., hereditary hypercoagulability) gene analysis, common variants (e.g., 677T, 1298C)
81302	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; full sequence analysis
81303	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; known familial variant
81304	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; duplication/deletion variants 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)
81330	SMPD1 (sphingomyelin phosphodiesterase 1, acid lysomal) (e.g., Niemann-Pick disease Type A) gene analysis, common variants (e.g., R496L, L302P, fsP330)
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, *28, *36, *37)
81361	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (eg, HbS, HbC, HbE)
81362	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s)
81363	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)
81364	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); full gene sequence
81412	Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1
81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucopolidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)

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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; each additional single drug or drug combination (List separately in addition to code for primary procedure)
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival
<b>Unlisted Codes</b> 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 it will be <b>denied as not covered</b> .	
81479	Unlisted Molecular Pathology
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.

## MEDICAL POLICY CROSS REFERENCES

- Genetic Studies and Counseling, GT234

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- Genetic Testing: *JAK2*, *CALR*, and *MPL* (Medicare Only), GT399
- Genetic Testing: CADASIL Disease (Medicare Only), GT406
- Genetic Testing: Hereditary Breast and Ovarian Cancer: Genetic Counseling and Testing (Medicare Only), GT380
- Genetic Testing: Inherited Susceptibility to Colorectal Cancer (Medicare Only), GT413
- Genetic Testing: Inherited Thrombophilias (Medicare Only), GT402
- Genetic Testing: Non-Covered Genetic Panel Tests (All Lines of Business except Medicare), GT235
- Genetic Testing: Pharmacogenetic Testing, GT306
- Genetic Testing: Reproductive Planning and Prenatal Testing (Medicare Only), GT384
- Genetic Testing: Whole Exome, Whole Genome and Proteogenomic Testing, GT389

## REFERENCES

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2. Centers for Medicare & Medicaid Services. LCA A55159. LCA Title: MoIDX: ENG and ACVRL1 Gene Tests Coding and Billing Guidelines. Effective 12/01/2018.
3. Centers for Medicare & Medicaid Services. LCA A55089. LCA Title: MoIDX: Aspartoacyclase 2 Deficiency(ASPA) Testing Billing and Coding Guidelines. Effective 10/10/2016.
4. Centers for Medicare & Medicaid Services. LCA A55142. LCA Title: MoIDX: Aspartoacyclase 2 Deficiency (ASPA) Testing Coding and Billing Guidelines. Effective 06/01/2018. Accessed 12/13/2018.
5. Centers for Medicare & Medicaid Services. LCA A55098. LCA Title: MoIDX: ATP7B Gene Tests Billing and Coding Guidelines. Effective 10/17/2016.

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6. Centers for Medicare & Medicaid Services. LCA A55143. LCA Title: MoIDX: ATP7B Gene Tests Coding and Billing Guidelines. Effective 06/01/2018. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55143&ver=6&Date=12%2f13%2f2018&DocID=A55143&bc=hAAAABAAA&h&r=r10&KeyWord=atp7b&KeyWordLookUp=Doc&KeyWordSearchType=Or&kq=true&bc=IAAAACAAAA&>. Accessed 12/13/2018.
7. Centers for Medicare & Medicaid Services. LCA A55100. LCA Title: MoIDX: BCKDHB Gene Analysis Billing and Billing Guidelines. Effective 10/17/2016. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55100&ver=5&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Bot&h&r=r10&KeyWord=BCKDHB&KeyWordLookUp=Doc&KeyWordSearchType=Or&kq=true&bc=IAAAACAAAA&>. Accessed 12/13/2018.
8. Centers for Medicare & Medicaid Services. LCA A55145. LCA Title: MoIDX: BCKDHB Gene Test Coding and Billing Guidelines. Effective 07/01/2018. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55145&ver=8&Date=12%2f13%2f2018&DocID=A55145&bc=hAAAABAAA&h&r=r10&KeyWord=BCKDHB&KeyWordLookUp=Doc&KeyWordSearchType=Or&kq=true&bc=IAAAACAAAA&>. Accessed 12/13/2018.
9. Centers for Medicare & Medicaid Services. LCA A55148. LCA Title: MoIDX: BLM Gene Analysis Coding and Billing Guidelines. Effective 07/01/2018. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55148&ver=6&Date=12%2f13%2f2018&DocID=A55148&bc=hAAAABAAA&h&r=r10&KeyWord=blm&KeyWordLookUp=Doc&KeyWordSearchType=Or&kq=true&bc=IAAAACAAAA&>. Accessed 12/13/2018.
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