



**Care1st Health Plan Arizona, Inc.**

**Easy Choice Health Plan**

**Harmony Health Plan of Illinois**

**Missouri Care**

**'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona**

**OneCare (Care1st Health Plan Arizona, Inc.)**

**Staywell of Florida**

**WellCare (Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)**

**WellCare Prescription Insurance**

## **Diagnostic and Predictive Genetic Testing**

**Policy Number: HS-021**

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9/4/2014; 11/5/2015; 1/11/2018**

### **APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

### **DISCLAIMER**

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at [www.wellcare.com](http://www.wellcare.com). All guidelines can be found at this site as well by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

### **BACKGROUND**

Genetic testing can be performed for several reasons; predominantly among these reasons are 1) using genetic testing as a diagnostic tool, and 2) using testing as a mechanism for predicting the presence of a specific disease in those with a familial history.

#### *Diagnostic/Confirmatory Testing in Symptomatic Individuals*

This testing is done to rule out, identify, or confirm a suspected genetic disorder in an affected individual. Diagnostic testing may be performed to help determine the course of the disease or choice of the relevant treatment.

### *Predictive Testing in Pre-Symptomatic Individuals*

Predictive testing is used to determine whether individuals who have a family history of a disease but no current symptoms have the gene alteration associated with the disease. Predictive genetic testing includes pre-symptomatic testing and pre-dispositional testing. When a specific mutation is identified through pre-symptomatic testing, the patient will eventually develop symptoms of a disease (e.g., testing for Huntington's disease before symptoms are present). In pre-dispositional testing, eventual development of symptoms is likely but not certain when the gene mutation is present (e.g., breast cancer).

### *Genetic Counseling and Informed Consent*

Individuals who are considering genetic testing should receive detailed counseling from a qualified professional prior to and following testing so that they are able to make informed decisions. Patients should be advised that genetic testing is a multi-step process that includes risk assessment, pretesting education and follow-up counseling after the test results are known. While genetic counseling should provide sufficient information to allow the individual and family to make well-informed decisions about the benefits, risks, limitations, and implications of genetic testing, it should also be nondirective in nature. Once the results of the test are known, the implications of either a positive or a negative test should be reviewed.

## **POSITION STATEMENT**

### **Applicable To:**

- Medicaid – Hawaii
- Medicare – Easy Choice Health Plan, Hawaii

NOTE: For all other lines of business, please refer to the current contracted vendor for Lab Management requests.

Genetic testing **is considered medically necessary** to establish a molecular diagnosis of an inheritable disease when ALL of the following criteria are met:

- The member displays clinical features, or is at risk of inheriting the mutation in question (pre-symptomatic); **AND**
- The result of the test will directly impact the treatment being delivered to the member; **AND**
- After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain, and an inheritable disease is suspected.

In the absence of specific information regarding advances in the knowledge of mutation characteristics for a particular disorder, genetic tests for inherited disease need only be conducted once per lifetime of the member.

Genomic microarray analysis is considered to be medically necessary for the diagnostic evaluation of patients suspected of having a genetic syndrome (for example, with congenital anomalies otherwise undiagnosed, dysmorphic features, developmental delays or intellectual delays).

Genomic microarray analysis is considered not medically necessary for the diagnostic evaluation of individuals with autism spectrum disorders, Asperger syndrome, and pervasive developmental disorder (PDD).

WellCare will cover **genetic testing for inheritable disorders in non-WellCare members** only when ALL of the following conditions are met:

- The information is needed to adequately assess risk in the WellCare member; **AND**
- The information will be used in the immediate care plan of the WellCare member; **AND**
- The non-WellCare member's benefit plan, if any, will not cover the test (a copy of the denial letter\* from the non-WellCare member's benefit plan must be provided).

WellCare may also request a copy of the certificate from the non-member's health insurance plan if: (1) the denial letter from the non-member's insurance carrier fails to specify the basis for non-coverage; (2) the denial is based on a specific plan exclusion; or (3) the genetic test is denied by the non-member's insurance carrier as not medically necessary and the medical information provided to WellCare does not make clear why testing would not be of significant medical benefit to the non-member.

**CODING**

**CPT®\* Codes** - *This list of codes may not be all-inclusive.*

- 81161** DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed
- 81200** ASPA (aspartoacylase) (eg, Canavan disease) gene analysis, common variants (eg, E285A, Y231X)
- 81201** APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence
- 81202** APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; known familial variants
- 81203** APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants
- 81205** BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X)
- 81206** BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative
- 81207** BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative
- 81208** BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative
- 81209** BLM (Bloom syndrome, RecQ helicase-like) (eg, Bloom syndrome) gene analysis, 2281del6ins7 variant
- 81210** BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)
- 81211** BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)
- 81212** BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
- 81213** BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants
- 81214** BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)
- 81215** BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
- 81216** BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
- 81217** BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
- 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)
- 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 regions for copy number variants (eg, Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic

- hybridization [CGH] microarray analysis)
- 81229** Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
- 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)
- 81240** F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant
- 81241** F5 (coagulation factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant
- 81242** FANCC (Fanconi anemia, complementation group C) (eg, Fanconi anemia, type C) gene analysis, common variant (eg, IVS4+4A>T)
- 81243** FMR1 (Fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
- 81244** FMR1 (Fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; characterization of alleles (eg, expanded size and methylation status)
- 81245** FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis, internal tandem duplication (ITD) variants (ie, exons 14, 15)
- 81250** G6PC (glucose-6-phosphatase, catalytic subunit) (eg, Glycogen storage disease, Type 1a, von Gierke disease) gene analysis, common variants (eg, R83C, Q347X)
- 81251** GBA (glucosidase, beta, acid) (eg, Gaucher disease) gene analysis, common variants (eg, N370S, 84GG, L444P, IVS2+1G>A)
- 81252** GJB2 (gap junction protein, beta 2, 26kDa; connexin 26) (eg, nonsyndromic hearing loss) gene analysis; full gene sequence
- 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)])
- 81255** HEXA (hexosaminidase A [alpha polypeptide]) (eg, Tay-Sachs disease) gene analysis, common variants (eg, 1278insTATC, 1421+1G>C, G269S)
- 81256** HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D)
- 81257** HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (eg, Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and Constant Spring)
- 81260** IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein) (eg, familial dysautonomia) gene analysis, common variants (eg, 2507+6T>C, R696P)
- 81261** IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology (eg, polymerase chain reaction)
- 81262** IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); direct probe methodology (eg, Southern blot)
- 81263** IGH@ (Immunoglobulin heavy chain locus) (eg, leukemia and lymphoma, B-cell), variable region somatic mutation analysis
- 81264** IGK@ (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma, B-cell), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
- 81265** Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [eg, buccal swab or other germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)
- 81266** Comparative analysis using Short Tandem Repeat (STR) markers; each additional specimen (eg, additional cord blood donor, additional fetal samples from different cultures, or additional zygosity in multiple birth pregnancies) (List separately in addition to code for primary procedure)
- 81267** Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; without cell selection
- 81268** Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; with cell selection (eg, CD3, CD33), each cell type

- 81270** JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant
- 81275** KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; variants in exon 2 (eg, codons 12 and 13)
- 81280** Long QT syndrome gene analyses (eg, KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); full sequence analysis
- 81281** Long QT syndrome gene analyses (eg, KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); known familial sequence variant
- 81282** Long QT syndrome gene analyses (eg, KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); duplication/deletion variants
- 81287** MGMT (0-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme), methylation analysis
- 81290** MCOLN1 (mucopolipin 1) (eg, Mucopolipidosis, type IV) gene analysis, common variants (eg, IVS3-2A>G, del6.4kb)
- 81291** MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
- 81292** MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
- 81293** MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
- 81294** MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
- 81295** MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
- 81296** MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
- 81297** MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
- 81298** MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
- 81299** MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
- 81300** MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
- 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
- 81303** MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; known familial variant
- 81304** MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; duplication/deletion variants
- 81310** NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants
- 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
- 81317** PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
- 81318** PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
- 81319** PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
- 81321** PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis ~~04/04/2013~~
- 81322** PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome)

- gene analysis; known familial variant ~~01/01/2013~~
- 81323** PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant ~~01/01/2013~~
- 81324** PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis ~~01/01/2013~~
- 81325** PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; full sequence analysis ~~01/01/2013~~
- 81326** PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; known familial variant
- 81330** SMPD1 (sphingomyelin phosphodiesterase 1, acid lysosomal) (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)
- 81331** SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A) (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis
- 81332** SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, \*S and \*Z)
- 81340** TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (eg, polymerase chain reaction)
- 81341** TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using direct probe methodology (eg, Southern blot)
- 81342** TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
- 81350** UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, \*28, \*36, \*37)
- 81355** VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variants (eg, -1639G>A, c.173+1000C>T)
- 81370** HLA Class I and II typing, low resolution (eg, antigen equivalents); HLA-A, -B, -C, -DRB1/3/4/5, and -DQB1
- 81371** HLA Class I and II typing, low resolution (eg, antigen equivalents); HLA-A, -B, and -DRB1/3/4/5 (eg, verification typing)
- 81372** HLA Class I typing, low resolution (eg, antigen equivalents); complete (ie, HLA-A, -B, and -C)
- 81373** HLA Class I typing, low resolution (eg, antigen equivalents); 1 locus (eg, HLA-A, -B, or -C), each
- 81374** HLA Class I typing, low resolution (eg, antigen equivalents); 1 antigen equivalent (eg, B\*27), each
- 81375** HLA Class II typing, low resolution (eg, antigen equivalents); HLA-DRB1/3/4/5 and -DQB1
- 81376** HLA Class II typing, low resolution (eg, antigen equivalents); 1 locus (eg, HLA-DRB1/3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
- 81377** HLA Class II typing, low resolution (eg, antigen equivalents); 1 antigen equivalent, each
- 81378** HLA Class I and II typing, high resolution (ie, alleles or allele groups), HLA-A, -B, -C, and -DRB1
- 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); 1 locus (eg, HLA-A, -B, or -C), each
- 81381** HLA Class I typing, high resolution (ie, alleles or allele groups); 1 allele or allele group (eg, B\*57:01P), each
- 81382** HLA Class II typing, high resolution (ie, alleles or allele groups); 1 locus (eg, HLA-DRB1, -DRB3, -DRB4, -DRB5, -DQB1, -DQA1, -DPB1, or -DPA1), each
- 81383** HLA Class II typing, high resolution (ie, alleles or allele groups); 1 allele or allele group (eg, HLA-DQB1\*06:02P), each
- 81400** Molecular pathology procedure, Level 1
- 81401** Molecular pathology procedure, Level 2
- 81402** Molecular pathology procedure, Level 3
- 81403** Molecular pathology procedure, Level 4
- 81404** Molecular pathology procedure, Level 5
- 81405** Molecular pathology procedure, Level 6
- 81406** Molecular pathology procedure, Level 7
- 81407** Molecular pathology procedure, Level 8
- 81408** Molecular pathology procedure, Level 9

- 81479** Unlisted molecular pathology procedure
- 83950** Oncoprotein; HER-2/neu
- 83951** Oncoprotein; des-gamma-carboxy-prothrombin (DCP)
- 84999** Unlisted chemistry procedure
- 88182** Flow cytometry, cell cycle or DNA analysis
- 88184** Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
- 88185** Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (List separately in addition to code for first marker)
- 88187** Flow cytometry, interpretation; 2 to 8 markers
- 88188** Flow cytometry, interpretation; 9 to 15 markers
- 88189** Flow cytometry, interpretation; 16 or more markers
- 88230** Tissue culture for non-neoplastic disorders; lymphocyte
- 88233** Tissue culture for non-neoplastic disorders; skin or other solid tissue biopsy
- 88235** Tissue culture for non-neoplastic disorders; amniotic fluid or chorionic villus cells
- 88237** Tissue culture for neoplastic orders; bone marrow, blood cells
- 88239** Tissue culture for neoplastic orders; solid tumor
- 88245** Chromosome analysis for breakage syndromes; baseline Sister Chromatid Exchange (SCE), 20-25 cells
- 88248** Chromosome analysis for breakage syndromes; baseline breakage, score 50100 cells, count 20 cells, 2 karyotypes (eg, for ataxia telangiectasia, Fanconi anemia, fragile X)
- 88249** Chromosome analysis for breakage syndromes; score 100 cells, clastogen stress (eg, diepoxybutane, mitomycin C, ionizing radiation, UV radiation)
- 88261** Chromosome analysis; count 5 cells, 1 karyotype, with banding
- 88262** Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding
- 88263** Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding
- 88264** Chromosome analysis; analyze 20-25 cells
- 88267** Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding
- 88269** Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding
- 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
- 88280** Chromosome analysis; additional karyotypes, each study
- 88283** Chromosome analysis; additional specialized banding technique (eg, NOR, C-banding)
- 88285** Chromosome analysis; additional cells counted, each study
- 88289** Chromosome analysis; additional high resolution study
- 88291** Cytogenetics and molecular cytogenetics, interpretation and report
- 96040** Medical genetics and genetic counseling service, each 30 minutes face-to-face with patient/family

**HCPCS®\* Codes - This list of codes may not be all-inclusive. Note: S-Codes are NON COVERED FOR MEDICARE**

- S0265** Genetic counseling, under physician supervision, each 15 minutes
- S3800** Genetic testing for amyotrophic lateral sclerosis (ALS)
- S3840** DNA analysis for germline mutations of the ret proto-oncogene for susceptibility to multiple endocrine neoplasia type 2
- S3841** Genetic testing for retinoblastoma
- S3842** Genetic testing for von hippel-lindau disease
- S3844** DNA analysis of the connexin 26 gene (GJB2) for susceptibility to congenital, profound deafness
- S3845** Genetic testing for alpha-thalassemia
- S3846** Genetic testing for hemoglobin e beta-thalassemia
- S3849** Genetic testing for Niemann-Pick disease
- S3850** Genetic testing for sickle cell anemia
- S3852** DNA Analysis for APOE epsilon 4 allele for susceptibility to Alzheimer's disease
- S3853** Genetic testing for myotonic muscular dystrophy

- S3854** Gene expression profiling panel for use in the management of breast cancer treatment
- S3855** Genetic testing for detection of mutations in the presenilin – 1 gene
- S3861** Genetic testing, sodium channel, voltage-gated, type V, alpha subunit (SCN5A) and variants for suspected Brugada Syndrome
- S3865** Comprehensive gene sequence analysis for hypertrophic cardiomyopathy
- S3866** Genetic analysis for specific gene mutation for hypertrophic cardiomyopathy (HCM) in an individual with a known HCM mutation in the family
- S3870** Comparative genomic hybridization (CGH) microarray testing for development delay, autism, spectrum disorder and/or intellectual disability
- S3890** DNA analysis, fecal, for colorectal cancer screening

**ICD-9-CM Procedure Codes** – No specific codes.

**ICD-10-PCS** – No applicable codes.

**ICD-10-CM Diagnosis Codes**

- D72.0** Genetic anomalies of leukocytes
- G24.1** Genetic torsion dystonia
- O28.5** Abnormal chromosomal and genetic finding on antenatal screening of mother
- P00.89** Newborn (suspected to be) affected by other maternal conditions
- Z13.71-Z13.79** Encounter for screening for genetic and chromosomal anomalies (Z13.79)
- Z14-Z15.89** Genetic susceptibility to other disease (Z15.89)
- Z31.430** Encounter for female for testing for genetic disease carrier status for procreative management
- Z31.438** Encounter for other genetic testing of female for procreative management
- Z31.440** Encounter for male for testing for genetic disease carrier status for procreative management
- Z31.448** Encounter for other genetic testing of male for procreative management
- Z31.5** Encounter for procreative genetic counseling
- Z84.81** Family history of carrier genetic disease

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

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**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

<b>Date</b>	<b>Action</b>
1/11/2018	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> </ul>
11/5/2015	<ul style="list-style-type: none"> <li>• Approved by MPC. Coding changes only.</li> </ul>
9/4/2014	<ul style="list-style-type: none"> <li>• Approved by MPC. Added clarification to lines of business.</li> </ul>
6/5/2014, 6/6/2013, 6/7/2012	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> </ul>
12/1/2011	<ul style="list-style-type: none"> <li>• New template design approved by MPC.</li> </ul>
8/2/2011	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> </ul>