



MEDICAL COVERAGE POLICY

SERVICE: Genetic Testing

Policy Number: 037

Effective Date: 07/01/2020

Last Review: 05/28/2020

Next Review Date: 05/28/2021

Important note:

Unless otherwise indicated, this policy will apply to all lines of business.

Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Genetic (Genomic) Testing

PRIOR AUTHORIZATION: Required.

POLICY: All genetic testing should be used for predictive, diagnostic or prognostic disease situations. Genetic testing for non-medical purposes, such as paternity, ancestry, genome-wide association studies (GWAS), and non-disease traits, such as baldness, eye color, are NOT medically necessary. Most genetic testing is once per lifetime or once per pregnancy (prenatal testing). When possible, testing should be performed at a contracted/network laboratory. If a non-contracted (out-of-network) laboratory is required, the member should be informed of difference in out-of-pocket charges. In addition, the provider should document the need for an out-of-network laboratory, e.g., targeted testing in another family member, gene not offered at contracted/network laboratory, etc. Finally, **medical necessity must be documented for every request.**

Hierarchy for genetic/genomic testing criteria

- I. For **Medicare-line** members:
 1. See sections V, VI, VII below using applicable Novitas-Solutions LCDs/LCAs or Palmetto GBA MoIDX LCDs/LCAs
 2. InterQual®
- II. For **Commercial** members:
 1. InterQual®
 2. See sections V, VI, VII below using applicable Novitas-Solutions LCDs/LCAs or Palmetto GBA MoIDX LCDs/LCAs
- III. For **Medicaid plans**, please confirm coverage as outlined in the Texas Medicaid TMPPM. Then use InterQual® if further guidance is needed.
- IV. If an appropriate criterion set is not found in the resources above, the request will be processed using the overarching principles that follow:

Coverage for genetic/genomic testing and/or screening may be medically necessary when all of the following criteria are met:

1. Appropriate genetic counseling occurs before and after testing.



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Members must have genetic counseling by a practitioner who has expertise in the genetic aspects of the condition being evaluated and who will discuss the results of the test and their clinical implications. Documentation of the counseling will accompany the preauthorization request.

Evidence of genetic counseling should include, but is not limited to the following:

- discussion of the types of test results (positive, negative, uncertain findings) that could be obtained,
- identifying problems that are known to occur due to test methodology,
- evaluation of the members risk for the specific disorder, the differential diagnosis, inheritance patterns, penetrance, variable expressivity and genetic heterogeneity
- evidence of informed consent
- a plan for posttest counseling

Note: genetic counseling must be performed by practitioners NOT employed by testing companies due to conflict of interest.

2. There must be a reasonable expectation, based on family history, pedigree analysis, risk factors, and/or symptomatology, that a genetically inherited or acquired condition exists and the member displays clinical features, or is at direct risk of inheriting the mutation in question (pre-symptomatic) or comes from the appropriate disease-specific population. A three-generation pedigree **MUST** accompany the request for testing, where appropriate, to aid in coverage determination.
3. Knowledge of the presence or absence of the condition would **DIRECTLY** affect medical care of the member:
 - a. The disease must be treatable and/or preventable AND
 - b. The test results will lead to a change in the intensity of surveillance frequency and /or treatment for that disease.
4. There are often options for single gene testing, multiple gene testing and panel testing.
 - a. If a single gene test meets other criteria and will answer the clinical question, SHWP will generally find such a test medically necessary.
 - b. If a multigene panel is requested, there must be evidence that there are two or more genes responsible for a specific condition or that there is the possibility that several genes can cause multiple diseases within the family. Most of the genes on the panel should be plausible explanations for the disorder observed
 - c. The smallest plausible gene panel will be authorized, to decrease variants of unknown significance. Broad multi-gene-based panels are not medically necessary when a more focused study is available.
 - d. If a panel is chosen, the list of genes should be on the request and in the accompanying documentation to explain why that particular panel was chosen
 - e. Multiple panels tested at the same time are not medically necessary
5. The test is performed in a CLIA certified laboratory, AND is FDA approved, AND is **recommended by recognized, national guidelines**.
6. The request **MUST** be submitted with the SWHP "Statement of Medical Necessity for Genetic Testing" located at the end of this policy, OR other documentation such as clinical documentation that addresses all of the questions in that document. In particular there must be a clear statement that explains how the test results will improve the medical management of the patient's condition. The statement "... is medically necessary" does NOT meet the criteria since it does not explain the change in management or surveillance that would take place if the test is positive and if it were negative.

Note: Genetic/genomic testing for specific germline conditions or mutations is limited to once per lifetime for the specific mutation or panel. Exceptions may be considered if there is a change in guidelines for

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genes that have not been tested or need reinterpretation of results.

V. Tests with specific policy guidance:

- A. **Cell-free DNA screening tests for microdeletions** (CPT 81422) have **NOT** been validated and are not deemed medically necessary.
- B. **Whole Genome Sequencing** may be medically necessary to identify or confirm the genetic etiology of a known or unknown disorder in clinically affected neonatal and pediatric patients. Medical necessity will be determined using the generic criteria listed at the beginning of this policy. In most cases whole genome sequencing will not be found medically necessary unless more targeted studies have failed to identify a mutation.

VI. SWHP will use the following Medicare resources for Commercial and Medicare lines:

Guidance for the following codes can be found in Novitas-Solutions LCD/LCA L35396/A52986 or LCD/LCA L35062/A56541. Use when directed to do so by items I and II at beginning of policy:

0018U	Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, algorithm reported as a positive or negative result for moderate to high risk of malignancy	L35396 A52986
0026U	Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, algorithmic analysis reported as a categorical result ("Positive, high probability of malignancy" or "Negative, low probability of malignancy")	L35396 A52986
81120	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants	L35396 A52986
81121	IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants	L35396 A52986
81161	DMD (dystrophin) (e.g., Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed	L35062 A56541
81170	ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis	L35396 A52986
81175	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence	L35396 A52986
81176	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; targeted sequence analysis	L35396 A52986
81200	ASPA (aspartoacylase) (eg, Canavan disease) gene analysis, common variants	L35062 A56541
81201	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence	L35062 A56541
81202	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; known familial variants	L35062 A56541
81203	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants	L35062 A56541
81205	BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, maple syrup urine disease) gene analysis, common variants	L35062 A56541
81206	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint	L35396 A52986
81207	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative	L35396 A52986

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81208	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; other breakpoint	L35396 A52986
81209	BLM (Bloom syndrome, RecQ helicase-like) (eg, Bloom syndrome) gene analysis, 2281del6ins7 variant	L35062 A56541
81210	BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)	L35396 A52986
81218	CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence	L35396 A52986
81219	CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9	L35396 A52986
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variant	L35062 A56541
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; known familial variants	L35062 A56541
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants	L35062 A56541
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; full gene sequence	L35062 A56541
81224	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; intron 8 poly-T analysis	L35062 A56541
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants	L35062 A56541
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities	L35062 A56541
81233	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)	L35396 A52986
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)	L35396 A52986
81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence	L35396 A52986
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)	L35396 A52986
81242	FANCC (Fanconi anemia, complementation group C) (eg, Fanconi anemia, type C) gene analysis, common variant (eg, IVS4+4A>T)	L35062 A56541
81243	FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	L35062 A56541
81244	FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; characterization of alleles (eg, expanded size and promoter methylation status)	L35062 A56541
81245	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15)	L35396 A52986
81246	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (eg, D835, I836)	L35396 A52986
81250	G6PC (glucose-6-phosphatase, catalytic subunit) (eg, Glycogen storage disease, type 1a, von Gierke disease) gene analysis, common variants (eg, R83C, Q347X)	L35062 A56541
81251	GBA (glucosidase, beta, acid) (eg, Gaucher disease) gene analysis, common variants (eg, N370S, 84GG, L444P, IVS2+1G>A)	L35062 A56541
81252	GJB2 (gap junction protein, beta 2, 26kDa, connexin 26) (eg, nonsyndromic hearing loss) gene analysis; full gene sequence	L35062 A56541
81253	GJB2 (gap junction protein, beta 2, 26kDa, connexin 26) (eg, nonsyndromic hearing loss) gene analysis; known familial variants	L35062 A56541

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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)])	L35062 A56541
81255	HEXA (hexosaminidase A [alpha polypeptide]) (eg, Tay-Sachs disease) gene analysis, common variants (eg, 1278insTATC, 1421+1G>C, G269S)	L35062 A56541
81256	HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D)	L35062 A56541
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; common deletions or variant (eg, Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, Constant Spring)	L35062 A56541
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	L35062 A56541
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	L35062 A56541
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)	L35062 A56541
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	L35062 A56541
81276	KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)	L35396 A52986
81287	MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme) promoter methylation analysis	L35396 A52986
81288	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis	L35062 A56541
81290	MCOLN1 (mucolipin 1) (eg, Mucopolipidosis, type IV) gene analysis, common variants (eg, IVS3-2A>G, del6.4kb)	L35062 A56541
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)	L35062 A56541
81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	L35396 A52986
81293	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	L35396 A52986
81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	L35396 A52986
81295	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	L35062 A56541
81296	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	L35062 A56541
81297	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	L35062 A56541
81298	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	L35062 A56541
81299	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	L35062 A56541
81300	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	L35062 A56541
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	L35396 A52986
81302	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; full sequence analysis	L35062 A56541

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81303	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; known familial variant	L35062 A56541
81304	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; duplication/deletion variants	L35062 A56541
81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant	L35396 A52986
81310	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants	L35396 A52986
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)	L35396 A52986
81313	PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (eg, prostate cancer)	L35396 A52986
81314	PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18)	L35396 A52986
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	L35396 A52986
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	L35396 A52986
81317	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	L35062 A56541
81318	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	L35062 A56541
81319	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	L35062 A56541
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)	L35396 A52986
81321	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis	L35396 A52986
81322	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant	L35396 A52986
81323	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant	L35396 A52986
81324	PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis	L35062 A56541
81325	PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; full sequence analysis	L35062 A56541
81326	PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; known familial variant	L35062 A56541
81327	SEPT9 (Septin9) (eg, colorectal cancer) promoter methylation analysis	L35396 A52986
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	L35062 A56541
81330	SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal) (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)	L35062 A56541
81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A) (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis	L35062 A56541
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)	L35062 A56541

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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)	L35396 A52986
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence	L35062 A56541
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)	L35062 A56541
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)	L35396 A52986
81342	TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)	L35396 A52986
81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis	L35396 A52986
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, drug metabolism, hereditary unconjugated hyperbilirubinemia [Gilbert syndrome]) gene analysis, common variants	L35396 A52986
81400	Molecular pathology procedure level 1	L35396 A52986
81401	Molecular pathology procedure level 2	L35396 A52986
81402	Molecular pathology procedure level 3	L35396 A52986
81403	Molecular pathology procedure level 4	L35396 A52986
81404	Molecular pathology procedure level 5	L35396 A52986
81405	Molecular pathology procedure level 6	L35396 A52986
81406	Molecular pathology procedure level 7	L35396 A52986
81407	Molecular pathology procedure level 8	L35396 A52986
81408	Molecular pathology procedure level 9	L35396 A52986
81410	aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis panel, must include sequencing of at least 9 genes, including FBN1, TGFBR1, TGFBR2, COL3A1, MYH11, ACTA2, SLC2A10, SMAD3, and MYLK	L35062 A56541
81411	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); duplication/deletion analysis panel, must include analyses for TGFBR1, TGFBR2, MYH11, and COL3A1	L35062 A56541
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	L35062 A56541
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	L35062 A56541

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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	L35062 A56541
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	L35062 A56541
81416	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome	L35062 A56541
81417	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence	L35062 A56541
81425	Genome sequence analysis	L35062 A56541
81426	Genome sequence analysis; each comparator genome	L35062 A56541
81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence	L35062 A56541
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	L35062 A56541
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	L35062 A56541
81435	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11	L35396 A52986
81436	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11	L35396 A52986
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	L35396 A52986
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	L35396 A52986
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)	L35062 A56541
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	L35062 A56541
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	L35396 A52986
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	L35396 A52986



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	variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels	
81479	Unlisted molecular pathology	L35396 A52986
81503	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score	L35396 A52986
81520	Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping)	L35396 A52986
81525	Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping),	L35396 A52986
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm	L35396 A52986
81540	Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes - algorithm reported as a probability of a predicted main cancer	L35396 A52986
81545	Oncology (thyroid), gene expression analysis of 142 genes	L35396 A52986
81552	DecisionDX-UM. Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes	L37033 A56906

Guidance for the following codes can be found in Palmetto GBA MoIDX LCDs/LCAs as noted. Use when directed to do so by items I. and II. at beginning of policy:

0037U	FoundationOne CDx™ (F1CDx)	Coverage with criteria	IQ or L35025 A56853
0045U	Oncotype DX® Genomic Breast DISC Score	Coverage with criteria	IQ or L35025 A56853
0047U	Oncotype DX® Genomic Prostate Score	Coverage with criteria	IQ or L37262 A56285 or L36153 A56285
81539	4Kscore test	E&I, unproven	L36763 A56932
81542	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, algorithm reported as metastasis risk score	Limited coverage	L35868 A56958

VII. The following tests considered experimental and investigational and are NOT considered medically necessary:

- a. Genetic testing (e.g., presenilin-1 gene, apolipoprotein E epsilon 4 allele, amyloid precursor gene, etc.) for the diagnosis and assessment of persons with Alzheimer disease and related dementias.
- b. Genetic testing for complex eye disorders such as age-related macular degeneration and late-onset primary open angle glaucoma, PreDx Diabetes Risk Test™, deCODE T2™, deCODE AF™, deCODE MI™, deCODE Glaucoma, deCODEme Cancer, deCODE BreastCancer™ and BREVAGen™ Breast Cancer Risk Stratification Test deCODE ProstateCancer 9p21MI Check, and deCODEme Cardio.
- c. Additional test codes considered experimental and investigational and are NOT considered medically necessary:

0003U	Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm	E&I Unproven
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	reported as a likelihood score	A52986
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score	E&I Unproven A52986
0009U	Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin fixed paraffin embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified	E&I Unproven A52986
0013U	Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement	E&I Unproven A52986
0014U	Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement	E&I Unproven A52986
0016U	Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification	E&I Unproven A52986
0017U	Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis	E&I Unproven A52986
81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)	E&I Unproven
81230	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis,	E&I Unproven
81231	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, P450 enzymes are involved in the hepatic metabolism of up to 50% of all clinically used drugs.	E&I Unproven
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variant(s) (eg, -1639G>A, c.173+1000C>T)	E&I Unproven
81422	Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21	E&I Unproven
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	E&I Unproven L35062
81440	Nuclear encoded mitochondrial genes (eg, neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes, including BCS1L, C10orf2, COQ2, COX10, DGUOK, MPV17, OPA1, PDSS2, POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, SUCLA2, SUCLG1, TAZ, TK2, and TYMP	E&I Unproven L35062
81460	Whole mitochondrial genome (eg, Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERFF], neuropathy, ataxia, and retinitis pigmentosa [NARP], Leber hereditary optic neuropathy [LHON]), genomic sequence, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection	E&I Unproven L35062
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed	E&I Unproven L35062
81470	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2	E&I Unproven L35062

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81471	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2	E&I Unproven L35062
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score	E&I Unproven
81493	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score	E&I Unproven
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	E&I Unproven
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)	E&I Unproven

VIII. Exclusions:

The following are examples of services that are not covered:

1. Routine, ongoing, or long-term genetic counseling.
2. Genetic testing to determine the paternity of a child.
3. Genetic testing to determine the sex of the child.
4. General population screening for genetic disorders (e.g., cystic fibrosis).

IX. Other information

Genetic Test codes with Prior Authorization (PA) diagnosis specifications:

81161	DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed	No PA if Prenatal Dx present
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)	No PA if Prenatal Dx present
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; known familial variants	No PA if Prenatal Dx present
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants	No PA if Prenatal Dx present
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; full gene sequence	No PA if Prenatal Dx present
81224	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; intron 8 poly-T analysis (eg, male infertility)	No PA if Prenatal Dx present
81238	F9 (coagulation factor IX) (eg, hemophilia B)	No PA if Prenatal Dx present
81259	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,	No PA if Prenatal Dx present
81302	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; full sequence analysis	No PA if Prenatal Dx present
81303	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; known familial variant	No PA if Prenatal Dx present



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81304	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; duplication/deletion variants	No PA if Prenatal Dx present
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	No PA if Prenatal Dx present
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence	No PA if Prenatal Dx present
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)	No PA if Prenatal Dx present
88267	Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding	No PA if Prenatal Dx present
88269	Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding	No PA if Prenatal Dx present

Definitions:

First-degree relative – a blood relative with whom an individual shares approximately 50% of his or her genes, including parents, full siblings and children

Second-degree relative – a blood relative with whom an individual shares approximately 25% of his/her genes, including grandparents, grandchildren, aunts, uncles, nephews, nieces and half- siblings.

MANDATES: None

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
HCPCS Codes:	
ICD-10:	
ICD-10 Not covered:	

CMS: There is no NCD.

POLICY HISTORY:

Status	Date	Action
New	08/01/2010	New policy
Reviewed	12/06/2011	Reviewed.
Reviewed	12/06/2012	Revised. BRCA added. Criteria revised
Reviewed	11/14/2013	BRCA criteria updated.
Reviewed	04/24/2014	Minor updates made.
Reviewed	07/02/2015	Extensively re-written
Reviewed	09/08/2016	Clarified criteria; added pharmacogenetics section.
Update	06/27/2017	Updated criteria for NIPT.



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Reviewed	08/22/2017	Set most testing limit to once per lifetime. Updated criteria. New request form.
Minor correction	11/28/2017	Removed discussion regarding FIT-DNA stool testing
Reviewed	06/26/2018	Significant revision of several coverage topics.
Addition	02/12/2019	InterQual® to be used instead of policy for five codes.
Major revision	09/26/2019	Policy re-written to direct reviews to InterQual®
Reviewed	05/28/2020	Redesign incorporating LCD and Palmetto GBA MoIDX

REFERENCES: The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence surrounding genetic testing and may modify this policy at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Calderon-Margalit R, Paltiel O. Prevention of Breast Cancer in Women Who Carry BRCA1 or BRCA2 Mutations: A Critical Review of the Literature. *Int J Cancer*. 2004 Nov 10;112(3):357- 64.
2. National Comprehensive Cancer Network. Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. Version 1. 2006.
<http://www.nccn.org/professionals/physiangls/PDF/geneticsscreening.pdf>
3. National Cancer Institute. Genetics of Colorectal Cancer (PDQ®). Last Modified 03/24/2006.
<http://nci.nih.gov/cancertopics/pdq/genetics/colorectal/healthprofessional>.
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6. Venesio T, Molatore S, Cattaneo F, Arrigoni A, Risio M, Ranzani GN.
7. High frequency of MYH gene mutations in a subset of patients with familial adenomatous polyposis. *Gastroenterology*. 2004 Jun; 126(7): 1681-5.
8. Sieber OM, Lipton L, Crabtree M, Heinimann K, Fidalgo P, Phillips RK, Bisgaard ML, Orntoft TF, Aaltonen LA, Hodgson SV, Thomas HJ, Tomlinson IP. Multiple colorectal adenomas, classic adenomatous polyposis, and germ-line mutations in MYH. *N Engl J Med*. 2003 Feb 27;348(9):791 -9.
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12. ACOG Committee Opinion 690, March 2017: Carrier screening in the age of genomic medicine
13. ACOG Practice Bulletin 102, March 2017 (reaffirmed 2016): Management of stillbirth
14. American College of Obstetricians and Gynecologists Committee Opinion No 691: Carrier screening for genetic conditions carrier screening for genetic conditions 2017
15. American College of Medical Genetics, Points to consider in the clinical application of genomic sequencing *Genet Med* 2012 Aug 14(8):759-61 Policy statement whole exome and whole genome testing
16. American College of Medical Genetics and Genomics Practice Guidelines



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SWHP Genetic Testing Prior Authorization Form

6/26/2018 version

Date of Request: ___/___/___

Date, if procedure has been scheduled: ___/___/___

Insured Member Information:

Name: _____ SWHP ID #: _____ Date of birth: ___/___/___

Gender: M F

Provider Information:

Requesting Provider Name: _____ Requesting Provider NPI: _____

Requesting Provider Address: _____

Office Contact Person: _____ Telephone #: _____ Fax #: _____

Supplying Provider Information:

Supplying Provider Name: _____

Supplying Provider Address: _____

Office Contact Person: _____ Telephone #: _____ Fax #: _____

Genetic Test Information:

Requested Genetic Test:

<input type="checkbox"/> BRCA 1 and 2, HBOC	<input type="checkbox"/> Breast expression RNA	<input type="checkbox"/> Hereditary Hemochromatosis Gene Analysis
<input type="checkbox"/> Colon Cancer Lynch Syndrome (list genes)	<input type="checkbox"/> Cystic Fibrosis	<input type="checkbox"/> Fragile X Syndrome
<input type="checkbox"/> Huntington's Disease	<input type="checkbox"/> Janus Kinase 2(JAK2)	<input type="checkbox"/> Chromosomal Microarray
<input type="checkbox"/> Familial Adenomatous Polyposis /Assoc. Polyposis Conditions	<input type="checkbox"/> Cardiology Gene Expression (AlloMap)	<input type="checkbox"/> NIPS (non-invasive prenatal screen)
<input type="checkbox"/> Multigene panel: Please list genes requested		

ICD-10 Codes:				
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<u>CPT Code</u>	<u>Test</u>	<u>CPT Code</u>	<u>Test</u>



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Medical Information:

Provide information to justify each test requested. (May attach dictation if it contains requested information.)

- 1) Why is the test appropriate for the patient? _____

- 2) Does the beneficiary exhibit clinical features of the mutation in question? If not, has a genetic variant been identified in a family member? (May attach dictation if it contains requested information.)

- 3) Has the patient given informed consent to the genetic test? Yes No
- 4) Has genetic counseling occurred? Yes No By whom? _____
- 5) What is the validity of testing and is the testing scientifically sound? (reference or link)

- 6) Is the patient willing to undergo the increased interventions that may potentially be required because of testing?
 Yes No
- 7) How will the results specifically impact or alter medical management of the patient?

- 8) What is the cost of the test? _____
- 9) Is multigene panel testing more cost efficient than the combined reimbursement for single codes? _____

Signature of Requesting Provider: _____ **Date:** ____/____/____