Medical Policy & Procedure

Policy Name:	Medical Policy: Genetic Testing/Molecular Diagnostics	Policy #:	MP-37

Policy Information

Owner Department:	Medical UM & Systems Department
Owner:	Assigned Medical Director
Electronic Signature/Date:	Krystal Revai (01/30/2024), Lori Slaughter (01/26/2024)

If there is a discrepancy between a medical policy and a patient's policy or plan document/summary plan description, the policy or plan document/summary plan descriptions provisions and limitations will govern the determination of benefits.

Purpose of the Policy

To make utilization decisions, Health Alliance uses written criteria based on sound clinical evidence for appropriately applying the criteria.

Statement of the Policy

To apply objective and evidence-based criteria when determining the medical appropriateness of health care services.

Interpretations

There is no evidence to support the use of genetic testing for individuals from the general population with average risk. Selected high-risk patients may benefit from screening for certain diseases.

Effective August 1, 2019, Health Alliance uses eviCore criteria to determine the medical necessity for Selected Genetic Tests. The eviCore criteria are available in the Health Alliance/eviCore provider prior-authorization portal.

1. **Preimplantation Genetic Screening (PGS) and Diagnosis (PGD) testing of Embryos uses eviCore criteria;** however, it is covered only for infertile couples/individual(s) whose medical plan specifically covers infertility treatment and in vitro fertilization (IVF).
   - **1.1** The couple/individual(s) must meet their plan infertility and IVF criteria to obtain embryos for testing and obtain and meet eviCore PA criteria to be covered for PGD prior to uterine implantation.
   - **1.2** Effective 1/1/2024, couples /individual(s) in the following group plans need to follow 1.1 above to be covered for PGD, however, eviCore PA requests for PGS obtained prior to uterine implantation will be covered for embryos created by plan approved IVF procedures.
     - State of Illinois HMO Employee Group Plan – 2001688
     - Federal Employee Health Benefit Group (FEHB) – 1000030
     - United Natural Foods, Inc. - 2001850

Medicare Advantage Criteria Details:

- MCD Search (cms.gov) – search for code in Medicare database
- NGS (IL) - LCD - Molecular Pathology Procedures (L35000) (cms.gov)

This LCD gives general guidance to the medically reasonable and necessary applications of the Molecular Pathology Procedures described in CPT range 81200 – 81408 (with the exception of HLA testing 81370 - 81383).

- Noridian (WA) - Article - Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527) (cms.gov)
- WPS (IA, IN) - LCD - MolDX: Molecular Diagnostic Tests (MDT) (L36807) (cms.gov)
- CGS (OH) - LCD - MolDX: Molecular Diagnostic Tests (MDT) (L36021) (cms.gov)
- Palmetto (NC) - LCD - MolDX: Molecular Diagnostic Tests (MDT) (L35025) (cms.gov)

Codes

***Codes listed are for informational purposes only and do not necessarily indicate prior authorization is or is not required or coverage is guaranteed.**

0214U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, 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, proband
0215U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, 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, proband
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
0231U	CACNA1A (calcium voltage-gated channel subunit alpha 1A) (e.g., spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions
0233U	FXN (frataxin) (e.g., Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
0234U	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
0235U	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
0236U	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (e.g., spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions
0238U	Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions,

	deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
81161	DMD (dystrophin) (e.g., duchenne/becker muscular dystrophy) deletion analysis, and duplication analysis, if performed
81177	ATN1 (atrophin 1) (e.g., dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81178	ATXN1 (ataxin 1) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81179	ATXN2 (ataxin 2) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81180	ATXN3 (ataxin 3) (e.g., spinocerebellar ataxia, Machado- Joseph disease) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81181	ATXN7 (ataxin 7) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81183	ATXN10 (ataxin 10) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (e.g., spinocerebellar ataxia) gene analysis evaluation to detect abnormal (e.g., expanded) alleles
81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (e.g., spinocerebellar ataxia) gene analysis; full gene sequence
81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (e.g., spinocerebellar ataxia) gene analysis; known familial variant
81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (e.g., myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81200	ASPA (aspartoacylase)(e.g., Canavan disease) gene analysis, common variants (e.g., E285A, Y231X)
81201 - 81203	APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated [FAP] gene analysis; full gene sequence, known familial variants, duplication/deletio variants
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, 2281del6ins7 variant
81220 - 81221	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; common variants (e.g., ACMG/ACOG guidelines) and with known familial variants
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; full gene sequence
81238	F9 (coagulation factor IX) (e.g., hemophilia B), full gene sequence

81240	F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability) gene analysis, 20210G>A 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)
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)
81251	GBA (glucosidase, beta, acid) (e.g., Gaucher disease) gene analysis, common variants (e.g., N370S, 84GG, L444P, IVS2+1G>A)
81252 - 81253	GJB2 (gap junction protein, beta 2, 26kDa; connexin 26) (e.g., nonsyndromic hearing loss) gene analysis; full gene sequence
81255	HEXA (hexosaminidase A [alpha polypeptide]) (e.g., Tay-Sachs disease) gene analysis, common variants (e.g., 1278insTATC, 1421+1G>C, G269S)
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 thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (e.g., Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and Constant Spring)
81258 - 81259	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis
81260	IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein) (e.g., familial dysautonomia) gene analysis, common variants (e.g., 2507+6T>C, R696P)
81269	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants
81271	HTT (huntingtin) (e.g., Huntington disease) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles
81274	HTT (huntingtin) (e.g., Huntington disease) gene analysis; characterization of alleles (e.g., expanded size)
81284	FXN (frataxin) (e.g., Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles
81285	FXN (frataxin) (e.g., Friedreich ataxia) gene analysis evaluation; characterization of alleles (e.g., expanded size)
81286	FXN (frataxin) (e.g., Friedreich ataxia) gene analysis; full gene sequence
81288	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis
81289	FXN (frataxin) (e.g., Friedreich ataxia) gene analysis evaluation; known familial variant(s)

81290	MCOLN1 (mucolipin 1)(e.g., Mucolipidosis, type IV) gene analysis, common variants (e.g., IVS3-2A>G, del6, 4kb)
81292 - 81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis or known familial variants or duplication/deletion variants
81295 - 81297	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis or known familial variants or duplication/deletion variants
81298 - 81300	MSH6 (mutS homolog 6 [E. Coli]) (e.g., jeredotaru mpm-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis or known familial variants or duplication/deletion variants
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
81302	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; full sequence analysis
81310	NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, exon 12 variants
81317	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis or known familial variants or duplication/deletion variants
81318	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81321 - 81323	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis, known familial variant, duplication/deletion variant
81324 - 81326	PMP22 (peripheral myelin protein 22) (e.g., Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis, full sequence analysis, known familial variant
81329	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; dosage/deletion analysis (e.g., carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed
81330	SMPD1 (sphingomyelin phosphodiesterase 1, acid lysosomal) (e.g., Niemann-Pick disease, Type A) gene analysis, common variants (e.g., R496L, L302P, fsP330)
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	SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (e.g., alpha-1-antitrypsin deficiency), gene analysis, common variants (e.g., *S and *Z)
81336	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; full gene sequence
81337	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; known familial sequence variant(s

81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81344	TBP (TATA box binding protein) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81353	TP53 (tumor protein 53) (e.g., Li-Fraumeni syndrome) gene analysis; known familial variant
81361 - 81364	HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia, hemoglobinopathy)
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)
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) [covered for glucokinase gene (GCK), hepatic nuclear factor 1-α (HNF1-α), and hepatic nuclear factor 4-α (HNF4-α) for maturity-onset diabetes of the young (MODY)]
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, regionally targeted cytogenomic array analysis) [covered for glucokinase gene (GCK), hepatic nuclear factor 1-α (HNF1-α), and hepatic nuclear factor 4-α (HNF4-α) for maturity-onset diabetes of the young (MODY)]
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 [covered for glucokinase gene (GCK), hepatic nuclear factor 1-α (HNF1-α), and hepatic nuclear factor 4-α (HNF4-α) for maturity-onset diabetes of the young (MODY)]
81408	Molecular pathology procedure, Level 9 (e.g., analysis of >50 exons in a single gene by DNA sequence analysis) ABCA4 (ATP-binding cassette, sub-family A [ABC1], member 4) (e.g., Stargardt disease, age-related macular degeneration), full gene sequence ATM (ataxia telangiectasia mutated) (e.g., ataxia telangiectasia), full gene sequence CDH23 (cadherin-related 23 [FBN1 sequencing]
81412	Ashkenazi Jewish associated disorders (e.g., 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
81434	Hereditary retinal disorders (e.g., 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
81442	Noonan spectrum disorders (e.g., 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
81448	Hereditary peripheral neuropathies (e.g., Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include sequencing of at least 5 peripheral neuropathy-related genes (e.g., BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, SPTLC1)

83080	b-Hexosaminidase, each assay
88245 - 88269	Chromosome analysis
88271 - 88275	Molecular cytogenetics
88323	Consultation and report on referred material requiring preparation of slides
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)
88342	initial single antibody stain procedure
88344	each multiplex antibody stain procedure
88360 - 88361	Morphometric analysis, tumor immunohistochemistry (e.g., Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, each antibody; manual or using computer-assisted technology

Providers are required to indicate the diagnosis and procedure codes when requesting review of coverage.

References

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History

Created Date:	07/28/98		
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Revision Date:	09/22/98	12/15/98	06/22/99
	08/24/99	03/28/01 – MDC	09/05/01 – MDC
	10/23/01 – MPC	01/23/01 – MDC	06/12/02
	06/25/02 – MPC	05/27/03 – MDC	06/25/03 – MPC
	05/27/03 – MDC	06/24/03 – MPC	05/26/04 – MDC
	06/08/05 – MDC	06/14/06 – MDC	08/23/06 - Added LCD link.
	06/13/07 – MDC	11/02/10 – MDC	02/23/11 – MDC
	04/11/12 – MDC	07/11/12 – MDC	04/10/13 – MDC
	07/10/13 – MDC	06/20/14	
	07/08/15 – MDC-Revision, added language for interpretation of InterQual "cover with limited evidence."		
	01/13/16	03/08/17	
	04/11/18 – MDC-Revision to add criteria for Carrier Screening consistent with ACOG Guidelines and no coverage for Preimplantion Genetic Screening as investigational.		
	12/20/18 – MDC-Updates for FoundationOne, BRCA 1 & 2 - MA, Microdeletion testing.		
	08/20/19 – MDC-Revision to point reviews to eviCore after August 1, 2019 and to maintain current policy for appeals related to denials issued prior to Aug. 1 and for Non-Prior Authorized testing appeals covered or disallowed back to the vendor with a date of service before August 1, 2019.		

	06/24/20 – MDC-Annual review, no changes.		
	12/21/21 – MDC-Annual review, points to eviCore, old criteria for pending appeals removed, codes added.		
	12/20/22 – MDC-Annual review, no changes.		
	1/16/24 – MDC – Annual review, Commercial members added PGS coverage mandated for Stated of Illinois HMO Group and 2 Self-Funded plans by their request. Medicare Advantage members – no changes.		