MEDICAL POLICY STATEMENT

INDIANA MARKETPLACE PLANS

Policy Name			Policy Number	Date Effective
Genetic Testing, Genetic Screening and Genetic Counseling			MM-0736	10/01/2019
Policy Type				
MEDICAL	Administrative	Pharmacy		Reimbursement

Medical Policy Statement prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased, or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

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A. Subject

Genetic Testing, Genetic Screening and Genetic Counseling

B. Background

Recent advancements in our understanding of the human genome have contributed to the rapid expansion of identified genetic mutations. Supported by new technologies and commercially available measurement tools, there are now ever-expanding numbers of genetic assays available for genetic screening and genetic testing. In some clinical situations, the results from testing can be of significant assistance in diagnosis, prevention, therapeutic treatment, or monitoring of conditions. This emerging field is divided into three categories – Genetic Counseling, Genetic Screening, and Genetic Testing.

GENETIC COUNSELING:

Genetic counseling is the process of education and recommendations provided by independent genetic professionals discerned from familial and medical histories to those at risk or currently having a genetic disease, to allow them to make informed decisions as well as gaining understanding of the effects of the disease. Genetic counseling is an integral component of the creation of a genetic testing environment that is informative and supportive to patients, both before and after they undergo testing. As outlined in the current edition of the MCG Care Guidelines, genetic counseling plays an essential role in genetic testing and is required as part of its pre-certification.

A genetic counseling consultation prior to actual testing involves evaluation of an individual or family for one or more of the following:

- diagnosing, confirming, or eliminating the existence of an inheritable genetic condition as well as assessing any risks versus benefits
- identifying medical management issues including modes of transmission, patterns of inheritance, treatment of disorders, evaluation, calculation, and communication of genetic risks, and potential of inheritance
- prospective evaluation of available genetic tests and education about alternatives
- explanation of complex clinical information to ensure informed decisions as well as promoting understanding of potential ethical, legal, and psychosocial implications

A genetic counseling consultation subsequent to genetic testing involves one or more of the following:

- ensuring appropriate interpretation and communication of testing results
- counseling to assist in any necessary adaptation to medical risks or conditions
- coordinating any necessary provider care and support of patient and family

GENETIC SCREENING:

Genetic screening is the process used to uncover genetic disorders or the potential for transmission of genetic disorders in specific populations determined to be at risk. Genetic screening uses a set of diagnostic tests that are not as rigid as those employed

in genetic testing. Genetic screening is a population-based method intending to find whom in the population is a carrier and/or has risk of getting a specific disease. Genetic screening uses simple medical diagnostic tests. In addition, as opposed to actual genetic testing, with genetic screening, individuals are asymptomatic. Generally, the next step following screening, if warranted, is actual diagnostic testing.

GENETIC TESTING:

Genetic testing, for clinical purposes, is analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect alterations or disease-related genotypes, mutations, phenotypes or karyotypes related to a heritable or acquired disorder. There are currently more than 6,000 genetic disorders identified and nearly 2,000 genetic tests currently in use today that are performed through a variety of methods including cytogenetic testing (examination of chromosomes and their abnormalities), biochemical testing (examination of proteins rather than genes), and molecular (direct examination of DNA or RNA).

C. Definitions

- Analytic Validity: the result of how well a genetic test measures the intended properties or characteristics being tested
- Clinical Validity: how well the genetic variant being analyzed is related to the presence, absence, or risk of a specific disease
- Clinical Utility: whether the test can provide information regarding diagnosis, treatment, management, or prevention of a disease or condition that will be helpful to a consumer
- Clinical Laboratory Improvement Amendments (CLIA): ffederal regulatory standards from 1988 applying to all clinical laboratory testing performed on humans in the US for the purpose of providing information for diagnosis, prevention or treatment of disease (excludes clinical trials and basic research)
- College of American Pathologists (CAP): an organization of certified pathologists providing accreditation and quality assurance to clinical laboratories
- Diagnostic Testing: the process of examination of specimens and results reported to providers or patients for the purpose of confirmation of diagnosis and identification of causes of a disease, as well as influencing an individual's choice about healthcare, lifestyle and disease or condition management
- Genetic Mutation: an alteration of a chromosome, gene, or protein from its natural state
- Genetic Panel Testing: an evaluation of many genes simultaneously and have been developed for numerous indications, including hereditary cancer risk assessment, pharmacogenetics, and diagnosis of congenital disorders. Many panel tests include genes that do not have demonstrated clinical utility for their testing
- National Comprehensive Cancer Network (NCCN): a not-for-profit alliance of 28 leading cancer centers focused on patient care, research, and education, whose mission is for the improvement of the quality, effectiveness, and efficiency of cancer care

- Prenatal Testing: testing prior to birth, to identify changes in genes or chromosomes in embryos or fetuses to identify any potential genetic or chromosomal disorders
- Prenatal Screening: a non-invasive process of analysis using maternal blood to identify the risk of a woman carrying a fetus with a chromosome abnormality or birth defect

D. Policy

I. Prior Authorization
   A. Prior Authorization for genetic testing IS required
   B. Prior Authorization for genetic counseling is not required

II. Genetic Testing: CareSource will review for medical necessity and approve genetic testing based on all of the criteria below found under ONE of the following situations:
   A. Published MCG policy with endorsed inclusion criteria meeting all of the following:
      1. Documentation of an assessment based on the relevant MCG Guideline AND
      2. The quality, safety, statistical validity, and clinical validity is scientifically supported in medical literature as endorsed by inclusion criteria of the relevant MCG Guideline AND
      3. *Genetic counseling has been performed*, as indicated by documentation supporting *ALL of the following items listed below:*
         a. *Counseling is provided by a healthcare professional* (as defined below) *with education and training in genetic issues relevant to the genetic tests under consideration*, AND
         b. *Counselor is free of commercial bias and discloses all (potential and real) financial and intellectual conflicts of interest*, AND
         c. *Process involves individual or family and is comprised of ALL of the following:*
            01. *Calculation and communication of genetic risks after obtaining 3-generation family history* AND
            02. *Discussion of natural history of condition in question, including role of heredity* AND
            03. *Discussion of possible impacts of testing (e.g., psychological, social, limitations of nondiscrimination statutes)* AND
            04. *Discussion of possible test outcomes (i.e., positive, negative, variant of uncertain significance)* AND
            05. *Explanation of potential benefits, risks, and limitations of testing* AND
            06. *Explanation of purpose of evaluation (e.g., to confirm, diagnose, or exclude genetic condition)* AND
            07. *Identification of medical management issues, including available prevention, surveillance, and treatment options and their implications* AND
            08. Written documentation that the patient has provided informed consent to the testing as evidenced by a statement detailing how the test results will affect the patient's medical management
   B. Published MCG policy where the Current Role Remains Uncertain:
      1. In the case of these policies, based on existing evidence, where currently there are no clinical indications for this technology and insufficient evidence exists to support their use in guiding clinical decision making, genetic testing

under these circumstances is approved as a covered medically necessary health benefit when ALL of the following criteria are met:

a. Documentation of assessment of patient risk factors and/or symptoms related to the particular genetic disease or disorder being tested (including relevant family history) AND
b. Genetic counseling has been performed in conformance with MCG guidelines AND
c. Documentation that the patient has provided informed consent to the testing as evidenced by a statement detailing how the test results will affect the patient's medical management, AND
d. Analytic validity, clinical validity, and clinical utility of the test or panel of tests, can be established through evidence based and literature supported guidelines by nationally recognized technology organizations such as the National Comprehensive Cancer Network (NCCN)

C. No Published MCG Policy:

1. Where the most current version of the MCG Care Guidelines contains no published MCG policy for the genetic test and/or genetic panels, testing may be approved only when ALL of the following criteria are met:
   a. Documentation of assessment of patient risk factors and/or symptoms related to the particular genetic disease or disorder being tested (including relevant family history) AND
   b. Genetic counseling has been performed in conformance with MCG guidelines AND
   c. Documentation that the patient has provided informed consent to the testing as evidenced by a statement detailing how the test results will affect the patient's medical management, AND
   d. Analytic validity, clinical validity, and clinical utility of the test or panel of tests, can be established through evidence based and literature supported guidelines by nationally recognized technology organizations such as the National Comprehensive Cancer Network (NCCN)

NOTE: The healthcare professional providing counseling must be one of the following: an independent board-certified or board-eligible medical geneticist, a board-certified MD medical geneticist, or a genetic nurse credentialed as either a Genetic Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APGN) and not employed by a commercial genetic testing laboratory. Qualified health professionals are not excluded if employed by or contracted with a laboratory part of an integrated health system that routinely delivers health care services beyond simply laboratory tests themselves. The clinical testing laboratory must be accredited by CLIA or CAP, the State and/or other applicable accrediting agencies.

III. Once Per Lifetime Testing

A. Absent specific evidence regarding advances in the body of knowledge of mutation characteristics for a particular disease or disorder, a genetic test will be covered only once per lifetime of a member.

Table A – Current as of June 26, 2019

MCG Policy #	MCG Policy Title	Genes and Gene Panels
ACG: A-0499	Breast or Ovarian Cancer, Hereditary	BRCA1, BRCA2
ACG: A-0504	Assisted Reproductive Technology	
ACG: A-0532	Breast Cancer Gene Expression Assays	
ACG: A-0533	Lynch Syndrome	EPCAM, MLH1, MSH2, MSH6, and PMS2 Genes
ACG: A-0534	Familial Adenomatous Polyposis	APC Gene
ACG: A-0535	Paraganglioma-Pheochromocytoma Syndromes, Hereditary	FH, MAX, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, TMEM127, and VHL Genes
ACG: A-0581	Neurofibromatosis	NF1 Gene
ACG: A-0582	Multiple Endocrine Neoplasia (MEN) Syndrome	MEN1 Gene
ACG: A-0583	Von Hippel-Lindau Syndrome	VHL Gene
ACG: A-0584	Li-Fraumeni Syndrome	TP53 Gene
ACG: A-0585	Cowden Syndrome	PTEN Gene
ACG: A-0586	Retinoblastoma	RB1 Gene
ACG: A-0587	Warfarin Pharmacogenetics	CYP2C9, VKORC1, and CYP4F2 Genes
ACG: A-0588	Chromosomal Microarray Analysis (CMA) - Autism Spectrum Disorders	
ACG: A-0590	Alzheimer Disease (Early Onset)	APP, PSEN1 and PSEN2 Genes
ACG: A-0591	Amyotrophic Lateral Sclerosis (ALS)	C9orf72 and SOD1 Genes
ACG: A-0592	Ashkenazi Jewish Genetic Panel	
ACG: A-0593	Ataxia-Telangiectasia	ATM Gene
ACG: A-0594	Brugada Syndrome	Channelopathy genes
ACG: A-0595	Canavan Disease	ASPA Gene
ACG: A-0596	Deafness and hearing loss, nonsyndromic	GJB2, GJB6, MT-RNR1, MT-TS1, POU3F4, PRPS1, and SMPX Genes
ACG: A-0597	Cystic Fibrosis	CFTR Gene and Mutation Panel
ACG: A-0598	Diabetes Mellitus (Maturity – Onset Diabetes of the Young)	ABCC8, APPL1, BLK, CEL, GCK, HNF1A, HNF1B, HNF4A, INS, KCNJ11, KLF11, NEUROD1, PAX4, PDX1 Genes
ACG: A-0599	Hemochromatosis	HFE Gene
ACG: A-0600	Factor V Leiden Thrombophilia	F5 Gene
ACG: A-0601	Malignant Melanoma (Cutaneous)	BAP1, CDK4, and CDKN2A Genes
ACG: A-0602	Fragile X Syndrome	FMR1 Gene
ACG: A-0603	Gaucher Disease	GBA Gene
ACG: A-0604	Hemoglobin C and E	HBB Gene
ACG: A-0605	Huntington Disease	HTT Gene
ACG: A-0606	Lesch-Nyhan Syndrome	HPRT1 Gene

ACG: A-0607	Long QT Syndromes (Jervell and Lange-Neilsen Syndrome, Type 1 and Type 2, Hereditary)	KCNE1 and KCNQ1 Genes
ACG: A-0608	Muscular Dystrophies (Duchenne, Becker)	DMD Gene
ACG: A-0609	Myotonic Dystrophy, Type 1	DMPK Gene
ACG: A-0610	Neuroblastoma	ALK, MYCN, and PHOX2B Genes and Gene Expression Profiling
ACG: A-0611	Niemann-Pick Disease (Acid Sphingomyelinase Deficiency)	NPC1, NPC2, and SMPD1, Genes
ACG: A-0612	Prostate Cancer	BRCA1and BRCA2 Genes
ACG: A-0613	Prothrombin Thrombophilia	F2 Gene
ACG: A-0614	Tay-Sachs Disease and Variants	HEXA Gene
ACG: A-0615	Wilms Tumor	WT1 Gene
ACG: A-0623	Heart Transplant Rejection Gene Expression Profiling (AlloMap)	
ACG: A-0624	Irinotecan Pharmacogenetics	UGT1A1 Gene
ACG: A-0627	Arrhythmogenic Right Ventricular Cardiomyopathy	ARVC Genes
ACG: A-0628	Azathioprine and 6-Mercaptopurine Pharmocogenetics	TPMT Gene
ACG: A-0629	Hyperhomocysteinemia	MTHFR Gene
ACG: A-0630	Platelet-rich plasma	
ACG: A-0631	Clopidogrel Pharmacogenetics	CYP2C19 Gene
ACG: A-0632	Integrated Molecular Pathology Testing (Topographic Genotyping)	PathFinderTG
ACG: A-0633	Familial Hypertrophic Cardiomyopathy, Nonsymdromic	Sarcomere Genes
ACG: A-0636	Catecholaminergic Polymorphic Ventricular Tachycardia	CALM1, CASQ2, RYR2, and TRDNGenes
ACG: A-0638	BRCA –	Uncommon duplication or deletion variants (large gene rearrangements)
ACG: A-0646	Pancreatitis, Hereditary	CFTR, CPA1, CTRC, PRSS1, and SPINK1 Gene
ACG: A-0647	Tamoxifen Pharmacogenetics	CYP2D6 Gene
ACG: A-0648	Familial Dilated Cardiomyopathy, Nonsyndromic	Nonsyndromic
ACG: A-0649	Carbamazepine Pharmacogenetics	HLA Testing
ACG: A-0651	Colon Cancer Gene Expression Assays	Oncotype DX
ACG: A-0652	Coronary Artery Disease	Gene Expression Testing
ACG: A-0653	Rasburicase Pharmacogenetics	G6PD Gene
ACG: A-0656	Coronary Artery Disease	KIF6 Gene

ACG: A-0657	Coronary Artery Disease	9p21 Allele
ACG: A-0658	Coronary Artery Disease Genetic Panel	
ACG: A-0659	Spinal Muscular Atrophy	SMN1 and SMN2 Genes
ACG: A-0665	5-Fluorouracil Pharmacogenetics	DPYD, MTHFR, and TYMS Genes
ACG: A-0668	CADASIL (Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy)	NOTCH3 Gene
ACG: A-0669	Myeloproliferative Neoplasms	JAK2 Gene
ACG: A-0670	Melanoma (Uveal)	Gene Expression Profiling
ACG: A-0671	Parkinson Disease	ATP13A2, GBA, LRRK2, PARK7, PINK1, SNCA and VPS35 Genes
ACG: A-0672	Telomere Analysis	
ACG: A-0673	Cancer of Unknown Primary	Gene Expression Profiling
ACG: A-0681	Maple Syrup Urine Disease - Type 1 or Type 2	BCKDHA, BCKDHB, and DBT Genes
ACG: A-0682	Bloom Syndrome	BLM Gene
ACG: A-0683	Fanconi Anemia	FANC and gene panel
ACG: A-0684	Glycogen Storage Disease, Type 1	G6PC and SLC37A4 Genes
ACG: A-0685	Familial Dysautonomia	ELP1 Gene
ACG: A-0686	Mucolipidosis IV	MCOLN1 Gene
ACG: A-0687	Rett Syndrome	CDKL5, FOXG1 and MECP2 Genes
ACG: A-0688	Von Willebrand Disease	VWF Gene
ACG: A-0689	Familial Mediterranean Fever	MEFV Gene
ACG: A-0690	Malignant Hyperthermia Susceptibility	CACNA1S, RYR1 Genes
ACG: A-0691	Charcot-Marie-Tooth Hereditary Neuropathy, Type 1	EGR2, FBLN5, LITAF, MPZ, NEFL, and PMP22Genes
ACG: A-0692	Psychotropic Medication Pharmacogenetics - CYP450 Polymorphisms and AmpliChip Panel	CYP450 Polymorphism
ACG: A-0693	Proteomics (VeriStrat)	
ACG: A-0704	Hereditary Hemorrhagic Telangiectasia	ACVRL1, ENG, GDF2, and SMAD4 Genes
ACG: A-0705	MicroRNA Detection - Cancer	
ACG: A-0706	Septin 9 (SEPT9) DNA Methylation Testing	
ACG: A-0707	Prader-Willi Syndrome DNA Methylation Testing	
ACG: A-0708	Angelman Syndrome	UBE3A Gene
ACG: A-0709	Proteomics – Ovarian Cancer Biomarker Panel	OVA1
ACG: A-0710	Whole Genome/Exome Sequencing - Cancer	
ACG: A-0711	Thyroid Nodule	Gene Expression Testing

ACG: A-0712	Prostate Cancer	Gene Expression Testing – Oncotype DX
ACG: A-0724	Noninvasive Prenatal Testing (Cell-Free Fetal DNA)	Aneuploidy Testing
ACG: A-0725	Polycystic Kidney Disease (Autosomal Dominant)	GANAB, PKD1, PKD2 & gene panels
ACG: A-0759	Acute Lymphoblastic Leukemia	BCR-ABL1 Fusion Gene Testing
ACG: A-0760	Acute Promyelocytic Leukemia	PML-RARA Fusion Gene Testing
ACG: A-0762	Ankylosing Spondylitis	HLA-B27
ACG: A-0763	Asthma	ADRB2 Gene
ACG: A-0764	Attention-Deficit Hyperactivity Disorder Medication Pharmacogenetics	ADRA2A, COMT, CYP2B6, and CYP2D6 Genes
ACG: A-0765	Beckwith-Wiedemann Syndrome	CDKN1C Gene
ACG: A-0766	Breast cancer gene expression assays	HER2 Gene
ACG: A-0767	Breast Cancer (Hereditary)	Gene Panel
ACG: A-0768	Autosomal and X-Linked Recessive Disease Carrier Screening	Expanded Gene Panels
ACG: A-0769	Celiac Disease	HLA Testing
ACG: A-0770	Chronic Eosinophilic Leukemia/Hypereosinophilic Syndrome	FIP1L1-PDGFRA Fusion Gene Testing
ACG: A-0771	Chronic Myelogenous Leukemia	BCR-ABL1 Fusion Gene Testing
ACG: A-0772	Colorectal Cancer	BRAF V600E
ACG: A-0773	Colorectal Cancer	KRAS and NRAS Genes
ACG: A-0774	Colorectal Cancer (Hereditary)	
ACG: A-0775	Cytochrome P450	3A4/3A5 Genotyping
ACG: A-0776	Maple Syrup Urine Disease, Type 3	DLD Gene
ACG: A-0777	Familial Hyperinsulinism	ABCC8, GCK, GLUD1, HADH, HK1, HNF1A, HNF4A, KCNJ11, PGM1, SLC16A1, and UCP2 Genes
ACG: A-0778	Familial Thoracic Aortic Aneurysm and Aortic Dissection, Nonsyndromic	HTAD and gene panel
ACG: A-0779	Gastric Cancer, Hereditary	CDH1 Gene
ACG: A-0780	Gastrointestinal Stromal Tumor (GIST)	KIT and PDGFRA Genes
ACG: A-0782	Gynecologic Cancer (Hereditary) - Gene Panel	
ACG: A-0783	Hepatitis C Medication Pharmacogenetics	IFNL3 and IFNL4 Genes
ACG: A-0785	Joubert Syndrome	gene testing and gene panels
ACG: A-0786	Lymphoma	T cell antigen receptor (TCR) gene rearrangement
ACG: A-0787	Malignant Melanoma	BRAF V600
ACG: A-0788	Marfan Syndrome	FBN1 Gene

ACG: A-0789	Molecular Profiling	
ACG: A-0790	Multiple Cancers, Including Cancer Syndromes (Hereditary)	
ACG: A-0791	Myelodysplastic Syndromes (somatic)	
ACG: A-0792	Nemaline Myopathy	ACTA1, CFL2, KBTBD13, KLHL40, KLHL41, LMOD3, MYO18B, MYPN, NEB, TNNT1, TPM2, and TPM3 Genes
ACG: A-0793	Fetal and Neonatal Alloimmune Thrombocytopenia	Human Platelet Antigen (HPA) Genotyping
ACG: A-0795	Non-Small Cell Lung Cancer (Somatic or Therapeutic)	
ACG: A-0796	Osteogenesis Imperfecta	MP1, COL1A1, COL1A2, CREB3L1, CRTAP, FKBP10, IFITM5, MBTPS2, P3H1, PLOD2, PPIB, SERPINF1, SERPINH1, SP7, SPARC, TMEM38B, and WTN1 Genes
ACG: A-0797	Pancreatic Cancer (Hereditary)	
ACG: A-0798	Paraganglioma-Pheochromocytoma (Hereditary)	
ACG: A-0799	Peutz-Jeghers Syndrome	STK11 Gene
ACG: A-0800	Post-Transfusion Purpura	Human Platelet Antigen (HPA) Genotyping
ACG: A-0801	Renal Cancer (Hereditary)	
ACG: A-0802	Usher Syndrome	ADGRV1 (GPR98), CDH23, CIB2, CLRN1, DFNB31, HARS, MYO7A, PCDH15, USH1C, USH1G, and USH2A Genes
ACG: A-0803	Male Infertility	Y Chromosome Microdeletion Analysis
ACG: A-0808	Alpha Thalassemia	HBA1 and HBA2 Genes
ACG: A-0809	Alzheimer Disease (Late Onset)	APOE Genotyping
ACG: A-0810	Chromosomal Microarray Analysis (CMA) - Developmental Delay	
ACG: A-0811	Chromosomal Microarray Analysis (CMA) - Neoplasms	
ACG: A-0812	Chromosomal microarray analysis (CMA) - Prenatal testing	
ACG: A-0815	Beta Thalassemia	HBB Gene
ACG: A-0816	Charcot-Marie-Tooth Hereditary Neuropathy, Type 2	HSPB1, MFN2, and MPZ Gene
ACG: A-0818	Charcot-Marie-Tooth Hereditary Neuropathy, Type 4	GD4, GDAP1, NDRG1, PRX, SBF2, and SH3TC2 Genes
ACG: A-0819	Charcot-Marie-Tooth Hereditary Neuropathy, Type X	AIFM1, GJB1, PDK3, and PRPS1 Genes
ACG: A-0820	Citalopram Pharmacogenetics	GRIK4 Gene

ACG: A-0821	Colon Cancer Gene Expression Assay	GeneFx Colon
ACG: A-0822	Colon Cancer Gene Expression Assay	ColoPrint
ACG: A-0823	Deafness and hearing loss, nonsyndromic	Miroarray & multigene
ACG: A-0824	Diabetes Mellitus (Permanent Neonatal Diabetes)	ABCC8, EIF2AK3, FOXP3, GATA4, GATA6, GCK, GLIS3, IER31P1, INS, KCNJ11, MNX1, NEUROG3, NKX2-2, PDX1, PTF1A, and RFX6 Genes
ACG: A-0825	Diabetes Mellitus (Transient Neonatal Diabetes)	ABCC8, HYMAI, KCNJ11, PLAGL1, and ZFP57 Genes
ACG: A-0826	Diabetes Mellitus, Type 2	KCNJ11, KCNQ1, PPARG, SLC16A11, and TCF7L2 Genes
ACG: A-0827	Familial Adenomatous Polyposis	
ACG: A-0828	Familial Adenomatous Polyposis	MUTYH Gene
ACG: A-0829	Fragile X-Associated Primary Ovarian Insufficiency	FMR1 Gene
ACG: A-0830	Fragile X-Associated Tremor/Ataxia Syndrome	FMR1 Gene
ACG: A-0831	Long QT Syndrome, Type 1 (Romano-Ward Syndrome, Hereditary)	KCNE1, KCNE2, KCNH2, KCNQ1, and SCN5A Genes
ACG: A-0833	Long QT syndrome (Andersen-Tawil syndrome, hereditary)	KCNJ2 Gene
ACG: A-0834	Long QT Syndrome (Timothy Syndrome, Hereditary)	CACNA1C Gene
ACG: A-0836	Malignant Melanoma (Uveal)	BAP1, CDK4, and CDKN2A Genes
ACG: A-0837	Melanoma (Cutaneous)	Gene Expression Profiling
ACG: A-0838	MicroRNA Detection - Heart Failure	
ACG: A-0839	MicroRNA Detection - Inflammatory Bowel Disease	
ACG: A-0840	MicroRNA Detection - Ischemic Heart Disease	
ACG: A-0841	MicroRNA Detection - Kidney Disease	
ACG: A-0842	Multiple Endocrine Neoplasia (MEN) Syndrome, Type 2	RET Gene
ACG: A-0843	Myeloproliferative Neoplasms	MPL Gene
ACG: A-0844	Myotonic Dystrophy, Type 2	CNBP Gene
ACG: A-0845	Naltrexone Pharmacogenetics	OPRM1 Gene
ACG: A-0846	Neurofibromatosis	NF2 Gene
ACG: A-0847	Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Fetal Rhesus D (RhD) Genotyping	

ACG: A-0848	Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Microdeletion Syndromes	
ACG: A-0849	Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Monogenic Disorders	
ACG: A-0850	Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Sex Chromosome Disorders	
ACG:A-0852	Polycystic Kidney Disease (Autosomal Recessive)	DZIP1L and PKHD1 Genes
ACG: A-0854	Prostate Cancer	HOXB13, MMR, PTEN, and TMPRSS2-ETS Fusion Genes
ACG: A-0855	Prostate Cancer	PCA3 Gene
ACG: A-0856	Prostate Cancer Gene Expression Testing - Decipher	
ACG: A-0857	Prostate Cancer Gene Expression Testing - Prolaris	
ACG: A-0858	Proteomics - Ovarian Cancer Biomarker Panel (ROMA)	
ACG: A-0859	Psychotropic Medication Pharmacogenetics	ABCB1, ADRA2A, BDNF, COMT, DRD, FKBP5, GNB3, HTR, MC4R, OGFRL1, SLC6A4, SPTA1, and TPH1 Genes
ACG: A-0861	Psychotropic Medication Pharmacogenetics - Gene Panels	
ACG: A-0862	Psychotropic Medication Pharmacogenetics - HLA Typing	
ACG:A-0864	Sickle Cell Disease	HBB Gene
ACG: A-0865	Whole Genome/Exome Sequencing - Cardiovascular Disorder	
ACG: A-0866	Whole Genome/Exome Sequencing - Immunodeficiency Disorders	
ACG: A-0867	Whole Genome/Exome Sequencing - Intellectual Disability	
ACG: A-0868	Whole Genome/Exome Sequencing - Metabolic Disorders	
ACG: A-0869	Whole Genome/Exome Sequencing - Mitochondrial Disorders	
ACG: A-0870	Whole Genome/Exome Sequencing - Autism Spectrum Disorders	
ACG: A-0871	Whole Genome/Exome Sequencing - Neurologic Disorders	
ACG: A-0872	Whole Genome/Exome Sequencing - Congenital Anomalies	
ACG: A-0904	Epilepsies, Hereditary	SCN1A Gene
ACG: A-0905	Epilepsies (Hereditary)	Gene Panel

ACG: A-0906	Familial Frontotemporal Dementia	C9orf72, GRN, and MAPT Genes
ACG: A-0907	Friedreich Ataxia	FXN Gene
ACG: A-0908	Spinocerebellar Ataxia	ATXN1, ATXN2, ATXN3, ATXN7, CACNA1A, and gene panels
ACG: A-0909	Loeys-Dietz Syndrome	SMAD2, SMAD3, TGFB2, TGFB3, TGFBR1, TGFRBR2
ACG: A-0910	Ehlers-Danlos Syndrome (Vascular)	COL3A1 Gene
ACG: A-0912	Retinal Disorders	Gene Panels
ACG: A-0913	Age-Related Macular Degeneration	Gene Panels
ACG: A-0914	Autism Spectrum Disorders	Gene Panels
ACG: A-0915	Noonan Syndrome	BRAF, KRAS, LZTR1, MAP2K1, NRAS, PTPN11, RAF1, RIT1, SOS1, SOS2, and gene panels
ACG: A-0916	Fabry Disease	GLA Gene
ACG: A-0917	Chromosomal Microarray Analysis (CMA) - Congenital Anomalies	
ACG: A-0918	Long QT Syndrome (Hereditary)	Gene Panel
ACG: A-0923	Intellectual Disability	
ACG: A-0924	Chromosomal Microarray Analysis (CMA) - Intellectual Disability	
ACG: A-0925	Developmental Delay	
ACG: A-0926	Whole Genome/Exome Sequencing - Developmental Delay	
ACG: A-0927	Gastric cancer - gene testing (somatic or therapeutic)	
ACG: A-0957	Congenital central hypoventilation syndrome	PHOX2B
ACG: A-0958	Familial hypercholesterolemia	APBO, LDLR, PCSK9

E. Conditions of Coverage

F. Related Polices/Rules

G. Review/Revision History

	DATE	ACTION
Date Issued	02/24/2015	Issued
Date Revised	04/05/2016	Included MCG 20th Ed. Revisions to Table A
Date Revised	06/05/2019	Included MCG 23rd Ed. Revisions to content and Table A.
Date Effective	TBD	

H. References

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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

Note: Effective 06/2019 CareSource will utilize the current edition of the MCG Care Guidelines' (Ambulatory Care: Genetic Medicine section) criteria when reviewing prior authorization requests for coverage of genetic test(s). This policy statement clarifies and supplements the individual guidelines in this set.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.