MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
02/24/2015 216 649.92 0.480 14 0248 1 re 4 Tm 1		2015

Policy Name	Policy Number
Genetic Testing, Genetic Screening and Genetic Counseling	MM-0003

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from criteria 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 that 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 guarantee 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.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

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 an ever expanding number of genetic assays available for the purpose of genetic screening and genetic testing. In some clinical situations the results may be linked to proven diagnostic and/or therapeutic results.

Genetic tests that are CLIA/CAP approved are commercially available and may be employed across a wide ranging number of clinical applications. These tests include the measurement of single defects as well Clinical utility

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acronym “ACCE”).

CareSource seeks to understand and apply clinical data as it applies to these four areas in order to identify genetic tests that can improve clinical outcomes. This process is supported by

evidence based and literature supported guidelines known as Milliman Care Guidelines (MCG) for Ambulatory Care Guidelines for Genetic Medicine (see table below).

For genetic tests not addressed by MCG CareSource utilizes independent assessments by nationally recognized technology organizations and other evidence based guidelines for the purpose of distinguishing tests that are safe and useful.

Genetic Counseling:
As outlined in the 19th edition of the Milliman Care Guidelines, Genetic Counseling plays an essential role in genetic testing and is required as part of its pre-certification.

Prenatal Testing: A sub set of genetic testing used to detect changes in the genes or

nationally recognized technology organizations. (CareSource routinely accesses reporting from the Hayes Genetic Test Index and the Genetic Testing Health Technology Assessment Info Service (HTAIS) of the ECRI Institute, as well as other recognized guideline sets).

Table A

MCG Policy Number	MCG Policy Title	Genes and Gene Panels
ACG: A-0499	Breast or Ovarian Cancer, Hereditary	BRCA1 and BRCA2 Genes
ACG: A-0532	Breast Cancer Gene Expression Assays	
ACG: A-0533	Lynch Syndrome	EPCAM, MLH1, MSH2, MSH6, and PMS2 Genes
ACG: A-0531	Genome-Wide Association Studies	
ACG: A-0534	Familial Adenomatous Polyposis	APC and MUTHY Genes, and Gene Panels
ACG: A-0535	Paraganglioma-Pheochromocytoma Syndromes, Hereditary	SDHB, SDHC, SDHD, and TMEM127 Genes
ACG: A-0581	Neurofibromatosis	NF1 and NF2 Genes
ACG: A-0582	Multiple Endocrine Neoplasia (MEN) Syndromes	MEN1 and RET Genes
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	Array-Based Comparative Genomic Hybridization (aCGH)	
ACG: A-0590	Alzheimer Disease	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	CACNA1C, CACNB2, GPD1L, HCN4, KCND3, KCNE3, KCNJ8, SCN1B, SCN3B, and SCN5A Genes

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ACG: A-0651	Colon Cancer Gene Expression Assays	
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-0665m

ACG: A-0710	Whole Genome/Exome Sequencing	
ACG: A-0711	Thyroid Nodule Gene Expression Testing	
ACG: A-0712	Prostate Cancer Gene Expression Testing	
ACG: A-0724	Noninvasive Prenatal Testing	Cell-Free Fetal DNA
ACG: A-0725	Polycystic Kidney Disease	PDK1, PKD2 and PKHD1 Genes

For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

HCPCS
CPT

AUTHORIZATION PERIOD

E. REVIEW/REVISION HISTORY
Date Issued: 02/24/2015
Date Reviewed: 02/24/2015, 04/[illegible]/2015
Date Revised: 04/2[illegible]015 - Include MCG 19th Ed. revisions

F. REFERENCES
1. Genomic Testing: ACCE Model Process for Evaluating Genetic Tests http://www.cdc.gov/genomics/gtesting/ACCE/index.htm
2. Raby BA, Kohlman V, Venne V. Genetic counseling and testing. In: Tirnauer JS (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2014
3. Public Health Genomics: http://www.cdc.gov/genomics/gtesting/ACCE/acce_proj.htm
4. Genetic Counseling and Testing
5. http://www.uptodate.com/contents/genetic-counseling-and testing?source=search_result&search=genetic+testing&selectedTitle=1%7E150
6. Milliman Care Guidelines (MCG): Ambulatory Care Guidelines for Genetic Medicine

Note: Effective 2015 CareSource will utilize the 19th edition of Milliman Care Guidelines' (Ambulatory Care: Genetic Medicine section) criteria when reviewing prior authorization request 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.

Independent medical review – 1/2015