MEDICAL POLICY STATEMENT

OHIO MARKETPLACE PLANS

Policy Name			Policy Number	Date Effective
Genetic Testing, Genetic Screening and Genetic Counseling			MM-0740	11/01/2019
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 recommend-4.004 (S)4.004 (cr)-2.998 (ee)2.998 (ni

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

x Diagnostic Testing: the process of examination of specimens and results to determ8 (n of)98 (an)2

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 AND

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	

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

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