REIMBURSEMENT POLICY STATEMENT
KENTUCKY MARKETPLACE PLANS

Original Issue Date	Next Annual Review	Effective Date
09/06/2017	04/01/2019	04/01/2018
Policy Name		**Policy Number**
Genetic Testing- Polymerase Chain Reaction		PY-0310
Policy Type		
Medical / Administrative / Pharmacy		**REIMBURSEMENT**

Reimbursement Policies prepared by CSMG Co. and its affiliates (including CareSource) are intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry-standard claims editing logic, benefits design and other factors are considered in developing Reimbursement Policies.

In addition to this Policy, Reimbursement of services is subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management 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 federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

This Policy does not ensure an authorization or Reimbursement of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced herein. If there is a conflict between this Policy 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.

CSMG Co. and its affiliates may use reasonable discretion in interpreting and applying this Policy to services provided in a particular case and may modify this Policy at any time.

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A. SUBJECT

Genetic Testing- Polymerase Chain Reaction

B. BACKGROUND

Polymerase Chain Reaction (PCR) is a genetic amplification technique that only requires small quantities of DNA, for example, 0.1 mg of DNA from a single cell, to achieve DNA analysis in a shorter laboratory processing time period. Knowing the gene sequence, or at minimum the borders of the target segment of DNA to be amplified, is a prerequisite to a successful PCR amplification of DNA.

PCR plays a diagnostic role when selected pathogens pose difficulties for specimen collection or culture characteristics (time, environment, or substrate constraints). For example, evaluating viral load by PCR technique for HIV helps gauge response to therapies. However, the technique is also so sensitive that amplified contaminant DNA is problematic to achieving valid test results. False positive results may also occur if DNA from one specimen contaminates another. The technique cannot distinguish DNA from colonizing organisms, or even DNA from dead microbes in a specimen, from those causing clinically significant infections. In fact, for many types of microbes the test sensitivities, specificities, and predictive values of PCR gene testing are not reported for large patient groups.

Repeated cycles of synthesizing complementary strands of DNA are performed in a stepwise manner up to 30 times to achieve adequate gene amplification for diagnosis. Cycles involve 1) denaturing DNA with heat to create single strands, 2) annealing PCR primers of oligonucleotides (short pieces of DNA of 20-30 base pairs each) to the DNA to be amplified, and 3) enzymatic synthesis of complementary DNA with Taq polymerase or Pfu polymerase.

All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. Although CLIA requires that waived tests must be simple and have a low risk for erroneous results, this does not mean that waived tests are completely error-proof. Errors can occur anywhere in the testing process, particularly when the manufacturer's instructions are not followed and when testing personnel are not familiar with all aspects of the test system. Some waived tests have potential for serious health impacts and unintended consequences if performed incorrectly. To decrease the risk of erroneous results, the test needs to be performed correctly, by trained personnel and in an environment where good laboratory practices are followed. CareSource may periodically require review of a provider’s office testing policies and procedures when performing CLIA-waived tests. CareSource will cover influenza testing with the CPT 87502 only when a CLIA-waived manufacturer testing system performs gene amplification by polymerase chain reaction (PCR) or nucleic acid amplification technology (NAT) testing. Appropriate indications must be documented in the member’s medical record and available for review by CareSource upon request.

C. DEFINITIONS

- **Polymerase Chain Reaction (PCR)** - a genetic amplification technique also known as a Nucleic Acid Amplification Test (NAAT)

D. POLICY

I. A Prior Authorization is not required for selected PCR testing.

II. CareSource considers nucleic acid amplification testing (NAAT) by polymerase chain reaction (PCR) to be medically necessary for the following indications in oncology and heritable conditions:

A. Chronic Lymphocytic Leukemia (CLL) [1]
B. BCR-ABL testing for Chronic Myelogenous Leukemia (CML) [2] [3] [4]
C. Mucosa-Associated Lymphoid Tissue (MALT) [5]
D. Lynch syndrome [6] [7]
E. BRAF mutation which is seen in colorectal carcinoma, gliomas, hepatobiliary carcinomas, melanoma, papillary thyroid carcinoma, ovarian teratomas and serous tumors, and hairy-cell leukemia (HCL). [8,9]
F. The use of PCR gene testing for persons who meet criteria has been demonstrated in a variety of heritable conditions and is supported by published literature or endorsed by consensus professional societies. These conditions include certain primary thrombophilias[10], Tay-Sachs and Canavan diseases[11], Fabry disease[12], Gaucher disease[13], Niemann-pick disease[14], Hemochromatosis[15], Rett syndrome[16], Huntington's disease[17], Celiac disease[18], Ankylosing spondylitis[19], Prader-Willi or Angelman syndrome, and other short-stature syndromes[20], Fragile X syndrome[21], and sickle-cell disease[22]. Applications of selected PCR techniques are also part of the workup and management for candidates donating organs and tissues. [23, 24] The first-line screening test for Tay-Sachs remains an enzyme activity test rather than genotyping. Genotyping is used for preimplantation diagnosis and confirmatory testing. In contrast, DNA-based testing is
used for Canavan screening and diagnosis.
G. Methylenetetrahydrofolate reductase (MTHFR) polymorphism testing has little clinical utility and does not meet medical necessity criteria as meta-analyses have disproven an association between elevated homocysteine and risk for coronary artery disease and between MTHFR polymorphisms and risk for venous thromboembolism.[25]

III. CareSource considers NAAT by PCR to be medically necessary for the following indications in infectious disease management:
A. Shiga toxin--producing Escherichia coli (STEC) [26]
B. C. difficile enterocolitis [27-29]
C. Entamoeba species [30,31]
D. Tuberculosis[32]
E. Staphylococcus aureus[33]
F. Actinomyces species may be identified in tissue specimens with a 16s rRNA sequencing and PCR assay.[34, 35]
G. Dengue is a mosquito-borne febrile illness and diagnosis requires laboratory confirmation by culture, NAAT or testing for dengue specific antibodies.[37] For other mosquito-borne illnesses such as West Nile virus and Zika, PCR also has diagnostic utility, including in saliva tests.[38] Ebola may be diagnosed by PCR techniques on plasma.[39]

IV. CareSource considers viral PCR testing in conjunction with a Clinical Laboratory Improvement Amendments (CLIA)-approved reference lab as medically necessary for indications endorsed in a primary or supplemental diagnostic approach as described by the Infectious Diseases Society of America (IDSA). [40] Many molecular diagnostic tests for viral pathogens include PCR techniques, offered by CLIA-certified reference laboratories. Viral syndrome testing is considered based on the patient's age, history, immune status, and other variables. According to the IDSA, diagnostic samples are obtained and tested for the most likely agents.[40] Samples are commonly held frozen in the microbiology laboratory for additional testing if necessary, given that it is not cost-effective to test initial samples broadly for multiple viruses.[40] These viral pathogens include:
A. Herpes virus infections [41, 42], Varicella and Zoster[43], Measles[44], Mumps[45], Cytomegalovirus [40], Adenovirus [40], Enterovirus [42], and Parvovirus [40].
B. For persons with positive HIV, ½ antigen/antibody combination immunoassays and either HIV-1 negative or indeterminate HIV-2 differentiation immunoassay, PCR testing is indicated.[40, 46, 47]

C. The diagnosis of hepatitis B (HBV) or C (HCV) typically begins with an antibody test for screening or in the presence of acute hepatitis. For hepatitis B, PCR viral genetic assays may be applied to determine viral genotype, detecting genotypic drug resistance mutations, and identifying core promoter/precore mutations.[48] For hepatitis C, persons with positive screening test results should undergo confirmatory or supplemental testing for HCV RNA by molecular test methods.

V. PCR techniques have been developed for a variety of respiratory pathogens and may be included in diagnostic algorithms for affected persons in the pediatric and adult populations. The Infectious Diseases Society of America/American Thoracic Society (IDSA/ATS) consensus guidelines on the management of community-acquired pneumonia in adults report that testing is optional for persons who are not hospitalized [49]. However, patients who require hospitalization should have pretreatment blood cultures, culture and Gram stain of good-quality samples of expectorated sputum and, if disease is severe, urinary antigen tests for S. pneumoniae and Legionella pneumophila, when available. [49] Evaluation of bronchoscopically obtained samples and/or thoracentesis-obtained samples of pleural fluid may be necessary for diagnosis in hospitalized persons unable to produce a sputum sample. PCR testing may be applied in selected cases where microorganisms are suspected based upon age, history, immune status, and other variables. PCR testing is available for Mycoplasma. [49]

VI. CareSource considers PCR testing for pathogens of other types or in other anatomic sites medically necessary as described by the IDSA and the American Society for Microbiology (ASM) in “A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2013 Recommendations by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM).”[40] Guidelines were developed by both laboratory and clinical experts and “provides information on which tests are valuable and in which contexts, and on tests that add little or no value for diagnostic decisions.”[40]

VII. For many pathogens, while a PCR test is available, the clinical utility is not clearly defined by available evidence, evidence is insufficient or inconclusive, or there is no support for quantification PCR testing. For Bartonella henselae and quintona species, immunofluorescent antibody assay serology is sensitive and specific, and there is no inconclusive evidence of an indication for quantification. [50, 51]. For many pathogens, such as Chlamydia pneumoniae, Hepatitis G, herpes simplex virus (HSV), Herpes virus-6, Legionella pneumophilia, Mycobacteria avium-intracellulare, Mycoplasma pneumoniae, Neisseria gonorrhoeae, and Streptococcus, group A guidelines from the IDSA do not have a recommendation for quantification.[40]

VIII. For sexually transmitted infections including Chlamydia, Gonorrhea, Syphilis, and other pathogens, refer to the CareSource Sexually Transmitted Infection (STI) policy.

E. CONDITIONS OF COVERAGE

HCPCS
CPT

AUTHORIZATION PERIOD

F. RELATED POLICIES/RULES

1. Genetic Testing, Genetic Screening and Genetic Counseling (MM-0003)
2. Sexually Transmitted Infections (PY-0037)

G. REVIEW/REVISION HISTORY

	DATE	ACTION
Date Issued	09/06/2017	New Policy.
Date Revised		
Date Effective	04/01/2018	

H. REFERENCES

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