

ADMINISTRATIVE POLICY STATEMENT

Wisconsin Marketplace

Policy Name & Number	Date Effective
Molecular Diagnostic Testing-WI MP-AD-1456	01/01/2025
Policy Type	
ADMINISTRATIVE	

Administrative Policy Statements 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 or Certificate of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other plan policies and procedures.

Administrative Policy Statements do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage or Certificate of Coverage) for the service(s) referenced in the Administrative Policy Statement. Except as otherwise required by law, if there is a conflict between the Administrative Policy Statement and the plan contract, then the plan contract will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject
Molecular Diagnostics Testing

B. Background

Molecular diagnostic testing (MDT) following a diagnosis or suspected diagnosis can help guide appropriate therapy by identifying specific therapeutic targets and appropriate pharmaceutical interventions. MDT utilizes a genetic amplification technique, polymerase chain reaction (PCR), that uses 0.1 mg of DNA from a single cell to achieve shorter laboratory processing times for results. 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.

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 that are cleared by the US Food and Drug Administration (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 low risk for erroneous results, this does not mean that waived tests are completely error-proof. Common Ground Healthcare Cooperative ("CGHC") may periodically require review of a provider's office testing policies and procedures when performing CLIA-waived tests.

C. Definitions

- **Polymerase Chain Reaction (PCR)** – A laboratory method used to look for certain changes in a gene or chromosome, which may help find and diagnose a genetic condition or a disease, or to look at pieces of the DNA from certain bacteria, viruses, or other microorganisms to help diagnose an infection.

D. Policy

- I. CGHC considers conventional testing, such as rapid antigen direct tests, direct fluorescent antibody testing, and cultures as lower cost and should be utilized before the higher cost molecular diagnostic testing (MDT) by PCR.
- II. Providers should utilize conventional testing first.
 - A. If conventional testing is:
 1. Positive – no further testing is medically necessary.
 2. Negative – if the member's presenting symptoms support the diagnosis, then MDT by PCR testing is medically necessary to confirm diagnosis. Examples of relevant diagnoses are, but not limited to, gastroenteritis, streptococcal pharyngitis, acute hepatitis, Shigellosis.
 - B. "Diseases complicating pregnancy" are an exception to the above.
- III. CGHC may request documentation to support medical necessity.

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

E. Conditions of Coverage
NA

F. Related Policies/Rules
NA

G. Review/Revision History

DATE		ACTION
Date Issued	09/25/2025	New policy. Approved at Committee.
Date Revised		
Date Effective	01/01/2025	
Date Archived		

H. References

1. National Cancer Institute at the National Institutes of Health. Polymerase chain reaction. Accessed July 25, 2024. www.cancer.gov