ADMINISTRATIVE POLICY STATEMENT
Indiana D-SNP

Policy Name & Number	Date Effective
Molecular Diagnostic Testing-IN DSNP-AD-1209	09/01/2022-07/31/2023
Policy Type	
ADMINISTRATIVE	

Administrative Policy Statement prepared by CareSource and its affiliates 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.

Administrative Policy Statements prepared by CareSource and its affiliates 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 Administrative Policy Statement. If there is a conflict between the Administrative 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.

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. Molecular diagnostic testing utilizes polymerase chain reaction (PCR), 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. 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 cleared by the U.S. 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. CareSource 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. It may also be used to look at pieces of the DNA of certain bacteria, viruses, or other microorganisms to help diagnose an infection.

D. Policy

I. CareSource 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 by PCR.

II. Providers should utilize the conventional testing first.
   A. If conventional testing is:
      1. Positive – no further testing is medically necessary.
      2. Negative – 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. Exception to the above are diagnosis of "diseases complicating pregnancy".

III. CareSource may request documentation to support medical necessity.

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E. Conditions of Coverage

NA

F. Related Policies/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	05/25/2022	New policy
Date Revised		
Date Effective	09/01/2022	
Date Archived	07/31/2023	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. National Cancer Institute at the National Institutes of Health (n.d.). Polymerase chain reaction. Retrieved on 05/03/2022 from www.cancer.gov.

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