

ADMINISTRATIVE POLICY STATEMENT D-SNP

Policy Name & Number	Date Effective
Molecular Diagnostic Testing-DSNP-AD-1362	IN, GA: 08/01/2023 OH: 09/01/2023
Policy Type	
ADMINISTRATIVE	

Administrative Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines. 2022 (b) (3) (a) (i) - 23 () (o) - (n) - (3) () (a) - (3) (n) - (3) (d) 56 (r) 33 (t) - 21 ch () (a) - (3) op n ass (e) - (3) (m) 33



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 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 from 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 (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.

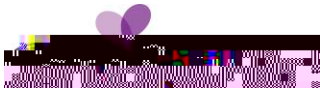
B. "Diseases complicating pregnancy" are an exception to the above.

III. CareSource may request documentation to support medical necessity.

E. Conditions of Coverage

NA

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



F. Related Policies/Rules
NA

G. Review/Revision History

DATE		ACTION
Date Issued	05/10/2023	No policy
Date Revised		
Date Effective	GA, IN: 08/01/2023 OH: 09/01/2023	
Date Archived		

H. References

1. National Cancer Institute at the National Institutes of Health. Polymerase chain reaction. Accessed May 01, 2023 from www.cancer.gov.

I. State-Specific Information

- A. Georgia
Effective: 08/01/2023
- B. Indiana
Effective: 08/01/2023
- C. Ohio
Effective: 09/01/2023

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