CareSource

REIMBURSEMENT POLICY STATEMENT
INDIANA MEDICAID

Policy Name	Policy Number	Effective Date
Molecular Diagnostic Testing for Gastrointestinal Illness	PY-0867	01/01/2021-09/30/2022

Policy Type			
Medical	Administrative	Pharmacy	REIMBURSEMENT

Reimbursement Policy Statement: Reimbursement Policies prepared byCareSource and its affiliates 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.

CareSource 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.

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 Diagnostic Testing for Gastrointestinal Illness

B. Background

Molecular testing, 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.

Gastrointestinal illness, as addressed in this policy, include Clostridium difficile, E. Coli, Salmonella, Shigella, Norovirus and Giardia. These infection and illnesses of the intestine can cause symptoms such as diarrhea, nausea, vomiting and abdominal cramping. There are three basic modes of transmission: in food, in water and person to person. While some of these illnesses will resolve on their own, others can spread throughout the body and require treatment to prevent a more devastating illness.

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. 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 genetic amplification technique also known as a Nucleic Acid Amplification Test (NAAT).
- **Medically Necessary** - Is the evaluation of health care services to determine if they are medically appropriate and necessary to meet basic health needs; consistent with the diagnosis or condition and rendered in a cost-effective manner; and consistent with national medical practice guidelines regarding type, frequency, and duration of treatment.

D. Policy

I. Prior Authorization is required for the Molecular Diagnostic Testing by PCR addressed in this policy.

II. CareSource considers Molecular Diagnostic Testing by PCR medically necessary for the following gastrointestinal illnesses:
   A. Clostridium Difficile
   B. Salmonella

C. Shigella
D. Norovirus
E. Giardia
F. E coli

III. Conventional testing, such as stool and saliva samples, for these illnesses is viewed as low cost. Not all cases of acute diarrhea are indicative of these illnesses, therefore, institutions should utilize conventional testing first, before using the higher cost Molecular Testing by PCR.

E. Conditions of Coverage

Reimbursement is dependent on, but not limited to, submitting approved HCPCS and CPT codes along with appropriate modifiers, if applicable. Please refer to the individual fee schedule for appropriate codes.

F. Related Policies/Rules

N/A

G. Review/Revision History

	DATE	ACTION
Date Issued	02/01/2020	New policy
Date Revised	10/28/2020	Updated the prior authorization requirement. Removed CPT and ICD-10 codes.
Date Effective	01/01/2021	
Date Archived	09/30/2022	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. Indiana Health Coverage Programs Fee Schedule. (2020, October 17). Retrieved 10/26/20 from www.provider.indianamedicaid.com.
2. Indiana Medicaid - Understanding Terms. (2019). Retrieved 10/26/2020 from www.in.gov/medicaid.
3. Multiplexed Molecular Diagnostics for Respiratory, Gastrointestinal, and Central Nervous System Infections. (2016, July 20). Retrieved 10/26/2020 from www.ncbi.nlm.nih.gov.

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