REIMBURSEMENT POLICY STATEMENT
OHIO MEDICAID

Original Issue Date	Next Annual Review	Effective Date
12/01/2018	12/01/2019	12/01/2018
Policy Name		**Policy Number**
Molecular Diagnostic Testing for Gastrointestinal Illness		PY-0448
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.

Contents of Policy

A. SUBJECT

Molecular 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**- Health care services or supplies needed to diagnosis or treat an illness, injury, condition, disease or its symptoms and that meet the accepted standards of medicine.

D. POLICY

I. No 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, when submitted with any combination of the CPT and diagnosis codes listed in the Conditions of Coverage of this policy.
   A. Clostridium Difficile
   B. Salmonella
   C. Shigella
   D. Norovirus
   E. Giardia

III. CareSource does not consider Molecular Diagnostic Testing by PCR medically necessary for gastrointestinal illnesses when billed with any other diagnosis code and will not provide reimbursement for those services.

IV. Conventional testing, such as stool and saliva samples for these illnesses is viewed as low cost and given that not all cases of acute diarrhea are indicative of these illnesses, institutions should utilize these before the higher cost Molecular Testing by PCR as the first testing option for the initial clinical presentation of acute diarrhea.

E. CONDITIONS OF COVERAGE

CODE	DESCRIPTION
87493	Infectious agent detection by nucleic acid (DNA or RNA); Clostridium difficile, toxin gene(s), amplified probe technique
87505	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets
87506	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets
87507	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets
A04.71	Enterocolitis due to Clostridium difficile, recurrent
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent
A02.0	Salmonella enteritis
A03.0	Shigellosis due to Shigella dysenteriae
A03.1	Shigellosis due to Shigella flexneri
A03.2	Shigellosis due to Shigella boydii
A03.3	Shigellosis due to Shigella sonnei
A03.8	Other shigellosis
A03.9	Shigellosis, unspecified
A04.0	Enteropathogenic Escherichia coli infection
A04.1	Enterotoxigenic Escherichia coli infection
A04.2	Enteroinvasive Escherichia coli infection
A04.3	Enterohemorrhagic Escherichia coli infection
A04.4	Other intestinal Escherichia coli infections
A07.1	Giardiasis [lambliasis]
A08.11	Acute gastroenteropathy due to Norwalk agent
K52.9	Noninfective gastroenteritis and colitis, unspecified
O99.611	Diseases of the digestive system complicating pregnancy, first trimester
O99.612	Diseases of the digestive system complicating pregnancy, second trimester
O99.613	Diseases of the digestive system complicating pregnancy, third trimester
O99.619	Diseases of the digestive system complicating pregnancy, unspecified trimester
O99.62	Diseases of the digestive system complicating childbirth
O99.63	Diseases of the digestive system complicating the puerperium

F. RELATED POLICIES/RULES

N/A

G. REVIEW/REVISION HISTORY

	DATE	ACTION
Date Issued	12/01/2018	
Date Revised	11/07/2018	Updated next review date to 12/01/2019
Date Effective		

H. REFERENCES

1. Multiplexed Molecular Diagnostics for Respiratory, Gastrointestinal, and Central Nervous System Infections. (2016, July 16). Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5091344/

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