REIMBURSEMENT POLICY STATEMENT
OHIO MEDICARE ADVANTAGE

Policy Name	Policy Number	Effective Date
Molecular Diagnostic Testing for Hepatitis B and C	PY-0874	12/01/2019

Policy Type			
Medical	Administrative	Pharmacy	REIMBURSEMENT

Reimbursement Policy Statement: 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.

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Table of Contents

Reimbursement Policy Statement 1
A. Subject 2
B. Background 2
C. Definitions 3
D. Policy 3
E. Conditions of Coverage 3
F. Related Policies/Rules 4
G. Review/Revision History 4
H. References 4

A. Subject

Molecular Diagnostic Testing for Hepatitis B and C

B. Background

Reimbursement policies are designed to assist you when submitting claims to CareSource. They are routinely updated to promote accurate coding and policy clarification. These proprietary policies are not a guarantee of payment. Reimbursement for claims may be subject to limitations and/or qualifications. Reimbursement will be established based upon a review of the actual services provided to a member and will be determined when the claim is received for processing. Health care providers and their office staff are encouraged to use self-service channels to verify member's eligibility.

It is the responsibility of the submitting provider to submit the most accurate and appropriate CPT/HCPCS code(s) for the product or service that is being provided. The inclusion of a code in this policy does not imply any right to reimbursement or guarantee claims payment.

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.

"Hepatitis B is a liver infection caused by the Hepatitis B virus (HBV). Hepatitis B is transmitted when blood, semen, or another body fluid from a person infected with the Hepatitis B virus enters the body of someone who is not infected. This can happen through sexual contact; sharing needles, syringes, or other drug-injection equipment; or from mother to baby at birth. For some people, hepatitis B is an acute, or short-term, illness but for others, it can become a long-term, chronic infection. Risk for chronic infection is related to age at infection: approximately 90% of infected infants become chronically infected, compared with 2%–6% of adults. Chronic Hepatitis B can lead to serious health issues, like cirrhosis or liver cancer. The best way to prevent Hepatitis B is by getting vaccinated." (1)

*"**Hepatitis C** is a liver infection caused by the Hepatitis C virus (HCV). Hepatitis C is a blood-borne virus. Today, most people become infected with the Hepatitis C virus by sharing needles or other equipment to inject drugs. For some people, hepatitis C is a short-term illness but for 70%–85% of people who become infected with Hepatitis C, it becomes a long-term, chronic infection. Chronic Hepatitis C is a serious disease than can result in long-term health problems, even death. The majority of infected persons might not be aware of their infection because they are not clinically ill. There is no vaccine for Hepatitis C. The best way to prevent Hepatitis C is by avoiding behaviors that can spread the disease, especially injecting drugs."* (1)

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.

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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 Hepatitis B and C infection, when submitted with any combination of the CPT and ICD-10 diagnosis codes listed in the Conditions of Coverage in this policy.

III. CareSource does not consider Molecular Diagnostic Testing by PCR for Hepatitis B and C to be medically necessary when billed with any other ICD-10 diagnosis code and will not provide reimbursement for those services.

IV. Conventional testing, such as serology or blood tests, are viewed as low cost and should be utilized before the higher cost Molecular Diagnostic Testing by PCR.

E. Conditions of Coverage

Reimbursement is dependent on, but not limited to, submitting Centers for Medicare & Medicaid Services (CMS) approved HCPCS and CPT codes along with appropriate modifiers. Please refer to the (CMS) fee schedule for appropriate codes.

- **The following list(s) of codes is provided as a reference. This list may not be all inclusive and is subject to updates.**

CPT Code	Description
87516	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, amplified probe technique
87517	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, quantification
87521	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique, includes reverse transcription when performed
87522	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, quantification, includes reverse transcription when performed
ICD-10 Code	**Description**
B16.0	Acute hepatitis B with delta-agent with hepatic coma
B16.1	Acute hepatitis B with delta-agent without hepatic coma
B16.2	Acute hepatitis B without delta-agent with hepatic coma
B16.9	Acute hepatitis B without delta-agent and without hepatic coma
B17.0	Acute delta-(super) infection of hepatitis B carrier
B18.0	Chronic viral hepatitis B with delta-agent
B18.1	Chronic viral hepatitis B without delta-agent
B19.10	Unspecified viral hepatitis B without hepatic coma
B19.11	Unspecified viral hepatitis B with hepatic coma
B17.10	Acute hepatitis C without hepatic coma

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B17.11	Acute hepatitis C with hepatic coma
B18.2	Chronic viral hepatitis C
B18.9	Chronic viral hepatitis, unspecified
B19.20	Unspecified viral hepatitis C without hepatic coma
B19.21	Unspecified viral hepatitis C with hepatic coma
O98.411	Viral hepatitis complicating pregnancy, third trimester
O98.412	Viral hepatitis complicating pregnancy, second trimester
O98.413	Viral hepatitis complicating pregnancy, third trimester
O98.419	Viral hepatitis complicating pregnancy, unspecified trimester
O98.42	Viral hepatitis complicating childbirth
O98.43	Viral hepatitis complicating the puerperium
Z20.5	Contact with and (suspected) exposure to viral hepatitis

F. Related Policies/Rules

N/A

G. Review/Revision History

DATE		ACTION
Date Issued	12/01/2019	New Policy
Date Revised	12/18/2019	Addition of code Z20.5
Date Effective	12/01/2019	
Date Archived		

H. References

1. Division of Viral Hepatitis Home Page | Division of Viral Hepatitis | CDC. (2019, July 23). Retrieved 7/29/19 from www.cdc.gov/hepatitis.
2. License Agreement. (2019, January 15). Retrieved 7/29/19 from https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/19CLABQ1.zip.
3. Medically Necessary. (2019, July 29). Retrieved 7/29/19 from https://www.healthcare.gov/glossary/medically-necessary/.

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

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