JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Provider Relations and Network Innovation Reimbursement Policy**	*Policy Number*	RPC.034
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		Approval Date	09/13/2023
	Subject **Laboratory Services, Professional**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

EHP	Johns Hopkins Advantage MD	Priority Partners	US Family Health Plan

Keywords: CLIA, Laboratory

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I. ABOUT OUR REIMBURSEMENT POLICIES:

The most current version of the reimbursement policies can be found on www.JHHP.com.

Johns Hopkins Health Plans (JHHP) reimbursement policies serve as a guide to assist in accurate claim submissions and outline the basis for reimbursement of services covered by a member's JHHP benefit plan. The determination that a service, procedure, item, etc. is covered under a member's benefit plan is not a guarantee that you will be reimbursed. Services must meet prior authorization and medical necessity guidelines appropriate to the procedure and diagnosis, as well as to the member's state of residence. Providers are expected to and must follow proper billing and submission guidelines. Providers are required to use industry standard, compliant codes on all claim submissions. Services must be billed with valid ICD-10 diagnosis codes, Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, place of service (POS) codes, and/or revenue codes as defined by the Centers for Medicare & Medicaid Services (CMS) and in the American Medical Association's (AMA's) "CPT Manual". The codes billed should denote the services and/or procedures performed. The billed code(s) are required to be fully supported in the patient's medical record and/or office notes and JHHPC reserves the right to request the records. Unless otherwise noted within the policy, our policies apply to both participating and nonparticipating providers and facilities.

JHHP policies apply to all practitioners, hospitals, providers, or suppliers eligible to bill the relevant HCPCS/CPT codes pursuant to applicable portions of the Social Security Act (SSA) of 1965, the Code of Federal Regulations (CFR), and Medicare rules. JHHP reimbursement policies are developed based on nationally accepted industry standards, coding principles, and follows CMS guidelines and the CMS developed National Correct Coding Initiative (NCCI) program to prevent inappropriate payment of services that should not be reported together. These policies may be superseded by mandates in provider or state contracts, or state, federal or CMS contracts and/or requirements. If appropriate, when coding/billing guidelines or current reimbursement policies are not followed, JHHP may:

- Reject or deny the claim
- Recover and/or recoup claim payment

JHHP reserves the right to modify policies at any time and publish new versions when necessary. System logic or setup may prevent the loading of policies into the claims platforms in the same manner as described; however, JHHP strives to minimize these modifications. When there is an update, policies will be published on our website.

II. PURPOSE:

To provide basic billing and reimbursement guidance of laboratory services, that are billed by participating and nonparticipating providers. Laboratory services performed, must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493, when appropriate.

III. POLICY STATMENT:

JHHP follows CMS, State, and American Medical Association (AMA) Current Procedural Terminology (CPT) guidelines. JHHP has identified CPT codes and HCPCS code that are not payable, not covered, or bundled (not separately reimbursed) which are applicable to this policy. Each line of business possesses its own unique guidelines for benefit and payment purposes, as such JHHP will align with regulatory, state and federal guidance to identify laboratory services that are eligible as reimbursable or non-reimbursable, as applicable to the member's plan. Due to changes in regulatory, CMS and State guidance, and provider contracts, additional codes may apply.

IV. GENERAL BILLING GUIDELINES FOR LABORATORY SERVICES:

A. Bill all laboratory services performed by the same provider, on same day on the same claim.
B. Physicians who order or refer a laboratory test are not permitted to bill JHHP for the service they didn't perform.
C. In alignment with CMS, JHHP will process claims on a first in/out approach and denying the second claim absent the appropriate modifier or a narrative to support that the service was separate and unique, in order to reduce the erroneous duplicative billing that can occur when the claim is billed by both the physician and laboratory for the same service.
D. In accordance with CMS, the date of service is the date the specimen was collected. If the specimen is collected over a period that spans two calendar dates, then the date of service must be the date the collection ended.
E. Evaluation and Management (E/M) services includes activities such as obtaining, reviewing, and analyzing appropriate diagnostic tests. The payment for reviewing results of laboratory tests, phoning results to patients, filing such results, etc., are included in the physician's payment for the E/M services to the patient, and will not be separately reimbursed.
F. When billing organ, disease, and genetic laboratory panels, laboratories shall bill the HCPCS panel test code and not unbundle the individual components if all components of the HCPCS panel are performed.
G. Claims for laboratory services will not be paid for services that are not reasonable and necessary.
H. For duplicate laboratory services, only one laboratory service is reimbursable when submitted from the same provider/ group.
I. JHHP aligns with CMS guidance for the billing, coding and payment of presumptive and definitive drug testing.
    - Documentation must support all tests ordered.
    - Presumptive and definitive drug tests must be ordered in writing by treating provider and all drugs/drug classes to be tested must be indicated in the order.
J. CLIA certificates are based on the complexity of testing a lab conducts. The levels of complexity are addressed as they relate to the HCPCS code description. As such, tests will be processed in accordance with CMS guidance, when applicable.
K. Report each service on a separate line, with quantity of one and append the appropriate modifier to indicate a repeat procedure.
    - Documentation must support the use of the modifier.

L. If a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure.

M. If, after a test is ordered and performed, additional related procedures are necessary to provide or verify the result, these would be considered part of the ordered test.

- **Example:** *If a patient has an abnormal test result and repeat performance of the test is done to verify the result, the test is reported as 1 unit of service rather than 2.*

N. Pathology and laboratory CPT codes describe services to evaluate specimens (e.g., blood, body fluid, tissue) obtained from patients to provide information to the treating physician. Consistent with CMS and CPT guidance, if a pathologist provides significant, separately identifiable face-to-face patient care services that satisfy the criteria set forth in the E/M guidelines developed by CMS and the AMA, a pathologist may report the appropriate code from the E/M section of the "CPT Manual".

O. When an interpreting physician at a testing facility determines that an ordered diagnostic test is clinically inappropriate or suboptimal, and that a different diagnostic test should be performed, the interpreting physician/testing facility may not perform the unordered test until a new order from the treating physician/practitioner has been received.

P. Each line of business possesses its own unique guidelines for benefit and payment purposes, as such JHHP will align with regulatory, state and federal guidance to identify laboratory services that are eligible as reimbursable or non-reimbursable, as applicable to the member's plan.

V. INAPPROPRIATE BILLING OF LABORATORY SERVICES:

A. A provider/supplier shall not report multiple HCPCS/CPT codes if a single HCPCS/CPT code exists that describes the services. This type of unbundling is incorrect coding.

B. HCPCS/CPT codes include all services usually performed as part of the procedure as a standard of medical/surgical practice. A provider/supplier shall not separately report these services simply because HCPCS/CPT codes exist for them.

C. Consistent with CMS, JHHP prohibits separate payment for duplicate testing or testing for the same analyte or pathogen by more than one methodology.

D. A claim for laboratory testing will require the presence of the performing (and billing) laboratory's CLIA number; if tests are referred to another laboratory, the CLIA number of the laboratory where the testing is rendered must also be on the claim.

E. Providers cannot bill JHHP or our members for any laboratory services for which they lack the applicable CLIA certification for.

F. Per the AMA and CMS, it is inappropriate to use modifier 76 or 77 to indicate repeat laboratory services.

VI. ORDERING, RENDERING and/or REFERRING PROVIDERS:

A. The name, address, and CLIA number of both the referring laboratory and the reference laboratory shall be reported on the claim.

B. The billing physician or supplier must report the name, address, and NPI of the performing physician or supplier even if the performing physician or supplier is the same or located elsewhere.

C. The test order/request must be clearly documented by the treating (ordering) or rendering physician, in the patient's record as to the intent to order the diagnostic test, and document the medical necessity supporting the ordered service.

E. Documentation may be requested by JHHP to verify the order for the diagnostic test (or the physician's intent to order). If the testing facility is unable to provide the physician's order or intent to order, the testing facility **must** request the information

from the treating (ordering) physician. Without the order or the intent to order, payment for the diagnostic test or service will be denied.

VII. CLIA WAIVED TESTS:

A. JHHP requires providers to include their CLIA number on the claim form for all CLIA waived tests.

B. QW modifier is used to identify CLIA waived tests and must be submitted in the first modifier field.

- Some CLIA waived tests do not require the QW modifier and if the modifier is appended in error, the service will be denied.

C. CLIA requires all laboratory testing sites to have one of the following certificates to legally perform clinical laboratory testing:

- Certificate of waiver
- Certificate of registration
- Certificate of accreditation
- Certificate for physician-performed microscopy

D. If a provider currently has more than one clinical lab testing site, each site requires a CLIA number. The provider should use the CLIA number that specifically represents the site where the test(s) was/were performed.

E. The CLIA number must be placed in Item 23 of the CMS-1500 claim form or the electronic equivalent.

VIII. UNLISTED AND MISCELLANEOUS CODES:

A. When there is no HCPCS/CPT code that describes the procedure, the claim may be pended for further review. If an existing or more appropriate code is identified, the claim will be denied.

B. Report a miscellaneous or unlisted procedure codes with a clear description of the service on the claim line.

C. Report a miscellaneous or unlisted procedure codes with a clear description of the service on the claim line. Refer to the JHHP **Unlisted Codes policy** for additional information.

IX. EXCEPTIONS & EXCLUSIONS:

I. **EXCEPTIONS:**

A. **ADVANTAGE MD:**

i. The ordering/referring provider NPI will be required for procedure codes 87632 and 87633.

ii. HCPCS code Q0091 is eligible for reimbursement is billable for MD Advantage members only. For all other products, JHHP considers Q0091to be part of the E/M and Pap smear codes and is not eligible for separate reimbursement.

B. **PPMCO**- Physicians' service providers cannot be paid for clinical laboratory services without both a Clinical Laboratory Improvement Amendments (CLIA) certification **and** approval by the Maryland Laboratory Administration, if located in Maryland. Refer to Maryland Department of Health for additional coverage guidance.

C. **USFHP**- CPT codes 81000 through 81003 (urinalysis), shall be separately reimbursed when appropriately billed with an Evaluation and Management (E/M) CPT code. Refer to the TRICARE manuals for additional guidance.

II. **EXCLUSIONS:**

A. **ADVANTAGE MD:** HCPCS codes U0003, U0004, and U0005 for COVID 19 laboratory tests are no longer payable.

B. **EHP:** HCPCS codes U0003, U0004, and U0005 for COVID 19 laboratory tests are not payable.
C. **PPMCO:** JHHP will process and reimburse laboratory services in accordance with Maryland Medicaid Administration reimbursement guidance.
D. **USFHP**: JHHP will process and reimburse laboratory services in accordance with TRICARE guidance. Please consult the authoritative guidance found in the TRICARE Manuals to obtain additional, specific information on policy, benefits, and coverage.

X. CODES, TERMS and DEFINITIONS:

Definition of Terms

Term	Definition
Billing Provider	A provider that submits a bill or claim to the payer.

Clinical Laboratory Services (CLS)	JHHP aligns with CMS and defines Clinical Laboratory Services as:
	• Biological
	• Microbiological
	• Serological
	• Chemical
	• Immunohematological
	• Hematological
	• Biophysical
	• Cytological
	• Pathological
	• Other examination of materials derived from the human body for:
	  • Diagnosis
	  • Prevention
	  • Treatment of a disease
	  • Assessment of a medical condition

Clinical Staff Member	A person (e.g., nurse, phlebotomist, or other health professional) who works under the supervision of a physician or other qualified health care professional, and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but does not individually report that professional service.

Diagnositic Test	For the purpose of this policy, JHHP defines a "diagnostic test" is to establish the presence (or absence) of disease as a basis for treatment decisions for individual patient. This includes, but not limited to: • Usually performed after abnormal screening test; • Services may begin as screening but become diagnostic; • Patient is having health problems or is at high risk; • Patient is symptomatic or has history of a disease/ condition; • Considered medical conditions, never considered preventive
Independent Laboratory	An independent laboratory is one that is independent both of an attending or consulting physician's office and of a hospital.
Laboratory Panel	The "CPT Manual" defines organ and disease specific panels of laboratory tests. If a laboratory performs all tests included in one of these panels, the laboratory shall report the CPT code for the panel.
Place of Service (POS)	Identifies where the service was performed.
Physician Office Laboratory	A laboratory maintained by a physician or group of physicians for performing diagnostic tests in connection with the physician practice.
Preventive Tests	Preventive tests are to detect early disease or risk factors for a disease in what appear as a healthy individual but who may be at an increased risk based on the following (includes, but not limited to): • Age • Gender • Life style • Other factors • Considered routine or screening • Patient is asymptomatic The U.S. Preventive Services Task Force makes recommendations to guide medical practices, patients and payers in determining what preventive or screening services are recommended for individual patients.
Proprietary Laboratory Analyses (PLA)	Proprietary Laboratory Analyses (PLA) codes are alpha-numeric codes describing manufacturers' tests.

Order/Request	For the purpose of this policy, JHHP considers a lab order/request as a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a patient. The order may conditionally request an additional diagnostic test for a particular patient if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/ practitioner. An order may be delivered via the following forms of communication: • A written document signed by the treating physician/ practitioner, which is hand delivered, mailed, or faxed to the testing facility; • A telephone call by the treating physician/practitioner or his/her office to the testing facility; and • An electronic mail by the treating physician/practitioner or his/her office to the testing facility.
Ordering Provider	The Ordering Provider is the individual who requested the services or items being reported on this service line.
Physician Services	A service may be considered to be a physician's service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgment. Direct visualization would be possible by means of x-rays, electrocardiogram and electroencephalogram tapes, tissue samples, etc.
Reference Laboratory	A laboratory that receives a specimen from another, referring laboratory for testing and that actually performs the test.
Referring Laboratory	A laboratory that receives a specimen to be tested and that refers the specimen to another laboratory for performance of the laboratory test.
Referring Provider	Referring Provider is the individual who directed the patient for care to the provider rendering the services being reported. *Examples include, but are not limited to, primary care provider referring to a specialist; orthodontist referring to an oral and maxillofacial surgeon; physician referring to a physical therapist; provider referring to a home health agency.*

Rendering Provider	The Rendering Provider is the person or company (laboratory or other facility) who rendered the care. The Rendering Provider is the individual who provided the care. In the case where a substitute provider (locum tenens) was used, that individual is considered the Rendering Provider.
Treating Physician	A physician who furnishes a consultation or treats a patient for a specific medical problem, and who uses the results of a diagnostic test in the management of the patient's specific medical problem. A radiologist performing a diagnostic interventional or diagnostic procedure is not considered a treating physician.

Modifiers

Modifier	Definition
QW	A Clinical Laboratory Improvement Amendment (CLIA) waived test. A CLIA waived test still requires providers to include their CLIA number on the claim.
59	A separate and distinct procedural service
76	A repeat procedure by same physician: the physician may need to indicate that a procedure or service was repeated subsequent to the original procedure or service.
77	A repeat procedure by another physician: the physician may need to indicate that a basic procedure or service performed by another physician had to be repeated.
90	Independent laboratories shall use modifier 90 to identify all referred laboratory services.

91	Repeat clinical diagnostic laboratory test: in the course of treatment of the patient, it may be necessary to repeat the same laboratory test on the same day to obtain subsequent (multiple) test results. Under these circumstances, the laboratory test performed can be identified by its usual procedure number and the addition of the modifier '-91'. Note: this modifier may not be used when tests are rerun to confirm initial results; due to testing problems with specimens or equipment; or for any other reason when a normal, one-time, reportable result is all that is required. This modifier may not be used when other code(s) describe a series of test results (e.g., glucose tolerance tests, evocative/suppression testing). This modifier may only be used for laboratory test(s) performed more than once on the same day on the same patient.

CPT Codes

CLIA Waived Tests	Any test on the CMS CLIA waived test list that has a QW beside the procedure code (i.e., 80047QW).

XI. REFERENCES:

This policy has been developed through consideration of the following:

- Clinical Laboratory Improvement Amendments (CLIA)
- Clinical Laboratory Fee Schedule (CLFS) Files | CMS
- CMS Regulations & Guidance
- COMAR- Maryland Department of Health- Maryland Medicaid Administration
- CPT® Copyright American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association
- NCCI for Medicaid | CMS
- NCCI for Medicare | CMS
- TRICARE Reimbursement Manual

XII. APPROVALS:

Date	Review/Revision	Reason for Modification	Approved By
9/13/2023	N/A	New Policy	Reimbursement Authorizations and Coding Committee (RAC)