Date: 05/19/2023

To: Laboratory of Dermatopathology Client
From: Compliance Department
Re: 2023 Annual Notice to Physicians

Laboratory of Dermatopathology is providing annual notification to our clients of the Medicare policies governing the ordering and reimbursement of laboratory tests. Laboratory of Dermatopathology is committed to promoting awareness of and adherence to these policies. In accordance with the Office of the Inspector General's (OIG) Compliance Program Guide for Clinical Laboratories, we are providing the following information about Medicare requirements:

CMS Medical Necessity Policy
Medicare will only pay for tests that meet the Medicare definition of "medical necessity". Medicare may deny payment for a test that the physician believes is appropriate, such as a screening test, which does not meet the Medicare definition of medical necessity. All diagnosis and clinical relevance for patient treatment should be noted in the patient's chart.

The OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law.

Individuals who knowingly cause a false claim to be submitted to Medicare may be subject to sanctions or remedies available under civil, criminal and administrative law.

CMS Signature Requirements
According to CMS' guidance on laboratory services documentation requirements, unsigned requisitions alone do not support physician intent to order. Physicians should sign all orders for diagnostic services to avoid potential denials. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/LabServices- ICN909221-Text-Only.pdf

Medicare Laboratory National Coverage Determinations (NCDs) and Local Coverage Determinations (NCDs)
Coverage determination policies define medical conditions through the inclusion on a list of ICD (diagnosis) codes for which these tests are covered or reimbursed by Medicare. HIPAA regulations require ICD codes to be present on each claim filed. These codes must also be documented in the patient's medical record.

NCDs: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDsICD10.html

LCDs: https://www.ngsmedicare.com/NGS_LandingPage/
National Government Services Medicare Jurisdiction K

Frequency Limitations for Laboratory Tests
Certain laboratory tests have specific frequency limitation requirements. The limitations may apply to tests that are included in NCDs and LCDs.

Medicare Preventive Screening Laboratory Tests
Certain preventive screening laboratory tests are covered services for Medicare beneficiaries. Benefit coverage is specific for each service, diagnosis codes, coverage requirements, and frequency limitations. https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html

American Medical Association (AMA) Organ or Disease-Oriented Panels
The AMA panels were developed for coding purposes only and should not be interpreted as clinical parameters. Organ and disease-oriented panels will only be paid by Medicare when all tests within the panel are deemed medically necessary by Medicare.
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c16.pdf
Section 90.2 – Organ or Disease Oriented Panels

In the case of custom test panels, all individual tests must meet medical necessity guidelines.

Reflex Testing
Reflex testing occurs when initial test results indicate that a second related test is medically appropriate or required by state, regulatory, or accreditation standards. Most tests can be ordered without a reflex. Find details at https://www.sonichealthcareusa.com/ap/testing-solutions/test-menu/.

Advance Beneficiary Notice of Non-Coverage (ABN)

- **Limited Coverage** – An ABN is required if the diagnosis is not covered
- **Frequency Limit** - An ABN is required at each encounter for frequency limited tests
- **Non-Coverage** – An ABN is required for experimental or research use tests or tests designated by Medicare as non-covered

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html
Manual 100-04 Medicare Claims Processing Manual
Chapter 30 Financial Liability Protections
Section 50 Form CMS-R-131 Advance Beneficiary Notice of Non-Coverage (ABN)

Medicare Clinical Laboratory Fee Schedule (CLFS)
Medicare reimbursement for laboratory CPT/HCPCS codes is located at.
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files

Additional details can be found at PAMA regulations.
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html

Medicaid reimbursement amount will be equal to, or less than, the amount of Medicare reimbursement.

Medicare Part B National Correct Coding Initiative (NCCI) Edits
The Medicare NCCI was implemented to promote national correct coding methodologies and to control improper coding leading to inappropriate payment.
https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html

Contact Information
The Medical Directors and other pathologists are available to discuss appropriate testing and test ordering. Please call 516-944-3882 for assistance. You may also contact our Compliance Department at APCompliance@sonichealthcareusa.com.

Please review this notice with all appropriate staff.

Thank you for supporting ***Laboratory of Dermatopathology.***