Date: October 29, 2021

Re: Laboratory Annual Notice

To: MWMC Referring Physicians and Licensed Independent Practitioners

From: John Goulart, MWMC Hospital Compliance Officer

As an integral part of MetroWest Medical Center's Laboratory Compliance Program, I am providing you with our annual notice. The contents of this notice are based on recommendations from the United States Health and Human Services (HHS) Office of Inspector General (OIG) who explains our shared obligations under federally-funded programs, such as: Medicare and MassHealth (Medicaid) in the Model Laboratory Compliance Plan at: https://oig.hhs.gov/authorities/docs/cpglab.pdf.

The MWMC Laboratory relies on the following information when performing testing ordered by referring physicians and licensed independent practitioners:

1. The patient's full legal name, gender, date of birth, or other unique identifier.
2. The name and telephone number or other suitable identifiers of the submitting physician (or other person authorized under state law) ordering the test and, if applicable, the individual responsible for utilizing the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or critical values.
3. The guarantor's identification and insurance information.
4. The name and CPT code (both are preferred) of the test(s) to be performed.
5. All of the patient's current ICD-10 CM diagnosis codes or a narrative diagnosis / signs and symptoms supported by your medical record documentation.
6. The ordering date.
7. The collection date and time of the specimen, if appropriate.
8. For microbiology:
    a. The source.
9. For pap smears:
    a. The source: (cervical or vaginal).
    b. The date of patient's last menstrual cycle.
    c. Other historical information, such as: whether the patient is pregnant, post-menopausal, had a previous abnormal result, treatment or biopsy.
10. The dated, handwritten signature of the physician or licensed independent practitioner authorized to directly order clinical laboratory tests under state law (requisitions marked by a signature stamp will be rejected for insufficient documentation)

In addition to our preferred requisition, the MWMC Laboratory accepts any form of order request as long as it meets all the above requirements. When physicians and licensed independent practitioners submit a testing request to MWMC Laboratory, they agree to cooperate with any audits which may be conducted by the hospital or outside entities which may include review of medical record documentation to support the accuracy of the Laboratory request as far back as ten years from the date of service.

When you submit a requisition / request for testing, we are relying on the fact that:

1. The information you submit on the requisition accurately reflects the medical reasons for requesting the specified tests.
2. The medical necessity and order for each of the individual tests you order has been appropriately documented in the patient's medical record.
3. Tests, including those that are components of American Medical Association-approved organ / disease-oriented panels, will only be ordered when each individual test is medically necessary for the diagnosis and treatment of the patient or to meet the preventing /screening criteria provided. These panels will only be billed to and paid by Medicare when all components meet medical necessity.
4. You are treating the patient in connection with the diagnoses, complaints or reasons listed on the requisition.
5. When you order tests for purposes of screening for asymptomatic patients that you believe are appropriate, even though the payer may not allow reimbursement, the fact that Medicare generally does not cover screening tests has been explained to the patient, and the requisition notes that the test is for screening purposes.
6. Upon request of the hospital, payer, or auditor, you agree to provide documentation from your office that reflects that the test was ordered and medically necessary for the patient.

When the MWMC Laboratory receives a requisition that does not contain the information listed above, it will be returned for completion. Without appropriate documentation and/or all current diagnostic information, the patient may refuse the test or be required to pay for services that would otherwise be a covered benefit.

MWMC Laboratory utilizes Local Medical Review Policy software, which is used to screen outpatient laboratory tests for medical necessity. The program screens tests ordered against diagnoses provided by the provider according to the National Coverage Decisions (NCDs) issued by the Centers for Medicare and Medicaid Services (CMS) and Local Coverage Determinations (LCDs) issued by Wisconsin Physician Services, the hospital's Medicare Administrative Contractor (MAC). If a particular test that is ordered for a Medicare patient does not meet the NCD or LCD medical necessity guidelines, the patient will be provided with an Advance Beneficiary Notice (ABN), which informs the patient of his/her potential financial responsibility for the tests if Medicare denies the claim. If an ABN is provided to the patient, the test will first be submitted to Medicare for an initial determination. If Medicare denies the test, the patient will then be billed for the test. Your patients will also be provided the opportunity to refuse the test if it is not likely to be covered by Medicare. You can access the Laboratory NCDs and LCDs at:

- CMS Laboratory NCDs: https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=Laboratory&keywordType=starts&areaId=all&docType=NCD&contractOption=all

- WPS LCDs: https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=WPS&keywordType=starts&areaId=all&docType=F,P&contractOption=all

The MWMC Laboratory does not offer custom chemistry testing panels because these produce increased charges to payers / patients and often result in testing that is not medically necessary.

Reflex and Confirmatory testing and Composite orders, listed on pages six and seven of this notice, will be performed as noted below. You can opt out of reflex testing by noting "no reflex" on the requisition / request.

The CMS Medicare Clinical Laboratory Fee Schedule is located at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html. The MassHealth (Medicaid) reimbursement amount may be equal to or less than the amount of Medicare reimbursement. This is the reimbursement that the hospital will receive for the test(s) we perform at the direction of your order.

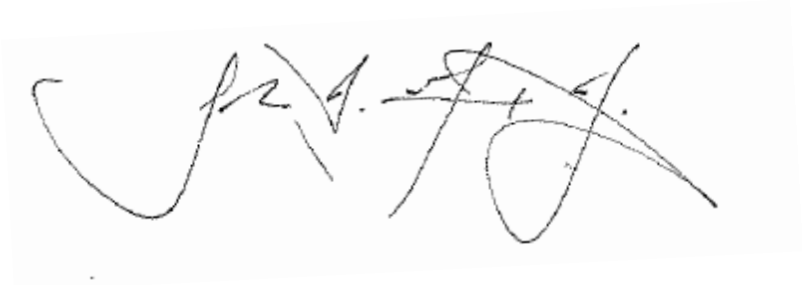
Standing orders for patients with repeat testing are allowed when they are submitted on a completed requisition and have the following additional elements for each test: 1.) A duration (up to one year is permissible), 2.) A frequency ("PRN" or "as needed" is prohibited), and 3). A medically necessary diagnosis.

Verbal orders are not accepted by the laboratory during normal office business hours. During these times, providers must fax completed requisitions to the Laboratory. Verbal orders, called in outside of normal business hours, will require the provider to review and sign the Verbal Order Fax Back Form or the Add-on Form that has been completed by the personnel receiving the verbal order.

Add-on testing for hospitalized patients should be placed in order entry along with the test code "ADDON". Add-on testing for ambulatory patients requires a completed requisition.

I greatly appreciate your support of MWMC's Laboratory Compliance Program. If you have any questions or comments regarding MWMC's Laboratory Compliance Program, please do not hesitate to contact our Laboratory Administrative Director, Deborah Rustin (Deborah.Rustin@mwmc.com | (508) 383-1221), the Laboratory's Medical Director, Saint AuFranc, MD. (Saint.Aufranc@mwmc.com | (508) 383-1090), or myself.

Thank you for your commitment to your patients.
Best Regards,
John



John A. Goulart, Jr., MSM-HCA, BSMT(ASCP), CHC, 340B ACE
Group Compliance Officer Lead | Massachusetts Market
Hospital Compliance Officer | MetroWest Medical Center

October 29, 2021

Monday, Wednesday, and Friday:
Framingham Union Hospital
85 Lincoln Street #1109, Framingham, MA 01701
T: (508) 383-1515

Tuesday and Thursday:
Leonard Morse Hospital
67 Union Street, #379, Natick, MA 01760
T: (508) 650-7639

LIST OF NON-STANDARD DIAGNOSTIC CLINICAL LABORATORY PANELS

MTHFR
Thyroglobulin, Quant
IGG Synthesis + Synthesis Rate
Lupus Anticoagulant
Factor II (Prothrombin DNA Analysis)
Ova & Parasites
Hemoglobinopathy Profile
Protein Electrophoresis, 24 Hour & Random
Microalbumin/Creatinine Ratio, random urine
Chlamydia/GC Nucleic Acid Amplification
AFB Culture, Smear, & Sensitivity
Viral Culture (HSV & Varicella)
Antineutrophil Cytoplasmic Antibody (ANCA)
Herpes Simplex (HSV) 1&2, PCR
Factor V Leiden Mutation Analysis
Primidone
RBC Folate
Heavy Metals Profile I, Urine
Gliadin Antibody Profile
Testosterone, Free with Total
Lyme Disease Antibodies, Reflex to Western Blot
Hereditary Hemachromatosis, DNA Analysis
Immunofixation
Antiphosphatidylserine, IGG, IGM, IGA
Sjogren's Antibodies
Drug Coma/Overdose Profile, Blood
Anticardiolipin Antibody IGG, IGM, IGA
Parvovirus B19, Human IGG/IGM
Aspergillus Antibodies, Quant DID
Antidiuretic Hormone Profile
Protein Electrophoresis, Serum
Cyclospora Smear, Stool
Influenza A&B, Direct Immunoassay
Ehrlichiosis (Granulocyte & Monocytic) Profile
Hypersensitivity Pneumonitis Profile
Chlamydia Trachomatic Culture
Platelet Antibody Profile
West Nile Virus Antibody, IGG, IGM
CMV Culture

Cadmium, Urine
Protein S Antigen
Thyroid Antibodies
Urine Drug Screen
Influenza A&B Antigen
Protein S Deficiency Panel
Saccharomyces Cerevisiae Profile
West Nile Virus Ab, CSF
Echovirus Antibodies
Coxsackie Virus Group B Antibodies by CF

DEPARTMENT OF LABORATORY MEDICINE

SUBJECT: **1.2.5 Reflexive, Confirmatory, and Composite Testing**

SUBMITTED BY: _____
Saint AuFranc, M.D., Laboratory Medical Director

APPROVED BY: _____
Medical Executive Committee

DATE APPROVED: **9/20/21 C&C, 10/5/21 MEC**

PURPOSE: To ensure Laboratory Reflex Testing is approved annually by the Medical Staff, meets medical necessity and is in accordance with Medicare, Medicaid and other payer requirements. Reflex testing is performed as a result of INITIAL test results and is used to further identify significant diagnostic information required for appropriate patient care.

A required Reflex test is a test which, if positive, requires an additional follow up test in order to have clinical value. Physicians may opt out of the specified Reflex testing by making a notation on the laboratory requisition or calling the laboratory at the time of the order.

Initial Test	CPT	Result	Reflex Order	CPT
ANA Screen	86038	Positive	ANA Titer	86039
ASO Screen	86063	Positive	ASO Titer	86060
BB Antibody Screen	86850	Positive	Antibody Identification And Antigen Typing	86870 86905
CBC with Diff	85025	Immature or abnormal cells present in significant quantities	Manual Differential	
C. Difficile EIA	87449 87324	Indeterminate	C. Difficile DNA	87493
CK and CKMB	82550 82553	CK < 135 U/L	CKMB Deleted	82550 only
Cold Agglutinin	86156	Abnormal	CAG Titer	86157
Cryptococcal Antigen	87450	Positive	Cryptococcal Titer	86406
DAT	86880	Positive	IgG + Complement IgG positive: Elution	86880x2 86860
Fetal Screen	85461	Positive	Fetal Hgb	85460
Hepatitis A Antibody	86708	Reactive	HAVAB, IgM	86709
Herpes Culture	87252	Positive	Herpes Typing	87140
Lipid w Reflex Direct LDL	80061	Triglyceride > 400 mg/dL	Direct LDL	83721
Microbiology Culture	**	Organism Growth	Organism ID Antibiotic Sensitivity	87186 87077
TSH w Reflex to FrT4	84443	Abnormal	Free T4	84439
UA w Sediment if needed	81003	Defined Abnormal Parameters	Urinalysis Sediment	81001

Initial Test	CPT	Result	Reflex Order	CPT
UA w Sediment and Culture if needed	81003	Positive leukocytes Positive Nitrite >5 WBCs/HPF All patients < 2yrs	Urine Sediment Urine Culture Antibiotic Sensitivity	81001 87186 87077

Reflexive, Confirmatory and Composite Testing

A Confirmatory test is an additional test procedure, which is performed to validate the accuracy of the initial test result**.**

Initial Test	CPT	Result	Confirmatory Test	CPT
Bilirubin, Urine	81003	Positive	Bilirubin Confirmation	81002
Protein, Urine	81003	Abnormal Colored Urine	SSA	
HIV	86703	Positive	HIV1 RNA	87535
Lyme Antibody	86618	Positive	Western Blot Confirm	84182x2
Rapid Strep	87880	Negative	Strep Culture	87081
Anti-treponemal IGG ELISA	86592	Reactive Equivocal	RPR / RPR Titer	86780 86593

A Composite order is a testing protocol that is used to further identify significant diagnostic information required for appropriate patient care.

Initial Test	CPT	Composite Order	CPT
Tissue Culture	87070	Anaerobic Culture	87075
Anaerobic Culture	87075	Aerobic Culture	87070
CSF, Fluid, Tissue, Deep Wound, and Respiratory Cultures	87070	Gram Stain	87205
Stool Culture	87045	Salmonella & Shigella Campylobacter	87045 87046
Stool Culture Bloody Stool	87045	Shiga Toxin	87427
Legionella Antigen	87899	S. Pneumonia Antigen	87899
Ova & Parasite (OP)	87177	Giardia Antigen DFA Cryptosporidium DFA	87269 87272
Giardia Antigen	87269	Giardia Antigen DFA Cryptosporidium DFA	87269 87272
Cryptosporidium Antigen	87272	Giardia Antigen DFA Cryptosporidium DFA	87269 87272
Pre-Natal Antibody ID	86870	Antibody Titer	86886
Urinalysis from ED on patients < 2 years old	81001or 81003	Urine Culture	87186