



METROPOLITAN
MEDICAL
LABORATORY

Annual Compliance Letter

- A. **Medical Necessity:** our requisitions are designed to emphasize physician choice. Only tests that are medically necessary for the diagnosis or treatment of the patient will be reimbursed. **Medicare may deny payment where there is insufficient documentation in the medical record to support the medical necessity of ordering the test(s).**

The Centers for Medicare and Medicaid Services (CMS) has 23 National Coverage Determinations (NCDs) regarding clinical laboratory tests. These decisions state the medical conditions for which laboratory tests are covered, reasonable and necessary on a national level. Additionally, Medicare carriers and fiscal intermediaries have the authority to develop and implement Local Coverage Determinations (LCDs) for the local area that does not conflict with the national determinations. The CMS national policies are listed at: www.cms.hhs.gov/mcd/index_section.asp?ncd_sections=40

The codes submitted must be ***based on the state in which a test is performed*** – please contact your Marketing Representative with any questions.

Medicare generally does not cover routine screening medical exams or screening tests. Of note, the Office of Inspector General (OIG) takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed, may be subject to civil, criminal or administrative penalties under the False Claims Act.

- B. **Problem Requisitions / Specimens:** Claims for reimbursement are submitted only for tests which have been both ordered and performed. If the laboratory receives a specimen without a test ordered or with unclear testing instructions, the ordering physician will be contacted and asked to provide a revised requisition to the lab (or detailed instructions). Laboratory staff may not add or change tests ordered.
- C. **Medicare Part B Claims:** an ICD-9-CM code must be included on all Medicare Part B Claims when a diagnostic test is ordered to establish medical necessity. Therefore, all requisitions must include the ICD-9-CM code as the reason for the test. Codes for signs and symptoms must be used when a definitive diagnosis has not been established.
- D. **Point of Care Testing:** All federal guidelines that apply to general laboratory testing also apply to POC testing. POC testing sites will be monitored in the same manner as other laboratory sites to ensure compliance.
- E. **Required Information:** Please use laboratory requisitions preprinted with your location information. The following information is required on all laboratory requisitions:

| | |
|--------------------------------------|----------------------------------|
| Patient Name | Social Security Number |
| Birth date | Copies of Insurance Card |
| Physician Name | Indicate specimen type |
| ICD-9 Diagnosis Code (sign/symptom) | Indicate Test(s) to be performed |
| Indicate if order is STAT or routine | |
| Date & Time of Specimen Collection | |

- F. **Standing Order Policy:** A standing order directs the laboratory to perform a particular test(s) at specified intervals for a defined time period without having to submit a new requisition form each time. Standing orders must be renewed in writing annually and must be submitted to the blood drawing facility. Scheduled orders for Nursing Home facilities must be updated yearly. Please provide the requirements written in section “E” in addition to: Start / Stop day, month and year, frequency the test is to be performed. The use of the phrase, “as the occasion arises, or as necessary” (PRN/prn) is not an acceptable frequency. Please state how often the test should be performed such as, “every two weeks”. When exceptions occur, you may use a regular requisition.
- G. **Add-on Test Request Policy:** This policy is to ensure that “add-on” requests for clinical laboratory tests are properly documented in accordance with federal guidelines. All “add-on” must be submitted on the (“Add-on Test Request” form). Please provide the eleven requirements written in section “E” as well.
- H. **Reflex Testing Policy:** Reflex testing may be performed in the absence of a specific written order when results of initial testing indicate that a second related test is medically appropriate.
- I. **Calculated Test Results:** Charges for calculations derived from other test results are not submitted for billing. The reporting of such calculations as a part of the test results does not affect any claims for reimbursements to federal or privately funded healthcare programs.
- J. **Direct Billing:** Other than for monthly diagnostic composite lab tests, direct billing is required for Medicare-reimbursed laboratory tests. More information about billing can be obtained for the Billing Officer (324-0471 extension 4745).
- K. **Panel Testing and Pricing:** All routine chemistry tests should be ordered separately except for those contained in federally defined laboratory panels. Test panel pricing is based on the cost of each component included in a test panel. In no cases are individual tests or profiles priced below cost. No tests are provided to customers or potential customers free-of-charge or at below cost either as a professional courtesy or in order to secure additional business. **Panels are paid -only when all components are medically necessary.** A complete listing of panel tests, CPT codes and prices is attached.
- L. **Prohibited Referrals:** It is Metropolitan Medical Laboratory PLC policy to comply with all aspects of the self-referral prohibitions and exceptions established by Stark I and II. More detailed information may be found at:

Anti-kickback Statute

<http://www.oig.hhs.gov/fraud/docs/safeharborregulations/MedicareSELECTNPRMFederalRegister.pdf>

Physician Self Referral Law, Stark I, II, III

<http://www.cms.hhs.gov/PhysicianSelfReferral/>

M. **Inducements:** Metropolitan Medical Laboratory PLC does not offer any inducements to physicians or entities in order to secure Medicare billings. All supplies and equipment provided to customers are directly related to specimen collection, processing, and reporting of test results. Any form of suspected inducement should be reported to the Metropolitan Medical Laboratory PLC Compliance Officer, Terry Masek, for investigation at (309) 762-8555 extension 3410. You may also call seven days a week to Metropolitan Medical Laboratory Confidential Message Reporting Line at (309) 762-8555 extension 5000.

N. **Monitoring:** All laboratory testing sites are regularly monitored to safeguard against unintentional violations of federal compliance guidelines. Monitoring activities are also aimed at raising awareness of federal guidelines and assisting in developing mechanisms for successfully meeting them.

O. **Web Site Summary**

Metropolitan Medical Laboratory PLC / Quad Cities Pathologists LLC
www.metromedlab.com

OIG Compliance Program Guidance for Clinical Laboratories
<http://oig.hhs.gov/authorities/docs/cpqlab.pdf>

The False Claims Act
<http://oig.hhs.gov/fraud/falseclaimsact.asp>

The Sarbanes-Oxley Act of 2002
<http://www.soxlaw.com/>

HIPAA Privacy Rule
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/>

Anti-kickback Statute
<http://www.oig.hhs.gov/fraud/docs/safeharborregulations/MedicareSELECTNPRMFederalRegister.pdf>

Physician Self Referral Law, Stark I, II, III
<http://www.cms.hhs.gov/PhysicianSelfReferral/>

Advanced Beneficiary Notices
<http://www.cms.hhs.gov/BNI/>

P. Panel Information

| Panel Name | CPT Code | Components | Medicare Payment |
|---|----------|--|------------------|
| Basic Metabolic Panel (Unit Code – 379) | 80048 | Calcium – 82310 Carbon Dioxide – 82374 Chloride – 82435 Creatinine – 82565 Glucose – 82947 Potassium – 84132 Sodium – 84295 Urea nitrogen (BUN) - 84520 | \$12.36 |
| Electrolyte Panel | 80051 | Carbon Dioxide – 82374 Chloride – 82435 Potassium – 84132 Sodium - 84295 | \$10.24 |
| Comprehensive Metabolic Panel (Unit Code – 365) | 80053 | Albumin – 82040 Bilirubin; total – 82247 Calcium – 82310 Carbon Dioxide – 82374 Creatinine – 82565 Glucose – 82947 Phosphatase; alkaline – 84075 Potassium – 84132 Protein, total – 84155 Sodium – 84295 Transferase; alanine amino (ALT) (SGPT) – 84460 Transferase; aspartate amino (AST) (SGOT) – 84450 Urea nitrogen (BUN) - 85420 | \$15.44 |
| Lipid Panel (Unit Code – 331) | 80061 | Cholesterol, serum or whole blood, total – 82465 Triglycerides – 84478 Lipoprotein, direct measurement, HDL Cholesterol – 83718 | \$19.57 |
| Liver Panel or Hepatic Function Panel (Unit Code – 388) | 80076 | Albumin – 82040 Bilirubin; total – 82247 Bilirubin; direct – 82248 Phosphatase; alkaline – 84075 Protein, total – 84155 Transferase; alanine amino (ALT) (SGPT) – 84460 Transferase; aspartate amino (AST) (SGOT) - 84450 | \$11.93 |

| Panel Name | CPT Code | Components | Medicare Payment |
|--|----------|---|------------------|
| Chlamydia & GC by PCR (Unit Code – 51110) | 87491 | Chlamydia Trachomatis by PCR – | \$51.24 |
| | 87591 | Neisseria Gonorrhoeae by PCR – | \$51.24 |
| Celiac IgA Profile (Unit Code – 10130) | | Immunoglobulin A – 82784 | \$13.58 |
| | | tTG-IgA – 83516 | \$16.85 |
| | | DGP-IgA – 83516 | \$16.85 |
| Extended Cardiac Risk Profile (Unit Code – 206) | | HgB A1C – 83036 | \$14.17 |
| | | Homocysteine – 83090 | \$24.63 |
| | | Lipoprotein A – 83695 | \$18.91 |
| | | Fibrinogen – 85384 | \$12.40 |
| | | hs C-reactive Protein -- 86141 | \$18.91 |
| Hepatitis Panel, Acute (Unit Code – 30002) | 80074 | Anti-HAV, IgM – 86709 Anti-HBc, IgM – 86705 Anti-HBs, Qual – 86706 Anti-HCV – 86803 “If positive, add HCV Riba” – 86803 HBsAg – 87340 | \$69.54 |
| Hepatitis Profile, Acute / Chronic (Unit Code – 31060) | | Anti-HAV, IgM – 86709 | \$16.44 |
| | | Anti-HBc, Total – 86704 “If positive, add Anti-HBc, IgM” – 86705 | \$17.60 |
| | | Anti-HBs, Qual – 86706 | \$17.60 |
| | | Anti-HCV – 86703 “If positive, add HCV Riba” – 86804 | \$15.68 |
| | | HBsAg – 87340 | \$20.02 |
| | | HBsAg – 87340 | \$22.61 |
| Hepatitis Profile, Chronic (Unit Code 31065) | | Anti-HBc – 86704 | \$17.60 |
| | | Anti-HBs – 86706 | \$15.68 |
| | | Anti-HVC - 86703 “If positive, add HCV Riba –86804 | \$20.02 |
| | | HBsAG – 87340 | \$22.61 |
| | | Anti-HBc, IgM – 86705 | \$15.08 |
| OB Profile (Unit Code – 5092) | | ABO & Rh Type – 86900 & 86901 | \$4.35 |
| | | Indirect Coombs – 86850 | \$4.35 |
| | | CBC – 85025 | N/A |
| | | HBsAG – 87340 | \$11.35 |
| | | RPR – 86592 | \$15.08 |
| | | Rubella, IgG Screen – | \$6.23 |
| | | Treponema – 87285 | \$21.02 |
| | | | \$17.52 |

Every test in a panel must be medically necessary for the treatment or diagnosis of the patient.

Q. Reflex Testing Performed by Metropolitan Medical Laboratory

| Test that reflex | Criteria for Reflex | Reflexed Test | Option for no reflex |
|-----------------------------|--|-----------------------|---------------------------|
| PSA 10042 | >4.0 < 10.0 ng/mL | Free PSA | PSA 10041 |
| Thin Prep ® with HPV 150200 | Atypical squamous cells -of undermined significance (ASC-US), -cannot exclude HSIL (ASC-H) Low grade squamous intraepithelial lesion (LSIL), High grade squamous intraepithelial lesion (HSIL). | HVP | Thin Prep ® no HPV 150100 |
| Thin Prep ® with HPV 150400 | Atypical squamous cells -of underdetermined significance (ASC-US) | HPV | Thin Prep ® no HPV 150100 |
| TSH 10016 | , 0.38 or . 4.70 U/ml | FT4 | TSH 10015 |
| UA 7006 | Urine Microscopic Reflex: Clarity=cloudy Protein ≥ 100 mg/dL WBC esterase ≥25uL Nitrite = positive Blood > 10 uL Urine Culture Reflex: >3 WBCs/hpf nitrate=positive bacteria≥moderate | Microscopic & Culture | UA 7015 |
| UA 7011 | Urine Microscopic Reflex: Clarity=cloudy Protein ≥ 100 mg/dL WBC esterase ≥25uL Nitrite = positive Blood > 10 uL | Microscopic | UA 7015 |

Please remember that you can order the initial test without the reflex option (order the initial test without indicating “with reflex” on the requisition). Our lab will perform reflex tests only when specifically indicated in your test requisitions that you desire the reflex test.

Please remember to supply appropriate ICD-9 codes with test requisitions to support the medical necessity of all tests order, including reflex tests, as required by Medicare regulations.

R. Laboratory National Coverage Determinations for the Centers for Medicare and Medicare Services

| | |
|---|---|
| Culture, Bacterial, Urine | Human Immunodeficiency Virus (HIV) Testing (Prognosis including monitoring) |
| HIV Testing (Diagnosis) | Blood Counts |
| Partial Thromboplastin Time | Prothrombin Time |
| Serum Iron Studies | Collagen Crosslinks, any method |
| Blood Glucose Testing | Thyroid Testing |
| Lipids | Digoxin Therapeutic Drug Assay |
| Alpha-fetoprotein | Carcinoembryonic Antigen |
| Human Chorionic Gonadotropin | Tumor Antigen by Immunoassay – CA125 |
| Tumor Antigen by Immunoassay – CA15-3 / CA27.29 | Tumor Antigen by Immunoassay CA19-9 |
| Prostate Specific Antigen | Gamma Glutamyl Transferase |
| Hepatitis Panel, Acute Hepatitis Panel | Fecal Occult Blood |
| Glycated hemoglobin / glycated protein | |

S. Clinical Laboratory Preventative Medicine Reference Coding Guide

Medicare pays for tests that are reasonable and necessary for the diagnosis and treatment of a patient. The program does not pay for most tests performed for screening purpose or for purposes that do not meet the Medicare definition of reasonable and necessary, as indicated by the submitted ICD-9 code. Screening is described as a test that is performed in the absence of signs or symptoms. There are a few screening tests that Medicare covers by statute. The covered screening laboratory tests are listed below with the frequency limitations and the appropriate ICD-9 diagnosis code.

Use these codes when ordering the following laboratory screening tests:

| Procedure | Covered Diagnosis Code | Frequency |
|--|--|--|
| Screening Fecal Occult Blood Test | V76.41 – screening malignant neoplasm rectum | <i>Over 50 yrs. old – Once every 12 months</i> |
| Prostate Cancer Screening (PSA-Screen) | V76.44 – screening malignant neoplasm prostate | <i>Over 50 yrs. old – once every 12 months</i> |
| Screening Pap Smear – Low Risk | V76.2 – screening for malignant neoplasm: cervix V76.47 – special screening for malignant neoplasm: vagina (S/P hysterectomy for non-malignant condition) V76.49 – special screening for malignant neoplasm; other sites (women without a cervix) | <i>Once every 24 months</i> |
| Screening Pap Smear – High Risk | V15.89 – other personal history presenting hazards to health. Cervical cancer high risk factors include: early onset of sexual activity (<16 yrs); multiple sex partners (5 or more) in a lifetime; history of sexually transmitted diseases (including HIV infection); fewer than 3 negative or any Pap smears within the previous 7 yrs. Vaginal cancer high risk factors include DES exposed daughters of women who took DES during pregnancy | <i>Once every 12 months</i> |