

**PHYSICIANS LABORATORY SERVICES  
ANNUAL NOTICE TO PROVIDERS  
2012**

The Office of Inspector General (OIG) requires all clinical laboratories to send an annual notice to physicians as part of their compliance program. Physicians Laboratory is dedicated to abide by all federal and state laws and regulations. As part of this commitment, the following information is provided for review.

**MEDICAL NECESSITY**

Title XVIII of the Social Security Act section 1862(a) (1) (D) excludes payment for services “which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”. Medicare provides specific policies regarding medical necessity via the National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). In order to meet Medicare guidelines the provider must document medical necessity for each test in the patient’s medical record, as well as accurately complete the test order requisition form including the appropriate third party billing information and diagnosis code(s). The ordering provider must ensure that all tests ordered meet all Federal and State requirements, including that the attending provider has specifically ordered the test(s) and that the tests are medically necessary and do not violate frequency limitations. All standing orders must be for a defined period of time and for a medical condition warranting a standing order. Providers may order any tests that they believe are appropriate for treatment of their patients; however, Medicare will only pay for tests that meet medical necessity requirements.

In the event that a provider would like to order testing that does not meet Medicare’s definition of “medical necessity”, the provider is responsible for having the patient sign a completed Advance Beneficiary Notice (ABN) prior to service. By signing this document, the patient assumes responsibility for the cost of any testing that is performed.

**NATIONAL COVERAGE DETERMINATIONS:**

The National Coverage Determinations (NCDs) include specific Medicare policies for twenty-three frequently ordered laboratory tests. The policy manual specifically dictates which ICD-9 codes support medical necessity, as well as the CPT codes for each of these tests. These rules are binding on all Medicare carriers. The twenty-three NCDs include:

|               |                     |                 |                     |
|---------------|---------------------|-----------------|---------------------|
| Urine Culture | HIV (Prognosis)     | HIV(Diagnosis)  | Blood Counts        |
| PTT           | Protime (INR)       | Iron Studies    | Collagen Crosslinks |
| Glucose       | Glycated Hemoglobin | Thyroid Testing | Lipid Testing       |
| Digoxin       | Alpha-fetoprotein   | CEA             | hCG                 |
| CA-125        | CA 15.3/CA 27.29    | CA 19-9         | PSA                 |
| GGT           | Hepatitis Panel     | Occult Blood    |                     |

The diagnosis provided by the physician will be compared to the ICD-9 codes listed in the NCD policies. ICD-9 codes that are not listed as covered codes in this manual will be denied for payment as they do not support medical necessity. In those instances in which a physician wants to order a test with an ICD-9 code that is not listed, an Advanced Beneficiary Notice (ABN) must be signed by the patient.

For the most recent version of the Medicare National Coverage Determinations (NCD) Coding Policy Manual and Change Report please refer to the website below:

National Coverage Determinations

[http://www.cms.gov/CoverageGenInfo/04\\_LabNCDs.asp](http://www.cms.gov/CoverageGenInfo/04_LabNCDs.asp)

### **LOCAL COVERAGE DETERMINATION**

Medicare contractors can establish additional policies pursuant to their areas of jurisdiction. These policies are called Local Coverage Determinations (LCDs) and also have specific ICD-9 codes that are required for payment. Currently, these include:

|                      |                             |
|----------------------|-----------------------------|
| Allergy Testing      | Cytogenetic Studies         |
| Diagnostic Pap Tests | Flow Cytometry              |
| Heavy Metal Testing  | Helicobacter pylori Testing |
| Vitamin D Assay      |                             |

For the most recent list of Local Coverage Determinations for the states of Nebraska, Iowa, Kansas and Missouri, please refer to the website below:

Local Coverage Determinations (WPS Health Insurance Medicare J5 MAC Part B)

<http://www.wpsmedicare.com/j5macpartb/policy/active/local/>

### **ADVANCE BENEFICIARY NOTICE (ABN)**

The Advance Beneficiary Notice (ABN) is provided to Medicare beneficiaries to inform the patient that Medicare may not pay for specific services. The provider is required to document the specific tests, the reason Medicare may not pay and the estimated cost of each test. By signing, the patient then assumes responsibility for payment of the tests in the event Medicare denies payment. The ABN must be completed prior to services being performed. Common reasons for Medicare denials include:

- The diagnosis code provided does not support medical necessity.
- Testing exceeded Medicare's frequency limitations.
- Testing is considered experimental or for research use.
- Testing is for screening purposes only.

**AMERICAN MEDICAL ASSOCIATION (AMA) APPROVED AUTOMATED ORGAN AND DISEASE PANELS**

The American Medical Association (AMA) has grouped specific tests into the following Organ and Disease panels. Panels should only be ordered when all components are considered medically necessary. All tests included in the Automated Organ and Disease Panels must be performed when ordered. All tests included in these panels may be ordered individually. The information below lists the components of each panel, CPT codes, and the Medicare Limitation for each.

**Comprehensive Metabolic Panel (CPT 80053)**

Medicare Limitation: \$14.87

Components: 82040 Albumin  
82247 Bilirubin, Total  
82310 Calcium  
82374 Carbon Dioxide  
82435 Chloride  
82565 Creatinine  
82947 Glucose  
84075 Alkaline Phosphatase  
84132 Potassium  
84155 Total Protein  
84295 Sodium  
84460 ALT  
84450 AST  
84520 Urea Nitrogen

**Basic Metabolic Panel (CPT 80048)**

Medicare Limitation: \$11.91

Components: 82310 Calcium  
82374 Carbon Dioxide  
82435 Chloride  
82565 Creatinine  
82947 Glucose  
84132 Potassium  
84295 Sodium  
84520 Urea Nitrogen

**Renal Function Panel (CPT 80069)**

Medicare Limitation: \$12.22

Components: 82040 Albumin  
82310 Calcium  
82374 Carbon Dioxide  
82435 Chloride  
82565 Creatinine  
82947 Glucose  
84100 Phosphorous  
84132 Potassium  
84295 Sodium

**Hepatic Function Panel (CPT 80076)**

Medicare Limitation: \$11.49

Components: 82040 Albumin  
82247 Bilirubin, Total  
82248 Bilirubin, Direct  
84075 Alkaline Phosphatase  
84155 Total Protein  
84460 ALT  
84450 AST

**Electrolyte Panel (CPT 80051)**

Medicare Limitation: \$9.87

Components: 82374 Carbon Dioxide  
82435 Chloride  
84132 Potassium  
84295 Sodium

**Lipid Panel (CPT 80061)**

Medicare Limitation: \$18.85

Components: 82465 Cholesterol, Total  
83718 HDL Cholesterol  
84478 Triglycerides

**Obstetric Panel (CPT 80055)**

Medicare Limitation: None Listed

Components: 85025 CBC  
87340 Hepatitis B Surface Antigen  
86762 Rubella Antibody  
86592 Syphilis, Qualitative  
86850 Antibody Screen, RBC  
86900 Blood Typing; ABO  
86901 Blood Typing; Rh (D)

**Acute Hepatitis Panel (CPT 80074)**

Medicare Limitation: \$59.87

Components: 86709 Hepatitis A IgM  
86705 Hepatitis B Core, IgM  
87340 Hepatitis B Surface Ag  
86803 Hepatitis C Antibody

**CUSTOM PANELS**

Physicians Laboratory does not encourage the use of custom profiles; however, in those instances in which a provider requests customization they will be required to date and sign a form acknowledging the following:

- The provider requested the custom test order profile
- The provider has been informed of the Medicare reimbursable amount and CPT codes for the custom panel and its components
- The provider is aware that the use of customized panels may result in Medicare denying reimbursement
- The provider must order individualized tests or a less inclusive profile when all of the tests in the custom panel are not medically necessary
- The provider recognizes that the "Office of Inspector General (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" (Federal Register, p. 45080).
- The provider is aware that the laboratory makes available the services of a clinical consultant to assist the physician in ensuring that appropriate tests are ordered

The Provider Acknowledgement Form must be signed annually.

## **REFLEX TESTING**

Physicians Laboratory utilizes reflex testing to validate primary test results or add additional testing when medically appropriate. A list is provided below that details all reflex testing that is performed at Physicians Laboratory, as well all reference laboratories.

### **PERFORMED AT PHYSICIANS LABORATORY**

| <b>INITIAL TEST</b>    | <b>REFLEX CRITERIA</b>                   | <b>ADDITIONAL TESTING<br/>(WHEN NECESSARY)</b>  |  |
|------------------------|--|---|--|
| Culture<br>(AFB)       | Positive growth                          | Sensitivity<br>ID<br>ID by Probe  | (CPT 87186)<br>(CPT 87118)<br>(CPT 87149)                |
| Culture<br>(Bacterial) | Positive growth w/<br>Clinical Relevance | Sensitivity<br>ID<br>Typing   | (CPT 87186)<br>(CPT 87077)<br>(CPT 87147)                |
| Culture<br>(Anaerobic) | Positive growth                          | ID  | (CPT 87076)  |
| Culture<br>(Fungus)    | Positive growth                          | ID<br>Typing  | (CPT 87106)<br>(CPT 87147)                               |
| Culture<br>(Tissue)    | Homogenization<br>Positive growth        | Homogenization<br>Sensitivity<br>Typing<br>ID   | (CPT 87176)<br>(CPT 87186)<br>(CPT 87147)<br>(CPT 87077) |
| Cytopathology Fluids   | Per Pathologist Request                  | Histologic Stains<br>Immunopathologic Stains<br>Flow Cytometry<br>Electron Microscopy |  |
| Drug Screens           | Positive                                 | Confirmation  | (CPT 80102)  |
| HIV ½ Antibody         | Positive                                 | Confirmation<br>HIV Western Blot  | (CPT 86689)  |
| Hepatitis Bs Antigen   | Positive                                 | Confirmation<br>Hepatitis Bs Ag Confirmation  | (CPT 87341)  |

**PERFORMED AT PHYSICIANS LABORATORY**

| <b>INITIAL TEST</b>                     | <b>REFLEX CRITERIA</b>  | <b>ADDITIONAL TESTING<br/>(WHEN NECESSARY)</b>   |             |
|---|---|--|-------------|
| HSV Culture w/ Typing 1 & 2             | Positive  | Typing   | (CPT 87140) |
| Surgical Pathology                      | Per Pathologist Request   | Histologic Stains<br>Immunopathologic Stains<br>Flow Cytometry<br>Electron Microscopy<br>Molecular Pathology |             |
| TrepSure<br>(Anti-treponemal EIA Assay) | Positive  | RPR  | (CPT 86592) |
| Urinalysis                              | Positive blood, protein, nitrites,<br>or leukocyte esterase and/or<br>cloudy appearance | Microscopic Exam<br>(Replace CPT 81003 w/<br>CPT 81001)  |             |
| Urinalysis w/ Reflex to Culture         | WBC > 5   | Urine Culture  | (CPT 87086) |
| Urine Testing<br>(Timed Samples)        | Any timed urine sample that<br>requires a volume measurement                            | Urine Volume   | (CPT 81050) |

**REFLEX TESTING - PERFORMED AT REFERENCE LABORATORIES**

| <b>INITIAL TEST</b>  | <b>REFLEX CRITERIA</b>                                    | <b>ADDITIONAL TESTING<br/>(WHEN NECESSARY)</b> |             |
|--|---|--|-------------|
| ANA, IgG Screen w/ Reflex<br>to IFA Titer (ARUP)                             | ANA antibodies detected                                   | IFA Titer                                      | (CPT 86039) |
| Arsenic, Urine with Reflex<br>to Fractionation (ARUP)                        | If total arsenic concentration<br>is between 35-2000 ug/L | Arsenic<br>Fractionated                        | (CPT 82175) |
| Factor XIII (13) Qualitative<br>With Reflex to Factor XIII<br>1:1 Mix (ARUP) | If clot lysis occurs in the initial<br>testing            | Factor XIII<br>1:1 Mix                         | (CPT 85291) |
| FTA IgG by IFA w/ Reflex<br>To FTA by TP-PA (ARUP)                           | FTA IgG Inconclusive                                      | FTA by TP-PA                                   | (CPT 86780) |

**REFLEX TESTING - PERFORMED AT REFERENCE LABORATORIES**

| <b>INITIAL TEST</b>  | <b>REFLEX CRITERIA</b>  | <b>ADDITIONAL TESTING<br/>(WHEN NECESSARY)</b>   |   |
|--|---|--|---|
| GHB, Serum (MEDTOX)  | Positive  | Confirmation   | (CPT 82542)                               |
| GHB, Urine (MEDTOX)  | Positive  | Confirmation   | (CPT 82542)                               |
| Hantavirus Ab IgG & IgM<br>w/ Reflex to Confirmation<br>(ARUP)               | Positive  | Confirmation   | (CPT 86790)<br>Each Procedure             |
| Heavy Metals Panel w/<br>Reflex to Arsenic Fractionated<br>(ARUP)            | If total arsenic concentration<br>is between 35-2000 ug/L   | Arsenic<br>Fractionation   | (CPT 82175)                               |
| HSV Type ½ IgG & IgM Abs<br>w/ reflex to Type 1 & 2<br>Glycoprotein G (ARUP) | If HSV 1 and/or 2 IgG is 1.10 IV<br>or greater, then HSV 1 gG-Specific IgG<br>and HSV 2 gG Specific IgG will be added   | HSV gG Type 1 IgG(CPT 86695)<br>HSV gG Type 2 IgG(CPT 86696)   |   |
| Lupus Anticoagulant Panel<br>(ARUP)  | PTT abnormal<br>Thrombin Time Normal<br>Thrombin Time Abnormal<br>Reptilase Time Normal<br><br>PTT Heparin Neutralization Abnormal<br>PTT 1:1 Mix Abnormal<br>dRVTT abnormal<br>dRVTT 1:1 Mix Abnormal<br>PNP & dRVVT Conf Normal | Thrombin Time (CPT 85670)<br>PTT 1:1 Mix (CPT 85732)<br>Reptilase Time (CPT 85635)<br>PTT Heparin (CPT 85730)<br>Neutralization (CPT 85525)<br>PTT 1:1 Mix (CPT 85732)<br>PNP (CPT 85597)<br>dRVTT 1:1 Mix (CPT 85613)<br>dRVVT Conf (CPT 85613)<br>Hexagonal (CPT 85598)<br>Phospholipid Neutralization |   |
| Motor & Sensory<br>Neuropathy Evaluation<br>(MAYO)                           | If ANNA screen is positive<br><br>Positive ELISA  | ANNA Titer<br>Western Blot<br>MAG Antibody   | (CPT 86256)<br>(CPT 84181)<br>(CPT 84181) |
| Myasthenia Gravis<br>Evaluation Adult<br>(MAYO)                              | If muscle AchR modulating<br>antibody value is (or exceeds) 90%<br>Acetylcholine receptor (AchR) loss<br>And striational antibody is detected   | GAD65 Ab Assay(CPT 86341)<br>CRMP-5-IgG (CPT 84182)<br>Neuronal VGKC (CPT 83519-59)<br>AChR Ganglionic (CPT 83519-59)<br>Neuronal Ab   |   |

**REFLEX TESTING - PERFORMED AT REFERENCE LABORATORIES**

| INITIAL TEST   | REFLEX CRITERIA  | ADDITIONAL TESTING<br>(WHEN NECESSARY)  |
|--|--|---|
| Paraneoplastic Autoantibody<br>Evaluation<br>(MAYO)                        | IFA patterns indeterminate<br><br>IFA patterns suggest CRMP-5-IgG<br>IFA pattern suggests NMO<br>IFA pattern suggests Amphiphysin Ab<br>IFA pattern suggest GAD65 Ab | Paraneoplastic<br>Autoantibody WB (CPT 84182)<br>CRMP-5-IgG WB (CPT 84182)<br>NMO IgG (CPT 86255)<br>Amphiphysin WB (CPT 84182)<br>GAD65 Ab (CPT 86341) |
|  | If Ach Receptor Binding Ab >0.02 or<br>If striational ab are > or = 1:60   | Ach Recep Mod Ab(CPT 83519) &<br>CRMP-5-IgG WB (CPT 84182)  |
| Purkinje Cell Cytoplasmic Ab<br>By IFA w/ Reflex to Titer and IB<br>(ARUP) | If Purkinje cell screen is 1:10  | PCA Titer (CPT 86256)<br>PCA Immunoblot(CPT 83516)  |
| Reticulin IgA Antibody w/<br>Reflex to Titer (ARUP)                        | If Reticulin Antibody is 1:5   | Reticulin IgA Titer(CPT 86256)  |
| Skeletal Muscle Antibody, IgG<br>With Reflex to Titer (ARUP)               | If Striated Muscle Ab is > 1:40  | Striated Muscle (CPT 86256)<br>Titer  |
| Smooth Muscle Ab, IgG<br>(ARUP)  | If Smooth Muscle Ab IgG ≥ 20   | Smooth Muscle (CPT 86256)<br>Ab, IgG IFA Titer  |

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