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PHYSICIANS LABORATORY SERVICES
ANNUAL NOTICE TO PROVIDERS
2017

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) (A) 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-four frequently ordered laboratory tests. The policy manual specifically dictates which ICD-10 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-four 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	STI Screening

The diagnosis provided by the physician will be compared to the ICD-10 codes listed in the NCD policies. ICD-10 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-10 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/Medicare/Coverage/CoverageGenInfo/LabNCDsICD10.html

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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-10 codes that are required for payment. Currently, these include:

Allergy Testing
Circulating Tumor Assays
Drug Testing
Flow Cytometry
Genetic Testing for CYP2C19, CYP2D6, CYP2C9 & VKORC1
Genetic Testing for Hypercoagulability/Thrombophilia (Factor V Leiden, Factor II Prothrombin, & MTHFR)
Molecular Diagnostic 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)
https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources/local-coverage-derterminations

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.

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 in ensuring that appropriate tests are ordered.

The Provider Acknowledgement Form must be signed annually.

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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 as all reference laboratories.

PERFORMED AT PHYSICIANS LABORATORY

INITIAL TEST	REFLEX CRITERIA	REFLEX TESTING (WHEN NECESSARY)	
ANA, IgG Screen w/ Reflex to Titer	ANA ≥ 20 Units	IFA Titer	(CPT 86039)
ANA, IgG Screen w/ Reflex to Connective Tissue Disease Profile	ANA ≥ 20 Units	dsDNA IgG	(CPT 86225)
		Smith ENA IgG	(CPT 86235)
		SSA IgG	(CPT 86235)
		SSB IgG	(CPT 86235)
		SCL-70 IgG	(CPT 86235)
		Chromatin	(CPT 86235)
		Centromere	(CPT 86235)
		RNP IgG	(CPT 86235)
Antibody Screen	Positive (Reflex requires Provider's Approval)	Antibody ID	(CPT 86780)
		Antibody Titer	(CPT 86886)
Beta Strep (Genital)	Positive Group B Strep w/ Penicillin Allergy	Sensitivity	(CPT 87186)
Culture, AFB & Smear	Positive growth	Sensitivity	(CPT 87186)
		ID	(CPT 87118)
		ID by Probe	(CPT 87149)
		ID by Sequencing	(CPT 87153)
	Respiratory Source	Concentration	(CPT 87015)
Culture, Aerobic (Urine, Genital, Fluid, Wound & Respiratory)	Positive growth w/ Clinical Relevance	Sensitivity	(CPT 87186)
		ID	(CPT 87077)
		Typing	(CPT 87147)
Culture, Anaerobic	Positive growth	ID	(CPT 87076)
Culture, Fungus	Positive growth	ID (Yeast)	(CPT 87106)
		ID (Mold)	(CPT 87107)
Culture, Tissue	Homogenization	Homogenization	(CPT 87176)
	Positive growth	Sensitivity	(CPT 87186)
		Typing	(CPT 87147)
		ID	(CPT 87077)

**If the antibody cannot be identified at PLS, the specimen will be forwarded to a referral laboratory for additional testing (additional CPT Codes will apply).

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REFLEX TESTING - PERFORMED AT PHYSICIANS LABORATORY

INITIAL TEST	REFLEX CRITERIA	REFLEX TESTING (WHEN NECESSARY)	
Cytopathology Fluids	Per Pathologist Request	Histologic Stains Immunopathologic Stains Flow Cytometry Electron Microscopy	
DNA Double Stranded (dsDNA) IgG w/ Reflex to IFA Titer	dsDNA > 200 IU/mL	IFA Titer	(CPT 86256)
Drug Screens	Positive	Confirmation	(CPT 80375)
Female Infertility Panel	EIA Positive EIA Positive & RPR Negative	RPR TP-PA	(CPT 86592) (CPT 86780)
HIV 1/2 Antibody	Positive	Confirmation	(CPT 86701) (CPT 86702)
Hepatitis Bs Antigen	Positive	Confirmation Hepatitis Bs Ag Confirmation	(CPT 87341)
HSV Culture w/ Typing 1 & 2	Positive	Typing	(CPT 87140)
HPV High Risk w/ Reflex to 16/18 Genotype	Positive for High Risk HPV	16/18 Genotype	(CPT 87625)
OB Panel I	EIA Positive EIA Positive & RPR Negative	RPR TP-PA	(CPT 86592) (CPT 86780)
OB Profile IV	EIA Positive EIA Positive & RPR Negative	RPR TP-PA	(CPT 86592) (CPT 86780)
OB Profile IV + Hep C	EIA Positive EIA Positive & RPR Negative	RPR TP-PA	(CPT 86592) (CPT 86780)
OB Profile VI	EIA Positive EIA Positive & RPR Negative	RPR TP-PA	(CPT 86592) (CPT 86780)
Pap, SurePath w/ Reflex to HPV (ACOG Guidelines)	Age < 21 or > 65 No HPV Age 21–29 HPV High Risk Screen if ASCUS Age 30–65 Pap & HPV Any Dx (Co-Testing) Age 30-65 Pap (Neg) HPV Screen (Pos)	 HPV High Risk HPV High Risk HPV 16/18	 (CPT 87624) (CPT 87624) (CPT 87625)

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REFLEX TESTING - PERFORMED AT PHYSICIANS LABORATORY

INITIAL TEST	REFLEX CRITERIA	REFLEX TESTING (WHEN NECESSARY)	
Pap, ThinPrep w/ Reflex to HPV (ACOG Guidelines)	Age 21–29 HPV High Risk Screen if ASCUS	HPV High Risk	(CPT 87624)
	Age 30–65 Pap & HPV Any Dx (Co-Testing)	HPV High Risk	(CPT 87624)
	Age 30-65 Pap (Neg) HPV Screen (Pos)	HPV 16/18	(CPT 87625)
Pap, ThinPrep Imaged w/ Reflex to HPV (ACOG Guidelines)	Age 21–29 HPV High Risk Screen if ASCUS	HPV High Risk	(CPT 87624)
	Age 30–65 Pap & HPV Any Dx (Co-Testing)	HPV High Risk	(CPT 87624)
	Age 30-65 Pap (Neg) HPV Screen (Pos)	HPV 16/18	(CPT 87625)
Partner Infertility Panel	EIA Positive	RPR	(CPT 86592)
	EIA Positive & RPR Negative	TP-PA	(CPT 86780)
Semen Analysis, Fertility	Absence of Sperm	Semen Fructose	(CPT 82757)
Surgical Pathology	Per Pathologist Request	Histologic Stains Immunopathologic Stains Flow Cytometry Electron Microscopy Molecular Pathology	
TrepSure (Anti-treponemal EIA Assay)	EIA Positive	RPR	(CPT 86592)
	EIA Positive & RPR Negative	TP-PA	(CPT 86780)
TSH w/ Reflex to Free T4	0.5 uIU/mL < TSH >5.0 uIU/mL	Free T4	(CPT 84439)
Urinalysis	Positive blood, protein, nitrites, or leukocyte esterase and/or cloudy appearance	Microscopic Exam (Replace CPT 81003 w/ CPT 81001)	
Urinalysis w/ Reflex to Culture	WBC > 5	Urine Culture	(CPT 87086)
Urine Testing (Timed Samples)	Any timed urine sample that requires a volume measurement	Urine Volume	(CPT 81050)

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REFLEX TESTING - PERFORMED AT REFERENCE LABORATORIES

INITIAL TEST	REFLEX CRITERIA	REFLEX TESTING (WHEN NECESSARY)	
Anabolic Steroids, Urine Screen w/ Reflex to Confirmation	Positive for any anabolic steroid	Confirmation	(CPT 80328)
ANCA, IgG	ANCA screen detects antibodies at a 1:20 dilution or greater, then a titer to end point will be added	End point titer	(CPT 86256)
Arsenic, Urine with Reflex to Fractionation	If total arsenic concentration is between 35-2000 ug/L	Arsenic Fractionated	(CPT 82175)
BCR-ABL1, Qualitative w/ Reflex to BCR-ABL 1 Quantitative	BCR-ABL1 Fusion Form Unknown Reflex detects the presence of p210 or p190 and then quantitates	BCR-ABL1 (p210) BCR-ABL1 (p190)	(CPT 81206) (CPT 81207)
Bordetella pertussis Culture	B. pertussis pathogen definitively identified	Aerobic Isolate	(CPT 87077)
Bordetella pertussis IgG by Elisa w/ Reflex to Immunoblot	B Pertussis IgG 1.0 U/mL or >	IgG Immunoblot	(CPT 86615)
Bordetella pertussis Antibodies IgA, IgG, and IgM by Elisa w/ Reflex to Immunoblot	B Pertussis IgA 1.2 U/mL or > B Pertussis IgG 1.0 U/mL or > B Pertussis IgM 1.2 U/mL or >	IgA Immunoblot IgG Immunoblot IgM Immunoblot	(CPT 86615) (CPT 86615) (CPT 86615)
Clostridium difficile Culture w/ Reflex to Cytotoxin Cell Assay	C. difficile culture is Positive	Cytotoxin Cell Assay	(CPT 87230)
Dilantin Total w/ Reflex to Free	Dilantin > 0.5 ug/mL	Dilantin Free	(CPT 80186)
GHB, Serum	Positive	Confirmation	(CPT 82542)
Hantavirus Ab IgG & IgM w/ Reflex to Confirmation	Positive	Confirmation Each Procedure	(CPT 86790)
Heavy Metals Panel 3 w/ Reflex to Arsenic Fractionated	If total arsenic concentration is between 35-2000 ug/L	Arsenic Fractionation	(CPT 82175)
Heparin Induced Thrombocytopenia Antibody (Reflexive)	Positive Heparin PF4 Screen Positive Heparin PF4 IgG	Heparin PF4 IgG Heparin Dependence	(CPT 86022) (CPT 86022)

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INITIAL TEST	REFLEX CRITERIA	REFLEX TESTING (WHEN NECESSARY)
HCV PCR w/ Reflex to Genotype	HCV Viral Load > 100 IU/mL	HCV Genotype (CPT 87902)
HSV Type 1 and/or 2 IgG and IgM w/ Reflex to Type 1 & 2 Glycoprotein G-Specific Ab, IgG	HSV 1 and/or 2 IgG ≥ 1.10 IV	HSV 1 gG Specific (CPT 86695) HSV 2 gG Specific (CPT 86696)
Herpesvirus 6 Antibody, IgM w/ Reflex to Titer by IFA	HHV6 IgM is detected at 1:10	HSV Titer (CPT 86790)
HTLV I/II Antibodies w/ Reflex To HTLV I/II Confirmation	HTLV I/II screen is repeatedly reactive	HTLV I/II Confirmation (CPT 86689)
Lupus Anticoagulant Panel	PT > 15.0 TCT > 20 APTT > 36 APTT Mix > 5 DRVVT > 45.7 DRVVT Ratio > 1.2	PT, Pt/Ctrl Mix (CPT 85611) TT, Pt/PSO4 Mix (CPT 85670) aPTT, Pt/Ctrl Mix (CPT 85732) HPNT (CPT 85598) dRVVT Mix Ratio (CPT 85613) drVVT Confirm (CPT 85613)
Motor & Sensory Neuropathy Evaluation w/ Immunofixation & Reflex	ANNA screen is positive at 1:10 or greater	ANNA Titer (CPT 86256) Western Blot (CPT 83516)
Myasthenia Gravis Evaluation Adult	If muscle AchR modulating antibody value is (or exceeds) 90% Acetylcholine receptor (AchR) loss and Striational Ab ≥ 1:60 (All four codes listed to the right will be added if these conditions are met).	GAD65 Ab Assay (CPT 86341) CRMP-5-IgG (CPT 84182) Neuronal VGKC (CPT 83519-59) AchR Ganglionic Neuronal Ab (CPT 83519-59)
Paraneoplastic Antibodies (PCCA-ANNA) by IFA w/ Reflex to Titer & Western Blot	If IFA Screen is Positive at 1:10, then a specific titer and Western Blot will be added	Titer (CPT 86256) Western Blot (CPT 83516)
Paraneoplastic Autoantibody Evaluation	IFA patterns indeterminate IFA patterns suggest CRMP-5-IgG IFA pattern suggests NMO IFA pattern suggests Amphiphysin Ab IFA pattern suggest GAD65 Ab If Ach Receptor Binding Ab >0.02 or If striational ab are ≥ 1:60	Paraneoplastic Autoantibody WB (CPT 84182) CRMP-5-IgG WB (CPT 84182) NMO IgG (CPT 86255) Amphiphysin WB (CPT 84182) GAD65 Ab (CPT 86341) Ach Recep Mod (CPT 83519-59) & CRMP-5-IgG WB (CPT 84182)

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Phenytoin, Total w/ Reflex to Phenytoin, Free	Phenytoin > 0.5 ug/mL	Phenytoin Free	(CPT 80186)
Respiratory Viral Culture	If definitive ID performed	Definitive ID	(CPT 87253)
Skeletal Muscle Antibody, IgG w/ Reflex to Titer	Striated Muscle Ab is > 1:40	Striated Muscle Titer	(CPT 86256)
Smooth Muscle Ab, IgG w/ Reflex to Titer	Smooth Muscle Ab IgG ≥ 20 Units	Smooth Muscle Ab, IgG IFA Titer	(CPT 86256)
Thyroglobulin Evaluation w/ Reflex to LC-MS/MS or CIA	TgAb Negative TgAb Positive	Tg CIA Tg LC-MS/MS	(CPT 84432) (CPT 84432)
Viral Culture	If definitive ID performed	Definitive ID	(CPT 87253)

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