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ANNUAL NOTICE TO PHYSICIANS 2006

Creighton University Medical Center (CUMC) and Creighton Medical Laboratories (CML) is providing physician clients with an annual notice of our commitment to adhere to all federal and state laws and program requirements of federal, state, and private health plans. This annual notice is in compliance with the regulations and requirements of the Office of Inspector General (OIG) of the Department of Health and Human Services, and the Center for Medicare and Medicaid Services (CMS).

The information below is provided to promote awareness of federal regulations and explain your need for documentation when ordering testing services for federally insured patients.

MEDICAL NECESSITY

Medicare will pay only for tests that meet the Medicare coverage criteria and are “reasonable and necessary to treat or diagnose an individual patient”. *Section 1862 (a) (1) (A) of the Social Security Act.*

- When instructing us to seek Medicare reimbursement, you must order only those tests that you believe to be medically necessary for patient diagnosis and treatment. This includes any and all tests that are components of ordered panels.
- As a provider, you are responsible to:
 - document medical necessity for each test in the permanent patient medical record
 - provide appropriate diagnostic information in the form of ICD-9 code(s) or narrative, with any test(s) for which you instruct us to seek Medicare reimbursement.
- As a provider, you are responsible for assuring the completion of an Advance Beneficiary Notice (ABN) in the circumstances outlined below:

ADVANCE BENEFICIARY NOTICES (ABN)

Medicare can deny reimbursement for tests based upon absence of medical necessity, routine health screening, investigational use only tests and frequency limitations. An ABN signed by the patient prior to service is necessary to document that the patient is aware that Medicare might not pay for a test and that the patient has agreed to pay for the testing in the event that Medicare payment is denied.

- Medicare frequently denies claims for laboratory tests for the following reasons:
 - Medicare does not usually pay for this service for the diagnosis provided.
 - Medicare will not pay for research or investigational use tests.
 - Medicare does not pay for this service based on frequency limitations.
 - Medicare does not pay for most routine screening tests.
 - Medicare does not pay for annual physical exams.
- If you order a test that you believe Medicare is likely to deny payment on, the laboratory requisition must be accompanied by an appropriately completed ABN. ABN's must be obtained prior to service being performed. Patients presenting directly to the Hospital to have blood drawn will be screened for the necessity of an ABN prior to the phlebotomy. Patients drawn at CML client sites must be screened by the client. If an ABN is necessary, a copy of the completed ABN must be sent to the laboratory with the test requisition and the specimen.

- Each ABN must be specific to each laboratory test ordered. Each test must be accompanied by the specific reason that Medicare might not pay for the test. Blanket waivers for all tests ordered on a Medicare patient are not allowed by Medicare and will not be accepted by CUMC/CML.

Without a signed ABN, the patient has no obligation to pay for the service. When payment for services are denied because of inappropriate medical necessity or lack of ABN documentation, CUMC/CML will notify the physician client of the issue. CUMC/CML will document these occurrence issues and your office account will be billed. If you have questions concerning documentation, please contact a Pathologist at (402) 449-4630.

CUSTOM PROFILES

Use of custom profiles is not generally encouraged by CUMC/CML. If a physician requests CUMC/CML to customize a test order profile, a signed physician acknowledgement is required from each physician who will be ordering the custom profile. Federal regulations require that acknowledgment forms be signed annually and returned to the laboratory. Custom Profiles for use in the Hospital will require approval by the Medical Staff. Physician acknowledgements will affirm:

- The custom test order profile was created at the request of the physician(s).
- The physician is informed of the amount Medicare will reimburse for each test included in the custom profile.
- The physician(s) will order individual tests or a less inclusive profile when one or more of the tests in the customized profile is not medically necessary for the patient.

2006 CPT CHANGES

The American Medical Association (AMA) has made 29 additions, 7 deletions, and 8 changes to the CPT 2005 coding manual that apply to Pathology. A summary of some of the more significant changes impacting CUMC/CML laboratory services is provided below. There is no phase-in period this year. These changes will be implemented January 1, 2006. If you have questions concerning CPT code changes, please contact a Pathologist at (402) 449-4630.

TEST NAME	2005 CPT CODES	2006 CPT CODES
Occult Blood, single specimen	82270	82270, 82271, 82272
Lipoprotein electrophoresis	83715, 83716	83700, 83701, 83704
Molecular diagnostics	83890-83912	New: 83900, 83907, 83908, 83909, 83914
Flow Cytometry, Immuno	86064, 86379, 86587	86335, 86357, 86367
Ova & Parasites, complex special stain (eg., trichrome, iron hemotoxylin)	88312, 88313	87209
Pathology consultation during surgery, cytologic examination	88161	88333, 88334

REFLEX TESTING

For some laboratory tests, when certain criteria are met, additional testing will be generated to provide more conclusive laboratory information for diagnosis and treatment. The CPT coding will accurately reflect the testing that is performed.

If you determine that reflex testing is not medically necessary; you must indicate this on the requisition by listing only the specific test or component needed or by writing "no reflex" on the requisition.

A list of current reflex testing is attached. CUMC/CML utilizes outside reference laboratories to perform esoteric testing. These reference laboratories utilize reflex testing. A list of representative panels/tests is attached. If you have any questions regarding reflex testing, please contact a Pathologist at (402) 449-4630.

**TESTS PERFORMED IN COMBINATION WITH OTHER LABORATORY TESTS AT
CUMC**

INITIAL TEST	CPT	REFLEX CRITERIA	CONFIRMATORY TEST	CPT
ABO & RH	86900, 86901	Front and back types do not match	A,B or A2 or A1 Lectin	86900, 86905
Antibody screen	86850	Positive results	Antibody identification, titer, direct coombs, elution, absorption, direct coombs, antigen typing, prewarming, enzyme, neutralization	86870 (per antibody), 86886, 86880, 86850, 86977, 86860, 86905, 86903, 86978, 86971, 86975.
Antinuclear antibody (ANA)	86038	Positive	ANA titer	86039
Body fluid cell count	89050	>5 WBCs	Body fluid cell count and differential	89051, 88108, 80500
Bronchoalvolar Lavage	88112, 89051	Per pathologist order	Pneumocystis smear	87205
CBC	85025	Certain cells on differential	Special stains, sickle identification	88313, 88318, 85660, 85060
Crossmatch compatability	86920, 86922	Incompatible (positive) results	Elution, absorption, direct Coombs, antigen typing, prewarming, enzyme, neutralization	86850, 86977, 86880, 86905, 86903, 86870, 86860, 86978, 86971, 86975
Cryptococcus Antigen	86403	Positive	Cryptococcus titer	86406
Culture (bacterial, viral, fungus, AFB)	87040, 87045, 87070, 87071, 87075, 87086, 87102, 87103, 87110, 87116, 87177, 87252, 87274	Certain specimen types, age, or positive growth	Stain, identification, and sensitivity	87046, 87076, 87077, 87088, 87106, 87107, 87118, 87140, 87147, 87149, 87070, 87176, 87181, 87184, 87185, 87186, 87187, 87188, 87190, 87205, 87206, 87253, 87254, 87273, 87591, 88312
Cytopathology fluids	88108, 88112, 88305, 88160, 88161	Per pathologist order	Histologic stains, immunopathologic stains, flow cytometry, image analysis, electron microscopy	88312, 88313, 88318, 88319, 88342, 88346, 88182, 88184, 88185, 88187, 88188, 88189, 88348, 88349
Direct Coombs	86880	Positive	Anti-complement and Anti-IgG	86880 x 2
Drug screen	80100, 80101	Positive	Confirmation testing	80100, 80102
DRVVT	85613	Positive	Mix performed, if positive, confirmation performed	85613 (possibly X2)
Fetal Screen	83030	Positive	Kleihauer Betke	85460

TESTS PERFORMED IN COMBINATION WITH OTHER LABORATORY TESTS AT CUMC

INITIAL TEST	CPT	REFLEX CRITERIA	CONFIRMATORY TEST	CPT
Hemoglobin electrophoresis	83020 x 2	Abnormal hemoglobin identified or Hemoglobin A2 done when MCV <80	Smear interp, Kleihauer-Betke, Hemoglobin A2, sickle ID, Hemoglobin F	85060, 85460, 83021, 85660, 83030
Hep B S Antigen	87340	Initial testing event is positive	HBSAg confirmatory neutralization	87341
HIV-1 Antibody	86701	Positive	Western Blot	86689-90
Homocystiene	83090	>10 U	MTHFR	83890, 83900, 83896 x4, 83912
Molecular Testing (eg, Prothrombin Gene Mutation, Factor V Leiden, MTHFR)	83890, 83898 or 83900, 83896, 83912, or multiples	Test results are inconclusive by RT-PCR	Full genetic sequencing process	83898 x2, 83909 x2, 83904 x2, 83912
Newborn Cord blood workup (ABO, RH, Direct coombs)	86900, 86901, 86880	Positive direct coombs	Antibody screen, antibody identification, elution, antigen typing	86850, 86860, 86870, 86903
Organism Identification	87046, 87070, 87076, 87077, 87088, 87106, 87107, 87118, 87140, 87147, 87149, 87205, 87206, 87253, 87254, 88312	Unable to identify organism by routine methods	Refer specimen for identification by Molecular Diagnostics Microsequencing	83891, 83908, 83909, 83912
Pap smear, liquid fixative	88142, G0123	ASCUS r/o CIN or per pathologist order	HPV testing	87621
Protein electrophoresis	84165	Monoclonal protein suspected	Immunofixation electrophoresis	86334, 86335
Rapid Strep	87430	Negative	Throat culture	87070
Surgical pathology	88300, 88302, 88304, 88305, 88307, 88309	Per pathologist order	Histologic or immunopathologic stains, flow cytometry, image analysis, electron microscopy, molecular pathology, MSI	88312, 88313, 88318, 88319, 88342, 88346, 88182, 88184, 88185, 88187, 88188, 88189, 88348, 88349, 88360, 88361, 88365, 88367, 88368
Syphilis testing	86592	Positive	Quantitation and FTA	86593, 86781
Urinalysis, Chem	81003	Positive blood, protein, nitrites, or leukocyte esterase	Microscopic exam	81001 instead of 81003

TESTS PERFORMED IN COMBINATION WITH OTHER LABORATORY TESTS AT CUMC

INITIAL TEST	CPT	CRITERIA	OTHER REQUIRED TEST(S)	CPT
24 hour urine collection for any analyte	Examples: 82340, 82436, 82945, 84133, 83735, 84105, 84300, 84156	If a 24 hour urine is tested, a volume must be performed to determine total 24 hour quantity of that analyte	Urine volume	81050
Antibiotic Synergy Testing	87181	One antibiotic combination tested	Testing of additional antibiotic combinations	87181 per combination
Blood Count, individual constituent (e.g., H/H, Platelet)		Laboratory performs and reports all analytic constituents for a blood count	Hemogram (Hgb, Hct, RBC, WBC, Plt)	85027
Blood Count, Absolute		Laboratory performs and reports all analytic constituents for a blood count	CBC (Hgb, Hct, RBC, WBC, Plt, Auto diff)	85025
Bone marrow	85097, 88305	CBC not ordered	CBC required	85025
Carbon Monoxide	82805		O2 Saturation, Methemoglobin, Reduced Hemoglobin	82375, 83050, 85018
CKMB	82553	Total CK not ordered	Total CK required	82550
Culture (Respiratory, CSF, Tissue, Fungal, AFB, other)	87070, 87071, 87102, 87103, 87116	Culture and stain/smear performed as panel. Charge added for tissue cultures that must be homogenized	Stain, fungus smear, or AFB smear, homogenization of tissue added when indicated	87205, 87206, 87176
Culture, Chlamydia	87110	Typing performed on all cultures	Chlamydia typing	87140
Culture, Colonization	87070	Specific organism colonization performed by isolation and identification	None	None
Culture, Stool	87045	Specific isolation of Salmonella and Shigella	Isolation of other enteric pathogens	87046
Epstein Barr Virus Antibodies		EBV Antibodies to nuclear Ag and viral capsid (IgG & IgM) Ag		86665 x 2, 86664
Fresh Frozen plasma, Platelets, Cryoprecipitate	Product	No previous blood type available Required product processing	Blood type, thawing, pooling, filters	86900, 86901, 86927, 86965
Hemoglobin electrophoresis	83020 x 2	Hemogram not ordered	Hemogram	85027
Herpes Simplex Virus by DFA	87274	Both Herpes Simplex 1 and 2 performed	Herpes Simplex 2	87273
Herpes Simplex Antibody by PCR	87529	Both Herpes Simplex 1 and 2 performed	Herpes Simplex 1 AND 2	87529 (x2 for entire test)
Immunofixation electrophoresis (serum, urine)	86334, 86335	Total protein and protein electrophoresis done with immunofixation electrophoresis	Total protein and protein electrophoresis	84155, 84156, 84165

**TESTS PERFORMED IN COMBINATION WITH OTHER LABORATORY TESTS AT
CUMC**

INITIAL TEST	CPT	CRITERIA	OTHER REQUIRED TEST(S)	CPT
Influenza Antibody A OR B	87400	Both A and B Antibody performed	Influenza Antibody A AND B	87400 (x2 for entire test)
Iron Binding Capacity (TIBC)	None (calculation)	Iron and Unsaturated Iron Binding Capacity not ordered	Iron, Unsaturated Iron Binding Capacity	83540, 83550
Leukemia/Lymphoma Markers	88184, 88185, 88187, 88188, 88189	CBC or cytospin not specifically requested	CBC and cytospin required	85025, 88108
Lymph Immune Markers	86064, 86359, 86360, 86379	CBC not specifically requested	CBC required	85025
Maturation Index	88155	Pap smear not ordered	Pap Smear	88142, G0123, 88164, P3000
Microalbumin / Creatinine Ratio	None (calculation)	Microalbumin and Creatinine not ordered	Microalbumin, Creatinine	82043, 82570
Molecular Testing (eg, Prothrombin Gene Mutation, Factor V Leiden, MTHFR, IgH Gene Rearrangement, Microsequencing, JAK2, MSI)	83890, 83894, 83896, 83898, 83912, 83909, 83907, 83908, or multiples	Component tests cannot be ordered separately	Lysis, isolation, extraction, amplification, and nucleic acid probes performed together	83890, 83894, 83896, 83898, 83912, 83909, 83907, 83908, or multiples
Ova and Parasites	87015	Trichrome, Iodine and Auramine O stains always performed	Stains performed	87206, 87209, 87210
PSA, Free %	None (calculation)	PSA, Total not ordered	PSA, Total and PSA, Free	84153 84154
Quad Screen (Maternal screening)		Alpha Fetoprotein hCG Estriol Inhibin A	Interpretation based upon patient information correlated with test results	82105 84702 82677 86336
Reticulocytes	85045	Hemogram not ordered	Hemogram	85027
Special microbial MIC testing	87188	MBC not ordered	Micro dilution / Broth Concentration	87187
Transferrin % Saturation	None (calculation)	Iron and Transferrin not ordered	Iron, Transferrin	83540, 84466
Transfusion reaction workup	86900, 86901, 86880, 86078, 87040	Specific patient response to blood administration	Other testing may be required based on severity of reaction	
Triple Screen (Maternal screening)		Alpha Fetoprotein hCG Estriol	Interpretation based upon patient information correlated with test results	82105 84702 82677
Urine Protein Electrophoresis	84166	Data required for proper interpretation of test values	Urine Protein and specimen volume	84156, 81001, 81002, 81003, 81050

**REPRESENTATIVE ESOTERIC TESTS PERFORMED
IN CONJUNCTION WITH OTHER LABORATORIES**

TEST/PROCEDURE	CPT CODES
ALKALINE PHOSPHATASE ISOENZYMES	84075 / 84080
ALLERGY Testing	86003 billed per allergen tested
Alpha -1 ANTITRYPSIN PHENOTYPE	82104 / 82103
Anti-NEUTROPHIL CYTOPLASMIC Ab, IgG	86255 plus 86256 if reflexed
BARTONELLA HENSELAE Ab, IgG & IgM	86611 x 2
B. PERTUSSIS Ab, IgG/IgA/IgM	86615 x 3
CELIAC PANEL	82784 plus 83516 x 1 to 5 / 86256 if reflexed
CHLAMYDIA Ab PANEL, IgG & IgM	86631x 3 / 86632 x 3
CREATINE KINASE ISOENZYMES	82552 / 82550
CYSTIC FIBROSIS MUTATION Panel	83890 / 83892 / 83901 / 83896 x 32 / 83894 / 83912
CYTOGENETIC STUDIES (KARYOTYPING) Codes are dependent upon specimen type and test findings. Call for patient specific codes.	
ENDOMYSIAL Ab, IgA with reflex	83516 plus 86256 if reflexed
EPSTEIN-BARR VIRUS Panel	86665 x 2 / 86664 / 86663
GLIADIN Ab, IgA & IgG	83516 x 2
HISTOPLASMA Ab	86698 x 3
IMMUNOGLOBULIN G Subclasses	82787 x 4
INFLAMMATORY BOWEL DISEASE Profile	86671 x 2 / 86255
ISOHEMAGGLUTININ Titer	86941 x 2
MULTIPLE SCLEROSIS Panel (Oligoclonal Band Profile)	83916 / 83873 / 82784 x 2 / 82040 / 82042
MYCOPLASMA PNEUMONIAE Ab, IgG & IgM	86738 x 2
NEUTROPHIL OXIDATIVE BURST Assay	88184 / 88185 x 2 to 8 / 88187
PARVOVIRUS B19 Ab, IgG & IgM	86747 x 2
PNEUMOCOCCAL Ab, IgG	86317 x 14
POLIOVIRUS Ab, 1, 2 and 3	86658 x 3
TESTOSTERONE, FREE AND TOTAL	84403 / 84270
THYROGLOBULIN	84432 / 86800
VON WILLEBRAND MODIFIED Panel	85246 / 85245
WEST NILE VIRUS Ab, IgG & IgM	86790 x 2