UC San Diego Health

Date: August 1, 2017

To: Physicians and Providers ordering tests from UC San Diego Health Clinical Laboratories

Subject: Annual Physician Compliance Notice

From: Ronald W. McLawhon, MD, PhD
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Center for Advanced Laboratory Medicine
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UC San Diego Health Clinical Laboratories are committed to ensuring compliance reimbursement regulations set forth by the Centers for Medicare and Medicaid Services. The Office of the Inspector General's "OIG Compliance Program Guidance for Clinical Laboratories" provides guidelines to health care providers who provide clinical laboratory testing services to Medicare and Medi-Cal beneficiaries. Included is the requirement that clinical laboratories provide an annual notice to physicians regarding pertinent Medicare rules, regulations, policies and billing requirements.

- **Medical Necessity:** Our requisitions are designed to emphasize physician choice. A physician must be able to order any test that he/she believes is appropriate and medically necessary for the diagnosis and/or treatment of his/her patient. You are encouraged to order tests separately whenever ALL the tests included in an approved panel are not needed.

  Section 1862(a)(1)(A) of the Social Security Act (42 U.S.C. 1395y(a)(1)(A) defines "medical necessity" as follows:

  "No payment may be made under [Medicare] part A or part B… for any expenses incurred for items or services… (1)(A) 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 and Medi-Cal may deny payment where there is insufficient documentation in the medical record (in the form of diagnosis codes, signs and symptoms) to support the medical necessity of each of the ordered tests.

  Medicare generally does not cover routine screening medical exams or screening tests.

  Please note: The OIG takes the position that a physician who orders medically unnecessary tests for which Medicare and Medi-Cal reimbursement is claimed may be subject to civil money penalties under the False Claims Act and other Federal statutes.

- **Required Information:** If you are ordering laboratory tests manually, please use laboratory requisitions preprinted with your location information. The following information is required on all laboratory requisitions:

- Patient name, Medical Record # (1234567-8) and birth date
- Current patient billing #
- Indicate test(s) to be performed
- Physician name
- Indicate if order is stat or routine
- PID#
- Indicate specimen type
- ICD-10 diagnosis code(s)
- Date and time of specimen collection

- **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. For questions regarding specific tests, please see the UCSD Laboratory Gateway https://www.testmenu.com/ucsd or see pages 5 and 6 of this notice for the laboratory's current reflex test list. Providers who prefer that reflex testing not be performed may contact the laboratory.

- **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 tests" must be submitted ordered in Epic or on the "Add-On Test Request" form. If the add-on order is a paper order, please provide the 9 requirements stated under **Required Information** above. An Epic order or written request for the added testing must be submitted before the laboratory reports the test results.

- **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 or electronic order each time. Manual standing orders must be renewed in writing **every six months** and must be submitted to the blood drawing location where the patient will access services using a standing order requisition form. Electronic standing orders must be renewed in Epic. Please provide the 9 requirements stated in **Required Information** as well as the following information:

    - Start/Stop day, month and year (6 month intervals - 06/01/16-12/01/16)
    - 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 or place a separate order in Epic

- **Panel Testing and Pricing:** All routine chemistry tests should be ordered separately except when all the tests contained in federally defined laboratory panels are medically necessary. Test panel pricing is based on the cost of each component included in a test panel. Individual tests or profiles are never 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 and billed only when all components are medically necessary**. A complete listing of panel tests, CPT codes and prices is attached.

- **Billing Practices:**

    - UC San Diego Health Clinical Laboratories will submit bills only for tests that are ordered and performed.

- Calculated test results are not billed. The reporting of such calculation as part of the test results does not affect any claims for reimbursement to federal or privately funded health care programs.
- Tests will only be billed if performed and reported. Tests that cannot be performed because of specimen limitations or technical problems will not be billed. If a portion of a panel cannot be performed, the panel will be credited and the remaining performed tests will be billed appropriately.

- No tests are provided to customers or potential customers free of charge or at less than cost either as a professional courtesy or in order to secure additional business.

- **Laboratory Web Site Resources**:

  UCSD Laboratory Reference:
  http://www.testmenu.com/ucsd

  Stark Law:
  http://www.cms.gov/PhysicianSelfReferral/

  UCSD Corporate Compliance
  http://health.ucsd.edu/compliance

  CMS Clinical Laboratory Center:
  http://www.cms.hhs.gov/center/clinical.asp

  CMS National Coverage Determinations (NCD's):
  http://www.cms.hhs.gov/mcd/index_section.asp?ncd_sections=40

  Local Coverage Determinations (LCD's):
  http://www.cms.hhs.gov/mcd/index_section.asp?ncd_sections=40

- **Laboratory/Pathology Clinical Consultants are available to assist you with any questions. Please contact:**

  Ronald W. McLawhon, MD, PhD, Chief Compliance Officer, UC San Diego Health Clinical Laboratories Compliance Program, 858-657-5685

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PANEL PROFILE INFORMATION 2017

PROFILE NAME	CPT CODE	COMPONENTS	MEDICARE PAYMENT
Basic Metabolic Panel	**80048**	Calcium (82310) Carbon Dioxide (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Potassium (84132) Sodium (84295) Urea nitrogen (BUN) (84520)	$11.60
Electrolyte Panel	**80051**	Carbon Dioxide (82374) Chloride (82435) Potassium (84132) Sodium (84295)	$9.62
Comprehensive Metabolic Panel	**80053**	Albumin (82040) Bilirubin; total (82247) Calcium (82310) Carbon dioxide (82374) Chloride (82435) 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) (84520)	$14.49
Lipid Panel	**80061**	Cholesterol, serum or whole blood, total (82465) Triglycerides (84478) Lipoprotein, direct measurement, HDL Cholesterol (83718)	$ 18.37
Liver Panel or Hepatic Function Panel	**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)	$11.21
Renal Function Panel	**80069**	Albumin (82040) Calcium (82310) Carbon Dioxide (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Phosphorus inorganic (phosphate) (84100) Potassium (84132) Sodium (84295) Urea nitrogen (BUN) (84520)	$11.91

Acute Hepatitis Panel	**80074**	Hepatitis A antibody, IgM antibody (86709) Hepatitis B core antibody, IgM antibody (86705) Hepatitis B surface antigen (87340) Hepatitis C antibody (86803)	$65.34

EVERY TEST IN A PANEL MUST BE MEDICALLY NECESSARY FOR THE TREATMENT OR DIAGNOSIS OF THE PATIENT

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REFLEX TESTING PERFORMED BY UCSD HEALTH SYSTEM CLINICAL LABORATORIES

When initial test results are positive or outside normal parameters, additional medically appropriate confirmatory test(s) may be ordered, unless declined. **The following reflex test(s) will be performed at an additional charge**:

Laboratory	Trigger	Reflex Test
Anatomic Pathology	Pap screen	HPV Current dx of ASCUS or AGUS, if no HPV testing has been performed in past 12 months and patient is 20 years or older. Current dx of LGSIL in post-menopausal women, if no HPV testing has been performed in past 12 months. In the absence of a clear history of menopause, any LGSIL in woman 50 or older.
	New diagnosis of primary or metastatic breast cancer. Diagnosis of breast cancer after neoadjuvant chemotherapy	ER, PR, and HER2/neu by IHC; Her2 FISH for invasive cancers
	New diagnosis of colon cancer	DNA Mismatch repair testing by IHC (MLH1, MSH2, MSH6, PMS2); testing for BRAF if MLH1 and/or PMS2 is abnormal
	Squamous cell carcinoma of head and neck	P16
	Heart biopsy - transplant	Trichrome (HISTO) and C4D (IF)
	Lung biopsy - transplant	GMS and CMV (IHC)
	Kidney- biopsy (medical)	PAS, Jones, Trichrome (HISTO) IgG, IgA, IgM, C3, C1q, kappa, lambda, fibrinogen, albumin, C4d (transplant), SV40 (transplant). (IF)
	Liver biopsy (medical)	Reticulin, trichrome, iron and PASD. (HISTO)
	New diagnosis of endometrial cancer in patient less than 50 years old	DNA Mismatch repair testing by IHC (MLH1, MSH2, MSH6, PMS2); testing for promoter methylation if MLH1 and/or PMS2 is abnormal; p53
Blood Bank	Positive antibody screen	Antibody identification and/or titer RBC Ag typing on patient
	Red cells requested on patient with positive antibody	Antigen typing to identify antigen-negative donor units
	Negative Rh test	Testing for weak D (aka, Du) on all cord blood
	All requests for ABO/Rh, antibody screen, crossmatch on neonates, if not previously performed on cord blood sample.	Direct Coombs test
	Positive autocontrol in antibody ID	Direct Coombs test
	Positive Direct Antiglobulin Test	Elution
	Transfusion on neonates	Hemoglobin S screening of donor units, CMV neg, Irradiated.
	Cord blood, if: Mother is type O or unknown Mother is Rh-negative Mother has clinically significant RBC antibody No maternal antibody screen in 8 months	All: Perform ABO/Rh (and weak D if Rh-neg) and DAT and perform corresponding antigen type if mother has a clinically significant antibody.
	Donor-directed red cell units	Irradiation
	Apheresis granulocytes	Crossmatch
	Red cells ordered on patient with known sickle cell disease	Red cell antigen matching of all donor units/HbS testing of unit
	Patient has warm auto-antibody	Adsorption and/or red cell phenotyping, supply or order phenotype matched units
	Equivocal Kleihauer/Betke	Fetal hemoglobin by flow cytometry
	Report of transfusion reaction	ABO/Rh, DAT, hemolysis on post-reaction blood; and if indicated; antibody screen, re-crossmatch; LDH, T/D bilirubin; haptoglobin; gram stain unit; culture unit; anti-HLA antibody tests; IgA level, anti-IgA antibody test
	Report of platelet refractoriness with anti-HLA and/or platelet specific antibodies	Antibody identification

	Prepare platelet order for a patient with anti-HLA and/or platelet specific antibodies	Order antigen-negative, or HLA-matched, or crossmatched platelets
Chemistry	Positive HIV-1/HIV-2 EIA Antibody	Geenius HIV 1 / 2 Assay at SDPH; Indeterminate results HIV ½ performed at SDPH, Further Indeterminate results sent to Quest (HIV-1 RNA Nucleic Acid Testing)
	Troponin with results **≥ 0.01 ng/mL**	**CK, CKMB and a CK relative index measurement**
Cytogenetics	Equivocal HER2 FISH	LIS1/RARA FISH as per recommendations in the 2013 revised ASCO/CAP HER2 reporting guidelines
	Product of conception (POC) culture failure	Microarray
Hematology/Coagulation	If free Protein S is < 65% in a non-pregnant or post-partum patient	Factor X activity plus Clinical Interpretation must be performed
	If Protein C is abnormal and the free Protein S is normal	Factor VII activity plus Clinical Interpretation must be performed
	If both Protein C and Protein S are abnormal	Factor X activity plus Clinical Interpretation must be performed
	Abnormal DRVVT (Screen)	DRVVT 1:1 mix, DRVVT- Confirm plus Clinical Interpretation
	Low ATIII, first time only	Clinical Interpretation must be performed
	Hemostasis Panel A: if APTT is prolonged	Do 1:1 mix, FIX, FXI and FXII
	CBCND with NRBC% >1.0 and no previous NRBC within 7 days.	Convert CBCND to CBC (add automated differential)
HLA	PRA Antibody screen	Antibody Identification
	PRA Antibody screen w/ background	PRA Antibody screen after DTT treatment
	Antibody Identification w/ background	Antibody Identification after DTT treatment
		Antibody Identification after adsorb
		Antibody Identification after dilution
Microbiology	Positive Microbiology Cultures	Identification, typing and/or susceptibilities will be performed on appropriate isolates
	Rapid Strep A	If negative, culture will be performed
	MTB PCR ordered	AFB culture performed
	Cryptococcus AG-CSF	CSF culture performed
	Positive GIPCR	Stool culture performed, if appropriate
	CSFME	CSF culture performed
Immunology	Positive antibody screen (AMA, ANCA, ANA, ASMA)	Antibody titer
	Positive cryoglobulin screen	Quantitative protein test; if result is >15 mg/dl, rheumatoid factor testing will be performed on the cryoglobulin supernatant and serum
Toxicology	Positive urine drug screen	Positive drug screening tests are reflexed to the appropriate drug/drug class confirmation test (some tests performed in house and others by outside laboratory)
Urinalysis	Positive urinalysis screen	Urine culture performed
Virology/Serology	Positive Syphilis Screen	Quantitative RPR
	Positive Syphilis Screen and Negative Quant RPR	Treponema pallidum particle agglutination assay (TPPA)
	Positive Rapid HIV-1	Geenius HIV 1 / 2 Assay at SDPH; Indeterminate results HIV ½ performed at SDPH, Further Indeterminate results sent to Quest (HIV-1 RNA Nucleic Acid Testing)
	Positive Coccidioides ID and/or CF	Quantitative Titer
	Positive VDRL	VDRL Quantitative Titer

LABORATORY NATIONAL COVERAGE DETERMINATIONS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES*

http://www.cms.hhs.gov/mcd/index_section.asp?ncd_sections=40

- Alpha-fetoprotein (190.25)
- Blood counts (190.15)
- Blood glucose testing (190.20)
- Carcinoembryonic antigen (190.26)
- Collagen cross links, any method (190.19)
- Digoxin Therapeutic Drug Assay (190.24)
- Fecal occult blood test (190.34)
- Gamma glutamyl transferase (190.32)
- Glycated hemoglobin/glycated protein (190.21)
- Hepatitis panel/acute hepatitis panel (190.33)
- Human chorionic gonadotropin (190.27)
- Human Immunodeficiency Virus (HIV) Testing (Diagnosis) (190.14)
- Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring) (190.13)
- Lipid testing (190.23)
- Partial thromboplastin time (190.16)
- Prostate specific antigen (190.31)
- Prothrombin time (PT) (190.17)
- Serum iron studies (190.18)
- Thyroid testing (190.22)
- Tumor antigen by immunoassay – CA 125 (190.28)
- Tumor antigen by immunoassay – CA 15-3/27.29 (190.29)
- Tumor antigen by immunoassay – CA 19-9 (190.30)
- Urine culture (190.12)

NORIDAN HEALTHCARE SOLUTIONS, LLC LOCAL COVERAGE DETERMINATIONS*

http://www.cms.hhs.gov/mcd/index_section.asp?ncd_sections=40

- Allergy testing (L34313)
- B-type Natriuretic Peptide (BNP) Testing (L35526)
- Circulating Tumor Cell Marker Assays (L35710)
- Controlled Substance Monitoring and Drugs of Abuse Testing (L36668)
- Flow Cytometry (L34215)
- MolDX - CDD: Oncotype DX® Breast Cancer for DCIS (Genomic Health ™) (L36941)
- MolDX- CDD: ProMark Risk Score (L36704)
- MolDX: APC and MUTYH Gene Testing (36882)
- MolDX: Biomarkers in Cardiovascular Risk Assessment (L36358)
- MolDX: BRCA1 and BRCA2 Genetic Testing (L36161)
- MolDX: Breast Cancer Assay: Prosigna (L36380)
- MolDX: Breast Cancer Index℠ Genetic Assay (L36314)
- MolDX: Chromosome 1p/19q Deletion Analysis (L36557)
- MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L36310)
- MolDX: GeneSight® Assay for Refractory Depression (L36323)
- MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36180)
- MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36155)
- MolDX: Genetic Testing for Lynch Syndrome (L36370)
- MolDX: HLA-B*15:02 Genetic Testing (L36145)
- MolDX: HLA-DQB1*06:02 Testing for Narcolepsy (L36551)
- MolDX: MGMT Promoter Methylation Analysis (L36188)
- MolDX: Molecular Diagnostic Tests (MDT) (L35160)
- MolDX: Molecular RBC Phenotyping (L36167)
- MolDX: NRAS Genetic Testing (L36335)
- MolDX-CDD: ConfirmMDx Epigenetic Molecular Assay (L36327)
- MolDX-CDD: Decipher® Prostate Cancer Classifier Assay (L36343)
- MolDX-CDD: Genomic Health™ Oncotype DX® Prostate Cancer Assay (L36364)
- MolDX-CDD: NSCLC, Comprehensive Genomic Profile Testing (L36194)
- MolDX-CDD: Percepta© Bronchial Genomic Classifier (L36886)
- MolDX-CDD: Prolaris™ Prostate Cancer Genomic Assay (L36348)
- Serum Magnesium (L36702)
- Special Histochemical Stains and Immunohistochemical Stains (L36351)
- Vitamin D Assay Testing (L36692)

*Based on information available on listed websites – check websites for current information