UC San Diego Health

Date: 03 July 2019

To: Our Valued Physicians and Providers Ordering Tests from UC San Diego Health Clinical Laboratories

Subject: 2019 Notice to Physicians

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 full compliance with all applicable federal and state laws and regulations, third party payer requirements, and industry best practices. To that end, and consistent with recommendations of the Office of the Inspector General ("OIG") for the U.S. Department of Health and Human Services Compliance Program Guidance for Clinical Laboratories, the purpose of this annual letter is to inform you about certain important laboratory practices and the regulations governing them.

- **Medical Necessity:** Our requisitions are designed to emphasize physician choice. A physician must be able to order any test that he/she believes is reasonable and medically necessary for the diagnosis or treatment of illness or injury for 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."

  Incomplete or illegible records can result in denial of payment for services billed to Medicare. In order for a claim for Medicare benefits to be valid, there must be sufficient documentation in the medical record to verify the services performed were "reasonable and necessary" and required the level of care billed. Additionally, if there is insufficient documentation on the claims that have already been adjudicated by Medicare, reimbursement may be considered an overpayment and the funds can be partially or fully recovered.

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

  Please note: The Office of Inspector General (OIG) believes that a physician who orders medically unnecessary tests and knowingly causes a false claim to be submitted may be subject to sanctions or remedies under criminal or administrative law.

- **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:

    1. Patient name
    2. Medical Record # (1234567-8)
    3. Birth date
    4. Current patient billing #
    5. Indicate test(s) to be performed
    6. Physician name
    7. Indicate if order is stat or routine
    8. PID#
    9. Indicate specimen type
    10. ICD-10 diagnosis code(s)
    11. 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 by placing an order in Epic or on the "Add-On Test Request" form. If the add-on order is a paper order, please provide the 11 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 may be used when ongoing treatment requires that specified testing be performed on a regular, periodic basis without having to submit a new order each time. All testing ordered is subject to applicable medical necessity and frequency guidelines. All standing orders must be verified and renewed every **six months** and must be submitted to the blood drawing location where the patient will access services. Please provide the 11 requirements stated in **Required Information** as well as the following information:

    - Effective date and End date of order, month and year (6 month intervals - 06/01/2019 - 12/01/2019)
    - Frequency with which the testing 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. **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 below 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

  Physician Self-Referral-Stark Law:
  http://www.cms.gov/PhysicianSelfReferral/

  UCSD Health Sciences Compliance Advisory Services
  https://medschool.ucsd.edu/compliance/Pages/default.aspx

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

  The Medicare Coverage Database (MCD) contains all National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs): http://www.cms.hhs.gov/mcd/index_section.asp?ncd_sections=40

- **The Director of Clinical Laboratories and the Laboratory Compliance Officer are available to assist you with any questions. Please contact:**

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PANEL PROFILE INFORMATION 2019

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)	$9.40
Electrolyte Panel	**80051**	Carbon Dioxide (82374) Chloride (82435) Potassium (84132) Sodium (84295)	$7.79
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)	$11.74
Lipid Panel	**80061**	Cholesterol, serum or whole blood, total (82465) Triglycerides (84478) Lipoprotein, direct measurement, HDL Cholesterol (83718)	$ 14.88
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)	$9.65
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)	$52.93

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)	$9.08

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 UC SAN DIEGO HEALTH 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 Oropharynx	P16
	Heart Biopsy - Transplant	Trichrome (HISTO) and C4D (IF)
	New diagnosis of cancer in lung: Lung biopsy/ cytology	PD-L1 (IHC)
	Kidney- Biopsy Native (medical)	PAS, Jones, Trichrome (HISTO) IgG, IgA, IgM, C3, C1q, kappa, lambda, fibrinogen, albumin, and FS-H&E
	Kidneys- Biopsy Transplant	PAS, Jones, Trichrome (HISTO) IgG, IgA, IgM, C3, C1q, kappa, lambda, fibrinogen, albumin, FS-H&E, C4d, and SV40 (send out).
	Muscle Biopsies	FS-Trichrome, FS-PAS, FS-H&E, Oil Red O, NADH, ATPase pH 4.3, ATPase pH 9.4, COX/SDH (combined stain), Acid Phosphatase, NSE (non-specific esterase)
	Liver Biopsy (medical)	Reticulin, Trichrome, Iron and PASD Stains. (HISTO)
	New diagnosis of endometrial cancer	DNA Mismatch repair testing by IHC (MLH1, MSH2, MSH6, PMS2); testing for promoter methylation if MLH1 and/or PMS2 is abnormal
	Sentinel lymph nodes, Melanoma of skin	Melan-A (IHC) or HMB-45 (IHC) or SOX10 (IHC) on each block
	Sentinel lymph nodes, gynecologic tract cancer	Pancytokeratins (IHC, x2; ultrastaging)
	Endometrial Serous Carcinoma	HER2/neu (IHC and FISH)
Blood Bank	Positive Antibody Screen	Antibody identification and/or titer RBC Ag typing on patient
	Positive Fetal Screen	The Kleihauer–Betke ("KB") test will be performed to measure the amount of fetal hemoglobin transferred from a fetus to a mother's bloodstream
	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	All: Perform ABO/Rh (and weak D if Rh-neg) and DAT and perform corresponding

	Mother is Rh-negative Mother has clinically significant RBC antibody No maternal antibody screen in 8 months	antigen type if mother has a clinically significant antibody.
	Donor-Directed Red Cell Units	Irradiation
	Apheresis Granulocytes	Crossmatch
Blood Bank	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	Multispot at SDPH; Indeterminate results HIV ½ performed at SDPH, Further Indeterminate results sent to Quest (HIV-1 RNA Nucleic Acid Testing)
	Troponin with results ≥ 14ng/L	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 7days	Convert CBCND to CBC (add automated differential)
HLA	PRA Antibody Screen	Antibody Identification
	HLA Antibody Screen with Suspected Prozone Inhibition	Dilution testing performed to identify high titer HLA antibody specificities
	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	Antibody titer

	(AMA, ANCA, ANA, ASMA)	
	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). Confirmation testing for multiple drug sub-classes may be performed when only one drug screening test, such as opiates, is positive. See UC San Diego Health Test Directory (www.testmenu.com/ucsd) for a directory of drugs/metabolites targeted and CPT codes included for each drug confirmation test.
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	HIV-1/HIV-2 Antibody EIA (performed in Chemistry), Multispot and HIV 1/HIV-2 EIA performed at SDPH, Indeterminate results sent to Quest (HIV-1 RNA Nucleic Acid Testing)
	Positive Coccidioides ID and/or CF	Quantitative Titer
	Positive VDRL	VDRL Quantitative Titer

Updated May 2019

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LAB NATIONAL COVERAGE DETERMINATIONS (NCDs) Alphabetical Index
FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES*

1	190.25	Alpha-fetoprotein
2	190.15	Blood counts
3	190.20	Blood glucose testing
4	190.26	Carcinoembryonic antigen
5	190.19	Collagen Crosslinks, any method
6	190.24	Digoxin Therapeutic Drug Assay
7	190.34	Fecal Occult Blood Test
8	190.32	Gamma Glutamyl Transferase
9	190.21	Glycated Hemoglobin/Glycated Protein
10	190.33	Hepatitis Panel/Acute Hepatitis Panel
11	190.27	Human Chorionic Gonadotropin
12	190.14	Human Immunodeficiency Virus (HIV) Testing (Diagnosis)
13	190.13	Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)
14	190.23	Lipid Testing
15	190.16	Partial Thromboplastin Time (PTT)
16	190.31	Prostate Specific Antigen
17	190.17	Prothrombin Time (PT)
18	190.18	Serum Iron Studies
19	190.22	Thyroid Testing
20	190.28	Tumor Antigen by Immunoassay – CA 125
21	190.29	Tumor Antigen by Immunoassay – CA 15-3/CA 27.29
22	190.30	Tumor Antigen by Immunoassay – CA 19-9
23	190.12	Urine Culture (Bacterial)

https://www.cms.gov/medicare-coverage-database/indexes/lab-ncd-index.aspx?bc=AgAAgAAAAAAA&

1	L34313	Allergy testing
2	L35526	B-type Natriuretic Peptide (BNP) Testing
3	L35710	Circulating Tumor Cell Marker Assays
4	L34215	Flow Cytometry
5	L36678	Lab: Bladder/Urothelial Tumor Markers
6	L37066	Lab: Coenzyme Q10 (CoQ10)
7	L36668	Lab: Controlled Substance Monitoring and Drugs of Abuse Testing
8	L36846	Measurement of Salivary Hormones
9	L36941	MolDX - CDD: Oncotype DX® Breast Cancer for (DCIS)Genomic Health ™
10	L37504	MolDX: BDX-XL2
11	L37070	MolDX: DecisionDx-UM (Uveal Melanoma)
12	L37120	MolDX: 4Kscore Assay
13	L37303	MolDX: AlloSure®Conor-Derived Cell-Free DNA Test
14	L36882	MolDX: APC and MUTYH Gene Testing
15	L36358	MolDX: Biomarkers in Cardiovascular Risk Assessment
16	L36161	MolDX: BRCA1 and BRCA2 Genetic Testing
17	L36380	MolDX: Breast Cancer Assay: Prosigna
18	L37822	MolDX: Breast Cancer IndexTM (BCI) Gene Expression Test
19	L36327	MolDX: ConfirmMDx Epigenetic Molecular Assay
20	L37673	MolDX: Corus®CAD Assay
21	L36310	MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing
22	L37616	MolDX: Cystatin C Measurement
23	L36343	MolDX: Decipher® Prostate Cancer Classifier Assay
24	L37750	MolDX: DecisionDX-Melanoma
25	L37295	MolDX: EndoPredict®Breast Cancer Gene Expression Test
26	L37350	MolDX: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs)
27	L36323	MolDX: GeneSight® Assay for Refractory Depression
28	L36180	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease
29	L36155	MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)
30	L36370	MolDX: Genetic Testing for Lynch Syndrome
31	L36364	MolDX: Genomic Health™ Oncotype DX® Prostate Cancer Assay
32	L37649	MolDX: Guardant360®Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer (NSCLS)
33	L36145	MolDX: HLA-B*15:02 Genetic Testing
34	L36551	MolDX: HLA-DQB1*06:02 Testing for Narcolepsy
35	L36188	MolDX: MGMT Promoter Methylation Analysis
36	L35160	MolDX: Molecular Diagnostic Tests (MDT)
37	L36167	MolDX: Molecular RBC Phenotyping
38	L37301	MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels
39	L36335	MolDX: NRAS Genetic Testing

40	L37746	MolDX: Oncotype DX AR-V7 Nucleus Detect for Men with Metastatic Castrate Resistant Prostate Cancer (MCRPC)
41	L37305	MolDX: Oncotype DX®Gnomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer
42	L36886	MolDX: Percepta© Bronchial Genomic Classifier
43	L36348	MolDX: Prolaris™ Prostate Cancer Genomic Assay
44	L37080	MolDX: Prolaris™ Prostate Cancer Genomic Assay for Men with Favorable Intermediate Risk Disease
45	L36704	MolDX: ProMark Risk Score
46	L37299	MolDX: Prometheus IBD sgi Diagnostic Policy
47	L36702	Serum Magnesium
48	L36351	Special Histochemical Stains and Immunohistochemical Stains
49	L36692	Vitamin D Assay Testing

https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=365&ContrVer=1&CntrctrSelected=365*1&LCntrctr=360*1%7c364*1%7c365*1%7c361*1%7c366*1%7c362*1%7c367*1%7c363*1%7c353*1%7c357*1%7c352*1%7c356*1%7c354*1%7c359*1%7c355*1%7c358*1%7c351*1%7c345*1%7c340*1%7c346*1%7c341*1%7c347*1%7c342*1%7c350*1%7c343*1%7c348*1%7c344*1%7c349*1%7c389*1%7c139*2&DocType=2&bc=AAACAAAAAAAA&#aFinal

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