



## 2018 Annual Notice to Physicians

Central Coast Pathology Laboratory is committed to promoting awareness and adherence to all federal laws and regulations. In accordance with the Office of Inspector General's (OIG) recommendation, this notice will provide our physician clients valuable information. The information contained within is intended to aid physician clients and the laboratory comply with the regulations and mitigate risks for all parties.

### PECOS - Medicare Ordering and Referring Information

As of 2014, Medicare requires all physicians or other eligible non-physician practitioners (NPP) to enroll in or have a valid opt-out record with the Center for Medicare and Medicaid Services' Provider Enrollment, Chain and Ownership System (PECOS) in order to order/refer items or services for Medicare beneficiaries. Information on the requirement and how to enroll is available at:

<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>

### Medical Necessity

Tests that are medically necessary for the diagnosis or treatment of a Medicare patient are covered and will be reimbursed. Screening or Investigational Use Only tests are not generally covered by Medicare, with some exceptions. An approved panel must only be ordered when every test in that panel is medically necessary. If all components of the panel are not medically necessary, individual tests or a less inclusive panel containing only the medically necessary tests should be ordered. The OIG takes the position that a physician who orders medically unnecessary tests for which Medicare reimbursement is claimed may be subject to civil penalties. As a Medicare participating provider, Central Coast Pathology Laboratory has a responsibility to make good faith efforts to ensure that all tests requested are performed and billed in a manner consistent with all federal and state laws and regulations.

### Billing Information

Section 4317 of the Balanced Budget Act of 1997 requires that the physician or other authorized ordering party submit diagnosis information on the laboratory order for submission of a Medicare claim. The diagnosis information provided should accurately describe the patient's condition on the date of service as documented in the patient's medical record. The laboratory requires the following information to enable the billing department to bill Medicare, Medicaid or other commercial insurance:

- ✓ patients full name
- ✓ patient's complete address, including city state and zip code
- ✓ patient's date of birth and gender
- ✓ patient's insurance (a copy of the patient's current insurance card is requested)
- ✓ ordering physician's full name
- ✓ valid diagnosis code(s) for each test, and
- ✓ valid ABN, when mandated by Medicare NCD/LCD policy.

### 2018 Medicare Clinical Laboratory Fee Schedule

Outpatient clinical laboratory services are paid based on a fee schedule in accordance with Section 1833(h) of the Social Security Act. Payment is the lesser of the amount billed, the local fee for geographic area, or a national limit. Co-payments and deductibles do not apply to services paid under the Medicare Clinical Laboratory Fee Schedule. Medi-Cal reimbursement will be equal to, or less than, Medicare reimbursement.

The 2018 Medicare Clinical Laboratory Fee Schedule can be viewed at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files-Items/18CLAB.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>

### **American Medical Association (AMA) Organ and Disease Oriented Panels**

AMA panels were developed for coding purposes only and should not be interpreted as clinical parameters. Each component in an AMA-defined panel must be considered medically necessary when ordering.

### **Custom Profiles**

Central Coast Pathology Laboratory does not encourage the use of custom profiles, however, in instance where clients insist on customization, the client is advised that custom profiles require a signed Physician Acknowledgement Form (PAF) upon inception with annual renewal thereafter. Custom profiles will not be created without completion of this form nor will they remain active without annual renewal. The PAF details CPT codes and the Medicare and Medi-Cal reimbursement paid for each component of the profile. Please be advised that ordering custom profiles may result in the ordering of tests which are not covered, reasonable or necessary and the 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 an administrative law.

### **Medical Laboratory National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).**

Centers for Medicare and Medicaid Services (CMS) has established National Coverage Determinations (NCD) that place restrictions on certain tests for Medical Necessity or Utilization. California Medicare carrier Noridian, has published Local Coverage Determinations (LCD) for certain tests. These policies define the medical conditions for which these tests are covered or reimbursed by Medicare. For these tests, the ordering provider is required to provide diagnostic information that supports the medical necessity for the test.

LCDs may be viewed at: <https://www.cms.gov/medicare-coverage-database/indexes/lcd-state-index.aspx>

NCDs may be viewed at: <https://www.cms.gov/medicare-coverage-database/indexes/lab-ncd-index.aspx>

### **Advance Beneficiary Notice of Noncoverage (ABN)**

Not all laboratory services are covered by Medicare. For statutorily excluded services, the laboratory may bill Medicare patients directly. For certain other laboratory tests, an Advance Beneficiary Notice of Noncoverage (ABN) is used to document that the patient has been made aware that Medicare may not pay for services and has agreed to pay the laboratory in the event payment is denied. A separate ABN must be used for each encounter. ABN's must be collected prior to services being rendered. Client-collected ABN's must be attached to the requisition when samples are submitted to the laboratory. The laboratory will be responsible for collecting the ABN from the patient only when there is a face to face interaction between the patient and the laboratory. More information is available at:

<https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>

### **Medicare Preventive Screening Laboratory Tests**

Certain preventive screening laboratory tests are covered benefits for Medicare patients. Benefit coverage is specific for each service, covered diagnosis codes, coverage requirements, and frequency limitations. A full list of tests may be viewed at:

## Reflex testing

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate for patient care. There are two types of reflex testing protocols – required and optional reflex tests.

### (a) Required Reflex Tests

Laboratory tests which, if positive, require additional separate follow-up testing in order to have clinical value. Reflex tests required by state, regulatory or accreditation standards are also considered to be of this type.

### (b) Optional Reflex Tests

Laboratory tests where the initial test results may have clinical value without the additional reflex testing.

## Clinical Consultant/Medical Director

The Laboratory Medical Director is available to provide guidance as requested.

<u>Performing Laboratory</u>	<u>Director Name</u>	<u>Director Contact Information</u>	
Bakersfield Laboratory:	James Hannah, MD	(661) 325-0744	<a href="mailto:jhannah@pallab.org">jhannah@pallab.org</a>
Central Coast Pathology Laboratory:	Michael V. Frost, MD	(805) 541-6033	<a href="mailto:mfrost@ccpathology.com">mfrost@ccpathology.com</a>
West Pacific Medical Laboratory:	Ronald Rocha, MD	(562) 906-5227	<a href="mailto:rocha@ccpathology.com">rocha@ccpathology.com</a>

## Supply Provision

The laboratory provides supplies that are used solely to collect, transport, process, or store specimens referred to our laboratory. Supplies are filled according to utilization.

## Attachments

The pages that follow will provide you and your staff with additional resources. Please take a moment to review and/or disseminate this information accordingly. We value your business and appreciate the opportunity to server your laboratory needs in conjunction with these initiatives.

- AMA Defined Organ or Disease Oriented Panels
- Reflex tests

*Thank you for supporting Central Coast Pathology Laboratory*

## AMA Defined Organ or Disease Oriented Panels

<b>Panel Name</b>	<b>Components</b>	<b>CPT Code</b>
Acute Hepatitis Panel	Hepatitis A AB, IGM Hepatitis B Core AB, IGM	Hepatitis B SAB Hepatitis C AB 80074
Basic Metabolic Panel	Calcium Chloride CO2 Bicarbonate Creatinine	Glucose Potassium Sodium Urea Nitrogen 80048
Comprehensive Metabolic Panel	Albumin Alkaline Phosphatase ALT AST Bilirubin, Total Calcium Chloride	CO2 Bicarbonate Creatinine Glucose Potassium Protein Sodium Urea Nitrogen 80053
Electrolyte Panel	Chloride CO2 Bicarbonate	Potassium Sodium 80051
Hepatic Function Panel	Albumin Alkaline Phosphatase ALT AST	Bilirubin, Total Bilirubin, Direct Protein 80076
Lipid Panel	Cholesterol, Total Triglycerides Cholesterol, HDL	80061
Obstetric Panel	Hepatitis B SAG Rubella AB Syphilis AB Screen RBC	ABO blood type RH Blood Type CBC 80055
Renal Function Panel	Albumin Calcium Chloride CO2 Bicarbonate Creatinine	Glucose Phosphorus Potassium Sodium Urea Nitrogen 80069

## Reflex Test List

A1A Total and 2 Mutations with Reflex to A1A Phenotype	LG1 IgG and CASPR3 IgG with Reflex Titers
AFB Identification With Reflex to Susceptibility	LIPID Panel w/Reflex to LDL For Elevated Triglyceri
Allergen Egg White IgE w/ Reflex to Components	Lupus Antibody Comprehensive Reflexive
Allergen Milk (Cow) IgE w/ Reflex to Components	Lyme Ab IgG/IgM Screen With Reflex
Allergen Peanut IgE w/ Reflex to Components	Miscellaneous Culture
ANA w/ Reflex to Titer and Autoimmune Plus Profile	Motor and Sensory Neuropathy Eval w/ Reflexes
ANA w/ Reflex to Titer and Autoimmune Profile	MPN Extended Reflex Panel (JAK-2) at NeoGenomics
ANA w/ Reflex to Titer To RDL (# 20)	Myocardial Antibody, IgG with Reflex to Titer
ANA with Reflex to Nuclear Antibody Profile	N-Methyl-D-Aspartate Receptor Antibody, IgG w/ Reflex Titer
Anaerobe Culture	Nasal Culture
ANCA with Reflex Titers To RDL (# 990)	O&P - Giardia/Crypto Screen w/ Reflex to Full Exam
Anti-Nuclear Antibody (ANA) with Reflex to Titer	Oxycodone Urine with Reflex Confirmation
Anti-Nuclear Reflex To DS DNA and ENA	Oxycodone/Oxymorphone, Urine Screen w/ Rflx to Quantitation
Arsenic, Urine w Reflex to Fractionated (24 HR or Random)	Phosphorus With Reflex To PTH
BCR-ABL1, Qualitative with Reflex to BCR-ABL1 Quantitative	Porphyria Plasma W/Reflex To Fractionation
Blood Culture	Protein C Activity w/ Reflex to Total Antigen
Bordetella pertussis Antibody IgA and IgG with Reflex	Protein S Activity w/ Reflex to Antigens
Bordetella pertussis, IgM by ELISA w/ Reflex to IB	PSA (Ultrasensitive) Total w/ Reflex Free PSA
Buprenorphine, Urine Screen with Reflex to Quantitation	Reflex HPV High Risk if ASC-US ThinPrep
Calcium With Reflex To PTH	RPR with Reflex to Titer and Confirmation
Celiac Disease Reflexive Cascade	Sansum Thyroid Reflex Panel
Cocci Immunodiffusion to SVRH Reflex CF UC Davis	Sickle Cell Screen w/ Reflex to Hemoglobin Electrophoresis
Cocci Immunodiffusion w/ Reflex To CF UC Davis	Smooth Muscle (F-Actin) Ab Screen Reflex To IgG Titer
Coxiella burnetii Antibodies, IgG/IgM, Reflex to Titer	SPEP With Reflex To Immunofixation (IFE)
Cryoglobulin, Qualitative w/ Reflex IFE	Stool Culture
Cystic Fibrosis (CFTR) 165 w/ Reflex Seq. & Reflex Dup/Del	Striated Muscle Antibodies, IgG with Reflex to Titer
Drug Screen 9 Panel, Serum, w/ Reflex Confirmations	Throat Culture (Full throat)
DRVVT with Reflex 1:1 Mix and Confirmation	Thrombin Time w/ Reflex to 1:1 Mixing Studies
DS DNA with Reflex to FARR	Thyroglobulin, Serum/Plasma with Reflex to LC-MS/MS or CIA
Eye/Ear Culture	Tissue Culture
Fragile X with Reflex Methylation	Tissue Transglutaminase IgA Reflex to Endomysial
Group B Streptococcus DNA Amplified w/ Reflex Suscept	Treponema pallidum (Syphilis) IgG/IgM w/ Reflex Confirmation
Hepatitis A Virus Antibody (Total), Reflex to IgM	Trichomonas Culture
Hepatitis B Virus Surface Antigen with Reflex to Confirmation	TSH with Reflex To Free T4
Hepatitis C Virus Genotype w/ Reflex NS5A Drug Resistance	TSH With Reflex To FT3 and FT4
Hepatitis C Virus RNA Quantitative PCR w/ Reflex Genotype	TSH with Reflex to FT3 and FT4 by Dialysis
Herpes Simplex DFA With Reflex To HSV Culture If Negative	Urinalysis Complete with Microscopic, Reflex to Culture
Herpes Simplex Virus Culture w/ Reflex to Typing	Urinalysis Microscopic with Reflex to Culture
Herpes Simplex Virus PCR w/ Reflex Typing	Urinalysis With Reflex to Microscopic and Culture
Herpesvirus 6 (HHV6) Antibody, IgM Screen w/ Reflex IFA Titer	Urine Culture
HIV 1, 2 Panel Screen w/ Reflex Confirmation	Vaginal/Cervical Culture
HIV 1/2 Antibody and p24 Antigen w/ reflex Confirmation	Varicella Zoster Virus DFA With Reflex If Negative
HTLV I and II Antibodies, with Reflex Confirmation	Varicella-Zoster and Herpes Simplex DFA w Reflex to Culture
Interferon Beta Neutralizing Antibody w/ Reflex Titer	Wound Culture