LABORATORY COMPLIANCE AND MEDICAL NECESSITY

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VCUHS Compliance Services and the Department of Pathology Laboratories are dedicated to strengthening compliance in accordance with the laws, rules, and regulations that govern our Health System. Our goal is to carry out all facets of the *Hospital and Laboratory Compliance Plans* through education, training, and monitoring in order to maintain a culture of compliance as an organizational effort.

MEDICAL NECESSITY

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The **Centers for Medicare and Medicaid Services (CMS)** is responsible for administering Medicare and other federally mandated healthcare programs throughout the United States. Medicare laws prohibit payment for services and items deemed by local Medicare Carriers as not medically reasonable and necessary for the diagnosis or treatment of an illness or injury. Documentation of "medical necessity" is required before a claim is paid. Medicare, with a few exceptions, will not pay for routine checkups or screening tests; defined as "diagnostic procedures performed in the absence of signs or symptoms."

To comply with these guidelines, physicians should:

- 1. Order tests that are medically necessary in diagnosing or treating their patients;
- 2. Provide or Enter all appropriate and correct ICD-9 codes in both their patient files and on the test request forms; and
- 3. Obtain the patient's signature and date on an Advance Beneficiary Notice (ABN) when prompted via Cerner, or, if Cerner is not available, when they believe that the service is likely to be denied.

LOCAL / NATIONAL COVERAGE DETERMINATIONS

To ensure that services being paid for by the Medicare program are medically necessary, CMS directed its Medicare carriers to establish policies - often referred to as **Local Coverage Determinations (LCDs)** or Limited Coverage tests - identifying laboratory tests and procedures that require additional medical necessity documentation before the laboratory can be reimbursed. LCDs outline how carriers will review claims to determine if Medicare coverage requirements have been met.

National Coverage Determinations (NCDs) have been established by CMS to identify 23 laboratory tests that require additional medical necessity

documentation for 66 different CPT codes and ICD-9 codes that are acceptable for each of these tests. LCDs are required to be consistent with National Coverage Determinations. LCDs can be obtained from the local Medicare Carrier or Fiscal Intermediary. NCDs are contained in the <u>Medicare National Coverage</u> <u>Determinations Manual</u> or by logging onto the CMS website <u>www.cms.hhs.gov/CoverageGenInfo/04_LabNCDs.asp</u>.

Whenever VCUHS receives a requisition without an ICD-9 code or diagnosis narrative for a limited coverage test, the Pathology Laboratories will contact the physician's office to obtain the missing information or ask for a copy of a properly executed **Advanced Beneficiary Notice (ABN)**.

ADVANCE BENEFICIARY NOTICE (ABN)

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When a physician/provider believes that a test or procedure may not meet medical necessity guidelines, an ABN notifying the patient of Medicare's possible denial of payment must be given to the patient. Patients must be notified before the test is ordered, that payment might be denied by Medicare; the patient can then decide if he or she wants the tests performed and accepts responsibility for payment. Without a valid ABN, the laboratory is prohibited from billing the patient for the services provided.

An acceptable ABN must meet the following criteria:

- The ABN notice must be given in writing, prior to testing or procedures being provided.
- The ABN notice must include the patient's name, date, description of test/procedure, the estimated costs of these services, the reason(s) each test/procedure may not covered by Medicare and the patient's final decision on how to proceed after the ABN notice has been explained.
- The patient must be asked to sign and date the ABN each time an ABN is required, indicating that he or she accepts financial responsibility for payment of the services provided should Medicare deny payment.

ABN FORM – ENGLISH [Go to Top]

(A) Notifier(s): (B) Patient Name:

(C) Identification Number:

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: If Medicare doesn't pay for (D) below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the (D) below.

(D)	(E) Reason Medicare May Not Pay:	(F) Estimated Cost:

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the (D) listed above. Note: If you choose Option 1 or 2, we may help you to use any other

(G) OPTIONS:	Check only one bo	ox. We cannot	choose a box for you.		
OPTION 1. I want the (<i>D</i>) listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.					
OPTION 2. 1w	ant the <i>(D)</i>	listed above,	but do not bill Medicare. You may		
			t appeal if Medicare is not billed.		
OPTION 3. I do	n't want the <i>(D)</i>	listed abo	ve. I understand with this choice		
I am not responsible fo	r payment, and I can	not appeal to s	ee if Medicare would pay.		
(H) Additional Informati	on:				

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

	(I) Signature:	(J) Date:	
	According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collecti	on of information unloss it displays a valid OMP control	
	number. The valid OMB control number for this information collection is 0938-0566. The time requi		
	average 7 minutes per response, including the time to review instructions, search existing data resour		
i	information collection. If you have comments concerning the accuracy of the time estimate or sugges	tions for improving this form, please write to: CMS, 7500	

Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850. Form CMS-R-131 (03/08)

Form Approved OMB No. 0938-0566

ABN FORM – SPANISH [Go to Top]

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(B) Nombre del paciente: (C) Número de identificación:

NOTIFICACIÓN PREVIA DE NO-COBERTURA AL BENEFICIARIO (ABN)

<u>NOTA:</u> Si Medicare no paga (D) ______a a continuación, usted deberá pagar. Medicare no paga todo, incluso ciertos servicios que, según usted o su médico, están justificados. Prevemos que Medicare no pagará (D) ______a continuación.

(D)	(E) Razón por la que no está cubierto por Medicare:	(F) Costo estimado:

LO QUE USTED NECESITA HACER AHORA:

- Lea la presente notificación, de manera que pueda tomar una decisión fundamentada sobre la atención que recibe.
- Háganos toda pregunta que pueda tener después de que termine de leer.
- Escoja una opción a continuación sobre si desea recibir (D) ______mencionado anteriormente.

Nota: Si escoge la opción 1 ó 2, podemos ayudarlo a usar cualquier otro seguro que tal vez tenga, pero Medicare no puede exigirnos que lo hagamos.

G) OPCIONES: Sírvase marcar un recuadro solamente. No podemos escoger un recuadro por
usted.
OPCIÓN 1. Quiero (D) mencionado anteriormente. Puede cobrarme ahora, pero
ambién deseo que se cobre a Medicare a fin de que se expida una decisión oficial sobre el pago, la
cual se me enviará en el Resumen de Medicare (MSN). Entiendo que si Medicare no paga, soy
esponsable por el pago, pero puedo apelar a Medicare según las instrucciones en el MSN. Si
Medicare paga, se me reembolsarán los pagos que he realizado, menos los copagos o deducibles.
OPCIÓN 2. Quiero (D) mencionado anteriormente, pero que no se cobre a
Medicare. Puede solicitar que se le pague ahora dado que soy responsable por el pago.
No tengo derecho a apelar si no se le cobra a Medicare.
OPCIÓN 3. No quiero (D) mencionado anteriormente. Entiendo que con esta

opción no soy responsable por el pago y no puedo apelar para determinar si pagaría Medicare. (H) Información adicional:

En esta notificación se da a conocer nuestra opinión, no la de Medicare. Si tiene otras preguntas sobre la presente notificación o el cobro a Medicare, llame al **1-800-MEDICARE** (1-800-633.4227/TTY: 1.877.486.2048)

Al firmar abajo usted indica que ha recibido y comprende la presente notificación. También se le entrega una copia.

(I) Firma:	(J) Fecha:

De conformidad con la Ley de reducción de los tramites burocraticos de 1995, nadie estará obligado a responder en todo pedido para recabar información a menos que se identifique con un número de control OMB valido. El número de control OMB valido para esta recolección de información es 0938-0566. El tiempo necesario para completar esta solicitud de información es calcula, en promedio, 7 minutos por respuesta, incluido el tiempo para revisar las instrucciones, buscar en fuentes de datos existentes, recabar los datos necesarios y llenar y revisar los datos recesarios. Si tiene comentarios sobre la precisión del cietupo o sugerencias para mejorar el presente formulario, sirvase escribir a: CMS, 7500 Security Boulevard, Attr: PRA Reports Clearance Officer, Baltimore, Marvland 21244-1850.

Formulario CMS-R-131 (03/08)

Formulario aprobado OMB Nº 0938-0566

ANNUAL PHYSICIAN NOTIFICATION

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The VCUHS Department of Pathology notifies healthcare providers at VCUHS and members of the medical community who refer laboratory samples for testing by sending an annual notification of the requirements and policies related to Medical Necessity, components of AMA approved test panels, and Advanced Beneficiary Notices on or about the onset of each calendar year.



February 2009

Annual Provider Notification of Medical Necessity and Laboratory Services

Dear Provider,

Providers are seeing an increase in denials related to medical necessity, even for legitimate services. Because appealing claims is often burdensome, many organizations choose to write off these denials. However, doing this means a loss of revenue and can puts an organization at risk for fraud and abuse charges.

Consistent denials for a single type of test repeatedly performed could cost a facility millions of dollars each year. Proper documentation efforts and compliant lab orders will help with compliance and to provide patients with the highest quality of care. Additionally, if a facility fails to obtain an advance beneficiary notice (ABN) for a non-covered service, then they are unable to bill the patient for the service, and the facility essentially provides "free" care. If a facility does this frequently enough, the government could find the hospital in violation of the anti-kickback statute for offering patients an inappropriate incentive.

Medical Necessity is defined as *diagnosing and treating an illness or injury; or improving the function of a malformed body member*. The patient's documented signs, symptoms, or diagnosis must support the services or treatment in order to be considered medically necessary. In general, Medicare covers only those items or services that are medically necessary.

Please note that the Office of the Inspector General may decide, at any time, that a physician is subject to civil penalties for ordering unnecessary tests.

Medicare does not cover certain screening tests, cosmetic surgeries, most vaccinations, selfadministered outpatient medicines, investigational drugs and treatment, or personal comfort items. However, Medicare now pays for influenza and pneumonia vaccinations; cervical, colon, and prostate cancer screenings; diabetes and cholesterol screenings; and monitoring and selfmanagement training for diabetes patients. VCUHS works hard to maintain corporate compliance. With that in mind, please double-check all documentation and lab orders to ensure that they are complete and correct. Taking the extra time to check orders will go a long way toward helping VCUHS achieve compliance. Enclosed is a chart outlining VCUHS's Laboratory Panel Components and the Medicare allowable amount charged for each test. Please review this enclosure and contact the Pathology Lab should you have any questions concerning this notification at (804) 828-9750.

Thank you for your continued efforts and support.

Sincerely, David S. Wilkinson, M.D., Ph.D., Chairman of Pathology Tom Dilts, Vice Chair for Lab Administration and Operations

(enclosure)

Panel Lab Tests Offered, Pricing Methodology and Fees

Panel	CPT	Components	Medicare
Description	CODE		Allowance
Electrolytes	80051	Carbon dioxide, Chloride Potassium, Sodium	\$9.80
Basic	80048	Calcium total, Carbon dioxide, Chloride,	\$11.83
Metabolic		Creatinine, Glucose, Potassium, Sodium, Urea	
		nitrogen	
Comprehensive	80053	Albumin, Bilirubin (total), Calcium (total) Carbon	\$14.77
Metabolic		dioxide, Chloride, Creatinine, Glucose,	
		Phosphatase, alkaline, Potassium, Protein, total,	
		Sodium, Transferase, alanine amino, Tansferase	
		(aspartate amino), Urea nitorgen	
Hepatic Panel	80076	Albumin, Bilirubin (total), Bilirubin (direct),	\$11.42
		Phosphatse (alkaline), Protein (total), Transferase	
	(alanine amino), Transferase (aspartate amino)		
Acute Hepatitis	80074	Hepatitis A antibody (IgM antibody), Hepatitis B	\$66.54
Panel		core antibody (IgM antibody), Hepatitis B surface	
		antigen, Hepatitis C antibody	
Lipid Panel	80061	Cholesterol (serum,total), Lipoprotein (direct	\$18.72
		measure, high density), Triglycerides	

These are the Panels available for ordering along with the proper CPT codes.

The Component Column outlines which tests are included in each profile.

The VCUHS Pathology Laboratory bills Medicare for the most appropriate profile. Our billing system bundles individual tests to the largest profile, components of panels only billed individually when they are ordered alone. Only AMA approved profiles are offered.

The financial column contains the Medicare National Limitation Amount for each profile.