EVANSTON NORTHWESTERN HEALTHCARE

news

Pathology Perspective

Volume VI, No. 1, 2007

MEDICARE COMPLIANCE INFORMATION

By: James Dohnal, Ph.D., Director of Core Laboratory, Evanston Hospital

Advance Beneficiary Notice (ABN)

Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS) Program Memorandum AB-02-168 (http://www.cms.hhs.gov/transmittals/downloads/ab02168.pdf)

An ABN is a written notice a physician or supplier gives to a Medicare Beneficiary before services/items are furnished when the physician or supplier believes that Medicare probably or certainly will not pay for some or all of the services or items on the basis of the following statutory exclusions.

- Medical reasonableness and necessity
- Custodial care
- Mammography
- Pap smear
- Pelvic exam
- Glaucoma
- Prostate cancer
- Colorectal cancer screening tests

ABN's are designed for use with Medicare beneficiaries only, including those who are dually-eligible for Medicare and Medicaid. ABNs are not for use with patients who are not Medicare beneficiaries. The purpose of the ABN is to inform a Medicare beneficiary, before he or she receives specified items or services that otherwise might be paid for, that Medicare probably will not pay for them on that particular occasion. The ABN, also, allows the beneficiary to make an informed consumer decision whether or not to receive the items or services for which he or she may have to pay out of pocket or through other insurance.

In addition, the ABN allows the beneficiary to better participate in his/her own health care treatment decisions by making informed consumer decisions. If the physician or supplier expects payment for the items or services to be denied by Medicare, the physician or supplier must advise the beneficiary before items or services are furnished that in their opinion the beneficiary will be personally and fully responsible for payment. To be "personally and fully responsible for payment" means that the beneficiary will be liable to make payment "out-of-pocket," through other insurance coverage (e.g. employer group health plan coverage), or through Medicaid or other Federal or non-Federal payment source. The physician or supplier must issue notices each time and soon as they make the assessment that Medicare payment probably or certainly will not be made.

To be acceptable, an ABN must be on the approved Form CMC-R-131, (see enclosed) must clearly identify the particular item or service, must state that the physician or supplier believes Medicare is likely (or certain) to deny payment for the particular item or service, and must give the physician's or supplier's reason(s) for their belief that Medicare is likely (or certain) to deny payment for the item or service.

A physician or supplier should not give an ABN to a beneficiary unless the physician or supplier has some genuine doubt regarding the likelihood of Medicare payment. Giving ABNs for all claims or items or services (i.e. "blanket ABNs") is not an acceptable practice. Notice must be given to a beneficiary on the basis of a genuine judgement about the likelihood of Medicare payment for that individual's claim.

A physician or supplier is prohibited from obtaining beneficiary signatures on blank ABNs and then completing the ABNs later. An ABN, to be effective, must be completed before the delivery to the beneficiary.

The CMS information brochure "What Doctors Need to Know about the Advance Beneficiary Notice (ABN) is located at: (http://www.cms.hhs.gov/medlearn/abn_readers.pdf)

ABN Instructions

- **Patient Name**

The physician or supplier enters the name of the patient, not substituting the name of an authorized representative.

⊙ **Medicare Health Insurance Claim Number (HICN)**

The physician or supplier enters the patient's Medicare HICN. Do not invalidate an ABN solely on the lack of a Medicare HICN unless the beneficiary recipient of an ABN alleges that the ABN was signed by someone else of the same name and you cannot resolve the matter with certainty.

⊙ **Medicare does not pay for these tests for your condition**

The physician or supplier specifies the laboratory tests for which he/she/it expects Medicare will not pay in the box. The laboratory tests at issue must be described in sufficient detail so that the patient can understand what laboratory tests may not be furnished. The use of standard laboratory test descriptions is permitted. HCPCS codes by themselves are not acceptable as descriptions.

⊙ **Estimated Cost**

The physician or supplier may provide the patient with an estimated cost of the items and/or services. The patient may ask about the cost and jot down an amount in this space. The physician or supplier should respond to such inquiries to the best of their ability. The lack of an amount does not invalidate the ABN: an ABN will not be considered to be defective on that basis. In the case of an ABN which includes multiple items and/or services, it is permissible for the physician or supplier to give estimated amounts for the individual items and/or services rather than an aggregate estimate of costs. (ENHLS can provide patient fee schedule upon request.)

⊙ **Options 1 and 2 Boxes**

The patient must personally select an option.

⊙ **Date**

The patient or his or her authorized representative should enter the date on which he or she signed the ABN. If the date is filled in by the physician or supplier and the beneficiary or his or her authorized representative does not dispute the date, you should accept that date. Do not reject ABNs simply because the date is typed or printed.

⊙ **Signature**

The beneficiary himself or herself may sign an ABN. In the case of a beneficiary who is incapable or incompetent, his or her "authorized representative", may sign an ABN. The beneficiary retains the patient's copy of the signed and dated ABN and the physician or supplier retains the original ABN. These copies will be relevant in case of any future appeal.

Diagnosis Codes (ICD-9)

Medicare regulations (Program Memorandums B-03-045, B-03-046, AB-03-091) require the ordering physician to provide the laboratory with accurate and encounter specific ICD-9 codes when ordering laboratory testing. Medicare uses this information to determine if the testing is eligible for reimbursement. Medicare has instructed the laboratory to contact the ordering physician if this information is not provided. A physician that does not provide this information on a regular basis is considered by Medicare to be in violation of Medicare regulations.

The most current information from the Center for Medicare & Medicaid Services (CMS) regarding National Coverage Determinations (NCD) can be found on the CMS website at:

http://www.cms.hhs.gov/coverage/labindexlist.asp

ENHLS Policy Regarding the Billing of Medicare

All ENHLS staff members must comply with all Medicare regulations at all times. Policies have been written with the goal of complete compliance and are reviewed regularly to ensure that they are compliant with the most current Federal regulations. Staff members are provided training in Medicare regulations and are clearly instructed to follow policy. They are encouraged to bring to the attention of management any policy or procedure that they think may be in conflict with the Medicare regulations. Their performance is monitored regularly and deviation from policy is addressed with additional training. Repeated deviation from policy results in disciplinary action up to and including termination. Any deviation from policy that might represent a deliberate attempt to violate the Medicare regulations are reported to the Medicare program.

Professional Courtesy

The Office of the Inspector General (OIG) interpret a discount on laboratory testing for physicians, their office staff and family members as a potential kickback to the physician. For this reason;

ENHLS DOES NOT OFFER PROFESSIONAL COURTESY, ON OUR LABORATORY SERVICES TO PHYSICIANS OR THEIR EMPLOYEES OR FAMILY MEMBERS.

Testing Supplies

A laboratory may provide a physician with supplies that are DIRECTLY related to the testing that is submitted to the laboratory in amounts PROPORTIONAL to the volume of testing performed. Any supplies outside of these limits are considered a kickback to the physician and therefor fraud. Additionally, multi-purpose supplies outside of these limits supplied are considered a kickback. For example, a fax machine supplied by the laboratory for faxing results is considered a kickback because the client could use the fax machine for non-laboratory purposes. Other items included in this category include latex gloves, laboratory coats and medical waste disposal.

Test Profiles

Federal law requires that each test billed to Medicare meet Medicare's medical necessity guidelines. Medicare believes that the use of profiles greatly increases the likelihood that medically unnecessary tests will be billed to Medicare. Therefore, the use of profiles is strongly discouraged. When ordering tests. Please use the following guidelines.

- Order tests on an individual basis determined by the patient's medical condition.
- Limit orders to only those tests that are directly related to the condition being treated.
- Limit profiles to the AMA CPT Code Committee/Medicare listed below.
- ENHLS does not offer customized profiles other then the ones recognized by the AMA and Medicare.

Effective January 01, 2007

Test Code	Profile Name (CPT/Medicare Fee)	Components
4255	Acute Hepatitis Panel 80074/$66.54	Hepatitis A IgM Ab (86709), Hepatitis B core IgM Ab (86705), Hepatitis B surface Ag (87340), Hepatitis C Ab (86803)
5005	Basic Metabolic Panel 80048/$11.83	Calcium (82310), Carbon dioxide (82374), Chloride (82435), Creatinine (82565), Glucose (82947), Potassium (84132), Sodium (84295), BUN (84520)
5130	Cardiac Risk 80061/$18.72	Cholesterol total (82465), HDL (83718), Triglycerides (84478), Relative risk, Calculated LDL
5006	Comprehensive Metabolic Panel 80053/$14.77	Albumin (82040), Bilirubin total (82247), Calcium (82310), Carbon dioxide (82374), Chloride (82435), Creatinine (82565), Glucose (82947), Alkaline Phosphate (84075), Potassium (84132), Protein total (84155), Sodium (84295), ALT/SGPT (84460), AST/SGOT (84450), BUN (84520)
21	Electrolytes 80051/$9.80	Carbon dioxide (82374), Chloride (82435), Potassium (84132), Sodium (84295)
5004	Hepatic Functional Panel 80076/$11.42	Albumin (82040), Bilirubin total (82247), Bilirubin direct (82248), Alkaline phosphate (84075), Protein total (84155), ALT/SGPT (84460), AST/SGOT (84450)
5011	Renal Function Panel 80069/$12.13	Albumin (82040), Calcium (82310), Carbon dioxide (82374), Chloride (82435), Creatinine (82565), Glucose (82947), Phosphorus inorganic (84100), Potassium (84132), Sodium (84295), BUN (84520)

Although approved by the AMA CPT Code Committee, Medicare generally denies the panels listed below.

5901	General Health 80050	Comprehensive Metabolic panel (80053), CBC w/Auto Diff/Platelet (85027), TSH (84443)
9002	Obstetric Panel 80055	CBC w/Auto diff/Platelet (85027), Hepatitis B Surface Ag (87340), Rubella (86762), RPR (86592), Antibody screen (86850), ABO (86900)/Rh (86901)

"Help Us to Help Your Patients"

By: Linda Blacklidge-Schroeder, Asst. VP Laboratory Services

The Hospital Outpatient Laboratories service over 10,000 patient visits each month. With all of these patients being seen on a walk-in basis, it is sometimes difficult to care for patients in the most efficient manner. We would welcome your assistance in helping us to help your patients.

Insurance Issues

Insurance requirements are confusing to most of us, but there have been some significant changes in the last several months that have affected the patients under our care. United Healthcare recently awarded their national lab contract to LabCorp instead of Quest Laboratories. Many patients and physicians interpreted this change to mean that patients were required to go to LabCorp. Since ENH Hospitals have a contract with United Healthcare to provide inpatient services, we are allowed to provide outpatient services as well. Our contract with United Healthcare is valid through March of 2008. Please let your patients, who have United Healthcare, know that they can still be serviced at the ENH Outpatient Laboratories.

We have seen some patients present with LabOne or Quest Test Requisitions. In these instances the patient must go to a LabOne or Quest Draw Station to have their lab work processed. Quest now owns LabOne, so patients may go to a Quest facility for either order. Failure to have their lab work performed by LabOne or Quest will result in denial of the charges and require that the patient assume charge liability. Location of local Quest draw stations can be determined by calling the phone number on the test requisition.

Laboratory Orders

Frequently patients are instructed to come to one of our Outpatient Labs to have blood work done. The patients are told that the orders will be put in the computer system and they do not require any paperwork. On many occasions, we are unable to find any computer orders on the patient. When this occurs, we contact the ordering physician to determine the testing required. If we are unable to contact the physician, we ask the patient if they know what testing is to be performed. If they do not know, we review the patient lab history of testing, (if available), or draw a "rainbow" of tubes so the patient can be served and not unduly inconvenienced. We then follow up with the physician to determine the appropriate testing. The point of this discussion is to bring to light the fact that not only is the patient inconvenienced, but every patient who is standing in line behind him/her is inconvenienced. We are tracking the number of patients who present without orders and have found it to be as high as 7%.

A related problem to "no orders," is multiple order sets placed by the same or several consulting physicians. When the lab staff pull up orders in Epic, it is difficult to determine which orders are to be released due to the multiple sets. Often, our only recourse is to ask the patient if they know what testing is supposed to be performed. The preferred procedure is for the physician offices to provide a final copy of the desired tests from Epic and instruct the patient to bring this order with them to the Outpatient Laboratory. Please make sure these orders contain the patient's name and birthday. We have noted patients presenting with copy of Epic orders that do not display the patient's name. Two patient identifiers are required to insure that we have properly identified the patient.

Hospital Registration

Hospital outpatients need to stop at Central Registration to register prior to proceeding to the OPL. (Outreach ENHLS clients and patients already set up with standing orders are exempt from this step). The registration process provides the Laboratory with a valid account number by which lab orders can be entered into the Lab Information System. Patients who present directly to the OPL need to be sent back to Registration before their lab orders can be processed. We are trying a number of different processes to improve this workflow. At Evanston and Highland Park Hospitals, we are having patients "phone register" from the OPL if they present first to the OPL. At Glenbrook Hospital, we are starting a pilot program having patients register in the Hospital system and register for Lab Services in one step. We are anxious to hear patients' perception of this new service. In the future, we are considering the possibility of advanced patient phone registration as provided by other ancillary services.

We look forward to your help in our endeavor to make the process in the Outpatient Lab easier for your patients. We welcome comments and suggestions from you on how we can continue to improve our services. If you gave any questions, please contact Linda Blacklidge-Schroeder at 570-2738 or LBlacklidge@enh.org

Use of Multispectral Imaging in Pathology

By: Keith J. Kaplan, MD, Department of Pathology and Laboratory Medicine, Evanston Hospital

Multispectral imaging (MSI) has been in use for over half a century. Owing to advances in digital photographic technology, multispectral imaging is now used in settings ranging from clinical medicine to industrial quality control. MSI entails acquiring several images of the same scene using different spectral bands. For instance, a digital color camera detects three separate images for the red, green and blue components of light. Collecting several spectral bands generally provides more information than would be obtained from a single monochrome image. This idea has been applied in the field of remote sensing for over 20 years by NASA and others. Earth observation satellites are capable of

acquiring over 50 spectral bands spanning visible and non-visible wavelengths such as infrared. The full set can be processed to identify different kinds of land use automatically.

MSI is in a transition period from its role as an exotic technique to being offered in one form or another by all the major microscopy manufacturers for routine clinical use in anatomic pathology as well as other medical specialties including gastroenterology for use in colon cancer screening, surgery for sentinel lymph node detection and dermatology for melanoma and non-melanoma (1). This is because MSI provides solutions to some of the major challenges in fluorescence-based imaging, namely ameliorating the consequences of the presence of auto-fluorescence and the need to easily accommodate relatively high levels of signal multiplexing. MSI, which spectrally characterizes and computationally eliminates auto-fluorescence, enhances the signal-to-background dramatically, revealing otherwise obscured targets. Some technologies used to generate multispectral images are compatible with only particular optical configurations, such as point-scanning laser confocal microscopy. Band-sequential approaches, such as those afforded by liquid-crystal tunable filters (LCTFs), can be conveniently coupled with a variety of imaging modalities, which, in addition to fluorescence microscopy, include brightfield (non-fluorescent) microscopy as well as small, noninvasive in-vivo imaging.

Brightfield microscopy is the chosen format for histopathology, which relies on immunohistochemistry to provide molecularly resolved clinical information. However, in contrast to fluorescent labels, multiple chromagens, if they spatially overlap, are much harder to separate and quantify, unless MSI approaches are used. In-vivo imaging is a rapidly growing field with applications in basic biology, drug discovery, and clinical medicine. The sensitivity of fluorescence-based in-vivo imaging, as with fluorescence microscopy, can be limited by the presence of significant autofluorescence, a limitation which can be overcome through the utilization of MSI (2).

Hematoxylin and eosin-based stains and immunohistochemical procedures together form the backbone of clinical histopathology. Novel imaging and analytical methods can extract additional qualitative and quantitative information from these relatively venerable procedures. In particular, MSI approaches appear promising. In immunohistochemistry, for example, they can be used to: 1) enable detection of target co-localization; 2) elucidate the spatial relationships between IHC-identified cell types; and 3) detect multiple signal transduction events. Moreover, MSI-enabled multiplexing can reduce sample depletion by allowing multiple studies to be performed on individual sections. Multiplexing is accomplished by measuring absorbance spectra at every pixel of an image - appropriate algorithms then automatically resolve absorption patterns of overlapping chromagens to generate quantitative images of individual analytes. Examples include ER and PR-expression in breast cancer, as well as of double-immunophenotyping in hematopathology. With standard H&E-stained slides, spatial and spectral characteristics of the samples can be used to generate reasonably accurate mimics of some special stains, particularly those highlighting fibrosis (2).

Using conventional color imaging, you would have to stain for ER and PR stains on successive sections, and would not be able to correlate co-expression on a cell-by-cell basis. All one could say is that the tumor is double-positive. Also, if you are seeking rare double-positive cells, you can't expect to discover those with single stains on serial sections. Literature suggest that it's important to identify whether an individual cell rather than a tumor is positive for ER/PR in terms of developing directed therapies going forward.

Determination of the expression and spatial distribution of molecular epitopes, or antigens, in patient tissue specimens has substantially improved the pathologist's ability to classify disease processes. Certain disease pathophysiologies are marked by characteristic increased or decreased expression of developmentally controlled antigens, that currently form the foundation for understanding lymphoid malignancies. While chromogens and organic fluorophores have been utilitized for some time in immunohistochemical analyses, developments in synthetic, inorganic fluorophore semiconductors, namely quantum dots, offer a versatile alternative reporter system. Quantum dots are stable fluorophores, are resistant to photobleaching, and are attributed with wide excitation ranges and narrow emission spectra (3,4).

Multispectral imaging promises to greatly increase the utility and information content of multiple simultaneous immunostains, enabling per-cell multiparameter measurements. In the case of H&E-stained slides, it appears that MSI can also extract additional information and reduce the use of special stains and their associated costs and delays (4).

The marriage of two technologies, a hyperspectral imaging microscope developed as part of the genome project and already translated to the pathology laboratory and a high performance image analysis package originally built by NASA for the analysis of remotely sensed planetary images, may potentially revolutionize the quality and speed by which pathological samples can be analyzed by eliminating the need for staining prior to imaging. Hyperspectral imaging provides an unprecedented ability for multiplexing and the ability to resolve minute but robustly detectable differences in spectral signatures, which once identified via software, can be artificially enhanced. We have demonstrated that this system can produce digitally stained images that closely resemble those from H&E stained samples, but

obtained directly from fresh or archived unstained samples, thus enabling the capability for immediate, real time analysis of surgically resected samples essential to adjust treatment and procedures.

We propose a new diagnostic capability is possible using hyperspectral digital microscopy, hyperspectral data analysis and surrogate biomarker techniques such that cellular and molecular (e.g. proteomic) approaches to disambiguating dysplastic or malignant cells or analyzing multiple surrogate prognostic markers simultaneously which may lead to significantly improved classification and prognosis of lesions, earlier diagnosis and more effective disease management.

Interested clinical investigators are encouraged to contact Dr. Kaplan at 847-570-4024 or kaplan@northwestern.edu.

References:

1. Tomatis S, Bono A, Bartoli C, Carrara M, Lualdi M, Tragni G, Marchesini R. Automated melanoma detection: Multispectral imaging and neural network approach for classification. Med Phys 2003;30(2):212-211.
2. Levenson RM, Mansfield JR. Multispectral imaging in biology and medicine: slices of life. Cytometry A 2006;69(8):748-758.
3. Byers RJ, Di Vizio D, O'connell F, Tholouli E, Levenson RM, Gossard K, Twomey D, Yang Y, Benedettini E, Rose J, Ligon KL, Finn SP, Golub TR, Loda M. Semiautomated multiplexed quantum dot-based in situ hybridization and spectral deconvolution. J Mol Diagn 2007;9(1):20-29.
4. Fountaine TJ, Wincovitch SM, Geho DH, Garfield SH, Pittaluga S. Multispectral imaging of clinically relevant cellular targets in tonsil and lymphoid tissue using semiconductor quantum dots. Mod Pathol. 2006;19(9):1181-1191.

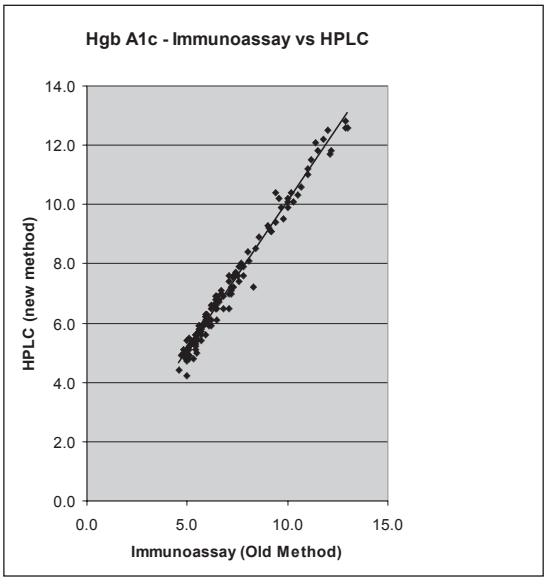
Hemoglobin Determination by HPLC

By: James Dohnal, Ph.D., Director of Core Laboratory, Evanston Hospital

On Monday February 12, 2007 the CORE Laboratory in the Department of Pathology and ENH Laboratory Services implemented a new methodology for Hemoglobin A1c determinations. The new methodology is a High Performance Liquid Chromatography (HPLC) assay using an ion-exchange column. The new method provides improved precision (CV of 1-2 % vs. 3-4% for the previous Immunoassay method).

Specimen requirements (whole blood in a Lavender Top Tube) remain unchanged and testing will continue to be performed on a daily basis between the approximately hours of 12 Noon and 3 AM.

The new method, as with the previous method, is certified by the National Glycohemoglobin Standardization Program (NGSP), so National guidelines concerning reference ranges and the interpretation of results should continue to guide your use of the values obtained. As would be expected with two methods that are by certified by the NGSP, correlation between the two methods is excellent. (See data below.)



HPLC method = 1.002(Immunoassay method) + 0.0523
R = 0.9911

131 data points: Mean = 7.08% (Immunoassay) vs. 7.14% (HPLC)
Median = 6.3% (Immunoassay) vs. 6.5% (HPLC)

In addition to quantitating the Hemoglobin A1c level, the new method will detect the presence of abnormal hemoglobins, although it can not provide a definitive identification. When abnormal hemoglobin is detected, the following comment will be appended to the report:

"An abnormal hemoglobin has been detected during the performance of the Hemoglobin A1c assay. If clinically indicated, please order a Hemoglobin electrophoresis determination."

If there are any questions or comments, please contact Dr Dohnal at 847-570-2784 or jdohnal@enh.org.

Editor: Robert Rosecrans, Ph.D.
rrosecrans@enh.org
847-926-5078