Medicare and the Laboratory

KATHY HANSEN

Keywords: Medicare, carrier, fiscal intermediary, medical necessity, correct coding, medically unlikely edits

Abbreviations: ABN = Advance Beneficiary Notice; ASCLS = American Society for Clinical Laboratory Science; BBA = Balanced Budget Act; CBC = Complete blood count; CCI = Correct Coding Initiative; CLFS = Clinical Laboratory Fee Schedule; CMS = Center for Medicare and Medicaid Services; CPT = Current Procedural Terminology; DRG = Diagnosis Related Group; EOB = Explanation of Benefits; FI = Fiscal intermediary; HCFA = Healthcare Financing Agency; HCPCS = Healthcare Common Procedure Coding System; HMO = Health Maintenance Organization; ICD = International Classification of Diseases; LCD = Local Coverage Decision; LMRP = Local Medical Review Policy; MAC = Medicare Administrative Contractor; MUE = Medically Unlikely Edit; NCD = National Coverage Decision; PC = Professional Component; TC = Technical Component; TEFRA = Tax Equity and Fiscal Responsibility Act ; UB = Uniform Billing

Clin Lab Sci 2009;22(2):94

LEARNING OBJECTIVES:

1. Describe the purpose of the Medicare program.
2. Compare the payment methodologies for inpatient and outpatient laboratory services under Medicare.
3. Describe the differences between a fiscal intermediary, a carrier, and a MAC.
4. List three mechanisms used by CMS to limit payments to laboratories for services provided to Medicare beneficiaries.
5. Contrast Correct Coding Initiative limitations with those imposed by Medically Unlikely Edits.

The Focus section seeks to publish relevant and timely continuing education for clinical laboratory practitioners. Section editors, topics, and authors are selected in advance to cover current areas of interest in each discipline. Readers can obtain continuing education credit (CE) through P.A.C.E.® by completing the continuing education registration form, recording answers to the examination, and mailing a photocopy of it with the appropriate fee to the address designated on the form. Suggestions for future Focus topics and authors, and manuscripts appropriate for CE credit are encouraged. Direct all inquiries to the Clin Lab Sci Editorial Office, Westminster Publishers, 315 Westminster Court, Brandon MS 39047. (601) 214-5028, (202) 315-5843 (fax). westminsterpublishers@comcast.net.

***Kathy Hansen, CLS(NCA)** is **Director of Laboratory Operations** at the University of Minnesota Medical Center, Minneapolis, MN and an **Advisor** for the ASCLS Government Affairs Committee*

***Address for Correspondence:** Kathy Hansen, Director, Laboratory Operations, University of Minnesota Medical Center, Fairview, MMC 198, 420 Delaware St SE, Minneapolis, MN 55455. Khansen3@fairview.org.*

This article discusses the impact on the laboratory of Medicare payment policies and limitations imposed on payment for laboratory services. As the size of the population receiving Medicare benefits increases, and other payers adopt similar polices, the challenge to the laboratory becomes greater.

The Medicare program was created by legislation amending the Social Security Act that was signed into law on July 30, 1965 by President Lyndon Johnson. The bill-signing ceremony was held at the Truman Library in Independence, MO, as a tribute to former President Harry S. Truman, who had first proposed health insurance legislation 20 years before.[1]

Medicare legislation passed despite opposition from the American Medical Association, which characterized it as socialized medicine.

Medicare has grown as the population has aged and currently covers 44.8 million beneficiaries[2], about 14% of the U.S. population, with this number expected to grow significantly as the 76 million members of the baby boomer generation, born in 1946–1964 [3], become eligible for the program's benefits. By 2031, the number of beneficiaries will be an estimated 77 million[4]. Medicare beneficiaries typically constitute a significant percentage of patients served by hospital laboratories, physician office laboratories, and independent laboratories. A report by the Institute of Medicine reported that in 1999, clinical laboratories derived 29% of their revenues from Medicare and 12% from Medicaid[5].

The Medicare program is designed to cover the cost of diagnosis and treatment for illness, and does not cover wellness services or screening for disease in the absence of symptoms. A few notable exceptions for screening services that are covered by Medicare were mandated by legislation passed by Congress. This list has grown over recent years and includes pap smears, mammograms, PSA screening, cholesterol, glucose, and occult blood testing[6].

Payment policies

Initially, laboratory testing under Medicare was paid based on a percentage of charges submitted by the laboratory. In 1984, 19 years after the Medicare program was started, the Medicare Outpatient Clinical Laboratory Fee Schedule (CLFS) was established as a method of controlling the cost of these services.[7] (The CLFS is discussed in detail in another section of these Focus articles.) The fee schedule identifies tests using codes known as Current Procedural Terminology (CPT) or HCPCS (Healthcare Common Procedure Coding System) codes. CPT codes are developed and maintained by the American Medical Association, and HCPCS codes are generated by CMS.

Laboratory testing provided to Medicare beneficiaries who are hospital inpatients is included in the payment for the admission under the Diagnosis Related Group (DRG), One prospective payment is provided for all services provided during the admission, based on the patient's diagnosis. DRGs were established under the Tax Equity and Fiscal Responsibility Act (TEFRA) legislation of 1983[8]. Separate payment is made for physician services, including pathology services, provided to a Medicare inpatient.

The Medicare program is administered by the Center for Medicare and Medicaid Services (CMS), formerly known as the Healthcare Financing Agency (HCFA). The payment policies promulgated by Medicare may also apply to Medicaid programs in the various states. The degree to which this is true varies by state. By statute, Medicaid cannot pay more for a given service than Medicare does. In addition, Medicare policies are often adopted or adapted by private insurers and health maintenance organizations (HMOs). Variations in payment policies present challenges to billing departments.

For purposes of payment, Medicare is divided into Medicare Part A, Part B, Part C, and Part D. Part A covers hospital inpatient services. Part B covers physician professional services and outpatient services provided in clinics and physician offices that are not hospital-based. For the hospital laboratory, this means that a test that has charges for both a technical component and a professional interpretive component, such as electrophoresis, may be billed to the Part A contractor for the technical component (TC) of the test and to the Part B contractor for the professional component (PC) if the pathologists providing that service are hospital employees. Part C covers Medicare managed care programs and Part D covers prescription drug benefits.

Historically, claims for Part A services have been submitted to a Fiscal Intermediary (FI) on a Uniform Billing (UB) claim form, and claims for Part B services are submitted to a Medicare carrier on a 1500 claim form. The exception is that hospitals may submit claims to their FI for Part B services for patients having hospital-based outpatient services. If the hospital bills professional fees for employed physicians, such as employed pathologists or radiologists, those claims must still go to the carrier. Providers are now required to submit claims electronically.

Another feature of laboratory payment policy relates to tests that are referred to a reference laboratory. Hospitals may bill these directly to the FI, for both inpatients and outpatients in hospital-based clinics, and the hospital pays the reference laboratory for the test. This is known as the "lab-to-lab" exception. However, services provided to all other outpatients or non-patients must be "direct billed" to Medicare by the performing laboratory, in this case the reference laboratory. The facility where the sample originates must provide the performing laboratory with billing information and the performing laboratory then submits the claim.

Once more than one hundred FIs and carriers were involved in processing claims for the Medicare program, generally one of each per state. Various insurance companies bid on contracts to serve as FIs and/or carriers, and these contracts have been awarded to different companies over the years. Now the FI or carrier is often located in a different state than the one(s) for which it processes claims.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provided for the consolidation of the activities of the FIs and carriers into 15 Medicare Administrative Contractors (MACs), which processes claims for both Part A and Part B services on a regional basis. CMS will replace the Medicare carriers and fiscal intermediaries with 19 MACs (15 for Part A and Part B claims processing and four for Durable Medical Equipment). The process of

awarding contracts to MACs began in 2005 and is to be complete by 2009. As of November 2008, nine of the 15 MAC contracts have been awarded.[9]

Improvements expected as a result of the implementation of MACs will affect both beneficiaries and providers:

- Most beneficiaries will have their Part A and Part B claims processed by same contractor, reducing the number of Explanation of Benefits (EOB) forms received.
- Providers will interface with a single MAC for Part A and Part B processing.
- Each MAC will be required to develop an integrated and consistent approach to medical coverage across its service area.

All of the information discussed above applies to Medicare Fee-for-Service, the original Medicare program and the one to which the majority of beneficiaries still subscribe. The Medicare managed care programs, also known as Medicare Advantage or Medicare HMOs, have different billing policies, which are more like those for an HMO or insurance plan and are unique to the specific plan.

Limitations on payment

Medical Necessity Policies

In the late 1990s, CMS began limiting utilization of laboratory services by establishing rules regarding medical necessity for tests. This program began with each carrier and FI establishing its own Local Medical Review Policies (LMRPs). In some states, the carrier and FI agreed to have the same LMRPs, but in many they differed.

The LMRPs spelled out which tests (identified by CPT code or HCPCS code) are covered by the policy. The policies included diagnosis codes (known as International Classification of Diseases or ICD-9 codes) that justify the ordering of that test, and in some cases, the frequency with which the test may be ordered. The ordering physician or provider is required to provide the laboratory with the reason that the test was ordered, either by providing a numeric diagnosis code or a narrative description of the reason. If that diagnosis is not found in the medical necessity policy for the test, the patient is asked to sign an Advance Beneficiary Notice (ABN), which obligates the patient to pay for the test if Medicare does not. ABNs must be presented in a format prescribed by CMS and available at http://www.cms.hhs.gov/BNI/Downloads/CMSR131L.pdf.

The laboratory industry objected to the proliferation of many different medical necessity policies in the different states, and advocated for change as part of the Balanced Budget Act of 1997 (BBA). BBA mandated a consensus-driven process called Negotiated Rulemaking (also known as Neg Reg) to develop consistent national medical necessity policies. A panel of advisors representing laboratory professionals, including the American Society for Clinical Laboratory Science (ASCLS), physicians, and other stakeholders worked with CMS staff during this process. The resulting product was 23 national policies, published as a final rule on 11/23/01 and put into effect on 1/1/03. National Coverage Determinations (NCD) are updated on a quarterly basis. Current NCDs may be found at http://www.cms.hhs.gov/CoverageGenInfo/04_LabNCDs.asp#TopOfPage.

NCDs cover tests which are frequently ordered on Medicare beneficiaries, including blood counts and urine cultures, but also lipids and a variety of tumor markers.

Individual carriers and FIs are still allowed to establish local policies in addition to the national policies, but

Table 1: Medicare Administrative Contractor (MAC) Awards

Jurisdiction	States	Awarded to:
1	American Samoa, CA, Guam, HI, NV, Northern Marianas	Palmetto GBA
2	AK, OR, WA	National Heritage Insurance Co.
3	AZ, MT, ND, SD, UT, WY	Noridian Administrative Services
4	CO, NM, OK, TX	TrailBlazer Health Enterprises
5	IA, KS, MO, NE	Wisconsin Physician Health Insurance Corp
6	IL, WI, MN	tbd
7	AR, LA, MS	Pinnacle Business Solutions
8	IN, MI	tbd
9	FL, Puerto Rico, U.S. Virgin Islands	First Coast Service Options, Inc.
10	AL, GA, TN	tbd
11	NC, SC, VA, WV	tbd
12	DE. DC, MD, NJ, PA	Highmark Medicare Services
13	CT, NY	National Government Services
14	ME, MA, NH, RI, VT	tbd
15	KY, OH	tbd

those policies cannot contradict information in the NCD. More recently, the names of these LMRPs were changed to Local Coverage Decisions (LCDs). It is hoped that the advent of the MACs will lead to consolidation and standardization of the LCDs, as mentioned earlier.

Correct Coding Initiative

In addition to the medical necessity policies, CMS has other mechanisms to review claims and deny what it sees as inappropriate charges. One mechanism is the Correct Coding Initiative (CCI)[10]. CCI edits are used to examine each submitted claim for pairs of codes that should not be billed on the same date of service (defined as date of specimen collection), according to CMS. Typical examples are CBC and hemoglobin, or basic metabolic panel and potassium (or any other member of the panel). The problem is that the claim forms accept only date of service, and not time of service. So if an outpatient has blood drawn more than once on the same day, such as before and after outpatient surgery, the contractor cannot determine that the CBC and hemoglobin were run at different times on separate samples. As more and more complex services are provided to outpatients, with the growth in ambulatory surgery and complex patients having multiple visits on the same day in multi-specialty clinics, the incidence of problems with CCI edits increases. A modifier can often be added to the CPT code to indicate that the test was done on a separate sample, and some providers have purchased software that screens claims for CCI edit problems before they are submitted to the FI or carrier for payment. This allows the opportunity to add a modifier to the claim before submission and avoid having it rejected and returned.

Medically Unlikely Edits

A more recent type of edit implemented by CMS is the Medically Unlikely Edits (MUEs). The purpose of these edits when initially proposed under the title of Medically Unbelievable Edits was:

"CMS' intent for these edits is to prevent the payment of obviously erroneous Medicare claims submissions. For example, CMS wishes to prevent payment for millimeters of a medical product when the unit of billing is liters or billing for 60 services when the provider meant to bill for 6 services. The medically unbelievable edits are not meant as Medicare payment policy but only to identify obvious mistakes in billing."[11]

However, the first proposed list of MUEs for the laboratory, circulated for comment in late 2005, went far beyond "obvious mistakes" and proposed limits which were unreasonable in light of accepted medical practice. The limit for most CPT codes was established as one, even when the description of the CPT code in question included the word "each," implying that more than one charge was expected. For example, the proposed limit for immunoglobulin was one per day, even though it is common practice to order immunoglobulins A, G, and M together. The proposed limit for biopsy code 88305 was two, even though this is the code used for skin biopsies or colon polyps, both of which frequently require more than two samples to be collected. Limits that might be appropriate for a routine visit to a primary care practitioner are not at all realistic in many more complex outpatient settings.

The initial proposed list of MUEs for laboratory services had only limited circulation for comment, but it raised so many concerns and objections from the laboratory community that CMS withdrew it and assigned development of MUEs to a contractor which used a different approach. MUE limits for sections of the laboratory CPT codes have been examined and circulated for comment to a limited number of professional associations, including ASCLS. Groups that wish to comment must limit the number of individuals who see the list and are prohibited from sharing or publishing the limits. ASCLS has commented on all eight sections of the MUE proposals, and a significant number of our requested changes have been agreed to by CMS, although by no means all of them. CMS has implemented a new section of MUEs each quarter since 4/1/07, and as more and more edits are implemented, providers are beginning to see increasing denials on the basis of MUE limits.

CMS initially refused to publish the MUEs on the grounds that laboratories' knowledge of the maximum number of codes they could bill for would lead to "fraud and abuse". The laboratory community objected and on October 1, 2008, CMS began publishing most MUEs on its web site.[12]

The future

The impending increase in the number of Medicare beneficiaries, combined with the fiscal and economic changes facing the US, will exert unprecedented pressure on the Medicare and Medicaid programs. The new administration is faced with the challenge of growing numbers of uninsured or underinsured Americans. Although no one knows how this dilemma will be addressed, some have suggested a Medicare-like approach to the problem of the numbers of the uninsured.

Whatever happens, continued pressure will exist to provide more services for fewer dollars. Laboratorians have been

creative over the years in improving productivity through automation, Lean (a method of making workflow more efficient by removing waste, unnecessary steps, and waiting time), and other techniques while maintaining and improving quality. These challenges are sure to continue as decisions are made regarding the future of Medicare.

Clin Lab Sci encourages readers to respond with thoughts, questions, or comments regarding this Focus section. Email responses to westminsterpublishers@comcast.net. In the subject line, please type "CLIN LAB SCI 22(2) FO MEDICARE". Selected responses will appear in the Dialogue and Discussion section in a future issue. Responses may be edited for length and clarity. We look forward to hearing from you.

REFERENCES

1. History of Medicare program available from www.cms.hhs.gov/history/01_Overview.asp accessed 2008 November 6.
2. Current number of Medicare beneficiaries available from http://statehealthfacts.kff.org/profileind.jsp?ind=290&cat=6&rgn=1 accessed 2008 November 11.
3. Number of U.S. citizens categorized as baby bommers available from http://www.census.gov/PressRelease/www/releases/archives/facts_for_features_special_editions/006105.html accessed 2008 November 11.
4. The Lewin Group. Laboratory Medicine: A National Status Report Chapter VIII – Reimbursement for Laboratory Medicine. Available from http://www.futurelabmedicine.org/ published May 2008, accessed 2008 November 7.
5. Institute of Medicine. Medicare laboratory payment policy: now and in the future. Washington, DC: National Academy Press, 2000.
6. Screening tests reimbursed by Medicare available from http://www.medicare.gov/Health/Overview.asp updated 2008 August 29, accessed 2008 November 10.
7. Social Security Act establishing the Clinical Laboratory Fee Schedule available from http://www.ssa.gov/OP_Home/ssact/title18/1833.htm#h1a accessed 2008 December 7.
8. Establishment of payment using Diagnosis Related Groups available from Key Milestones in CMS Programs www.cms.hhs.gov/history/01_Overview.asp accessed 2008 November 6.
9. Awards of Medicare Administrative Contracts available from http://www.cms.hhs.gov/MedicareContractingReform/Downloads/MACJurisdictionFactSheet.pdf updated October 2008 accessed 2008 November 7.
10. Correct Coding Initiative information available from http://www.cms.hhs.gov/NationalCorrectCodInitEd/NCCIEP/itemdetail.asp accessed 2008 November 8.
11. Medically Unbelievable Edits available from http://www.cms.hhs.gov/Transmittals/2005Trans/itemdetail.asp accessed 2008 December 7.
12. Publishing of Medically Unlikely Edits press release available from http://www.cms.hhs.gov/apps/media/press/release.asp accessed 2008 December 7.