What surgeons should know about . . .

Changes in the Medicare coverage process

by Jean A. Harris, Regulatory and Coding Specialist, Washington Office, Socioeconomic Affairs Department

Over the last few months, a number of changes have been made in the Medicare coverage process—all designed to make the coverage process more open, predictable, and understandable. This is a progress report on what changes have been made, what the staff of the Medicare program hopes it will accomplish, and early experiences with the changes.

Q. Let's start with something that has not changed. How, conceptually, does the Medicare program decide what is "covered"? Who makes coverage determinations?

A. The authorizing statute, the Social Security Act, gives authority to cover about 55 categories of benefits; a covered service must fit into at least one of these categories. Some categories are quite narrowly defined in the statute, and some are very broadly defined. An example of a very narrowly defined covered item is blood clotting factors for hemophiliac patients. Physicians' services, on the other hand, are defined very broadly as "professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls."

The statute also says the service must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Over the years, this definition has been interpreted to mean that the service must be safe, effective, non-investigational, and furnished in an appropriate setting by qualified personnel. In the case of drugs, biologicals, and devices, the service generally must have Food and Drug Administration (FDA) clearance or premarketing approval.

Preventive services are generally not covered by the Medicare program. Some very specific services, however, have been covered by Congress. Examples are influenza vaccine, breast cancer screening, and colon cancer screening.

The Health Care Financing Administration (HCFA) is responsible for all aspects of the Medicare program, including making coverage determinations. If it has made a national coverage determination on a service, the fiscal intermediaries and carriers that process Medicare claims are bound by that decision. If, however, HCFA has not made a national coverage determination, the fiscal intermediaries and carriers must decide whether the service in question is covered by Medicare. Since different organizations may reach different conclusions, a specific service may be covered in one area of the country and not covered in another.

Incidentally, the decision on how much to pay for a service is made separately, after the coverage decision, and by different people. Often multiple decisions must be made. For example, a service provided in a hospital or ambulatory surgical center requires decisions about how much to pay the institution and how much to pay the physician.

Q. What are the major changes made in the coverage process?

A. HCFA has made a number of commitments to change the coverage process, including the following:

• In addition to pursuing coverage determinations the agency makes on its own as it has been doing, it will respond to requests from outside the agency. Anyone who requests a formal national determination of coverage and gives HCFA the necessary information about the service will generally receive an answer within 90 days.

• The agency will post information regarding all national coverage determinations on the HCFA Web site. It will add to the posting such items as meetings and requests for assessments so the public can track progress through the coverage process and participate if interested. At the end of the process, the Web site will show the results of the process.

• HCFA has established a formal Medicare Coverage Advisory Committee (MCAC) to advise it on whether services are "reasonable" and "necessary." The practice of requesting a technology assessment of the safety, efficacy, and effectiveness of a service will continue; assessments are obtained from an impartial third party, such as the Agency for Healthcare Research and Quality (AHRQ—formerly known as the Agency for Health Care Policy and Research). Either type of referral will extend the process beyond the 90-day time frame.

Q. This is the first time HCFA has had a coverage advisory panel. What will the MCAC do and how is it structured?

A. The MCAC will provide advice on whether a service can be considered "reasonable" and "necessary." It will offer advice on issues on which there is a significant medical or scientific controversy, a major potential impact on the Medicare program, or broad public controversy.

The full MCAC consists of 70 individuals broken up into six panels, each roughly parallel to a major coverage category. The six panels are: Drugs, Biologics, and Therapeutics; Laboratory and Diagnostic Services; Medical and Surgical Procedures; Diagnostic Imaging; Durable Medical Equipment; and Medical Devices and Prosthetics. Each panel has eight to 10 voting members, a member of industry, and a public member. Each of the panels will, of course, take up work in its area of expertise. The chairperson and vice-chairperson of each panel make up an executive committee, which has been charged with a number of responsibilities, including overseeing the assignment of work to the individual panels and reviewing the panels' work products.

All MCAC meetings are announced in the *Federal Register* about 30 days in advance of the actual meeting so that people will have the opportunity to attend and present their views. All evidentiary presentations must be made in writing 20 days before the meeting. All meetings

must be open to the public and must include an opportunity for those not on the agenda to comment.

Following the meeting, the MCAC will make its recommendation to HCFA as quickly as possible. HCFA will decide to adopt the recommendation (or adopt it with modifications) within 60 days and will post the decision on its homepage.

The MCAC replaces the HCFA Technical Advisory Panel. That panel included a mixture of HCFA physicians, carrier and fiscal intermediary medical directors, and physicians from other government agencies such as the FDA.

Q. What is the mix of physicians and nonphysicians on the MCAC? Are any Fellows of the College on the MCAC?

A. The precise mix of physicians and nonphysicians is dependent on what the panel will be evaluating. For example, nonphysicians make up the majority of the voting members of the Durable Medical Equipment Panel. At the other extreme, all voting members of the Medical and Surgical Procedures Panel are physicians.

Angus J. McBryde, MD, FACS, was nominated by the American College of Surgeons and is serving on the Medical and Surgical Procedures Panel. Two other members of the College are serving on the same panel—Michael D. Maves, MD, FACS, and H. Logan Holtgrewe, MD, FACS. Serving on the Diagnostic Imaging Panel are Kim J. Burcheil, MD, FACS, Steven Guyton, MD, FACS, and Michael Manyak, MD, FACS.

Q. Has HCFA increased the staff devoted to the coverage process? In particular, do they have more physicians working in the area?

A. Yes, HCFA has been working on increasing the staff working on coverage issues. The agency now has half-a-dozen physicians and has also increased the number of nonphysicians. Kenneth B. Simon, MD, FACS, is one of the HCFA staff physicians working on the coverage process.

Q. What is the difference between what the MCAC will do and the technology assessments performed under contract to HCFA?

A. The technology assessments that are performed under a contract to HCFA are usually very large bodies of work or deal with very complex issues. More time and expertise is required to organize and assess the material than the HCFA staff or the MCAC can devote to it. Examples are the assessment of support surfaces for pressure ulcers, which was recently completed, and the assessment of intestinal and multivisceral transplantation, which is now being conducted.

Q. Has HCFA done any work on subjects surgeons might be interested in?

A. The agency is continuing to work on a modification of the policy for support surfaces for pressure reducing therapy. As mentioned above, they have a completed technology assessment and are now answering some questions posed by manufacturers of support surfaces. As this article is written, they estimate an early May completion. Also, they will be actively working on a policy on intestinal and multivisceral transplantation when that technical assessment is completed.

The agency has established or modified Medicare coverage policies for a number of services of interest to readers of the *Bulletin* and posted

information about them on the Web site. However, the changes will not become effective until the necessary billing and claims processing instructions have been prepared. The services for which they have completed work include:

- Percutaneous image-guided breast biopsy, including directional, vacuum-assisted breast biopsy, automated surgical biopsy, and needle core biopsy.
- Cryosurgery ablation of the prostate.
- Electrical stimulation for fracture healing.
- Liver transplantation.
- Prolotherapy for chronic low-back pain.
- Transmyocardial revascularization for severe angina.

Q. What is the address for HCFA's Web site? What kind of material relating to coverage is there?

A. HCFA's Web site address for coverage is http://www.hcfa.gov/quality/8b.htm. (Their homepage, which covers all aspects of HCFA's responsibilities, is http://www.hcfa.gov.) There is information on the coverage process, including the MCAC, and reports on pending and completed coverage determinations. The material on pending determinations includes a description of the issue, the name of the requester, the name and phone number of the lead HCFA person who is working on the issue, actions taken, and the date a decision is expected. The material on completed determinations contains a very detailed analysis of the issues presented and, for items that have been through the revised process, a complete list of actions taken in the process of reaching a final decision.

Q. How well has HCFA succeeded in introducing these changes to the coverage process?

A. The experience so far can best be described as a "mixed bag." On the one hand, it has become a more public process, primarily because of the availability of material through the Web. The quality of the work that goes into the coverage process has improved, largely because the agency has increased the staff of physicians. On the other hand, it is having problems getting the MCAC running as smoothly as they would like. At the first meeting of the executive committee, a number of questions were raised about the way the MCAC functions. Meetings of MCAC panels have been postponed until HCFA develops guidelines on the evaluation of evidence for them to use. The changes HCFA makes over the next few months will be critical in making the revised process function as well as it initially promised. Ω