



## policy points

### A Move Toward Consistency The Health Care Finance Administration (HCFA) has issued a new set of national standards for determining the services and items for which Medicare will pay.

BY JEFF ATKINSON



“Reasonable and necessary” are the key words for deciding what services will

be covered or not covered by health insurance, including under the Medicare system. Until recently, what was covered under Medicare depended on the state in which the patient received care, resulting in substantial coverage discrepancies among the states. New standards to guide coverage decisions will allow more of these decisions to be made on a national basis, providing more consistent coverage.

When Congress established

the Medicare system in 1965, the statute declared that services and items paid by Medicare must be “reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.”

Congress delegated the authority to make decisions regarding what is “reasonable and necessary” to the Health Care Finance Administration (HCFA). HCFA, in turn, dele-

gated the authority to decide what is covered or not covered to local contractors called “carriers” and “fiscal intermediaries” that handle the day-to-day paper work and make payments on behalf of Medicare.

“Fiscal intermediaries” handle payments to hospitals under Part A of Medicare; “carriers” handle payments to physicians under Part B of Medicare. Local Blue Cross plans often serve as intermedi-

aries and carriers for their respective states.

When an intermediary or carrier makes a local coverage decision (LCD), the decisions are binding only in the area in which they were issued, which generally is a single state. This system has resulted in inconsistencies in coverage decisions. Some local contractors would pay for a given service or item, and others would not.

#### Elimination of inconsistencies

To eliminate some of the inconsistencies and to provide a more efficient decision-making process for evaluating new technologies and treatments, HCFA this year has established national standards to guide coverage decisions. The stan-

The goal of the new standards is to make the process “open, accountable,... understandable, and predictable,” according to Nancy-Ann DeParle, the Administrator of HCFA.

## POLICY POINTS

Continued from previous page

dards will affect the more than 39 million people covered by Medicare, which includes persons age 65 and over, as well as persons of any age with end-stage renal disease and certain long-term disabilities. The coverage decisions will determine whether physicians, hospitals, and other providers will be paid for the services and items.

The goal of the new standards is to make the process "open, accountable, ... understandable, and predictable," according to Nancy-Ann DeParle, the Administrator of HCFA.

Under the new rules, HCFA may initiate its own national coverage decisions (NCDs) on issues it considers important, including when there is a significant medical advance and when there are conflicting coverage decisions made by local contractors.

### Requests for coverage

Requests for an NCD also can be made to HCFA by individuals and organizations. The requests must be in writing and contain a complete description of the item or service in question, a compilation of the medical and scientific information currently available, and a description of any clinical trials under way. If the item in question is a drug or device regulated by the Food and Drug Administration (FDA), the status of the FDA proceedings also must be given.

Once an application is complete, HCFA generally will respond to the party that made the request within 90 days. HCFA may refer the issue to the Medicare Coverage Advisory Committee for further study and recommendation.

The Advisory Committee is divided into six panels that are roughly parallel to Medicare benefit categories: (1) Laboratory and Diagnostic Services; (2) Drugs, Biologics, and Therapeutics; (3) Medical and Surgical Procedures; (4) Diagnostic Imaging; (5) Durable Medical Equipment; and (6) Medical Devices and Prosthetics. Once the Advisory Committee has issued its

### National Coverage Decisions Under Medicare

Since establishing rules this year for making national coverage decisions (NCDs) under Medicare, the federal Health Care Finance Administration (HCFA), has issued 19 NCDs and has 16 reviews pending (as of September 2000). The completed and pending reviews are listed below along with the numbers assigned by HCFA's Coverage and Analysis Group (CAG).

#### COMPLETED DETERMINATIONS:

- Augmentative and Alternative Communication (AAC) Devices (#CAG-00055)
- Autologous Stem Cell Transplantation for AL Amyloidosis (#CAG-00050)
- Autologous Stem Cell Transplantation for Multiple Myeloma (#CAG-00011)
- Breast Biopsy (#CAG-00040) (the decision specifies the circumstances in which image-guided biopsies will be approved)
- Cardiac Monitoring by Electrical Bioimpedance (#CAG-00001)
- Continuous Subcutaneous Insulin Infusion Pump (#CAG-00041)
- Cryosurgery Ablation of the Prostate (#CAG-00031)
- Electrical Stimulation for Fracture Healing (#CAG-00043)
- External Counterpulsation Therapy (#CAG-00002)
- Extracorporeal Immunoabsorption Using Protein A Columns for Treatment of Rheumatoid Arthritis (CAG-00057)
- Ferrlecit (#CAG-00046)
- Helicobacter Pylori Testing (#CAG-00006)
- Liver Transplantation (#CAG-00053)
- Positron Emission Tomography (#CAG-00025)
- Pressure Reducing Therapy (Support Surfaces) (CAG-00017)

- Prolotherapy for Chronic Low Back Pain (#CAG-00045)
- Re-Evaluation of Criteria for Medicare Approval of Transplant Centers (CAG-00061)
- Transmyocardial Revascularization for Severe Angina (#CAG-00004)
- Ultrasound Stimulation for Nonunion Fracture Healing (CAG-00022)

#### PENDING DETERMINATIONS:

- Actinic Keratoses Treatment (#CAG-00049)
- Acupuncture (#CAG-00062)
- Ambulatory Blood Pressure Monitoring (#CAG-00067)
- Biofeedback for Treatment of Urinary Incontinence (CAG-00020)
- Cardiac Pacemakers (#CAG-00063)
- Cryosurgical Salvage for Recurrent Prostate Cancer (#CAG-00064)
- Diabetic Peripheral Neuropathy with Loss of Protective Sensation (LOPS) (#CAG-00059)
- Electrostimulation for Treatment of Wounds (#CAG-00068)
- FDG-Positron Emission Tomography (PET) (#CAG-00065)
- Human Tumor Assay Systems (#CAG-00044)
- Intestinal and Multivisceral Transplantation (#CAG-00036)
- Lymphedema Pump (#CAG-00016)
- Noninvasive Positive Pressure RADs for COPD Patients (#CAG-00052)
- Ocular Photodynamic Therapy with Verteporfin (#CAG-00066)
- Pelvic Floor Electrical Stimulation for Treatment of Urinary Incontinence (CAG-00021)
- Sacral Nerve Stimulation for Treatment of Urge Urinary Incontinence (CAG-00058)

Lists of completed coverage decisions and the status of pending decisions can be obtained on line at [www.hcfa.gov/quality/8b.htm](http://www.hcfa.gov/quality/8b.htm)

## POLICY POINTS

Continued from previous page

recommendation, HCFA usually will make its decision within 60 days of receipt of the committee's recommendation.

A coverage decision by HCFA can take several forms. HCFA can decide that an item or service will be covered nationally, with or without limitations on coverage. Alternatively, HCFA can decide that the item or service will not be covered, thus precluding local contractors from making payments for the item or service; or HCFA can make no national decision, thus leaving the decision on coverage to the local contractors.

### "Benefit" and "added value"

The new rules for making national coverage decisions utilize two primary criteria: "medical benefit" and "added value to the Medicare population."

An item or service will be considered to provide a medical benefit "if it produces a health outcome better than the natural course of the illness or disease with customary medical management of symptoms."

The demonstration of evidence of benefit will need to include "objective clinical scientific evidence" of the effect of the service or item on mortality, life-expectancy, or quality of life. Quality of life measures should include a nationally recognized standard metric system such as Quality Adjusted Life Years (QALY) or Disability Adjusted Life Years (DALY). HCFA said that it also may consider other general criteria such as "a beneficiary's preference, compliance, and well-being" in determining the level of medical benefit.

The criterion of "added value to the Medicare population" encompasses several considerations, including: improvement of health outcome, access to a different clinical modality, and substitution for an existing item or service at lower cost. An example of a different clinical modality would be the use of a new medication instead of surgery. One of the reasons for allowing coverage of different

modalities to accomplish the same purpose, said HCFA, is "that there are legitimate differences between beneficiaries, medical practices by region, and delivery systems' capabilities."

If a "breakthrough" service (or item) offers substantially more benefit than an existing service, then the breakthrough service will be covered, even if it costs more. If, however, a new service costs more but does not deliver more benefit, then the new service is not likely to be covered.

When a national coverage decision is made, local contractors will apply the new decision to individual cases, deciding whether a particular patient has a condition for which the new service is appropriate.

### Insulin pumps covered

The first national coverage decision made under the new rules was coverage of insulin pumps for Medicare beneficiaries with Type 1 diabetes, also known as juvenile onset diabetes. After reviewing scientific data and consulting with different groups regarding the pump's effectiveness, HCFA concluded the pumps "will improve the quality of [beneficiaries'] lives" and "offer them a choice to better control their condition so that they are more active and productive." The time period from the application to cover insulin pumps to HCFA's decision to cover the pumps was within the 90-day period set by the new rules.

Other recent national coverage decisions include coverage for:

- Prolotherapy (also known as "proliferative injection therapy") for chronic low-back pain;
- Liver transplantation for patients with hepatitis B (but not for patients with liver cancer);
- Breast biopsy (the decision specifies the circumstances in which image-guided biopsies will be approved); and
- Cryosurgery ablation of the prostate.

As of September 2000, HCFA had is-

sued 19 national coverage decisions and 16 coverage decisions were pending. (For a list of completed and pending determinations, see "National Coverage Decisions" on page 18.) After a decision to cover a new service or item is made, a separate department in HCFA issues a "coverage instruction" which includes coding and billing information.

### Strategic application decisions

Health-care providers and manufacturers who develop a new service or product for which they want to be able to obtain payments from Medicare have a strategic decision to make: Do they seek a national coverage decision or a local coverage decision? If the service or product is primarily for local use, a local coverage decision may suffice. If the provider or manufacturer wishes a nationwide market, a national decision would be preferable.

Nonetheless, an applicant for coverage hoping for a nationwide market may take a cautious approach. If the applicant has some doubts about whether HCFA will approve nationwide coverage, it may be prudent to seek local approval first. That way, if an applicant is rejected in one market, the applicant would still have a chance to obtain approval in other markets. A denial for coverage on a national level, however, would preclude coverage on a local level.

Currently about 90 percent of coverage decisions are made by local carriers and intermediaries and 10 percent of coverage decisions are made nationally. Under the new system, HCFA expects the proportion of national coverage decisions to increase. With advances in technology and more rapid flow of information, health-care coverage decisions for Medicare, as well as for other insurers, are likely to become even more centralized and uniform. ■

*Jeff Atkinson teaches courses in health-care reform and health-care contracts at DePaul University College of Law in Chicago. He also writes on legal, medical, and ethical issues.*