The Health Care Financing Administration and Medicare Policies

by John Whyte, M.D., M.P.H.

Physicians as well as patients are very interested in Medicare's drug policies, especially as they relate to cancer drugs. Medicare will pay for drugs under certain circumstances. Although there is presently no prescription drug benefit, the authority to cover some drugs is provided if it is incident to physician's service. For a drug to be covered by Medicare, the following five questions must be answered:

1. Has the drug obtained approval from the Food and Drug Administration (FDA)? (As with medical devices, FDA approval is a prerequisite, not a guarantee of coverage.)

2. Does the statute mandate coverage?

3. Is the drug medically necessary?

4. Is the drug being used for an approved indication?

5. What is the route of administration?

Presently, only drugs that are not self-administered are eligible for coverage. The Benefits Improvement and Protection Act (BIPA) has specified that drugs are considered not to be self-administered when they are "not usually self-administered by the patient." This is a new HCFA policy. Previously HCFA had based self-administration on the drug itself and not whether an individual patient was capable of administering it.

As mandated by Congress, Medicare does reimburse for several drugs: oral anti-cancer drugs, oral anti-emetics, immunosuppressives, blood clotting factors, antigens, and epoetin alfa.

Due to the efforts of cancer care providers, an oral anti-cancer benefit also exists. The benefit stipulates that the drug must have the same active ingredient and the same indication as the IV form, and it must be part of a chemotherapeutic regimen. This provision currently includes methotrexate, cyclophosphamide, etoposide, melphalan, busulfan, capecitabine (a prodrug), and MTIC (a prodrug).

An oral anti-emetic benefit was also recently enacted. To be covered, a drug must act as full therapeutic replacement for the IV form, and be used within 48 hours of chemotherapy. This is not an anti-nausea benefit; the purpose is to aid in absorption.

MAKING COVERAGE DECISIONS

HCFA has the authority to decide what Medicare covers. This authority is granted under Section 1862(a)(1)(A) of the Social Security Act, which restricts all coverage and payment to that which is found "reasonable and necessary" for the treatment of illness or injury. This provision gives the Secretary of Health and Human Services, acting through HCFA, the authority to determine the coverage of services under Medicare. The statute is actually phrased in the negative, stating that "we shall *not* pay for those services, which are not reasonable and necessary." Because of this phrasing, the premise that a device or procedure *might* be of benefit, to some patients, in some circumstances, is not a criterion on which the Medicare program can base coverage decisions. There must be evidence of effectiveness.

Medicare is a defined benefit program, and a service must fall into one of 55 statutorily defined benefit categories as a first step toward coverage. A service must then satisfy HCFA's process for determining whether it can be considered "reasonable and necessary." This process is also undergoing revision, with a Notice of Intent published in the May 16, 2000, *Federal Register*, outlining some thoughts as to how HCFA could interpret these words.

There are two general methods by which Medicare coverage decisions are made. The first is through local carrier discretion. Medicare contractors develop coverage policies known as local medical review policies (LMRPs). They consult with a group of local practicing physicians on a Carrier Advisory Committee, and then publish LMRPs in their local bulletin. The second method is through the development of national coverage policies. Few people understand that most new items and services are covered by the first process, and only about 10 percent are covered by the second. Both methods rely upon evidence of medical effectiveness; however, many people find it confusing when there is disparity in policies. This disparity due to carrier discretion is an acknowledgment that physician practices vary by geography. If all policies were determined at the national level, there might be slower diffusion of technology. Although local policies can be overturned for individual patients by administrative law judges, there is only limited review by federal courts for national coverage policies.

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Within the past year, HCFA changed its process for making national coverage policy. These changes are an attempt to make the program more understandable, predictable, timely, and inclusive. The new process is outlined in the April 27, 1999, *Federal Register*. This notice attempts to explain how an issue enters the national process and proceeds through a coverage decision. Within the past 18 months, more than 15 national coverage decisions have been made under this new process.

In general, the new process focuses on a review that is evidence-based with continued emphasis on authoritative evidence and demonstrated medical effectiveness. HCFA wants to see:

- that benefits outweigh reasonably anticipated risks
- evidence of improved health outcomes (functional outcomes)
- that the device or procedure complies with all regulatory requirements. (Remember that FDA approval is a prerequisite but not a guarantee to coverage.)

RESPONDING TO REQUESTS

HCFA encourages health care providers and the public in general to become involved in a national coverage determination. To do so, one needs to submit in writing a "formal request for a national coverage decision." Supporting documentation and a full description of the service in question, including benefit category, should be provided. In addition, the medical/scientific information currently available should be compiled and submitted along with a description of clinical trials that are underway.

Within 90 days, HCFA will respond to such a request. Its possible decisions include 1) national noncoverage, 2) carrier discretion, 3) national coverage without limitations, or 4) national coverage with limitations.

With regard to ordering technology assessment, HCFA has arranged to work with the Agency for Health Research and Quality (AHRQ) and its 12 evidence-based practice centers to perform its technology assessments. In general, HCFA expects these assessments to be completed within three to six months.

HCFA may issue a "Referral to Medicare Coverage Advisory Committee" (MCAC). The MCAC presently includes 75 members representing a broad range of disciplines, including clinical medicine, public health, data and information management, economics, and ethics. There are six panels (Medical/Surgical, Drugs/Biologics/Therapeutics, Laboratory, Diagnostic Imaging, Medical Devices, and Durable Medical Equipment) and an Executive Committee. The MCAC makes recommendations concerning coverage of various procedures or devices.

Within 180 days of a national coverage determination, we hope to have implemented any program changes and made payment effective. Still, there is often a time lag between when HCFA announces a national coverage decision and when a procedure or device is actually covered through our payment systems.

Again, the process is meant to be open and inclusive. HCFA maintains a current list of issues that it is considering for national coverage decisions, as well as those issues for which decisions have already been made. Several topics would be of interest to the hematology/oncology community, including autologous stem cell transplantation for multiple myeloma, autologous stem cell transplantation for amyloidosis, human tumor assays, and use of epoetin alfa in oncology patients.

The new century is an exciting time to be involved in medical technology, and HCFA encourages everyone to become involved in the new national coverage process for these new procedures or devices. For regular updates, visit our web site at www.hcfa.gov.

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