APPENDIX B

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Medicare covers items and services that are included in a Medicare benefit category, are not statutorily excluded, and are reasonable and necessary based on section 1862(a)(1)(A) of the Social Security Act. Although the statute sets forth the broad categories of benefits covered by Medicare, neither the statute nor regulations provide an all-inclusive list of the specific items and services that are reasonable and necessary for beneficiaries' medical care. The Centers for Medicare & Medicaid Services (CMS) and the contractors who review, process, and adjudicate Medicare claims—including the fiscal intermediaries (FIs) for Part A services, carriers for certain Part B services, and durable medical equipment regional contractors (DMERCs)—determine whether services are reasonable and necessary, and, therefore, covered under Medicare.

There are several ways for services to be covered under Medicare. The vast majority of explicit coverage decisions are developed by Medicare's contractors. These decisions, referred to as local medical review policies (LMRPs), apply only to specific services provided in the contractor's regional jurisdiction. Contractors also can make individual decisions about the coverage of a particular service for a beneficiary. In addition to developing coverage decisions through Medicare's contractors, CMS implements policies through the national coverage decision (NCD) process. NCDs are national policies on the coverage of specific medical services. Both the local and the national coverage processes explicitly consider whether services meet Medicare's statutory requirements for "reasonable and necessary" care.

The NCD and LMRP processes are not the only means by which Medicare can develop and implement coverage policies. Policies affecting the coverage of services are also published in Medicare's provider manuals and program memorandums. These policies are developed by CMS; like NCDs, they are binding for all contractors and apply nationwide. Finally, Medicare's coding requirements may also implicitly affect the coverage of services.

It is worth noting that the majority of services—including those that fall into an existing payment method or category—do not go through Medicare's explicit coverage process. Rather, these services are paid through CMS's prospective payment mechanisms. Under Medicare's prospective payment systems (PPSs), providers serve as the purchaser and make decisions about which items and services will be furnished in the payment bundle. Broader payment bundles, such as the diagnosis-related groups in the hospital

Statutory limits on Medicare coverage

Title VIII of the Social Security Act authorizes Medicare beneficiaries to obtain health services from any institution, agency, or person qualified to participate in the Medicare program. The statute lists categories of items and services eligible for Medicare coverage and specifies that no payment may be made for services that are not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (Social Security Act, Title XVIII, Section 1862(a)(1)(A)). In recent years, Medicare has also been statutorily authorized to cover certain preventive services—mainly disease screenings—through statute. ■

inpatient PPS, provide more leeway for providers to furnish services of their choice compared with narrower payment bundles, such as the ambulatory payment classification groups in the hospital outpatient PPS. As discussed in Chapter 4, both the hospital inpatient and outpatient PPSs provide additional payment for certain new technologies.

This appendix summarizes the process by which coverage decisions are made in the Medicare program. First, we describe the process by which NCDs are made. Then we summarize the local coverage decision making process and assess some of the similarities and differences between the national and local coverage decision making process. In the next two sections, we describe examples of coverage policies made in CMS's provider manuals and explain how Medicare's coding process may affect the coverage of new services. Lastly, we describe the current process by which coverage decisions can be appealed and the changes to the appeal process mandated by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA).

The national coverage determination process

The NCD process, administered by CMS staff in the agency's national office in Baltimore, is usually reserved for those items or services that have the potential to affect a large number of beneficiaries and that have the greatest impact on Medicare (National Health Policy Forum 2001). NCDs cannot vary from region to region because all contractors and Medicare+Choice (M+C) plans are required to follow NCDs. The NCD process is initiated when CMS receives a formal request from the public. In addition, CMS staff can initiate the process if they find that: (1) inconsistent local coverage policies exist; (2) the service represents a significant medical advance, and no similar service is currently covered by Medicare; (3) the service is the subject of substantial controversy; or (4) the potential for rapid diffusion or overuse exists.

The NCD process is initiated less frequently than the local medical review process. Over the past 30 years, CMS has made about 300 national coverage decisions. By contrast, Medicare's contractors have made about 9,000 local coverage decisions during the past decade (Davison 2002). CMS makes relatively few NCDs because:

- Most decisions to cover services are not controversial.
- Most services do not meet the criteria (listed previously) for CMS to initiate an NCD.
- Limited resources may affect CMS's ability to initiate more NCDs.
- Manufacturers and providers of a medical service may be apprehensive about requesting an NCD because they perceive that the decision could result in an "all or nothing" scenario in terms of their ability to obtain Medicare reimbursement.

A negative NCD can be especially problematic for providers of a service for which Medicare constitutes a large share of the market. However, NCDs are sometimes written for a specific clinical indication of an item or service and can be modified once new clinical information is available. For example, CMS implemented an NCD in 1991 to cover the implantation of an automatic defibrillator for patients with a documented episode of life-threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction. In 1999, CMS modified the NCD to include three additional clinical indications (CMS 1999).[1]

CMS uses an evidence-based approach to evaluate items and services for coverage. This approach is based on applying the best available medical evidence according to the generally accepted hierarchy of evidence.[2] CMS refers most NCD requests to outside impartial groups to supplement the agency's scientific and medical expertise. One such expert group—the Medicare Coverage Advisory Committee (MCAC)—was chartered by the Secretary in 1998 to supplement the agency's clinical expertise and allow for public input and participation. The MCAC, which consists of six medical specialty panels and an Executive Committee, gives CMS its opinion on whether a specific item or service meets the criteria for Medicare coverage.[3] The

1 The three additional indications are: (1) a documented episode of cardiac arrest due to ventricular fibrillation not due to a transient or reversible cause; (2) ventricular tachyarrhythmia, either spontaneous or induced, not due to a transient or reversible cause; or (3) familial or inherited conditions with a high risk or life-threatening ventricular tachyarrythmias such as hypertrophic cardiomyopathy.

2 In reviewing coverage, CMS weighs the medical and scientific evidence in accordance with a fairly standardized hierarchy that ranks the relative authority given to various types of studies. This hierarchy of evidence is as follows, ranked with the most authoritative first:
(1) Controlled clinical trials published in peer-reviewed medical or scientific journals;
(2) Controlled clinical trials completed and accepted for publication in peer-reviewed medical or scientific journals;
(3) Assessments initiated by CMS;
(4) Evaluations or studies initiated by Medicare contractors; and
(5) Case studies published in peer-reviewed medical or scientific journals that present treatment protocols.

3 The six specialty panels are: medical and surgical procedures; drugs, biologics and therapeutics; medical devices; durable medical equipment; laboratory and diagnostic services; and diagnostic imaging. An Executive Committee—including the chair and vice chairs of each of these committees, a representative at-large, two industry representatives, and two consumer representatives—tries to ensure that consistent standards for decision-making are applied across the panels. An issue is first reviewed and discussed by one of the specialty panels, which develops specific recommendations. The recommendations are then forwarded to the Executive Committee for review and the preparation of a final recommendation to CMS.

MCAC serves only an advisory role; all final decisions are made by CMS. The agency uses other outside groups, including the Agency for Healthcare Research and Quality, to perform technology assessments—independent, systematic analyses of the safety and effectiveness of medical services.

The process of making most NCDs is relatively lengthy because of the many steps involved, which often include convening the MCAC and conducting a technology assessment. For the 10 NCDs made in fiscal year 2001, the average time from the date of the decision memorandum (announcing CMS's intent to implement a decision) to the date of implementation was 156 days (Thompson 2002).[4] Six of the 10 decisions exceeded CMS's self-imposed time frame of 180 to 270 days.

National coverage policies are published in Medicare's coverage issues manual. In addition, information about both national and local coverage decisions is available through the Internet. CMS's website includes current information about NCDs being developed as well as those that have been decided and implemented.[5] CMS's website also provides a mechanism to search through national and local coverage policies, as well as supplying links to contractors' websites which post draft and final LMRPs.

Local medical review process

Medicare's contractors are tasked with reviewing claims for services furnished by providers, physicians, and suppliers and paying only for those services that meet Medicare's coverage requirements. Consequently, contractors play an important role in protecting the integrity of the Medicare program. LMRPs are administrative and educational tools to assist providers in submitting correct claims for payment. They may contain instructions about any or all of the following types of provisions: coding, benefit category, statutory exclusion, or medical necessity.

LMRPs are developed by each contractors' medical director. These policies outline how contractors will review claims to ensure that they meet Medicare coverage requirements. Each medical director evaluates the medical necessity and reasonableness of services furnished to beneficiaries by providers within the contractor's jurisdiction. Circumstances for which medical directors may develop new or revised LMRP include:

- certain services demonstrating a significant risk to the Medicare trust fund, as identified by potentially high cost or high volume of services;
- need for developing uniform LMRPs across the contractor's multiple jurisdictions; and
- frequent denials being issued or anticipated for an item or service.

LMRPs must be consistent with national guidance that includes decisions and policies made through the NCD process or published in CMS's provider manuals or program memorandums. Contractors can develop LMRPs for services not covered by national guidance. In addition, LMRPs can provide more specific information about an NCD. For example, several contractors have issued LMRPs about the use of intravenous iron therapy furnished to end-stage renal disease (ESRD) patients to treat iron deficiency anemia.[6] These LMRPs provide specific instructions about the intravenous iron therapy NCD implemented by CMS in December 2000. Finally, the existence of one or more LMRPs does not preclude CMS from making an NCD. As noted in the previous section, CMS may consider making an NCD because of varying LMRPs.

The process for developing a LMRP includes drafting language based on a review of medical literature and the contractor's understanding of local practices. LMRPs must consider and be based on the strongest evidence available (HCFA 2000). Contractors are required to permit interested parties to submit scientific, evidence-based information and have open meetings for the purpose of discussing draft LMRPs. Carriers must establish carrier advisory committees (CACs) in each state, which provide a forum for information exchange between carriers and physicians. CACs meet at least three times per year and are composed of physicians, a beneficiary representative, and representatives from other medical organizations (CMS 2002a).

In contrast to NCDs, LMRPs apply only in the contractor's jurisdiction. Consequently, coverage policies vary across localities because contractors can each set policies within their specific geographic jurisdiction. CMS encourages contractors who operate in two or more states to develop uniform local coverage policies across all jurisdictions to the extent possible. In addition, medical directors from the carriers and FIs participate in work groups for specific clinical areas, such as chronic pain management, anesthesiology, and clinical

4 The 10 coverage determinations were for: (1) intestinal and multivisceral transplantation; (2) biofeedback for the treatment of urinary incontinence; (3) pelvic floor electrical stimulation for the treatment of urinary incontinence; (4) ocular photodynamic therapy with verteporfin; (5) cryosurgical salvage therapy for recurrent prostate cancer; (6) positron emission tomography for the diagnosis and treatment of selected oncologic conditions; (7) percutaneous transluminal angioplasty of the carotid artery concurrent with stenting; (8) liver transplantation for patients with hepatocellular carcinoma; (9) coverage of liver transplants in nonapproved centers during the emergency in Houston; and (10) coverage of liver transplants in nonapproved centers during the emergency in Houston (amendment).

5 CMS's website, which provides information about national and local coverage policies, is available at http://www.cms.hhs.gov/coverage/.

6 Contractors that have implemented LMRPs concerning the use of intravenous iron therapy include First Coast Service Options, Inc. and the Mutual of Omaha Insurance Company.

laboratory services. These groups provide the medical directors an opportunity to discuss issues related to coverage, including issues raised by providers and beneficiaries.[7] In contrast to the local decisions made by the FIs and carriers, the four DMERCs are required to create one set of coverage policies that apply nationwide.

Generally, contractors cannot develop policies to cover experimental or investigational services. However, beginning in 1995, Medicare has permitted the coverage of certain devices for which the Food and Drug Administration (FDA) has granted an investigational device exemption (IDE) and the coverage of certain services related to those devices (HCFA 1995).[8] Specifically, contractors can consider covering a device for which the FDA has: (1) granted an IDE; (2) provided a classification of nonexperimental investigational device, for which underlying questions of safety and effectiveness have been resolved for that device type (i.e., the device falls under "category B"); and (3) required that clinical trials be conducted, with beneficiaries participating in the FDA-approved clinical trial. The intent of this rule was to provide the opportunity for beneficiaries to gain quicker access to new services while permitting opportunities for providers and manufacturers of the service to build the body of evidence necessary for seeking broader coverage. Medicare does not cover investigational devices granted an IDE that are classified as "category A"—experimental and investigational devices for which absolute risk of the device type has not been established.

Coverage policies implemented in program manuals

Coverage policies also can be implemented through policies published in Medicare's program manuals and memorandums.[9] Program manuals, including the Medicare intermediary manual and the Medicare carrier manual, contain operating instructions, policies, and procedures based on statutes, regulations, and directives. Program memorandums are another vehicle for CMS to transmit new policies and procedures that are often but not necessarily linked to a specific program manual. Policies published in manuals and memorandums can set forth when and under what circumstances services may be covered and paid for by Medicare. For example:

- The Medicare intermediary manual provides coverage information about hemodialysis treatments furnished to ESRD patients. This policy limits Medicare's payment for hemodialysis furnished to beneficiaries with ESRD to a maximum of three treatments per week even though hemodialysis can be furnished on a daily basis. Medical directors can make individual coverage determinations for beneficiaries who require more than three hemodialysis treatments per week (CMS 2003).
- CMS issued a program memorandum in 2002 about the coverage of diagnostic services furnished by qualified audiologists. The memorandum set forth the specific circumstances for which diagnostic services provided to evaluate the symptoms associated with hearing loss or ear injury would be covered by Medicare and the qualifications audiologists need to be considered qualified by Medicare (CMS 2002b).

These policies are developed by CMS staff and are binding on all contractors. The number of coverage decisions implemented in this manner is unknown.

Medicare's coding process

CMS's coding requirements may implicitly affect the coverage of new services. (See Chapter 4 for a related discussion on paying for new technologies in Medicare's PPSs.) Medicare's payment systems are organized around standard sets of codes that describe the services furnished by providers to beneficiaries. All services must be appropriately coded for providers to receive payment from Medicare. Some providers contend that delays in updating codes result in delays in payments for new services, although there is no clear evidence of problems with access to these services. Timely coding updates are especially important in the outpatient sector, where payment bundles are small and most services require a code for providers to be paid. Organizations who assign new outpatient codes include CMS, the American Medical Association, the Health Insurance Association of America, and the Blue Cross Blue Shield Association.

Appeals process

Beneficiaries and providers have the opportunity to appeal the denial of coverage for services that contractors believe do not fall within a Medicare benefit category, are not reasonable and necessary, or are otherwise excluded by statute or regulation. Currently, the appeals process for Part A and Part B services offers up to five levels for beneficiaries and providers wishing to

7 Meetings of these clinical work groups are not required to take place in public settings.

8 Manufacturers submit marketing applications for clearance or approval of devices to the FDA. For certain devices, the FDA may require that clinical trials be conducted to obtain clinical information to determine the device's safety and effectiveness. Generally, for these devices to be shipped lawfully for purposes of conducting the clinical trial, the sponsor must obtain an approved IDE from the FDA.

9 This section specifically excludes national coverage decisions published in program memorandums and the coverage issues manual.

appeal a contractor's initial determination that a claim should not be paid, either in full or in part, by Medicare.[10]

The process begins when contractors notify beneficiaries and providers (the appellants) in writing of the reasons that they have denied coverage for a service. The appellants may request that the applicable contractor reconsider or review the denial of coverage (Figure B-1). If dissatisfied with the reconsideration of the denial of coverage, appellants can appeal the decision to Administrative Law Judges (ALJs), who are employed by the Social Security Administration. After the hearing with an ALJ, cases may be appealed to the Departmental Appeals Board of the Department of Health and Human Services, the final level of administrative appeal. Cases may then be appealed to the U.S. Federal District Courts.

As set forth in Figure B-1, the process has separate paths for appeals of Part A and Part B claims. Currently, depending on the type of service that is being appealed, the appeals process differs in terms of:

- the time frames for Medicare to act on an appeal,
- the minimum value amount of a claim to be appealed to an ALJ,
- the availability of an expedited review,
- the use of independent external reviewers, and
- the right of beneficiaries to continue receiving a service.

Figure B-1 shows some of the differences in the time frames for Medicare to act upon an appeal. Appellants have from 60 days for Part A services to 6 months for Part B services to file a reconsideration. The minimum value of services that can be appealed to an ALJ varies for Part A and Part B services. For inpatient hospital services only, appellants can ask for an expedited review by a Quality Improvement Organization (QIO) for a noncoverage decision. Inpatients cannot be discharged from the hospital or charged for additional time in the hospital until the QIO issues a determination within one full working day after receiving the request.

FIGURE B-1 **Medicare's process for appeals of Part A and Part B claims**

Part A	Level of appeal	Part B
Initial determination		Initial determination
60 days to file ↓	First	6 months to file ↓
FI reconsideration AIC = $0		Carrier review AIC = $0
	Second	6 months to file ↓ Carrier hearing AIC ≥ $100
60 days to file ↓ Administrative law judge AIC ≥ $100	Third	60 days to file ↓ Administrative law judge AIC ≥ $500; $100 for home health (A/B split)
60 days to file DAB may decline review ↓ Departmental Appeals Board AIC = $0	Fourth	60 days to file DAB may decline review ↓ Departmental Appeals Board AIC = $0
60 days to file ↓ Federal District Court AIC ≥ $1,000	Fifth	60 days to file ↓ Federal District Court AIC ≥ $1,000

Note: FI (fiscal intermediary), AIC (minimum amount in controversy), DAB (Departmental Appeals Board).

Source: Centers for Medicare & Medicaid Services. Medicare and Medicaid programs: changes to the Medicare claims appeal procedures, Federal Register. November 15, 2002, Vol. 67, No. 221, p. 69312–69363.

Two sections of BIPA call for CMS to modify the appeals process:

- Section 521 establishes uniform processes for handling appeals of Part A and Part B services after being furnished to a beneficiary. For example, BIPA establishes that disputed services must be worth at least $100 for appellants to appeal to an ALJ, sets forth a 90-day time limit for the ALJs and the Departmental Appeals Board to each make a decision about the case, and allows appellants to escalate the case to the next level if this deadline is not met. In addition, Section 521 establishes a new appeals entity—qualified independent contractors—to reconsider contractors' initial determinations.
- Section 522 clarifies when national and local coverage policies can be challenged by beneficiaries before receiving services. Section 522 also requires that CMS submit annual reports to the Congress regarding the amount of time the agency took to complete and fully implement NCDs for the previous fiscal year.

CMS has not yet fully implemented the changes mandated by BIPA. The agency has published proposed rules to implement Sections 521 and 522 and has submitted a report to the Congress on the time required for CMS to complete and fully implement the 10 NCDs made in fiscal year 2001 (Thompson 2002).

10 The section focuses on appeals related to Part A and Part B services. Medicare has a separate process for appeals related to M+C services, including an external review process and an expedited process for certain types of appeals.

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