

# Medicare Patient Access to Technology: The Lewin Group

*Medicare is playing an increasingly important role in determining whether America's seniors and disabled will have access to innovative medical technology, according to a new study by The Lewin Group. Contrary to common perception, approval of a new medical technology by the Food and Drug Administration does not mean it will be available to Medicare beneficiaries.*

*The Lewin Report –The Medicare Payment Process and Patient Access to Technology – provides the first- ever comprehensive analysis of Medicare patient access to advanced medical technology. Because of problems that have arisen in the program, the report concludes, it takes the agency 15 months to 5 years, and some times even longer, to add new technologies to Medicare.*

*The report examines four technologies to illustrate the impact of Medicare delays on innovation and patient access.*

- ◆ *An advanced bone density scanning technology was under review by Medicare for seven years before gaining coverage.*
- ◆ *A new, less-invasive treatment for benign prostatic hyperplasia encountered delays of up to two years in receiving local Medicare coverage.*
- ◆ *Few Medicare-age patients receive cochlear implants, which can restore hearing to severely deaf people, because of payment problems.*
- ◆ *It took Medicare several years to update reimbursement for implantable defibrillators to an adequate level, creating patient access problems for this life-saving technology.*

“Addressing the level of uncertainty associated with the Medicare coverage, coding and payment processes should therefore be a key issue for policy makers,” Lewin concludes. Reforms should be considered to “harmonize and streamline” these processes “in order to reduce the length of the process and to ensure that covered devices are appropriately reimbursed.”

## **KEY FINDINGS**

**The Medicare process for coverage, coding, and payment for many medical technologies is complicated and time-consuming, impeding patient access and discouraging innovation of breakthrough technologies.**

- Potentially, thousands of patients could go without an important new technology in the period of time required to obtain Medicare coverage.
- Patient access to new technologies can be impeded by inadequate payment that can influence providers' use of technology. Providers may limit performance of procedures, eliminating certain services, and use older and less expensive technologies despite increased benefit to patients of newer devices.
- Small companies are particularly vulnerable to hurdles posed by Medicare's uncoordinated and time-consuming processes. They often have fewer resources to invest in meeting higher evidence requirements, pursuing national or local coverage decisions, obtaining coding, and pursuing adequate payment. As a result, small companies may shift the focus of new product development to less innovative technologies that may have the most predictable routes to coverage and payment.

## **THE MEDICARE COVERAGE PROCESS**

*Coverage decisions by the Health Care Financing Administration (HCFA) or its local contractors are critical for providing Medicare patient access to new medical technologies. Non-coverage can effectively block utilization by Medicare patients.*

*The Medicare coverage process can be complex, time-consuming and expensive. It can frustrate and delay manufacturers' attempts to develop and launch new products. Recent trends toward increasing evidence requirements for coverage raise the hurdles to patient access and market viability for many technologies.*

**While recent changes to the Medicare national coverage process offer some important improvements, the process can still be unpredictable and time-consuming.**

- HCFA took steps to improve the openness of its national coverage process in an April 1999 notice. In principle, HCFA can complete the first step of this process – making the initial coverage decision – in 90 days and can complete the entire process in 12 months. In practice, Lewin says, the process can take five years or more.
- More complex or controversial issues, which HCFA predicts will constitute the majority of decisions face significant additional delays because they are referred to the Medicare Coverage Advisory Committee (MCAC) or to other agencies (e.g., the Agency for Healthcare Research and Quality) or non-federal organizations for technology assessment. There are no timeframes for these reviews.

**The local coverage process remains a critical avenue for obtaining coverage. However, its transparency and openness could be improved.**

- The majority of Medicare coverage decisions are made at the local level by HCFA's contractors rather than at the national level. The local coverage process remains a critical

avenue for obtaining coverage and should be preserved. However, the transparency, openness and predictability of the process could be significantly improved.

**Medicare coverage requirements are increasing in general, and remain unpredictable in certain important ways. These conditions raise hurdles for patient access to new medical technology and increase risk to manufacturers.**

- HCFA’s recent Notice of Intent (NOI, issued May 2000) to establish coverage criteria could create new hurdles to patient access.
- The notice represents an increased role for the federal government in the practice of medicine. It suggests that HCFA, rather than a patient’s provider, would determine whether a treatment is appropriate for a specific patient group.
- The NOI clearly represents an increase in evidence requirements for coverage that pose particular challenges to the industry. Satisfying HCFA’s need for required population-specific clinical data can be very costly, and can extend well beyond the evidence required for market approval by the FDA. The added expense of conducting such trials may inhibit manufacturers from pursuing development and marketing of some devices, thereby limiting availability of these technologies or patient access to them.
- For technologies judged to be equivalent in benefit to other Medicare-covered technologies, cost will be the key criterion used to determine coverage. This could limit availability of new devices and diagnostics based on cost rather than patient care considerations.

## **THE MEDICARE CODING PROCESS**

*Medicare’s payment systems are organized around standard sets of codes that describe services or procedures. Since coding systems link devices and procedures to Medicare payment, appropriate coding is critical for Medicare coverage and proper reimbursement. New codes should support pricing commensurate with new product value. However, payment may not be adequate for a new technology under an existing code, especially if the payment amount was based on older technology. Without appropriate coding, “new and improved” technologies are paid the same as “old and unimproved” technologies.*

**Obtaining adequate Medicare payment can take many months or years, impeding use of medical technology and patient access.**

- Obtaining proper coding can add several years to the process of gaining consistent coverage and reimbursement under Medicare. In order to remove time delays, coding updates must become more frequent.
- It takes 15-27 months to obtain a new code for use by physicians’ offices, clinical laboratories and durable medical equipment providers.

- The process of gaining a coding and payment adjustment in the inpatient setting often takes two years or more. However, the process takes even longer when a brand new inpatient code must be obtained.

## **THE MEDICARE PAYMENT PROCESS**

*After Medicare assigns a procedure code for a new medical technology, the payment levels can be assigned. **If the initial payment level is inadequate to cover the cost of the device, it may take several years to obtain a more appropriate reimbursement amount. In many cases, payment is never adjusted to adequate levels.***

***Inadequate payment rates create a strong disincentive for performing a procedure using a specific device, thereby restricting utilization and patient access to what may clinically be the most preferable device.***

**Medicare's procedures for updating payment amounts play a critical role in providers' adoption of and patients' access to new medical technologies.**

- Medicare fee schedules are updated annually at best. The process is lengthy, confusing, and in many cases inconsistent. Updates to the physician fee schedule payment are time-consuming and do not fully take into account the costs of innovative medical technologies. In addition, fee schedule payments are heavily discounted and therefore may not cover the costs of a new technology. Variability in Medicare's procedures for setting payment rates for new lab tests and durable medical equipment can result in inadequate payment and restrict patient access.
- In both the inpatient and outpatient settings, Medicare has moved toward prospective payment systems (PPS) for facility reimbursement. Under PPS, single, all-inclusive payments include reimbursement for the cost of medical devices used in the provision of care. Thus, under Medicare, providers have the financial incentive to use the least expensive device that is possible and medically acceptable, but what may not be the clinician's optimal choice.
- Obtaining appropriate reimbursement for new technologies can be a daunting task in the hospital inpatient setting. First, a manufacturer or provider must obtain a new inpatient code, which takes a least a year.
- Second, data collected using the new code must demonstrate that a new payment category is warranted. HCFA has almost exclusively used internal data in making these decisions, and requires a full year of data before acting. It then takes another year to implement the payment change.
- In practice, Lewin says, HCFA rarely increases payment of new technology in the inpatient setting. Gaining a reimbursement increase is particularly difficult for medical technologies that are used in small patient populations.

- Recent reform to outpatient payment, if properly implemented by HCFA, could improve payment for new technologies in this setting. Changes such as a separate “pass-through” payment for new technologies and more frequent coding updates are designed to better account for the increased costs of new and improved technology. Similar improvements should be applied more broadly to Medicare.

# **Solutions: Removing Medicare Patient Access Barriers**

The Lewin Report calls for changes to harmonize and streamline Medicare's coverage, coding and payment systems in order to reduce the length of the process and to ensure that covered devices are appropriately reimbursed.

Legislation introduced by Reps. Jim Ramstad (R-MN) and Karen Thurman (D-FL) (H.R. 4395, the Medicare Patient Access to Technology Act) would help eliminate barriers to patient access that have arisen in Medicare's coverage, coding and payment procedures for innovative medical technology.

## **ELIMINATING COVERAGE DELAYS**

H.R. 4395 would reduce the one- to five-year delays in Medicare coverage decisions by:

- ◆ Requiring Medicare to issue annual reports on the timeliness of its decisions
- ◆ Streamlining the Medicare Coverage Advisory Committee by allowing HCFA to receive advice directly from the committee's six panels
- ◆ Requiring the Medicare Payment Advisory Commission to include a medical technology expert.

## **ELIMINATING CODING DELAYS**

H.R. 4395 would reduce coding delays of 15-27 months by requiring HCFA to:

- ◆ Issue temporary codes at the time of FDA review.
- ◆ Eliminate the arbitrary six-month device marketing requirement before accepting applications for outpatient coding changes.
- ◆ Accept applications for new coding modifications throughout the year instead of only at one annual deadline and act on requests within 30 days.
- ◆ Update codes on a quarterly rather than annual basis.

- ◆ Consider opening to the public its outpatient coding committee meetings.

### **KEEPING PAYMENT UP-TO-DATE**

Medicare's payment systems lag behind advances in medical technology. It takes HCFA at least two years, and often longer, to make adjustments to its inpatient payment system. H.R. 4395 requires:

- ◆ Annual updates to Medicare payment systems
- ◆ Better use of internal Medicare data and broader use of external data
- ◆ Annual reports from HCFA on the impact of the new hospital outpatient prospective payment system on patient access to advanced medical technology.
- ◆ Annual reports by MedPAC on both patient access to technology in the outpatient setting and HCFA's procedures for making timely changes to its inpatient payment system to incorporate new technology

### **REMOVING ACCESS BARRIERS TO DIAGNOSTIC TESTS**

Medicare problems unique to diagnostics tests often create serious patient access barriers for these products. H.R. 4395 requires Medicare to:

- ◆ Set clear, open procedures for coding and payment decisions for these products.
- ◆ Explain the basis for its coding and payment decisions and make the data available to the public.
- ◆ Establish formal methods for setting reimbursement rates and create an appeals mechanism.