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HEALTH LAW

Payment for New Health Care Technologies: The Long and Winding Road

Your company has just made a medical breakthrough and discovered the next great advance in diagnostic testing, pharmaceuticals or medical devices. So, now, like the inventor of the proverbial “better mousetrap” all you have to do is sit back and wait for the world to beat a path to your door. Right? Well, if you do, it may be a very long wait.

The road from development of a new medical technology to payment is long, difficult and treacherous. With the explosion of new technology in the past 20 years, no health care issue has taken on greater importance than the process by which insurers and managed care plans, both public and private, decide whether to pay for new products and services. It is an area that the developers of new products may all too often not understand, leaving them with a potential major advance in medicine, but without a way to get it reimbursed by insurance companies or health plans.

The Steps

The pathway from development to payment involves at least three separate steps. First, there is the regulatory approval process. For most new drugs, medical devices and diagnostic tests, the Food and Drug Administration (FDA) will have a role, and usually a major one, in the approval of the product or service. The FDA's approval or clearance usually can only be obtained after a demonstration of the product's safety and effectiveness. However, product approval is not the same as payment approval. So the second step is to obtain coverage for the product, which will likely require insurers to make a judgment concerning the product's “medical necessity,” a simple term that masks a complex web of medical, legal and economic considerations. Finally, once the technology is *covered*, each insurer (public or private) must determine what it is willing to pay for the new product or service and what type of reimbursement methodology will be

applied. Additionally, it may be necessary to go to one of the organizations that establishes medical and procedure codes applicable to the product or service, such as the American Medical Association's "Current Procedural Terminology," referred to as "CPT," to ensure that once the technology is approved, covered and priced, physicians and hospitals will have a way to communicate to the payor what the product or service is and to bill for it.

Part of any successful strategy for bringing a new technology to the medical marketplace is understanding the steps and how they interrelate. Each step is important. During the regulatory approval process, proper guidance concerning FDA's procedures and requirements is essential. Similarly, during the payment-setting process, it is important to understand the intricacies of various reimbursement methodologies that may ultimately affect "the bottom line"—the amount that is paid for the product or service. Nonetheless, it is the coverage decision-making step that often may seem the most mysterious and opaque to outsiders. After all, once the government says a technology is safe and effective, shouldn't that mean that it will be paid for? The answer, unfortunately, is "not necessarily."

Medical Necessity

Twenty-five or thirty years ago, when medicine was much simpler, decisions about whether to cover a new product or service could be made quickly, with only a small amount of clinical evidence. The

increasing complexity of medical practice and the legal implications of making incorrect or unsupported decisions has made that simplistic *ad hoc* process a thing of the past. Today, most insurers—including Medicare, which is the world's largest health insurance program—have established formal processes for evaluating new and existing technologies and making coverage decisions.

While insurers often are contractually obligated to cover medically necessary care, the determination of what *is* medically necessary is a difficult one. Some insurers have specified criteria for use in assessing medical necessity. For example, in determining medical necessity, one large Blue Cross Blue Shield Plan requires the product or service to be:

- appropriate for symptoms, diagnosis and treatment of a condition, illness or injury;
- provided for diagnosis, direct care or treatment;
- in accordance with standards of good medical practice;
- not primarily for the convenience of the member or the member's provider; and
- the most appropriate supply or level of service that can be safely provided to the member.

One state Medicaid program, which also covers only medically necessary care, requires that there be no comparable treatment that is "more conservative or less costly" and that all treatments meet the professionally recognized standard of health care

"as determined by peer reviewed medical literature or local and regional medical experts."

Medicare also has a medical necessity requirement, although it is found among the "exclusions" from coverage; that is, the Medicare statute states that the program cannot pay for items and 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." In fact, this limitation is so restrictive that Congress had to pass special legislation so that Medicare could pay for certain "screening" services, such as Pap smears, mammograms and prostate screening—services with clear clinical value, but which are not being used to diagnose or treat a current illness or injury.

The Evaluation Process

To determine what new technologies to cover, most private insurers have established processes to obtain information through systematic reviews of published literature, in combination with input from clinical specialists. Many also have some type of independent "Medical Affairs Committee" that reviews the coverage decisions made by the insurer. In virtually all cases, the emphasis is on clinical evidence; *i.e.*, data from clinical trials or peer-reviewed literature that demonstrate the effectiveness and benefits of a particular type of medical intervention.

The national Blue Cross Blue Shield Association, an organization that

represents the nation's 43 local Blue Cross Blue Shield plans, has established a Technology Evaluation Center (TEC), which is staffed by physicians and scientists, who review various new medical technologies and determine whether they will improve health outcomes such as length of life, quality of life or functional ability. The TEC is assisted by an outside panel of medical experts, which has the final scientific and clinical authority for the TEC assessments. In making its determinations concerning new technology, the TEC uses the following criteria, among others:

- The scientific evidence concerning the effect of the new technology should demonstrate that the technology could measure or alter the physiological changes related to a disease, injury, illness or condition. In addition, there should be evidence, or a convincing argument based on established medical facts, that such measurement or alteration affects health outcomes.
- The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
- The technology should improve the net health outcome as much as, or more than, established alternatives.

The evaluations made by the TEC are then used by individual Blue Cross Blue Shield plans to determine whether to cover a new technology.

The Medicare Response

Medicare, which covers health care services to the nation's elderly and the disabled, is often the most important insurer when a company is seeking coverage for a new technology. Not only does the sheer size of the program give it importance—Medicare covers about 39 million Americans—but many other private insurers often look to Medicare's decisions in deciding whether they will also cover a new product or service.

Medicare, however, has had difficulty establishing its own coverage process. Although Medicare is a national program, it relies on a network of "contractors," most of whom are themselves insurance companies, to review and process Medicare claims. Part of the contractors' responsibility is to make determinations concerning coverage for new products and services. There are no clear standards for the review, and contractors usually look at whether the service has demonstrated effectiveness, whether it is appropriate for patients' needs, and how it compares in potential costs and benefits to other existing technologies. Because some contractors cover specific geographical areas, and some cover specific providers, there may be considerable variation among contractors both in whether a particular technological advance is covered and the circumstances under which it is covered.

After several unsuccessful attempts to create a more standardized, national process during the 1980s, Medicare

finally took steps to establish a comprehensive national coverage process in 1999. At that time, the Health Care Financing Administration, the agency within the Department of Health and Human Services that oversees Medicare, which recently changed its name to the Centers for Medicare and Medicaid Services (CMS), established a comprehensive process to make coverage decisions that would apply nationally. Although local contractors continue to make many, if not most, initial coverage decisions, the new process allows CMS itself or outside parties to request a "National Coverage Decision." National Coverage Decisions apply across the entire Medicare program and supercede any contrary local decisions made by a contractor. CMS has proposed, but not yet finalized, criteria that would be used in making these coverage decisions. For example, the new item or service is supposed to have demonstrated "medical benefit" and "added value" to the Medicare population, but the definitions of these terms have been controversial. As a result, no final action has been taken on the criteria.

For the first time, CMS also has established an advisory panel of outside experts, the Medicare Coverage Advisory Committee ("MCAC"), to advise CMS on whether new products and services should be covered. The MCAC is divided into an Executive Committee and six smaller panels, each of which focuses on specific products or services. In making recommendations, a panel is to determine whether the scientific evidence is adequate to allow it to make

conclusions about the effectiveness of a particular intervention in routine clinical use in the Medicare population and how the effectiveness of the new intervention compares to other established services and items. The panel then reports back to the Executive Committee.

Some coverage decisions have emerged from the MCAC, but a variety of internal problems have also been encountered. Not only are

the criteria and other procedures to be used by MCAC still being developed, but Congress periodically directs CMS to make changes to the MCAC process. Thus, the Medicare coverage process remains a “work in progress” and companies seeking coverage from Medicare must be very careful not to become lost in a regulatory morass.

Conclusions

The best advice for companies attempting to negotiate this complex process is to have a clear understanding of its various components, their interrelationships, and their goals. Clearly, however, at least in the field of health care, discovering the “better mousetrap” is only the beginning, not the end, of the long and winding road.

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