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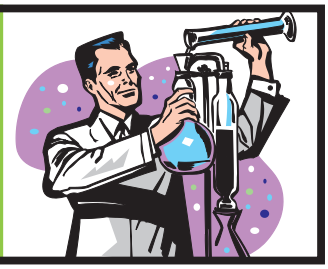
Life Sciences A Practice Focus

Don't Forget Medicare

Getting covered by the giant health plan is critical to a new drug's success.



By Beth L. Roberts
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Many life science companies recognize the need for patent protection and Food and Drug Administration approval. What they may not recognize is that these are only the beginning of their regulatory concerns. IP and drug approvals can help bring a new product to market, but Medicare's OK is essential to bring the product to patients.

Medicare is the federal health care program for 35 million Americans over age 65 (and another 6 million younger Americans with certain disabilities or end-stage renal disease). If a new medical technology treats conditions affecting senior citizens, Medicare coverage is an absolute necessity for commercial success. As the United States' largest health insurance program, Medicare also has enormous influence over other health plans: When Medicare decides to pay for a new treatment, other insurers often follow its lead.

Planning for Medicare should begin well before the FDA approves the new technology. Ideally, life science companies in the early stages of research should be considering how a future product might be treated under Medicare. Whether a procedure is performed in an inpatient or outpatient setting, whether a drug is administered intravenously by a physician or self-administered as a pill by a patient can radically affect reimbursement.

Stated most simply, life science companies with promising products must address three distinct Medicare issues—coverage, coding, and payment.

Are You In or Are You Out?

The path to reimbursement begins by asking whether Medicare will cover the new technology at all. The drug or device must fall into one of the program's benefit categories, such as inpatient and outpatient hospital care, physician services, diagnostic laboratory services, skilled nursing facility care, home health care, hospice care, durable medical equipment, and some drugs. Plus, the technology must not be specifically excluded from coverage. For example, hearing aids and most dental care and cosmetic surgery are excluded.

Additionally, Medicare will pay only if the technology is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." This key language from the Social Security Act gives the Centers for Medicare and Medicaid Services (CMS) and its contractors broad discretion to decide whether and under which circumstances new technologies will be covered. Medicare examines not only whether the drug or device has FDA approval but also whether it is appropriate for the Medicare population, where it will be used, and whether it has been proven medically necessary for the relevant disease or condition.

Medicare's coverage decisions can be made at both the national and local levels. Most new technologies simply achieve coverage when health care providers submit the first successful claims. For a smaller number of products, the CMS or its contractors use formal decision making. The CMS can opt for a national coverage decision setting a single policy for all Medicare contractors, or it can let each contractor set its own policies, allowing for gradual acceptance of new technologies and recognizing regional variations in medical practices.

No matter which procedure is used, life science companies must be prepared to push for coverage. They may need to give health care providers information to help get claims processed. Early discussions with Medicare contractors about new products can be helpful. And companies seeking formal coverage deci-

sions will need to support their claims with clinical trial data, particularly from trials that included Medicare beneficiaries.

Take a Number

Claims cannot be processed without codes. Almost every health care product or service that can be purchased in America has a number assigned to it under at least one coding system. Providers must use the codes to receive payment for their services. Insurers, including Medicare, use the codes to identify procedures, diagnoses, drugs, and devices, and to match services rendered to payment rates. Accurate coding also allows the CMS to select data from the more than 600 million Medicare claims processed each year when it needs to analyze utilization and payment for specific technologies.

Some new products are similar enough to existing products to share their codes. However, if new and old technologies vary greatly in price, dosage, or the resources needed to use the product, the new technology will need its own unique code.

The type of code and the procedures for obtaining it depend on the type of product and the setting in which it will be used. Medicare relies on several coding systems maintained by different organizations, including the CMS, the American Medical Association, and the International Classification of Diseases–Ninth Edition–Clinical Modification (ICD-9-CM) Coordination and Maintenance Committee. These organizations typically take from six months to more than two years to grant new codes. Given the possible delay, manufacturers need to watch deadlines closely.

Until specific codes are issued, providers may sometimes submit claims for new technologies under miscellaneous codes. But these claims, for the most part, must be processed manually and must be supported by clinical information demonstrating medical appropriateness.

Issues involving the choice of a code have become more important as federal prosecutors have focused on coding and coding advice as the basis for suits under the False Claims Act and other laws.

Check, Please

Finally comes the matter of reimbursement. A new product may have a code and be recognized as covered, but if Medicare doesn't pay for it at an appropriate rate, Medicare beneficiaries will have little effective access. Again, payment is dependent on the type of product and the setting for its use. Medicare has different payment systems for different settings—from physicians' offices to ambulatory surgery centers. Additional payments for certain new technologies are permitted under some systems but not others.

Congress has also attempted to adjust some payments to accommodate new technologies, but elaborate payment formulas can undermine these efforts. Under the hospital inpatient and outpatient prospective payment systems, for example, Congress has enacted several laws to enhance payment for new drugs and devices. But the CMS has interpreted these provisions narrowly or has used methodologies that tend to produce little improvement in payment rates.

Adding to the complexity of these systems are frequent regulatory and legislative changes, including the recent Medicare Prescription Drug, Improvement, and Modernization Act. In addition to a new prescription drug benefit, the 2003 act creates two new reimbursement methodologies for drugs. The new system will be phased in over two years. In each year of the phase-in, certain drugs will be excluded from these methodologies and paid under different rules. The act also alters payments for certain drugs administered in hospital outpatient departments, creating payment ceilings and floors for two years and then establishing payments based on acquisition costs in 2006 and beyond.

The CMS itself has developed ways to limit payment for new technologies. The agency can adjust payment rates up to 15 percent per year for some items when it determines that existing rates are "inherently unreasonable." The CMS has also applied a "least costly alternative" policy under which two products that the CMS deems "clinically equivalent" are both covered by Medicare, but are paid based on the cost of the less expensive option. And a third attempt to limit reimbursement—using a "functionally equivalent" test to restrict payments for a new biological product to the rate applicable for an older product—was introduced in the final 2003 hospital outpatient payment rule. However, the Medicare Modernization Act prohibits further use of this standard, with a very narrow exception.

In short, getting Medicare to embrace new technologies is a challenge that requires knowledge of a dense array of statutes, regulations, and agency guidances. The rules are complicated, but the lesson is simple: If you are counting on reimbursement for your new life science technology, don't wait until your product is launched to get Medicare advice.

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