

# Disease Management: A Pharmaceutical Industry Perspective

***Disease management is carving out a place for itself in the health care industry, and the pharmaceutical industry should keep a hand on the carving knife.***

**By Stan Bernard**

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The term "disease management" is one of the most popular phrases in the pharmaceutical industry today, yet few people agree on its meaning. First, the term "disease management" is a misnomer. Physicians and other providers do not manage diseases; they manage patients. We use the term "disease management" here because it has become accepted jargon, although "comprehensive patient health management" would be a more appropriate term.

Disease management is a methodology designed to rectify some of the efficiency and effectiveness problems in the current delivery of health care. The discipline addresses coordination and continuity of care, accountability, alignment of incentives, and quality measurements in an effort to streamline and otherwise improve many aspects of health care. In the simplest terms, disease management is the application of business principles to the art and science of medical practice. The concept of disease management can further be defined as a comprehensive, integrated system for managing patients across the health care continuum by using best practices, clinical practice improvement, information technology, and other resources and tools to reduce overall costs and improve measurable outcomes in the quality of care.

It is noteworthy that pharmaceutical products go unmentioned in the above definition. Medicines are some of many therapeutic interventions that can help manage conditions in some patients; as such, they are a significant but relatively small part of overall disease management.

Dr. Robert Browne of Integrated Disease Management has described the concept of disease management by characterizing what it is *not*. Disease manage-

ment is *not*, nor should it be, a pharmaceutical company marketing tool or a new form of drug promotion. In its truest sense, disease management represents a paradigm shift in the way payers and providers deliver and value health care. It is distinct from and extends beyond a product promotion strategy. Disease management is *not* a physician education seminar, a patient-compliance program, a treatment guideline, or even a menu of such tactics.

Further, disease management is *not* capitation or risk sharing. By coordinating clinical, business, and information systems, disease management helps to lay the foundation upon which a financial risk arrangement can operate. Finally, disease management is *not* outcomes research, although the terms are often used synonymously. Outcomes research is an important component of disease management, but it is only one of a number of different methodologies used to measure the clinical, economic, and humanistic consequences of disease management interventions. This article examines the most common questions that concern disease management and looks ahead to the pharmaceutical industry's role in the promising approach.

## **DOING WHAT IS BEST**

The spectrum of disease management systems is unlimited. However, there are a number of principles common to many of the disease management systems that leading providers are currently developing and implementing.

Disease management involves coordinating care for patients across the entire health care continuum from birth to death. The process involves managing not only the patient with a particular disease,

but also the healthy patient. Too often providers focus on providing intensive and costly services to patients with acute episodes of disease; disease management advocates seek a greater focus on preventive, comprehensive care to improve the health of the entire population.

To provide such care throughout the lifespan, providers and payers must integrate their health care systems. Upon entering an integrated health care system, all patients should undergo a full health status assessment to determine their relative health risks. Establishing risk is important because disease management focuses on appropriate allocation of health care resources based on patient profiles and risks. The patients at greatest risk must have their modifiable risks altered and be monitored closely over time.

For those patients who have or develop disease, there must be a multidisciplinary provider team to coordinate patient care. A physician with the necessary training to direct overall patient care should head the provider team. In addition, disease management calls on "physician extenders"—for instance nurses, nurse practitioners, and physician assistants—to conduct many of the more routine services and procedures that physicians have traditionally performed. Companies must align financial and other incentives for plan administrators and members of the provider teams to focus on the overall system objective: providing appropriate, cost-effective care.

Companies should implement "best" clinical practices as determined by using process and outcomes measures. Dr. John E. Wennberg and others have consistently demonstrated the wide variation in clinical care provided for identical disease conditions and procedures in different locations. Although researchers have been able to document the variations in care, the challenge has been to determine the best way to provide optimal care for specific populations of patients with certain diseases.

The primary reason for the deficiency has been a lack of comprehensive, readily available *clinical* information. In fact, much of the outcomes data-base analyses conducted to date rely heavily on financial information from computerized insurance claims data and not on the clinical data usually found in written patient medical records. Increasingly, computer-

ized patient records and other types of automated health care information systems will incorporate clinical information and draw information from disparate database systems, including those focused on hospitals, physician services, outpatient services, diagnostic procedures, pharmacy, and laboratories.

By measuring and analyzing the clinical processes that result in the best clinical, economic, and quality-of-life outcomes, integrated health care systems can determine and constantly update the best medical practices for their providers, a process known as "clinical practice improvement." The effective dissemination of clinical guidelines and the implementation of best practices will be critical to the success of health care plans, as will provider compliance to the guidelines. Encouraging and training patients to play a major beneficial role in their own disease care will also be important. Integrated systems that effectively implement such disease and health management systems will have the necessary data and provider control to accurately manage their risks and will gain a significant, sustainable competitive advantage in a capitated health care marketplace.

#### **SUM OF ITS PARTS**

Companies can use many tools and resources in designing disease management systems. What follows is a summary of the key components categorized in three ways: system design, system implementation, and system measurement and improvement.

First, one of the principal tools for designing a disease management system is "disease modeling." Disease modeling requires analysis of the critical points in a disease process, pinpointing the areas that have the greatest impact on the clinical, economic, and humanistic outcomes of care. An excellent example of disease modeling is in the management of AIDS. As the understanding of the disease has improved, providers have advanced from treating AIDS as a hospital-based disease to treating it as a community-based long-term illness.

Clinical practice guidelines are another essential design component. The guidelines help patients and practitioners choose the appropriate course of health care for specific conditions.

Medical professional societies (such

as the American College of Cardiology), government agencies (the Agency for Health Care Policy and Research), managed care organizations, and third-party vendors are the primary developers of clinical practice guidelines—alternately described as "practice parameters" and "clinical protocols." Unfortunately, many of the guidelines are too unspecific to implement in many health care settings.

Second, most providers recognize that effectively implementing disease management systems is a far greater challenge than designing them. Thus, "care process mapping" has become a popular means of applying disease management. A care map represents a project management plan for *how* care should be provided in a specific setting, in contrast to clinical guidelines that serve as a blueprint delineating *what* needs to be done. Care mapping diagrams are usually detailed, comprehensive process charts, and provider teams typically design them.

Several other tools help management take disease management from the drawing board to practice. Case management provides intensive, customized care for unique or challenging patient conditions; provider compliance programs increase clinical practitioners' adherence to guidelines, formularies, and other health plan stipulations; and patient education and compliance programs reinforce disease management initiatives among those who receive care.

System measurement and improvement is the third category of disease management components. Companies must measure all aspects of disease management programs to determine the results of such systems in improving overall patient care. Measures include clinical, economic, and humanistic outcomes; care processes or best practices; provider profiles and plan report cards; and analyses of cost accounting and resource use.

Health care systems must deploy extensive information systems to measure disease management's various components. Measuring and executing clinical practice improvement initiatives and other disease management tools requires collecting, integrating, analyzing, and communicating information with reasonably sophisticated information technology systems.

## SYSTEMS IN ACTION

The classic disease management system is the “Managed Care Chronic Illness Model for Asthma” program at the National Jewish Center for Immunology and Respiratory Medicine in Denver, Colorado. The National Jewish Center has developed a comprehensive, community-based health management program for asthma that incorporates many fundamental disease management interventions. The center uses an integrated, population-based continuum-of-care approach to provide early preventive care and, where appropriate, specialized care in an asthma “center of excellence” hospital.

Inpatient and outpatient multidisciplinary provider teams design individualized treatment plans to achieve the best possible outcomes, even teaching patients techniques for asthma self-management. The National Jewish Center’s program has demonstrated marked improvements in patients’ quality of life, as well as significantly reduced emergency room visits, hospital visits, and hospital days.

Similarly, Group Health Cooperative of Puget Sound, a leading staff-model health maintenance organization (HMO), has installed a coordinated program called the “Diabetes Roadmap Effort.” The initiative relies on practice teams that use medical guidelines and care, process mapping to deliver routine diabetes

assessments, improved clinical management, and comprehensive patient education that can include group therapy sessions. Employing a sophisticated

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information system called the diabetes registry, providers can identify high-risk diabetic patients and measure the processes and outcomes of care.

In an excellent example of teamwork between managed care providers and

pharmaceutical companies, Group Health is developing its diabetes disease management program with the assistance of Eli Lilly and Boehringer Mannheim. According to Group Health’s Michael Hindmarsh, the two companies are supporting the development of population-based managed care products, including patient education videos and outcomes analyses.

## PHARMA’S ROLE

There are three major reasons why pharmaceutical companies are involved in disease management programs. First, companies need to satisfy the needs of their evolving customer base, primarily managed care organizations (MCOs). As MCOs become more integrated and provide complete services across the patient care continuum, they will be competitively compelled to introduce disease management programs. The integrated systems will increasingly focus on high-cost, inefficiently managed chronic care conditions, many of which can be treated effectively by pharmaceutical products. As a result, customers see the pharmaceutical industry—an industry replete with physician behavior modification techniques, clinical and outcomes research expertise, and financial resources—as a valuable partner in the development of disease management programs. Con-

## COMPONENT APPROACH

In the component approach to managing health care, budget management assumes paramount importance. Such a strategy creates incentives to reduce to overall pharmacy budget without regard for associated health care costs.

Diseases	Budgets				
	Hospital	Ambulatory Care	Physician Services	Laboratory/Diagnostic Services	Pharmacy
CAD	\$\$\$\$	\$	\$\$\$	\$\$\$	\$\$
Diabetes	\$\$	\$\$	\$	\$\$	\$
Asthma	\$\$	\$\$	\$	\$	\$
Cancer	\$\$\$	\$\$	\$\$	\$\$	\$\$
Depression	\$	\$\$\$	\$\$	\$	\$\$
AIDS	\$\$	\$\$	\$\$	\$\$	\$\$\$
Total Costs	\$	\$	\$	\$	\$

## SYSTEMS APPROACH

In the disease management approach to managing health care, health care delivery systems bear greater responsibility for the overall health of the patient than they do in a more component-driven approach.

Diseases	Budgets					Total Costs	Quality Measurements
	Hospital	Ambulatory Care	Physician Services	Laboratory/Diagnostic Services	Pharmacy		
CAD	\$\$\$\$	\$	\$\$\$	\$\$\$	\$\$	\$	↑↑
Diabetes	\$\$	\$\$	\$	\$\$	\$	\$	--
Asthma	\$\$	\$\$	\$	\$	\$	\$	↓
Cancer	\$\$\$	\$\$	\$\$	\$\$	\$\$	\$	↑↑↑
Depression	\$	\$\$\$	\$\$	\$	\$\$	\$	↓↓
AIDS	\$\$	\$\$	\$\$	\$\$	\$\$\$	\$	↑

EDS MANAGEMENT CONSULTING SERVICES

versely, companies concerned about the increasing control such plans are having over pharmaceutical usage are anxious to form partnerships.

Besides satisfying current and future customers, companies need to demonstrate the cost-effectiveness of their products. According to the Boston Consulting Group, the vast majority of the managed care marketplace uses a "component approach" to manage pharmaceutical products—as well as other health care services and products. (See "Component Approach.") In the component paradigm, the goal of most managed care plans is to minimize expenditures in each of the component budgets. Such a strategy creates positive incentives for a managed care pharmacy director or a contracted pharmacy benefit management company to reduce the overall pharmacy budget without regard to associated health care costs.

Several studies have demonstrated flaws in the component approach to pharmaceutical management. For example, in a study reported in the 10 October 1991 *New England Journal of Medicine*, Stephen Soumerain and Jerry Avorn evaluated the impact of 11 months of drug caps—a maximum of three reimbursed prescriptions per month—on Medicaid patients in New Hampshire. Although the use of pharmaceuticals fell 35 percent, the number of elderly Medi-

caid patients entering nursing homes increased by more than 50 percent. Predictably, overall Medicaid health care costs went up.

The component management approach fails primarily because it is unable to recognize the intricate interrelationships between costs and components. If pharmacy directors took the component strategy to its extreme and eliminated the use of medicines altogether, they would indeed realize significant savings in the pharmacy budget—at an astronomical cost in hospitalizations, physician services, and other areas.

Finally, pharmaceutical companies concern themselves with disease management because financial risk continues to flow downstream. Until the sixties, patients paid for most of their own health care expenses. In the sixties and seventies, however, government and large employers began to reimburse for health care costs. Over time, payers asked large insurers, such as Blue Cross/Blue Shield, to accept the financial risk.

In the eighties, insurers increasingly relied on MCOs to manage their costs and risks, and the MCOs have in turn looked to providers and contractors—primarily physicians and hospitals—to accept some of the risk and accept capitated payments. Now, as managed care becomes more competitive, MCOs are looking to suppliers, including pharma-

ceutical companies, either to share risk or accept full capitation in exchange for making their products available to managed care patients. (See "Systems Approach.")

The rationale for the risk-sharing strategy is twofold. First, MCOs simply want to spread their financial risk. Second, managed care plans are increasingly held accountable for both economic and clinical outcomes. Therefore, some MCOs expect companies to provide outcomes guarantees based on the performance of their products. Consequently, if companies are going to be held accountable for the performance of their products, they need to ensure positive clinical and economic outcomes. For companies to prosper in such an arrangement, they must coordinate many aspects of patient care—hence the need for company-sponsored disease management programs.

### TAKING AIM

The primary target audiences for disease management programs will be pharmaceutical companies' principal customers, the MCOs, which currently influence or control more than half of the distribution and use of pharmaceutical products. MCOs include HMOs, integrated health care delivery systems, insurance companies, hospital management companies, government agencies, pharmacy benefit

management companies, and long-term care providers.

As the MCO's primary customers, large employers will be another major target group. The confusion in the business landscape was illustrated in a recent exchange between an employee health benefits manager of a Fortune 100 company and the company's pharmacy benefit management (PBM) firm. When the PBM asked the company what it meant when it said it needed disease management programs for its employees, the benefits manager said, "I don't know what it is, but we need it." Although disease management remains unclear to many employers, they recognize that it has the potential to lower their health care costs and improve the health of their employees. MCOs are recognizing disease management's appeal and are taking pains to market disease management programs to employers.

Providers will also be major audiences for disease management programs, particularly because of their critical roles in disease management programs. Many clinical practitioners are initially resistant to using clinical guidelines and other disease management tools. However, once research demonstrates that such interventions significantly improve clinical outcomes, providers will probably support and even lead the initiatives.

The ultimate customers of disease management programs are patients. Once patients have experienced the quality of care that programs such as the National Jewish Center's asthma program or Group Health's diabetes program provide, they are unlikely to seek a return to routine care. If disease management programs run properly, patients will be the main drivers of disease management initiatives. They will bring the impetus for developing programs to their employers, to MCOs and, in some cases, to the MCO's pharmaceutical company partners.

## MARKETS AND MARKETERS

Pharmaceutical company disease management initiatives usually center on chronic, high-cost disease states that are predominantly treated with pharmacotherapy. Many such illnesses can be better managed—both clinically and financially—using a disease management approach. Current disease management programs typically target asthma and diabetes. Other conditions with

strong potential for disease management include AIDS, cancer, depression and other mental health conditions, ulcers and gastrointestinal diseases, osteoporosis, and cardiovascular diseases including hypertension, hypercholesterolemia, heart failure, and angina.

Generally, MCOs' capabilities and resources for managing such disease states include access to patients and, to varying degrees, health care data. Most health plans manage a network of physicians and other health care providers who have extensive experience and knowledge regarding patient care. Further, the plans usually have substantial financial and actuarial systems and expertise.

Pharmaceutical companies offer MCOs several advantages in the development and implementation of disease management programs. Foremost, companies often have significant capabilities and expertise in clinical and economic research and development processes,

***The ultimate customers of disease management programs are patients.***

both of which are valuable skills in developing a disease management approach. Companies also have therapeutic area knowledge and experience in developing provider/patient education and compliance programs. MCOs, which have difficulties altering provider attitudes, approaches, and actions, are particularly impressed by pharmaceutical companies' behavior modification techniques. Finally, companies have far greater financial and personnel resources than most MCOs, adding to their allure.

It is important to recognize that the capabilities of both MCOs and pharmaceutical companies may change dramatically over the next few years. Several companies have already purchased PBMs with their own pharmacy data records and pharmacy intervention programs. Eli Lilly and Zeneca have both set

up separate divisions for offering disease management programs. Other companies committed to disease management initiatives are recruiting and hiring physicians, case managers, actuaries, information technology experts, and other specialists to create disease management programs of their own.

## FROM BLUEPRINT TO STRUCTURE

The roles of pharmaceutical and other health care companies will largely depend on their respective objectives, capabilities, and resources. Perhaps more critical is the issue of who will own the disease management programs. Three different models of ownership are offered below.

**R & D model.** Pharmaceutical companies will manage the development of disease management programs the same way they manage the development of their pharmaceutical compounds. Companies develop drugs by working with a number of expert investigators and institutions to test different attributes of the products—efficacy, pharmacokinetics, and toxicity, for instance—and they will use the same method with disease management initiatives. Companies will pay knowledgeable health care organizations to test certain disease management components—clinical guidelines, patient compliance programs, or outcomes measures. The companies will then package the component pieces and market a tested disease management service or product.

**Squatter's rights model.** MCOs that team with pharmaceutical companies to develop components of disease management systems will claim proprietary rights to use the system only in their plan. MCOs may also commercialize the program themselves because it was developed within their system.

**Joint venture model.** Early on, shared systems or components of disease management systems will be the most common ownership scenario. For example, a jointly developed provider compliance program will stipulate that pharmaceutical companies only distribute the program to noncompetitors of the MCO that helped in its development. Alternatively, the company could sell a jointly developed clinical software program and provide a licensing fee to the MCO.

## FRAMING THE FINANCES

As disease management programs evolve, companies will have a myriad of financial options depending on the exact

nature of the program. Three such possibilities are

**Value-added option—"offering."** The most basic of disease management initiatives will be those that pharmaceutical companies offer as "value-added" programs, perhaps consisting of clinical guidelines, medical education programs, and patient compliance programs. The programs will be offered free to enhance customer relationships, or as part of a pharmaceutical contract incentive.

**Consulting service—"carve-in."** Pharmaceutical companies provide a disease management consulting service for which they are compensated through either standard consulting fees or risk sharing. Other creative contracting arrangements are also possible. The various options are a "carve-in" because the MCO that uses a company for consulting retains financial and other control of the care providers. Eli Lilly's Integrated Disease Management division currently offers such a service to some of its customers.

**Provider services—"carve-out."** At the other extreme of financial relationships, some companies or their subsidiaries will become care providers for some "carved-out" disease conditions. Such providers will be reimbursed much as managed care providers are today, through capitation and other risk-sharing arrangements. Some companies may develop carved-out expertise internally; others will move

more quickly by acquiring the skills externally. Zeneca's recent purchase of Salick Health Care, a provider of capitated oncology services, is an example of the latter.

#### **TAILORED FOR PHARMA**

MCOs and other health care organizations—including Group Health Cooperative of Puget Sound, Intermountain Health Systems, Kaiser Permanente, Lovelace Health Systems, and the Mayo Clinic—have demonstrated that disease management initiatives can be effective. In particular, two major characteristics of successful disease management organizations are significant integration of health care delivery providers and of information systems. Despite the success of disease management programs, there are many challenges and obstacles health care organizations must address to successfully establish disease management systems of their own. The challenges are particularly daunting for nonprovider organizations such as pharmaceutical companies.

Companies first must demonstrate to health care organizations and providers that their programs are more than simply new promotional programs, they are true collaborative clinical initiatives. Companies must be aware of what the MCOs want to provide—cost-effective, high-quality care. Second, companies must develop clinical and managerial

expertise and provide the necessary financial and personnel resources to establish effective disease management programs. Finally, companies will have to document with various outcomes measures and other objective techniques that their disease management systems add real value to the ongoing patient care efforts of their managed care customers.

Regardless of who develops and implements disease management systems, it is clear that the concept of disease management is one that will ultimately alter the delivery of health care. Instead of an uncoordinated, patient-based, acute care-focused, and unaccountable component-management approach, companies can help remake health care as an integrated, population-based, prevention-oriented, measurable, continuous care system.

No one should underestimate the complexity, cost, or time required to deploy disease management systems, but the ultimate outcome of the paradigm shift will be more cost-effective, high-quality care for the benefit of patients, providers, and payers. And, although the move toward disease management will be difficult, pharmaceutical companies are uniquely suited to help—with their wealth of products, R&D capabilities, therapeutic area knowledge, educational programs, and human and financial resources—and can play an integral part if they so choose. ■

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