

Chapter 7: Coverage and Reimbursement

The coverage and reimbursement policies of public and private organizations that pay for, provide or insure conventional health care services have played and will continue to play a crucial role in shaping the health care system in this country. Likewise, policies influencing coverage of and reimbursement for non-conventional health care therapies will play an increasingly important role in the future of complementary and alternative medicine (CAM), as well as the future structure of the nation's health care system.

Today, coverage of CAM is evolving in benefit design, type and number of interventions offered, and availability. Consumers and health care providers may use available coverage for a CAM therapy as a principal intervention or as an integral part of the treatment of certain health conditions, such as acupuncture for management of chronic pain. The direction taken by health plan coverage of CAM in the future will shape consumer access to CAM services, the degree of integration of CAM and conventional medicine, and the philosophical foundation of the nation's health care system.

Although a considerable segment of the U.S. population is uninsured -- a significant public policy issue in itself -- health care coverage is widely available in this country. Recent census data indicate that 86 percent of the population had some type of health insurance during the year.¹ Included in that number are 32 million people (11 percent of the population) covered by Medicare, the federal insurance program for the elderly and for eligible persons who are disabled or who have end-stage renal disease. Other significant sources of health care coverage include private employer and sponsors of benefits, the Office of Personnel Management (OPM) for Federal employees, State and other public employers, the Department of Defense (DOD) for the military community, the Department of Veterans Affairs (VA) for veterans, and Federal and State programs providing Medicaid and other health coverage for the economically disadvantaged. Researchers estimate that, in 2001, Federal and State programs (i.e., Medicare, Medicaid, and the State Children's Health Insurance Program) accounted for 44 percent of the nation's health expenditures and that insurers and other private sources were responsible for 40 percent.² The entities, whether public and private, that pay for or bear most of the cost of coverage are the purchasers of health care.

With some exceptions (e.g., fee-for-service Medicare), purchasers obtain health care coverage for their employees or eligible persons by "buying" health plans in the private market. Less commonly, purchasers directly contract with, or employ, health care providers.

¹ The remainder, or approximately 14 percent of national health expenditures, were paid out-of-pocket.

The entities that sell health plan coverage to purchasers are insurance and managed care companies, which include preferred provider organizations (PPOs) and health maintenance organizations (HMOs). These companies undertake all the tasks associated with operating health plans, including marketing, enrollment, paying or operating networks of thousands of providers (physicians, hospitals, clinics, nursing homes, therapists, and so on), and bearing -- or sometime sharing with providers -- most of the financial risk of health care coverage. That is, they shift the potential for financial loss from purchaser to themselves. Even federally sponsored programs such as Medicare, and Federal sponsors such as DOD (for the military, retirees, and dependents), have in place special programs that shift not only delivery of care but financial risk to managed care companies. Some purchasers, including a number of employers, self-insure and assume the risks inherent in providing health care coverage, although these purchasers are the exception rather than the rule.

Consumers are sheltered from most of the costs associated with conventional health care, as well as from the risks of future, unknown expenses because purchasers, insurers, and managed care companies shoulder them. In contrast, most fees for CAM services and products are paid by consumers. This direct financial relationship between provider and consumer has the merit of enhancing the consumer's interest and participation in his or her treatment. Furthermore, some CAM practitioners feel that their ability to control fees -- and to avoid time-consuming claims payment and network participation requirements -- enables them to spend more time with clients and to maintain a high level of individualized care. On the other hand, without insurance coverage, access to CAM services is limited by the consumer's ability to pay. Many consumers are unable, or perhaps unwilling, to obtain CAM treatments or to integrate them into their care because the treatments are not covered under their health plan.

Coverage of CAM

In the last several years, a number of health plans have begun to cover certain CAM services, although the prevalence of this coverage is relatively low, compared to coverage of conventional therapies. Information on this trend is available from an annual survey of employer-sponsored health plans that recently began to include questions regarding a few specific CAM services offered in benefit packages. In 1998, 49 percent of survey respondents indicated that chiropractic was covered; by 2000, the number had risen to 70 per cent. Over the same time period, coverage of acupuncture rose from 12 per cent to 17 percent, and coverage of massage therapy increased from 10 percent to 12 percent. The survey also found that large employers (those with more than 20,000 employees) were more likely to offer CAM benefits than medium and smaller employers. PPOs and indemnity insurers were more likely than HMOs to offer health plans that include CAM benefits.³

Insurance and HMO coverage of CAM will very likely have an impact on use of CAM services. It has been reported that fully covered persons made twice as many visits to chiropractors as individuals with no health plan coverage or those required to pay 25 percent of costs.⁴ In a recent survey of over 2,000 households, health insurance coverage was found to be the strongest correlate for frequent use of CAM practitioners.⁵

Even where there is health plan coverage, it is often limited. For example, the CAM benefit may cover only one or a few CAM services as the data above indicates. Other limitations include ceilings on the number of visits covered, restrictions on clinical applications, and fixed qualifications for the type of practitioner; for example, ten acupuncture visits might be covered for pain management provided by a medical doctor, and thus would not be covered if provided by a professionally-trained acupuncturist.

Why have employers begun to ask their health insurance and managed care companies to cover CAM benefits? Surveys indicate that they do so primarily in response to employee requests. Other reasons cited in the findings include: 1) attracting and retaining employees, 2) State mandates, and 3) the potential medical benefits of CAM. Although most respondents anticipated increasing their coverage of CAM programs in the future, they cited a number of obstacles to such increases, including inadequate research, regulatory concerns (e.g., licensure), lack of understanding and knowledge about CAM, and lack of data on utilization and costs.⁶ A recently published survey of health plans new to offering CAM benefits supports these findings: The plans are offering CAM benefits in response to market research, consumer demand, to attract and retain enrollees, and at the request of purchasers.⁷

At present, CAM is being offered as part of a health plan in several ways, including:

- As a rider, or supplement, to the basic benefit package, often with controls on usage, such as copayments, benefit limits (e.g., visit limits, annual limits), or use of an approved network of CAM providers.
- As a discount program whereby covered employees (or members) pay out-of-pocket but are eligible for discounts off professional CAM fees and CAM products (discounted fees are usually tied to an approved network of CAM practitioners).
- As a defined, core benefit. This benefit is managed by limiting the type of CAM services covered (e.g., only chiropractic, or only chiropractic and acupuncture), requiring a preauthorization or a referral by a primary care physician, or setting visit or dollar limits and higher co-payments than for routine physician visits.
- As a CAM benefit account, typically an annual dollar amount.

Employers also may offer prevention, wellness, or health promotion programs, on-site or off-site. These typically include smoking cessation, weight control,

stress reduction, yoga, health club memberships, and other special programs. More recently, employers have become interested in educational programs to help employees with chronic diseases manage their conditions. Employers who have introduced such programs do so to decrease absenteeism, improve productivity and morale, and achieve some cost savings. Like health benefit coverage, employer-based programs to promote health are often limited in scope and restricted to certain modalities.

Overcoming Barriers to Coverage of Safe and Effective CAM

Health care interventions known to be safe and beneficial should be reviewed and considered for coverage under health benefit programs, regardless of whether the interventions are considered conventional medicine or CAM. Such consideration has not occurred often for CAM interventions, and may continue to occur infrequently because of numerous barriers inherent in the health care industry. The Commission believes that these barriers to coverage and reimbursement of CAM should be addressed. Doing so does not imply that CAM should be treated differently from conventional medicine -- on the contrary, CAM should be held to the same standards as conventional medicine.

The fundamental barriers to coverage and reimbursement identified by the Commission are addressed in the remainder of this chapter. They are clustered into two broad issue areas that must be addressed as purchasers, insurers, managed care organizations, Federal agencies, States, and others respond to consumers' increasing use of CAM interventions. The first area involves the need for health services research to test the benefits and cost-effectiveness of CAM interventions, and to effectively communicate the findings. The second area is the need for equivalent and impartial consideration of safe, effective CAM interventions, especially in developing coverage policy.

Testing the Benefits and Cost-Effectiveness of CAM Services and Products, and Communicating the Findings

Effectiveness of CAM Therapies

A growing body of evidence shows that many CAM interventions are effective in treating or helping to treat a range of health conditions. However, insurance and managed care executives have indicated to the Commission that CAM services and products are not covered, or receive limited coverage, because there is not enough evidence of "medical effectiveness."^{8, 9, 10}

Understandably, decision-makers for organizations that purchase health plans or for the health plans themselves are concerned that their limited dollars be spent on care that has been shown to be safe and efficacious. In the face of ever-rising health care costs and the vicissitudes of the economy, purchasers and payers

also want value and accountability for their investment. The addition of State-mandated benefits, as well as the constant stream of new technologies, drugs, and treatment protocols, has left these parties cautious about expanding any health care benefits.

At the operational level, government agencies like the Centers for Medicare and Medicaid Services (CMS), insurers, and managed care organizations invest significant time and resources to determine which benefits are covered, for how long, which practitioners are authorized to perform the services, and how payment will be made. Except for chiropractic and, increasingly, acupuncture and massage therapy, much of CAM is not covered. The services that are covered are often accompanied by limitations, such as global visit limits that are unrelated to individual patient needs or course of treatment.

With the rising cost of health care and heightened sensitivity to price in the market place, the addition of new benefits is a major undertaking. Taken together, economic and market forces, as well as pressures to manage the use of services in today's health insurance world, are creating the need for more evidence of the clinical effectiveness of CAM interventions. Evidence of clinical effectiveness in the treatment of illnesses and injuries will form the basis for sound coverage and reimbursement policies for CAM.

The Commission strongly supports more health services research to establish the medical and clinical efficacy of CAM therapies. Because research dollars are limited, cooperative efforts between the public and private sectors are needed to identify and resolve methodological issues that challenge health services research and to establish research priorities.

In addition to research on safety and efficacy, health services research is needed to evaluate the outcomes of CAM interventions in improving health status, treating acute and chronic conditions such as with heart disease, diabetes, and HIV infection, and supporting the care of persons with life-threatening diseases such as cancer. Research and demonstrations are needed to develop and test models of providing CAM (including integrative and collaborative programs), to compare conventional and CAM approaches for the same condition, to test the effectiveness of individual and combined CAM interventions, to test CAM offered in conjunction with conventional therapies, and to conduct population-based studies. Likewise, research is needed on whether CAM, health promotion programs, and prevention efforts increase worker morale, reduce stress, lessen the incidence of workplace disabilities and workmen's compensation claims, shorten treatment duration for illness and injuries, and improve productivity.

To maximize resources, vested parties should be brought together to develop a comprehensive, cohesive agenda. The parties would, at a minimum, identify priority questions for research and demonstrations, issues in applying common research methodologies, data needs, and ways in which the public and private

sectors could coordinate their efforts. The parties will need to commit to carrying out this agenda and invest financial resources to build the needed research base. Participants should include the Department of Health and Human Services (DHHS), including the Agency for Health Research and Quality (AHRQ), the National Institutes of Health (NIH), CMS, the Health Resources and Services Administration (HRSA), DOD, VA, private research and other foundations, health industry associations, medical associations and experts, CAM associations and experts, and representatives for employers, States, and consumers.

Lifestyle Modification and Heart Disease

- Comprehensive lifestyle changes have been used successfully as an alternative to coronary artery bypass surgery and coronary angioplasty in treating heart disease. The lifestyle modification program tested includes exercise, a low-fat plant-based diet, stress management, and group support. A Mutual of Omaha study with 333 patients (194 followed the lifestyle changes, and 139 were a control group) demonstrated that lifestyle changes can be used to avoid invasive interventions for at least 3 years without increasing the risk of a heart attack, stroke, or death. In addition, savings were estimated at \$29,500 per patient.¹¹
- Preliminary findings of the Highmark Blue Cross Blue Shield lifestyle modification program include significant decreases in cholesterol, blood pressure, weight, stress and depression. Cost savings range from 30 to 60 percent, and actuaries estimate that Highmark will save over \$16,000 on each person who might have required bypass surgery or angioplasty. In another study, Highmark compared claims of individuals before and after entering the program. Results show that claims dropped from an average of \$546 per member to \$273 in the year after entering the lifestyle modification program.¹²
- A meta-analysis of the literature concluded that " -- all the available evidence suggests that the comprehensive lifestyle program is highly likely to be cost saving, and extremely unlikely to be cost increasing."¹³

Cost Effectiveness and CAM

Public pressure to make CAM more accessible is increasing, yet without adequate information on the use, costs and overall cost-effectiveness of CAM benefits, lawmakers, health plans, and employers are ill-equipped to make decisions about offering CAM services. Costs and cost-effectiveness of health care interventions are important factors in any consideration of changes in coverage. There is growing evidence of cost-savings from CAM interventions, such as massage therapy and the use of mind-body medicine in a variety of

clinical situations.¹² For example, researchers in two randomized trials found that pre-term babies who received massage and comforting touch had greater weight gain and were discharged earlier than babies who did not receive this care. Hospital stays were shortened by 5 to 6 days, and savings averaged more than \$10,000 per infant.¹³ While research like this is encouraging, further evidence needs to be gathered regarding CAM interventions, especially those that are widely used by consumers or where clinical and cost effectiveness is promising.

Cost Effectiveness and Mind/Body Medicine: A Sample

- Researchers have found that a self-management course designed to help arthritis patients handle disability, pain, depression, and anxiety resulted in positive outcomes. Clinical improvement was found to correlate with a positive outlook and a strong sense of control over their disease. The best predictor of clinical improvement was the patient's belief in his or her improvement. The cost of the course was \$54 per person. After 4 years, physician visits had decreased 43%, for a saving of \$648 for persons with rheumatoid arthritis and \$189 for those with osteoarthritis.^{15,16}
- Researchers placed 109 patients with chronic pain into a group intervention program where they received information about pain and behavioral treatment approaches, as well as yoga, relaxation techniques, and life coping skills. They found that the program, while not eliminating the pain, reduced anxiety, depression, and hostility. The clinic's estimated savings from reduced clinic visits were \$110 per patient the first year, and \$210 per patient in the second year. Estimates did not include savings in the area of prescription drugs or diagnostic tests.¹⁷
- In another randomized trial, researchers found that an audiotape providing guided imagery for diminished blood loss and rapid healing had significant results. Patients using this tape lost 43% less blood and were discharged at least a day earlier.¹⁸

More information is needed on the cost-effectiveness of specific CAM interventions for various conditions, different models of CAM practice, the clinical and financial impact of integrating CAM with conventional medicine, and the relative costs of CAM treatments and conventional medical treatments. Information is also needed regarding whether CAM interventions reduce the use of conventional medical services and pharmaceuticals by people with heart disease, cancer, chronic pain, or other chronic illnesses, as well as by the terminally ill. The short- and long-term costs and benefits of wellness programs and self-care need to be studied, as does the impact of CAM practices on the short- and long-term health status of men, women, and children. Likewise,

employers and other purchasers need to know more about the impact of CAM and health promotion programs on workplace costs, including productivity, workmen's compensation and disability costs, and recruitment and retention. Finally, Congress, the Executive Branch, and decision makers in both the public and private sectors need information about the impact of CAM on patterns and costs of health care in the United States.

The information needed by purchasers, insurers, and managed care organizations can be obtained only through health services research, demonstrations, and evaluations in the areas of cost, cost-benefit, and cost-effectiveness of CAM practices and products. These studies, which ideally should stem from the research agenda discussed earlier, will require the support of the Federal government, States, employers, private research organizations, the insurance and managed care industries, and other entities. Participants in building cost-effectiveness research are the same as those identified above for research into the clinical effectiveness of CAM.

Cost is not always a threshold for coverage. Health plans cover a number of costly conventional medical interventions, including heart and lung transplants. The Commission believes that the cost of CAM services and products should not in itself pose a barrier to coverage. Rather, cost should be approached in the same manner as the costs of conventional interventions.

Coding for CAM Interventions

On an operational level, insurers and managed care organizations need data bases to design health benefit plans, set premiums, conduct actuarial analyses, perform quality-of-care studies, manage provider networks, and manage the costs and use of health services. Policy makers and health researchers need data bases to conduct the clinical and health services research in which public policy and programs are grounded. Much of the data used by health plans, researchers, and policy makers are drawn from claim, or transaction, forms, such as the CMS/HCFA 1500 or the UB-92.

A number of the information fields on claim forms are assigned standardized, nationally accepted codes for data management purposes. The use of such codes has helped create powerful data bases that drive much of health care. Standard coding has become even more critical now that the Secretary of Health and Human Services is implementing administrative requirements stemming from the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These requirements impact heavily on the electronic filing of claims; in particular, the act contains a provision that fines practitioners and insurance companies up to \$10,000 per code for incorrectly submitting and processing claims. Practitioners are charged for miscoding, and insurance companies are fined for paying fraudulent claims.

Government agencies, insurance companies and managed care organizations use uniform coding systems -- such as the International Classification of Disease to denote diagnosis, Common Procedural Terminology (CPT) to denote medical procedures, dental codes for dentistry, national drug codes for prescriptions, and the CMS/HCFA Common Procedure Coding System for supply items and some procedures -- as part of the electronic record of information about items and services used. Because coding has evolved along with conventional health care, including reimbursement trends, these systems have limited capability to capture CAM practices and products. For example, CPT codes, a set of more than 8,000 procedure codes developed by the American Medical Association for use throughout conventional health care, provides for a few CAM services including two codes for acupuncture.

More recently, a coding system for CAM procedures, services and products (as well as nursing services) has been developed and is being used in a number of settings. This system, ABCcodes developed by Alternative Link, contains 4,000 codes and captures a large amount of detail regarding specific CAM interventions. For example, it has 37 codes reflecting acupuncture services.

Currently, there is some variation regarding which coding system is used in CAM practice settings. Some practitioners use CPT, some use ABCcodes, and some use both. As part of their reimbursement policies, insurance companies may require the use of CPT codes. There is concern that the use of conventional coding systems, such as CPT, in limits the data that can be generated for CAM interventions.

If not resolved, limited coding capability will present a barrier to health services research on the safety, benefits, and cost-effectiveness of CAM interventions, as well as on the efficiency of models of integration and collaboration, where claims data are needed by researchers. In addition, the absence of nationally recognized, standardized codes for use in claims filing creates a significant challenge for CAM practitioners as HIPAA transaction requirements move toward implementation. To address these issues, any coding system for CAM that may be adopted by the Secretary of Health and Human Services should reflect the nature and scope of identified CAM interventions, and should allow for modifications to the coding system over time. If these issues cannot be addressed in line with HIPAA implementation dates and compliance requirements, then the Secretary should consider alternative strategies that would allow CAM practitioners to comply with the law.

Supporting Coverage of CAM Through Information

Purchasers, insurers, managed care organizations, and other sponsors of health care coverage need access to timely, reliable information about safe, efficacious,

and cost-effective CAM practices and products. Such information will promote equitable consideration of safe and effective CAM interventions in developing health benefit packages, supporting executive decision-making, and guiding policy-makers.

Those who help develop benefit packages, including health benefits consultants, have well-established methods and processes for making such changes in coverage. At the same time, there are many barriers to changing the status quo, including concerns about the financial impact of a health benefit not previously offered to the public or for which few data exist. Cost estimates for a new benefit are often low because it is difficult to estimate the number of persons who will qualify for or need the new service, or who actually use the service. Purchasers and providers are willing to respond to consumer demand but find it difficult to make significant changes to benefit packages without sufficient, reliable information.

The paucity of clinical and health services research, together with publication and dissemination issues discussed in the chapter on research, have created an information vacuum. Insurers, managed care organizations, public purchasers, employers, and other sponsors are increasingly willing to consider coverage of CAM interventions, but they need an adequate base of information in order to make decisions.

Federal support is needed to bridge this information gap. The National Center for Complementary and Alternative Medicine in NIH, for example, could consider making more health services research findings available electronically. Such information is used by employers, other purchasers, insurance and managed care industries, health benefits experts, health care associations, health education institutions, health policy bodies, foundations, professionals, and consumers.

There is a need also for Congress and other government leaders to understand the use of CAM within Federal programs, as well as impediments to the coverage of safe and effective CAM interventions. Reports may be necessary from DHHS (particularly Medicare, Medicaid, and community health centers), DOD, VA, and OPM.

More generally, there appears to be a need for the health care industry to become more informed about CAM, research on CAM modalities, and the international experience with such modalities. To meet this need, the Commission encourages health care associations and provider groups to include CAM topics at annual and other pertinent health care meetings. Government leaders and Federal agencies with health care programs also need more information about CAM and are encouraged to help management and staff become more informed. These informational needs may merit or even require

Federal support and leadership to develop informational programs on the broad and complex field of CAM.

Recommendation 23: Evidence should be developed and disseminated regarding the safety, benefits, and cost-effectiveness of CAM interventions, as well as the optimum models for complementary and integrated care.

Actions

- 23.1 The Secretary of Health and Human Services should convene a joint public and private task force to identify and set priorities for researching health services issues related to CAM and to help purchasers and health plans make prudent decisions regarding coverage of and access to CAM.
- 23.2 Federal agencies, States, and private organizations should increase funding for health services research, demonstrations, and evaluations related to CAM, including outcomes of CAM interventions, coverage and access, effective sequencing and integration with conventional therapies, effective models for service delivery, and the use of CAM in underserved, vulnerable, and special populations.
- 23.3 Federal, State, and private entities should fund health services research on the costs, cost-benefits, and cost-effectiveness of CAM interventions and wellness programs.
- 23.4 Secretary of Health and Human Services and the National Committee for Vital and Health Statistics should authorize a national coding system that supports standardized data for CAM. This system should make possible the collection of data for clinical and health services research on CAM, and support compliance with the electronic claims requirements of the Health Insurance Portability and Accountability Act.
- 23.5 The National Center for Complementary and Alternative Medicine, through its clearinghouse, should provide information on health services research, demonstrations, and evaluations of CAM services and products.
- 23.6 Public agencies and private organizations should support the development of informational programs on CAM targeted to health plan purchasers and sponsors, health insurers, managed care organizations, consumer groups, and others involved in the provision of health care services.
- 23.7 Congress should request periodic reports from appropriate Federal departments on coverage of and reimbursement for CAM practices and products for Federal beneficiaries, Medicaid beneficiaries, Federal employees, military personnel, veterans, and eligible family members and

retirees, as well as any legislative, regulatory, or programmatic impediments to covering safe and effective CAM interventions.

Equitable and Impartial Consideration of Safe, Effective CAM Interventions

Coverage Policies and Processes

Any medical or health care intervention that has undergone scientific investigation and has been shown to improve health or functioning or to be effective in treating the chronically or terminally ill should be considered for inclusion in health plan coverage. To accomplish this, current methods, standards, and processes used to gather evidence and make decisions regarding coverage for conventional medicine should be extended to CAM. These methods, standards, and processes should not be prejudiced toward any philosophy of health care, but give equitable consideration to safe and efficacious interventions for both conventional health care and CAM. The Commission's intent, in general, is that conventional medicine and CAM be considered in a similar manner with adjustments to accommodate differences in philosophical approach, not to unilaterally propel CAM into the conventional model. This challenge should be met by private employers and sponsors of health coverage, insurers, managed care organizations, and Federal purchasers including DHHS, DOD, VA, and OPM. Within DHHS, it is particularly important for CMS and HRSA to address CAM throughout their policies and procedures, and to identify statutory and regulatory issues.

The Medicare Coverage Process

The Medicare law has 55 defined benefit categories. Within these categories, services and products must be "reasonable and necessary" in order to be covered. CMS, which administers the program, has coverage regulations and maintains coverage manuals that contain definitions, criteria for determining what is reasonable and necessary, and other guidance regarding benefits. Coverage questions not addressed by law, regulations, or manuals are answered through two methods:

- Decisions by contractors who pay claims for the Medicare program. These contractors have their own processes, and may issue their own coverage rulings, called Local Medical Review Policies (LMRPs), which are not applicable outside the contractor's area. About 90 percent of Medicare coverage decisions are made this way.
- The formal, labor-intensive, and lengthier national coverage policy process. This process is managed by CMS and is used mostly for significant advancements in treatment, expensive interventions, and situations in which there is wide disagreement or inconsistency among contractors.

Medicare Coverage Issues for CAM

- **Definitional constraints:** Medicare benefit and practitioner categories contain restrictions. For example, Medicare can reimburse for acupuncture if provided by a physician but not if provided by a professionally trained acupuncturist because acupuncturists are not recognized in the law.
- **Expert consultation:** CAM experts have not participated in coverage advisory groups at CMS or in Medicare fiscal intermediary and carrier decisions.
- **Same-day billing:** For office or clinic settings, Medicare requires that many services provided on the same day be bundled and billed together. This helps the program avoid paying for services which are unnecessarily fragmented in order to maximize Medicare payment. This policy, however, poses a hardship for many patients who use conventional and CAM services at integrated clinics, requiring them to make additional trips for services that may be billed separately.
- **Anti-kickback rules:** The restrictions on referrals and other aspects of these rules pose problems and unresolved issues for physicians and CAM practitioners in integrated practice settings.

Adequate evidence as to safety and efficacy already exist for considering coverage of some CAM interventions. Where there is such evidence, CAM practices and products should be considered for coverage and reimbursement through processes similar to those already in use, modified only to the extent necessary to accommodate the fundamental differences in philosophy and treatment approach that underpin CAM. For example, private health insurance and managed care companies conduct a number of activities that contribute to the benefit design process, including cost-benefit comparisons between current and proposed packages; appraisals of the competition; review of long-term corporate goals; estimates of potential financial liability and losses; and assessments of key factors such as employer and customer requests, potential revenues from redesigned packages, and trends in the economy and market place.

The often-engrained viewpoints within both conventional medicine and CAM may hamper efforts to modify coverage processes to consider including CAM interventions. Each health care industry has knowledge gaps and negative perceptions about the other. For example, those who are skeptical about CAM may oppose coverage on the basis that CAM interventions are not backed by

valid, reliable research. Those who support CAM may be more willing to accept preliminary research findings as persuasive evidence that CAM services should be covered. Such differences in perspective may be overcome through cooperative efforts and working relationships between CAM and conventional health care experts. The public and private sectors offer many opportunities for CAM and conventional health care experts to work together, for example, advisory committees and other workgroups related to health services research and coverage.

Determining When to Pay For or Provide CAM

Once health insurers, managed care companies, and government agencies have decided to cover a benefit, additional procedures must be followed before arriving at a decision to approve or pay for it in a particular situation. The procedures commonly include two questions: 1) Are the circumstances for use of the service or product investigational, and 2) Is use of the service or product medically necessary in the current situation? For example, a health insurance company may decide to add acupuncture to its benefit, but may limit coverage to situations in which acupuncture is no longer considered investigational, such as control of nausea during cancer treatment and treatment of certain pain conditions. In addition, the company will review each request to approve or pay for the service on a case-by-case basis to determine whether acupuncture was indeed medically necessary in that situation.

A health care service or product is considered no longer investigational if it has been proven through scientific methods to be safe and effective at improving health outcomes, or if, in cases where the scientific evidence is still unfolding, expert consensus regarding its safety and efficacy is established. Various parties, such as a national professional association, a government agency such as CMS, or an organization hired to advise a health insurance or managed care company may make such a determination. In the private health care market, insurers and managed care companies often follow one another's lead in determining whether a service or product is safe and beneficial.

The process of determining what is medically necessary is critical to controlling use of and spending on health care services, determining the cost estimates on which premiums are based, and maintaining the financial soundness of the insurance and managed care industries. Decisions are usually made by practitioners on the basis of criteria that have been developed by bodies of experts, including professional organizations, academic medical institutions, private companies, and, in some circumstances, the insurers and managed care companies themselves. Often, the criteria are developed from studies sponsored by or the work of advisory groups for government agencies, such as AHRQ, CMS, and NIH. Government-funded programs, like Medicare develop their own

coverage criteria and offer guidance either nationally or at the local level through Medicare payment contractors.

Insurers and HMOs rely heavily on medical necessity criteria to define the extent of a benefit, manage the use of it, and make claims payment decisions. Controlling health care use and expenditures is fundamental to managing a company's insurance risk and to the financial stability of managed care and third-party reimbursement systems.

Methods of determining investigational status and medical necessity work for CAM as long as interventions fit the conventional medical model, but they often restrict the integration of, and the complementary use of, "alternative" services and products. At this time, few criteria are available to guide practitioners in deciding the medical or, more generally, the clinical necessity of CAM interventions. New medical and health services research on CAM, when published, will help to fill this need. Agencies of DHHS (including NIH, AHRQ, and CMS) could convene groups of experts and hold conferences to assess the state-of-the-science of a particular CAM approach or treatment, and develop consensus statements, guidance for clinical use, and coverage policy. Other government bodies and nongovernmental organizations could sponsor similar efforts.

Federal leadership is needed to help guide changes in health plan coverage for safe and effective CAM services and products and to develop criteria for the use of CAM interventions. The Secretary of Health and Human Services, preferably through a centralized CAM office, should work with insurance companies, health care and professional associations, health insurers and managed care companies and associations, employers, other Federal departments, States, CAM professionals and associations, benefits experts, and others to accomplish these goals.

To make coverage of CAM more readily available to consumers, private and public entities should develop clinical necessity criteria or clinical appropriateness criteria for circumstances in which CAM is proven to be safe and effective. Such circumstances could include preventing a condition or the progress of a condition, allaying symptoms or side-effects of conventional treatments such as pain or nausea, and helping patients, particularly with life-threatening illnesses, cope with their conditions.

Coverage and the Need for Authority to Practice

Coverage of and reimbursement for most health care services are linked to a provider's ability to furnish services legally within the scope of their practice. This legal authority to practice is given by the State in which services are provided. Thus, even if insurers, managed care organizations, employers, and other health

plan sponsors are interested in covering safe, cost-effective CAM interventions, they cannot do so unless there are properly licensed (or otherwise legally authorized) practitioners in a State. State laws and processes that establish professional standing protect the public by ensuring that covered health benefits are provided by qualified practitioners whose services should meet recognized standards of care. Moreover, in the absence of such laws, health insurers, managed care organizations, and any other entities that provide services would be at increased risk of liability if an adverse event occurred.

CAM practitioners qualified to furnish safe, beneficial services for which purchasers, insurance companies, managed care organizations, and other payers are willing to pay should have the ability to practice legally in their State, just as conventional practitioners do.

Other Issues

The Internal Revenue Code allows employers and other health plan sponsors to deduct the costs of providing accident and health insurance. Although the Federal code includes chiropractic and acupuncture as deductible medical expenses, the current policy approach is weighted heavily toward conventional medical care and physician direction of services. This approach could be modified to allow purchasers, health insurers, and managed care companies to develop health benefit packages that include safe and beneficial CAM interventions that qualify fully for favorable tax treatment under the law and regulations. In addition, Federal policy-makers are encouraged to monitor evidence on the benefits and cost-effectiveness of CAM interventions and health promotion programs with an eye to possible modifications of the tax code in the future.

Recommendation 24: Insurers and managed care organizations should offer purchasers the option of health benefit plans that incorporate coverage of safe and effective CAM interventions provided by qualified practitioners.

Actions

- 24.1 Health insurance and managed care companies should modify their benefit design and coverage processes in order to offer purchasers, for their consideration, health benefit plans that include safe and effective CAM interventions.
- 24.2 Health insurance and managed care companies should make use of CAM expertise in the development of benefit plans that include safe and effective CAM interventions.

24.3 Health insurers, managed care organizations, CAM professional associations,

CAM experts, private organizations that develop medical criteria, and Federal agencies are encouraged to develop appropriate clinical criteria and guidelines for the use of CAM services and products.

Recommendation 25: Purchasers, including Federal agencies and employers, should evaluate the possibility of covering benefits or adding health benefit plans that incorporate safe and effective CAM interventions.

Actions

- 25.1 Employers, Federal agencies, other purchasers and sponsors should enhance the processes they use to develop health benefits and give consideration to safe and effective CAM interventions.
- 25.2 Public purchasers such as the Centers for Medicare and Medicaid Services and the Department of Defense, employers, other health benefit sponsors, and health industry organizations should include CAM practitioners and experts on advisory bodies and workgroups considering CAM benefits and other health benefit issues.
- 25.3 The Secretary of Health and Human Services, preferably through the Federal CAM coordinating office when established, should maintain a list of opportunities for CAM experts to participate on advisory committees and other workgroups.
- 25.4 The Secretary of Health and Human Services should direct agencies under his authority to convene workgroups and conferences to assess the state-of-the-science of CAM services and products and to develop consensus and other guidance on their use.
- 25.5 State governments should consider, as part of evaluating and reviewing their regulations, how regulation of CAM practitioners could affect third-party coverage of safe and effective CAM interventions.

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