8/28/01

Coverage and Reimbursement Work Group

List of Issues:

Issue 1: Fair and Impartial Consideration: CAM practices and products proven to be safe and efficacious should be given equitable consideration for coverage and reimbursement, and the processes used in deciding to offer coverage should be the same as or similar to those used for conventional medical practices and products.

Issue 2: Costs and Cost-effectiveness: Information is needed to develop and price CAM benefits, and to evaluate the cost-effectiveness of CAM benefits.

Issue 3: Standards for Practice and Practitioners: Coverage and reimbursement require assurances that CAM (as well as conventional medical) practitioners have appropriate education and training, meet established standards for licensure or certification, and are providing services within professionally-accepted standards of practice.

Issue 4: Determining When to Pay or Provide CAM: Insurers, managed care plans, and publicly financed health benefit programs use necessity and appropriateness standards as parameters for defining coverage and making coverage decisions. Like conventional medicine, CAM needs to develop such standards.

Issue 5: Encourage Information Dissemination: At this early stage of integration of CAM into the U.S. health care system, ready access to information about safe, efficacious, and cost-effective CAM practices and products is warranted. Such information should assist employers and other purchasers, as well as insurers and managed care plans to fairly consider extending coverage to these CAM practices and products.

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Issue 1: Fair and Impartial Consideration: CAM practices and products proven to be safe and efficacious should be given equitable consideration for coverage and reimbursement, and the processes used in deciding to offer coverage should be the same as or similar to those used for conventional medical practices and products.

Discussion: The fundamental steps toward coverage and reimbursement for CAM depend on research to assess and demonstrate what is safe and clinically effective, then for purchasers and insurers to give CAM practices fair and unbiased consideration.

There are differing views as to the current barriers to coverage in this regard. Those who support conventional medical coverage may believe that there is a lack of valid and reliable research, or certainly inadequate proof, to support expanding coverage to many areas of CAM. Those supportive of CAM may believe that even where there has been an accumulation of solid evidence, even evidence of cost savings, it is extremely difficult to change the traditional approach to health care coverage and reimbursement. **[should we insert an example of the latter? If so, any ideas?]**

Certainly, those responsible for health benefits are concerned that their limited health care dollars be spent on care that is noninvestigational and proven to be safe and efficacious. Purchasers and payers also want value and accountability for their health care investment. In addition to these industry standards, a quarter century of battling health care inflation, as well as the impact of even small changes, has left these parties cautious about expanding health care benefits. Further, purchasers and payers are constantly approached by practitioners, researchers, drug companies, device manufacturers, etc., to cover new products or medical protocols – adding to the caution and slowness with which purchasers and payers respond. Thus, there are real concerns regarding how CAM practitioners and providers can increase access to safe, clinically effective CAM modalities through third party reimbursement and health plan coverage for consumers.

Background: [to be inserted]
Challenges:

Draft Recommendations:

1. A public-private partnership should be established to develop a multiyear health services research plan that identifies and addresses CAM research and demonstration questions, issues, data, methods, priorities, and coordination. **[should we coordinate this recommendation with NCCAM?]**

2. Public entities (AHRQ, NIH, CMS/formerly HCFA, HRSA, DOD, VA, etc.) and private organizations (research and other private foundations, employers, industry associations, etc.) should fund and jointly fund health services research and demonstrations on the safety and clinical effectiveness of CAM practices and products, as well as the clinical efficacy of various models for providing CAM services (integration, collaboration, etc.) within the U.S. health care system.

3. CAM practitioners should be integrated into the coverage and coverage-related processes, including:

- Federal agencies that provide health benefits (CMS, DOD, VA, etc.) must include CAM practitioners on coverage advisory bodies, coding work groups, and related working bodies;
- Insurers and managed care organizations should include CAM practitioners on coverage advisory bodies and related working bodies;
- Professional associations, health policy institutions, and foundations should include the expert advice, consultation, and information of CAM practitioners and CAM experts;
- CAM practitioners are encouraged to seek out opportunities to advise and participate in bodies, public or private, that address issues related to coverage, reimbursement, coding, health services research, and CAM-related demonstrations projects.

Issue 2: Costs and Cost-effectiveness: Information is needed to develop and price CAM benefits, and to evaluate the cost-effectiveness of CAM benefits.

Discussion: Another fundamental step toward coverage and reimbursement for CAM services and products is establishing adequate information on the cost of the benefit and overall cost-effectiveness. Operationally, insurers and managed care plans need information on expected utilization of a service (or product) and on practitioner/provider levels of payment. This information is critical in establishing the premium price for a covered benefit, and ultimately to the financial stability of the health plan.

Utilization and provider payment data for CAM services is not readily available to insurers and managed care plans (HMOs). Even where insurers and HMOs are able to price and develop a successful CAM benefit, as has been possible for chiropractic and acupuncture services, little is know about the cost-effectiveness of various models of CAM practice, the clinical and financial impact of integration with conventional medicine, or the relative costs of CAM treatments versus the costs of conventional medical treatments. Thus, cost information is needed at both an operational level and a more system wide level for CAM.

Key to developing this information is the implementation of a common claim form and a nationally recognized, acceptable coding system for CAM. The other critical need is for health services research on the costs and cost-effectiveness of CAM services, including different models of providing CAM services (e.g., CAM stand-alone services, integrating CAM with conventional medicine, collaboration between CAM and conventional medicine).

Background:
Challenges:

Draft Recommendations:

4. DHHS **[CAM Central? CMS?]**, working in partnership with the private sector (including professional and industry associations for CAM and

conventional medicine, insurers, managed care organizations, and researchers), should identify and build national acceptance on the part of CAM for a common claim form and a coding scheme that supports a) the philosophies and practices of CAM, and b) the integration of CAM into the U.S. health care system.

5. Public and private entities (identified in Issue 1) should fund or jointly fund health services research on the cost-effectiveness of CAM services, the clinical and cost-effectiveness of various models of providing CAM services, and comparisons of the costs and outcomes of CAM therapies and conventional medical therapies for the same conditions.

6. **[do we want a recommendation on a unified data system? Is a unified data system realistic?]**

Issue 3: Standards for Practice and Practitioners: Coverage and reimbursement require assurances that CAM (as well as conventional medical) practitioners have appropriate education and training, meet established standards for licensure or certification, and are providing services within professionally-accepted standards of practice.

Discussion: Purchasers, insurers, and managed care organizations need assurances that the health benefits provided under their sponsorship are of acceptable quality and meet recognized standards of care. They link coverage and reimbursement to "tests" of professional accountability, usually education and training, State licensure or certification, and compliance with professionally-adopted standards of practice. Requiring such assurances from health professionals, including CAM practitioners, also helps minimize the risks associated with any type of health care and the potential financial liability in the event of adverse outcomes.

Background:
Challenges:

Draft Recommendations:

7. CAM professions should establish appropriate models for professional accountability at the national level. For most CAM professions, this includes establishing strong standards for education and training as well as accreditation for their centers of learning **[we need to coordinate with the Education Group on this];** working with State governments to establish legal authority to practice and a scope of practice; developing professional standards of practice.

8. State governments should work with CAM professions to establish fair and impartial programs for licensure and certification. **[work with Access Group?]**

Issue 4: Determining When to Pay or Provide CAM: Insurers, managed care plans, and publicly financed health benefit programs use necessity and appropriateness standards as parameters for defining coverage and making coverage decisions. Like conventional medicine, CAM needs to develop such standards.

Discussion: Insurers and HMOs rely heavily on "medical necessity" criteria to define the extent of a benefit, manage utilization, and make claims payment decisions. The management of health care expenditures and utilization is fundamental to financial stability under managed care and third-party reimbursement systems. For many CAM services and products, criteria for necessity and appropriateness are not well established, are not in a format typically used by payers, or are not readily accessible to payers. In addition, CAM criteria may have an approach different from the disease-based medical necessity criteria of conventional medicine. CAM services, such as acupuncture, may be used to enhance or support a conventional medical therapy, help prevent the onset or progression of a disease in at-risk individuals, or promote wellness and general disease prevention. Thus, even if criteria were developed, payers would have to accept the alternative approach to necessity criteria. Federal leadership may be necessary to initiate, promote, and direct this innovative effort.

Background: [to be inserted]
Challenges:

Draft Recommendations:

9. DHHS **[CAM Central?]** should form a task force that develops model CAM necessity and appropriateness criteria (similar to medical necessity criteria) for CAM services proven to be safe and effective. **[do we need a time limit for this, and allow the market place to assume this responsibility at some point in time?]** Insurers and HMOs should utilize the model criteria in developing and implementing CAM benefits.

Issue 5: Encourage Information Dissemination: At this early stage of integration of CAM into the U.S. health care system, ready access to information about safe, efficacious, and cost-effective CAM practices and products is warranted. Such information should assist employers and other purchasers, as well as insurers and managed care plans to fairly consider extending coverage to these CAM practices and products.

Discussion: The "players" is developing benefit packages, including health benefits consultants, have well-established methods. In addition to routine approaches, purchasers and payers have inducements to maintain more

traditional packages of benefits, especially from consumers. Generally, those who are beneficiaries of covered benefits are disinclined to give up or have any significant change made to traditionally covered benefits. Further, if a new benefit is added, it is difficult to modify the benefit and maintain beneficiary satisfaction. Thus, it is difficult for purchasers and providers to make significant changes to benefit packages without sufficient, high-confidence information.

Background: [to be inserted]
Challenges:

Draft Recommendations:

10. DHHS **[CAM Central?]** should sponsor, or co-sponsor with external partners, an easily accessible, continuously updated website that would provide information on CAM practices and products proven to be safe, clinically efficacious, and cost effective. Information should be provided for both consumer and professional use. An out reach effort should be made to inform purchasers, such as employers and community health centers, of the availability of this website.

11. DHHS, DOD, and VA should periodically report to Congress, the President, and each other the status of research, coverage, access and availability of CAM services for their respective beneficiaries or through their respective sponsorships.

12. Purchasers (such as employers), health benefits experts, health care associations, providers, medical educational institutions, health policy bodies, foundations, etc. should integrate CAM topics into their informational and development meetings, such as annual meetings,

Topics NOT Addressed in Draft Recommendations
(From previous briefing documents)

a. Tax incentives to promote CAM
b. Special provisions in health insurance policies that would allow persons who have a catastrophic health condition or who are terminally ill to opt out of routine coverage and obtain CAM and extraordinary medical (conventional in nature) services and products.
c. Coordinating medical record information among CAM and conventional practitioners (Information Group?)
d. Expand Medicare coverage to cover CAM services under the "incident to" (a physician's service) provision.
e. Open the National Health Service Corps to licensed CAM practitioners.
f. Explore ways to expand coverage of CAM for federal employees, the military, veterans, etc. (a role for CAM Central?)

g. Establishing relative value-based payment rates for CAM practitioners, or let the market drive the payment rates (I think we discussed this briefly last time?)

50-63

Draft Recommendations for Coverage and Reimbursement:

1. The Commission recommends that a public-private body (DHHS; DOD; VA; representatives of the research community, insurance industry, and managed care organizations, employers, etc.) be convened to develop a multiyear health services research plan that identifies and addresses CAM research and demonstration questions, methodologies, data, priorities, and coordination. The Commission recommends that DHHS work within the partnership to target public and private resources on research priorities, maintain public-private coordination, and build cooperation.

2. The Commission recommends that public entities (AHRQ, NIH, CMS/formerly HCFA, HRSA, DOD, VA, etc.) and private organizations (research and other private foundations, employers, industry associations, etc.) fund and jointly fund health services research and demonstrations on the safety and clinical effectiveness of CAM practices and products, as well as the efficacy of various models for providing CAM services (integration, collaboration, etc.) within the U.S. health care system. The Commission encourages funding bodies to cooperate with the priorities established in Recommendation 1.

3. The Commission encourages health care purchasers including insurers, managed care organizations, Federal and State agencies, and other health plan sponsors to develop and maintain a process, as conducted for conventional therapies, for incorporating safe and efficacious CAM interventions into health benefit packages.

4. The Commission encourages
   - Federal agencies that provide health benefits (CMS, DOD, VA, etc.) to include CAM practitioners on coverage advisory bodies, coding work groups, and related working bodies.
   - Insurers and managed care organizations to include CAM experts on coverage advisory bodies, and related working groups.
   - Professional associations, health policy institutions, and foundations to consider advice, consultation, and information from CAM practitioners and other CAM experts.
   - CAM practitioners to seek out opportunities to advise and participate in bodies, public or private, that address issues related to coverage, reimbursement, coding, health services research, and CAM-related demonstrations projects.

5. The Commission recommends that public and private entities (DHHS; DOD; VA; research organizations, foundations, insurance industry, managed care organizations, employers, etc.), as with conventional medicine, fund or jointly fund health services research on the cost-effectiveness of CAM interventions, including the specific interventions for various conditions, and the impact of CAM on health care costs. The Commission recommends funding to study

the clinical and cost-effectiveness of various models of providing CAM services, and comparisons of the costs and outcomes of CAM therapies and conventional medical therapies for the same conditions. Studies on the costs and benefits of CAM practices, wellness programs, and self-care on health status are encouraged.

6. The Commission recommends that purchasers, insurers, managed care organizations, and other health plan sponsors consider coverage of CAM interventions shown to be safe and cost-effective.

7. The Commission recommends Federal agencies responsible for health care coverage and services investigate and report to their respective administrators on how safe, cost-effective CAM therapies may be integrated into federal programs.

8. The Commission recommends that DHHS, working in partnership with representative from the private sector (including professional and industry associations for CAM and conventional medicine, the American Medical Association, insurers, managed care organizations, and researchers), conduct a study of current coding processes and CAM, consider the issues associated with appropriate coding for CAM, and report to the Secretary of DHHS.

9. In order to increase access to and coverage of CAM therapies shown to be safe and cost-effective, the Commission encourages State governments to grant legal authority to practice to those CAM professions seeking licensure, or equivalent stature, within the State.

10. The Commission encourages DHHS to support private sector efforts to develop model CAM necessity and appropriateness criteria for CAM services shown to be safe and effective.

11. The Commission encourages insurers, managed care organizations, and benefit experts to work cooperatively with CAM professions to develop criteria for appropriate coverage of CAM benefits.

12. The Commission recommends that DHHS sponsor, or co-sponsor with external partners, an easily accessible, continuously updated website that provides information on CAM practices and products proven to be safe, clinically efficacious, and cost effective. The Commission believes that information should be provided for both consumer and professional use. The Commission encourages an out-reach effort be made to inform purchasers, such as employers and community health centers, of the availability of this website.

13. The Commission encourages DHHS, DOD, and VA to periodically report to Congress, the President, on the status of research, coverage, access and availability of CAM services for their respective beneficiaries or through their respective sponsorships.

14. The Commission encourages purchasers (such as employers), health benefits experts, health care associations, providers, medical educational institutions, health policy bodies, foundations, etc. to integrate CAM topics into their informational and development meetings, such as annual professional meetings,

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Summary of CAM: Coverage and Reimbursement
Work Group Conference Call #1
August 15, 2001

Participants: George DeVries (Facilitator). Linnea Larson, Dean Ornish, Ming Tian, Steve Groft, Michele Chang, Ken Fisher, Maureen Miller

Steve Groft outlined the process for Work Groups to develop draft recommendations, and George DeVries led the group through the "straw dog" (first cut) document.

DeVries explained his directive for the document to focus on barriers to coverage and reimbursement for CAM services. The Work Group also discussed the alternative to develop specific coverage and reimbursement policy recommendations for CAM modalities. The Group agreed, however, that specific coverage policies is beyond the scope of the Commission and is not feasible given the complexity of developing coverage policy, staffing and time. Participating Commissioners agreed to focus on barriers.

Ornish stated his opinion that the overriding approach should be to treat CAM commensurate with how conventional medicine is treated. That is, the standards for covering safe and efficacious CAM services and products should be the same as those for conventional medicine: not more or less, but the same. One example, acupuncture, was briefly discussed. Acupuncture has been proven to be safe and effective in treating several conditions, but insurance coverage for these diagnoses is still not available. From testimony and experience, the Commissioners observed that many insurance companies (and other payers), in large part, do not cover acupuncture because they presume the cost adds to the cost of conventional services, thus increasing overall expenditures. Sufficient evidence on cost substitutions or savings that may be associated with acupuncture is not generally available.

Commissioners recognized that some coverage of CAM is available, but that coverage is limited in scope or not included in most insurance policies. They also agreed that CAM coverage and reimbursement should be based on scientific evidence as to safety and efficacy, and not to address the safety and efficacy of specific CAM modalities. It was suggested that the Group look again at Marcia Angell's testimony. Agreement was reached to revise the document, adding as the first issue that CAM and conventional medicine should be held to the same standards of safety, medical efficacy, and cost effectiveness.

There was discussion whether Issue 2 regarding costs should be separate or merged with the issue of effectiveness addressed in Issue 1. DeVries explained the need for a separate focus. He voiced some concern about using the overarching "level playing field" issue to address cost barriers. Discussions helped clarify two divergent cost issues: a) the limited utilization and cost information for specific CAM treatments and b) broader cost issues such as the impact of CAM services on overall treatment costs for given conditions,

comparisons of the relative costs (and effectiveness) of CAM and conventional treatment modalities, and the impact of CAM on overall health care costs.

Agreement was reached to consolidate several of the draft recommendations.

The Work Group discussed and agreed to retain Issue 3 regarding professional standards for licensure, certification, and practice. The "equal standards" approach was discussed, and staff will develop wording to recognize that CAM practitioners should be held to professional standards the same as conventional practitioners, such as national standards for education, training, entry to practice, State licensure and certification. DeVries pointed out that licensure and certification is critical for third party reimbursement, and that sanctions to practice or a must in this area.

Likewise, the Work Group agreed that medical necessity standards, as raised in Issue 4, are also necessary for coverage and reimbursement. DeVries also observed that medical necessity determinations are already being performed in order to obtain payment for a covered service.

The Work Group discussed a proposal by Fins to merge this group with the Access Work Group. Participant agreed that, while there is overlap, the issues here were complex and large enough to merit a separate work group. The Commissioners were willing to coordinate with the Access Work Group, share information and progress, and to possibly merge efforts later, or even in drafting the Final Report. In closing, the Group agreed to another conference call,

8/15/01

TOPIC: CAM: Coverage and Reimbursement
Facilitator: George DeVries
Staff Lead: Maureen Miller

1 - 3 PM

List of Issues:

Issue 1. Clinical Effectiveness and Safety: Purchasers of health care coverage, such as employers, are hesitant to extend coverage to CAM services and products – or to cover an integrated approach to health care -- if the modalities are in an investigational stage or have not undergone research to test clinical effectiveness. Consumers, purchasers, and insurers need assurance that newly introduced or emerging modalities of health care, whether CAM or within the conventional medical model, are effective and safe.

Issue 2: Service Delivery and Costs: Purchasers and other health plan sponsors, insurers, managed care companies, and providers do not have the information needed to develop and price a cost-effective core CAM benefit, or to foster new paradigms of health care.

Issue 3. Standards for Practice and Practitioners : Purchasers of health care, along with insurers and managed care companies, may be hesitant to cover CAM services without assurances that the practitioners have appropriate education and training, meet established standards for licensure or certification, and are providing services within professionally-agreed-to standards of practice.

Issue 4. When Is CAM Necessary?: Covering CAM as a core benefit in an insurance or managed health plan, or as a publicly financed benefit, will likely require criteria as to the necessity or appropriateness of the service in order to approve or pay for the CAM benefit.

Issue 5. Putting Research into Action: It is difficult for employers other health plan sponsors, providers, and practitioners to monitor and act on CAM research findings given the myriad of journals and reports, here and abroad, on conventional medicine and CAM.

Present
- George DeVries
- Teresa Larson
- Dean Ornish
- Meng Tsai

Absent
Concetta Bourg
Joe Fins

Issue 1. Clinical Effectiveness and Safety: Purchasers of health care coverage, such as employers, are hesitant to extend coverage to CAM services and products – or to cover an integrated approach to health care -- if the modalities are in an investigational stage or have not undergone research to test clinical effectiveness. Consumers, purchasers, and insurers need assurance that newly introduced or emerging modalities of health care, whether CAM or within the conventional medical model, are effective and safe. modalities having Scientific evidence documentation etc to a standard similar to other modalities currently covered

Discussion: Employers, public programs that reimburse for health care, and other health plan sponsors are extremely concerned that limited health care dollars be spent on care that is efficacious and safe. A quarter century of battling health care inflation has left these parties tentative about changing or expanding health care benefits. Purchasers of health care coverage, as well as health insurers and managed care companies, are regularly approached by practitioners, drug companies, device manufacturers, and others within the health care industry to cover new products or medical protocols. Key among the criteria used to make coverage decisions is clinical effectiveness and safety.

Background:

- Insert data and information from the William Mercer survey on employer benefits.
- Insert info from John Weeks.
- Insert information on the Medicare coverage process.
- Insert examples of CAM coverage in response to research findings.

Challenges:

- Coverage of CAM is growing and building the experience and satisfaction of consumers, physicians and other providers, insurers and managed care companies, as well as purchasers. [Weeks, 5/14/01] On the other hand, the insurance methods (these will be outlined above as part of the Mercer info) used to provide coverage usually do not include making CAM services part of the core benefit package and do involve modifying the overall approach to health care away from the current disease-initiated encounter system.

- Research is needed to compare the relative effectiveness of allopathic and CAM treatments of the same health condition, as well as relative costs.

- Published findings of clinical effectiveness will help create demand for CAM services and products among consumers and also among purchasers of health care coverage, particularly employers, as they compete to hire and retain the best labor force. Likewise, such findings will influence insurance and managed care companies as they design

competitive benefit packages that meet the health care demands of consumers and purchasers.

Draft Recommendations:

1. DHHS, working in partnership with the private sector (employers, researchers, etc.) and States should develop a 5-year plan to address the needs and priorities for research in the clinical effectiveness and safety of CAM services and products, as well as integrated systems of health care.

2. AHRQ, NIH, CMS (formerly HCFA), HRSA, DOD, VA should fund research or jointly fund research on the clinical effectiveness of CAM services and practices.

3. Employers, insurers, managed care companies, and research foundations should work together to develop and fund, and/or jointly work with a federal agency on the clinical effectiveness of CAM services and practices.

4. The public and private sectors should develop and fund research to explore the best practices and clinical effectiveness of integrated models of health care.

Issue 2: Service Delivery and Costs: Purchasers and other health plan sponsors, insurers, managed care companies, and providers do not have the information needed to develop and price a cost-effective core CAM benefit, or to foster new paradigms of health care.

Discussion: Reliable utilization estimates and fair professional fees are key pieces of information necessary to establish a premium amount for a core CAM benefit, but is unavailable for many CAM services. Even where insurers are able to price a CAM benefit, such as for chiropractic visits and acupuncture, successful models for core benefit design and integration with conventional medicine are not readily available. Health plans and providers also need information on the additional administrative costs associated with managing expanded categories and networks of practitioners, start-up and maintenance costs, and long-term financial outcome -- costs or savings. There are other concerns, too, such as whether costs for CAM services will be additive or supplant some of the costs of conventional medical care, the impact on premiums and the ability to compete in the health care market, and ultimately the impact on health care costs.

Background:

- Insert information and issues on coding.

Challenges:

- CAM practitioner fees should recognize education, training, skills, and time with patient/clients, and enable practitioners to maintain their health care philosophy and focus on the whole person.

Draft Recommendations:

5. DHHS, working in partnership with the private sector (employers, insurers, managed care organizations, researchers, etc.) and States should develop a 5-year plan to initiate and support health services research into the cost-effectiveness of CAM services and products, the development of and information infrastructure, and to enhance the efficient progression toward integration with conventional medicine.

6. AHRQ, NIH, CMS (formerly HCFA), HRSA, DOD, VA should fund research or jointly fund health services research stemming from the 5-year plan.

7. Employers, insurers, managed care companies, and research foundations should work together to develop and fund, and/or jointly work with a federal agency, on CAM health services research.

8. DHHS, working in partnership with the private sector (including professional associations, employers, researchers, etc.) should develop agreement on a coding scheme for CAM services that dually supports CAM practices and the integration of CAM into the U.S. health care system.

9. DHHS, working in partnership with the private sector (including professional associations, employers, researchers, etc.) should develop a unified data system for CAM to assist with tracking the process and outcomes of CAM services/products across local, regional, and national settings.

Issue 3. Standards for Practice and Practitioners : Purchasers of health care, along with insurers and managed care companies, may be hesitant to cover CAM services without assurances that the practitioners have appropriate education and training, meet established standards for licensure or certification, and are providing services within professionally-agreed-to standards of practice.

Discussion: Standards for education, training, performance and practice ensure safe and high quality health care at the point of service delivery. In addition, such standards help manage the inherent risks with any type of health care, particularly practice standards.

Background:

Challenges:

- Practice standards will benefit not only the CAM professions, but will help purchasers, insurers, and managed care companies define a covered benefit, assure quality, and defend against the potential of malpractice and liability.

Draft Recommendations:

- Discuss national professional standards for education, training, licensure and certification of practitioners. [Need to coordinate with the Education Work Group.]

- Discuss clinical practice standards.

what is a covered benefit

Issue 4. When Is CAM Necessary?: Covering CAM as a core benefit in an insurance or managed health plan, or as a publicly financed benefit, will likely require criteria as to the necessity or appropriateness of the service in order to approve or pay for the CAM benefit.

Discussion: Insurers and HMOs rely heavily on "medical necessity" criteria to manage claims payment and utilization of health care resources. The management of health care expenditures and utilization is fundamental to financial stability under managed care and third-party reimbursement schemes, The difficulty for CAM is that some services, such as acupuncture, may be used as part of treatment for an illness or injury, help prevent the onset of certain diseases in at-risk individuals, or promote wellness.

Background:

- Some CAM benefit designs in current use do not involve the core benefit package of a health plan and do not require necessity or appropriateness criteria. For example, a spending account or ceiling for CAM services, or the availability of a discounted CAM network of providers, would not require such decision tools.

Challenges:

- Establishing "necessity" and appropriateness criteria will have to be approached differently for CAM services, and will require clarification of the CAM benefit.

Draft Recommendations:

- Discuss necessity and appropriateness criteria, clinical guidelines.

Issue 5. Putting Research into Action: It is difficult for employers other health plan sponsors, providers, and practitioners to monitor and act on CAM research

findings given the myriad of journals and reports, here and abroad, on conventional medicine and CAM.

Discussion: Purchasers (especially employers), other health plan sponsors, providers, and practitioners do not follow routinely CAM research journals, and conventional medical journals do not publish CAM research studies routinely (as discuss elsewhere in this report). Because CAM research is in an early stage and the breath and scope of studies are just emerging, intervention may be necessary to translate these findings into the health care system, including health benefit coverage.

Background:

Challenges:

Draft Recommendations:

- DHHS should implement, or co-sponsor with external partners, an easily accessible, continuously updated website that would provide information on the clinical and cost effectiveness of various CAM treatments, as well as comparisons of allopathic and CAM treatments for the same health condition, supplemented by other information as available.

  - Information should be provided for both consumer and professional use.

- DHHS, DOD, and the VA should periodically report on the status of research, coverage, access and availability of CAM services and products for their respective beneficiaries or through their respective federal support programs.

Coverage and Reimbursement

Work Group Members: George DeVries (Facilitator), Joe Fins, Linnea Larson, Conchita Paz, Dean Ornish, Ming Tian
Staff Lead: Maureen Miller

Issue 1: Fair and impartial consideration of safe, efficacious CAM therapies

Background:
Those responsible for health benefits are concerned that limited health care dollars be spent on care that has been shown to be safe and efficacious. Purchasers and payers, in the face of ever-rising health care costs, also want value and accountability for their health care investment. Experience with new and mandated benefits, as well as the constant stream of new technologies, drugs, treatment protocols, etc. has left these parties cautious about expanding health care benefits. These and other factors contribute to consumer, and practitioner, concerns regarding coverage, reimbursement, and access to CAM therapies.

Insurers, managed care organizations, and purchasers of health care (such as employers and federally-sponsored programs) invest significant time, resources, and analyses into developing benefit packages. With the rising cost of health care and heightened price sensitivity in the market place, the addition of new benefits is a major undertaking. One step in the process is consideration of research and demonstrations on the safety and efficacy of an unproven or investigational therapy.

For many CAM interventions, insurers, managed care organizations and purchasers do not consider expansion of coverage because clinical research and health services research are limited or nonexistent, and safety and efficacy have not been adequately demonstrated.

For some CAM interventions, there is adequate evidence as to safety and efficacy. Where there is such evidence, CAM practices and products should be given fair and equitable consideration for coverage and reimbursement. Likewise, the processes used in deciding coverage policy should be the same as or similar to those used for conventional medical practices and products.

There is a challenge to this latter standard: building a consensus on the adequacy of the evidence given inbuilt viewpoints within both conventional medicine and CAM. Those who support conventional medical coverage, or who are skeptical about CAM, may hold on longer to beliefs that valid and reliable research is lacking, or certainly inadequate, and thus oppose expanding

coverage to many areas of CAM. Those supportive of CAM may believe that even where there has been an accumulation of solid evidence, even evidence of cost savings, there is bias and opposition to changing the traditional approach – or to adopting coverage of CAM services.

- Insurers, managed care organizations, administrators of public and military health care programs, and other health plan sponsors want to know whether treatments are clinically efficacious, and whether there are few side effects or adverse events. There are studies that indicate certain CAM therapies meet this standard, such as the impact of stress reduction on certain disease conditions. [Pelletier et. al., Current Trends in the Integration and Reimbursement of CAM by Managed Care, Insurance Carriers, and Hospital Providers, 1997

- In the absence of adequate research on the clinical efficacy of CAM therapies, insurers and managed care organizations are making decisions regarding coverage of CAM. A survey of insurers resulted in the following factors as determinants of CAM coverage:
  - consumer interest (based on quantitative research or employer requests)
  - proof of clinical efficacy (based on published, peer-review articles of randomized controlled trials or expert advice)
  - State mandated benefits. [Pelletier, et. al., Current Trends . . ., 1997]

- Typical models for offering CAM as part of an insurance product are:
  - An additional "rider" to the basic benefit package, commonly for an additional $1 to $2.50 per employee (or per member) per month. Utilization may be controlled by use of a credentialed network of CAM providers, co-payments, and benefit limits.
  - Discount programs whereby covered employees (or members) pay out-of-pocket but are eligible for 15 to 30 per cent discounts off professional CAM fees and CAM products. Discounted fees are usually tied to a pre-approved, credentialed network of CAM practitionsers.
  - A defined core benefit that is part of the employee benefit package. Utilization of this benefit is managed by limiting the type of CAM services covered (e.g., only chiropractic, acupuncture, and massage therapy are covered), requiring pre-authorization or physician referral, visit limits, dollar limits, and higher co-payments.
  - A CAM benefit account, such as a $500 annual maximum benefit. (J Weeks 5/14/01)

- Employers also may offer wellness and health promotion programs, on-site or off-site. These often include smoking cessation, weight control, stress reduction, yoga, etc. Employers also need this information, as well as reliable information on the ability of CAM to decrease absenteeism,

improve morale and productivity, and decrease disabilities. [KKing, Washington Business Group on Health,5/14/01]

Challenges:

More health services research is needed to establish the safety 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 safety and efficacy, health services research is needed to evaluate models of CAM, including integrative and collaborative programs, for effectiveness and best practices.

Insurers, managed care organizations, and purchasers, such as employers and federal programs, often lack routine processes for staying abreast of research on CAM, gathering the input of expert CAM practitioners, or addressing the concerns and questions of their network physicians, many of whom are not receptive to coverage of CAM.

Draft Recommendations:

1. A public-private partnership should be established to develop a multiyear health services research plan that identifies and addresses CAM research and demonstration questions, issues, data, methods, priorities, and coordination.

2. Public entities (AHRQ, NIH, CMS/formerly HCFA, HRSA, DOD, VA, etc.) and private organizations (research and other private foundations, employers, industry associations, etc.) should fund and jointly fund health services research and demonstrations on the safety and clinical effectiveness of CAM practices and products, as well as the clinical efficacy of various models for providing CAM services (integration, collaboration, etc.) within the U.S. health care system.

3. Health care purchasers including insurers, managed care organizations, Federal agencies, and other health plan sponsors should have a process for evaluating research on CAM and considering inclusion of CAM interventions in health benefit packages.
   - Federal agencies that provide health benefits (CMS, DOD, VA, etc.) must include CAM practitioners on coverage advisory bodies, coding work groups, and related working bodies.
   - Insurers and managed care organizations should have a process for assessing clinical and health research results, health benefits survey information regarding CAM, and technical information on CAM services and products; and should include CAM experts on coverage advisory bodies and related working groups.

- Professional associations, health policy institutions, and foundations should include the advice, consultation, and information provided by CAM practitioners and other CAM experts.
- CAM practitioners are encouraged to seek out opportunities to advise and participate in bodies, public or private, that address issues related to coverage, reimbursement, coding, health services research, and CAM-related demonstrations projects.

Issue 2: Information on the utilization, costs, and cost-effectiveness of CAM therapies

Background: Another barrier to coverage and reimbursement for CAM therapies is establishing adequate information on the utilization, costs and overall cost-effectiveness of CAM benefits. Health plans and health researchers are hindered in performing cost and actuarial analyses, risk-benefit analyses, and other types of benefit assessments due to the paucity of comparable data. Common claim forms, such as the HCFA 1500 and the UB-92 are not routinely used for CAM, nor is there a widely accepted coding system such as the CPT codes used for conventional services. Common claim forms and coding are essential tools for insurers and managed care plans in gathering and analyzing utilization patterns, setting provider payments, establishing sound premiums, and managing financial risk.

Even where insurers and HMOs are able to price and develop a successful CAM benefit, as has been possible for chiropractic and acupuncture services, little is known about the cost-effectiveness of various models of CAM practice, the clinical and financial impact of integration with conventional medicine, or the relative costs of CAM treatments versus the costs of conventional medical treatments. Little is known as to the impact of wellness programs and self-care on health status, or the impact of CAM practices on long-term health status, workplace productivity, or the patterns and costs of health care in the U.S.

- Several surveys of physicians indicate a belief that CAM leads to more effective care and more cost-effectiveness care. In other surveys, a significant proportion of users of CAM reflect a belief that they use fewer conventional services. In a survey of HMO executives, over half hold a belief that CAM is at least cost-neutral. [Jweeks 5/14/012; Integrator: Jan – Feb 2001, May 2001, April 1999]

- In surveys of large employers and employee benefits professionals, a substantial number of respondents indicate a belief that CAM provides a "potential" for cost savings. [JWeeks 5/14/01, Integrator: December, and July-August 2000]

- Increasing numbers of Blue Cross/Blue Shield HMOs and PPOs are offering CAM coverage or discount networks, particularly chiropractic and acupuncture. These plans assume that, in addition to competitive pressures (consumer demand) and State mandates, CAM treatments have the potential to save money through improved health status and by replacing higher cost conventional services and products. There is a concern, however, that CAM is additive in cost. [AKorn 5/14/01]

- Advocates of CAM believe that insures, managed care organizations and other health plan sponsors will find coverage of CAM cost-effective because CAM therapies can be less expensive than allopathic medicine, financial risk is reduced because CAM attracts healthier members to the health plan, CAM practitioners often focus on disease prevention. These beliefs are based largely on a few studies and surveys.

- In order to further research on the cost-effectiveness of CAM, and to compare the costs of CAM and conventional medicine, common data terminology is needed. The Common Procedure Terminology (CPT) and CPT codes should be developed for CAM. [Pelletier, et. al., Current Trends . . . 1997]

- A survey of elderly persons living in California who had purchased a Medicare (Blue Shield) supplemental policy found that CAM users spent an average of $699 annually on chiropractors, acupuncturists, and massage therapists. The reasons for seeking CAM services are, in order of frequency, back problems, chronic pain, health improvement, and arthritis. Over three fourths of the survey respondents have used the supplemental CAM coverage; the remaining had not. [JAstin, et. al., CAM Use Among Elderly Persons: One-Year Analysis of a Blue Shield Medicare Supplement, 1999]

- Employers continue to experience expensive increases in the cost of employer-sponsored health benefit programs. In recent years, the increases have been twice the rate of general inflation. The rate of increase was 8.1 per cent in Year 2000, and the average cost of health care coverage per employee was $4,430. The numbers are even higher for employer coverage of retirees not yet eligible for Medicare (under 65 years of age). The cost of covering retirees who have Medicare increased 17 per cent, due mostly to prescription drug costs. (William M. Mercer, News Release via the Internet, 2001)

- Employers, insurers, and managed care organizations are interested in responding to consumer demand for CAM, and continuously work on competitive health benefit plans. They also are very concerned about rising health care costs and are seeking information on the safety and cost-effectiveness of CAM; the utilization of CAM; and whether CAM

services are duplicative, additive or replacements to conventional care. [JMacPherson 5/14/01, JDillard 12.4/00, KKing 5/14/00]

Challenges:

Without the use of a common claims form and coding system, insurers and managed care companies cannot create the statistical data bases necessary to make health benefit policy and pricing decisions for CAM benefits. In addition, they cannot monitor the outcomes of these decisions, and make timely adjustments to the benefit structure and premium prices. Although some data is available, health plans will likely limit their core benefit coverage of CAM therapies until these benefits can be managed in a prudent and fiscally sound manner.

More empirical evidence of the cost-effectiveness of CAM is needed. Currently, there is inadequate health services research, health care demonstrations, and evaluations to assess whether CAM interventions

- are more cost-effective than conventional treatments for the same conditions;
- reduce treatment costs and improve outcomes when integrated -- or used collaboratively -- with conventional therapies;
- reduce utilization of conventional medial services and pharmaceuticals across the population; or for specific groups of persons such as the chronically ill, the terminally ill, individuals with chronic pain; or for certain conditions such heart disease or cancer;
- add to or reduce health care costs over the long-term.

There is little if any health services research, demonstration projects, and evaluations to assess the impact of CAM interventions and wellness programs on employee health and performance. Questions include whether CAM and wellness programs increase worker productivity, decrease workmen's compensation costs and disabilities, and decrease sick leave and absenteeism.

Draft Recommendations:

4. DHHS, working in partnership with the private sector (including professional and industry associations for CAM and conventional medicine, the American Medical Association, insurers, managed care organizations, and researchers), should facilitate the use of the Center for Medicare Services' (formerly HCFA) claims forms for billing CAM sservices, and modify nationally accepted coding systems to incorporate commonly used CAM therapies. In making modifications, the partnership should address methodological issues associated with the application of conventional systems to alternative health care approaches.

5. Public and private entities (identified in Issue 1) should fund or jointly fund health services research on the cost-effectiveness of CAM services, the

clinical and cost-effectiveness of various models of providing CAM services, and comparisons of the costs and outcomes of CAM therapies and conventional medical therapies for the same conditions. Studies should be conducted on the costs and benefits of CAM practices, wellness programs, and self care in the workplace.

6. Federal agencies that are responsible for health care coverage and services should investigate and report to the appropriate federal leadership on how to integrate safe, cost-effective CAM therapies into federal programs.

Issue 3: Licensure as a requirement for coverage and reimbursement

Background: Coverage and reimbursement for health care services are routinely linked to the provider's ability to legally practice within the State. Licensure, scope of practice and other State laws regarding authority to practice form the legal structure within which purchasers, insurers, and managed care organizations must operate. These laws not only protect the public, they give assurances that covered health benefits will be provided by qualified practitioners and meet recognized standards of care. The lack of State licensure for some CAM practitioners is a barrier to gaining coverage and reimbursement for CAM therapies.

Insurers and managed care companies typically use professional standards, practice guidelines, and other nationally-accepted parameters as guidance in defining a covered benefit or making case-by-case coverage determinations. Such recognized professional guidance also helps minimize risk and potential financial liability in the event of adverse outcomes. The lack of professional standards and other guidelines, developed at a national level, is an impediment to coverage and reimbursement by health plans.

- A survey of managed care organizations found that selection of CAM providers for the health plan was based on evidence of State licensure or board certification, appropriate training, malpractice insurance, and compliance with standards of practice (including quality improvement standards). [Pelletier, et. al., Current Trends . . . . 1997]

- Insert data on State licensure and certification (from George D.)

Challenges:
Insurers, managed care organizations, hospitals, and public and other sponsors of health plans are constrained in offering CAM benefits where practitioners are not licensed by the State or recognized under a comparable certification program. In addition, insurers and managed care organizations require

professionally-accepted standards of care to guide coverage decisions and manage risk.

Draft Recommendations:

7. In order to increase access to and coverage of safe and efficacious CAM therapies, State governments are encouraged to grant legal authority to practice to those CAM professions that have appropriately and adequately matured.

8. CAM professions should establish processes and standards that promote public safety, quality care, and accountability including standards for education and training, accreditation for centers of learning, and professional standards of practice.

Issue 4: Determining when to pay for or provide CAM

Background:
Insurers, managed care plans, and publicly financed health benefit programs use necessity and appropriateness standards as parameters for defining coverage and making coverage decisions. Like conventional medicine, CAM needs to develop such standards.

Insurers and HMOs rely heavily on "medical necessity" criteria to define the extent of a benefit, manage utilization, and make claims payment decisions. The management of health care expenditures and utilization is fundamental to financial stability under managed care and third-party reimbursement systems. For many CAM services and products, criteria for necessity and appropriateness are not well established, are not in a format typically used by payers, or are not readily accessible to payers. In addition, CAM criteria may have an approach different from the disease-based medical necessity criteria of conventional medicine. CAM services, such as acupuncture, may be used to enhance or support a conventional medical therapy, help prevent the onset or progression of a disease in at-risk individuals, or promote wellness and general disease prevention. Thus, as CAM criteria are developed, payers probably will learn new approaches or modify current approaches to "medical" necessity criteria. Federal leadership may be necessary to initiate, promote, and direct this innovative effort.

- A survey of insurers and managed care organizations found that, where CAM is a covered benefit, visits will be approved (or reimbursed) only if found to be medically necessary. Medical necessity determinations include proof of efficacy, case review, and service delivery by licensed practitioners. [Pelletier, et. al., Current Trends . . . . 1997]

- It is typical for covered persons to receive a "Certificate of Coverage" or "Explanation of Benefits." These documents specify the benefits that are

covered and those that are excluded. Most insurers and managed care organizations use these documents to state that only "medically necessary" services are covered and how this is determined, e.g. case review, medical literature, reports and guidelines by national organizations, professional standards, attending and expert physician opinions. For much of CAM, these guideposts do not exist or are inadequate, making CAM a challenge for benefit design. [JKelly 5/14/01]

- For many CAM interventions, it will be difficult to use the same methods for determining medical necessity or treatment protocols as conventional medicine, i.e. CAM practitioners usually assess the whole person, and often use touch or energy or other alternative assessment technique to guide the diagnosis and treatment. [WSickels 5/14/01]

Challenges:
The evidence and guidelines normally used by health plan sponsors in making coverage determinations are largely lacking for CAM. Medical literature does not provide or is inadequate in providing information to guide decisions regarding the necessity or appropriateness of CAM interventions.

CAM experts need to be involved in the development of practice guidelines and standards of care.

Draft Recommendations:

9. DHHS should support private sector efforts to form develop model CAM necessity and appropriateness criteria for CAM services shown to be safe and effective.

10. Insurers, managed care organizations, and benefit experts are encouraged to work with CAM professions to develop criteria for appropriate coverage of CAM benefits.

Issue 5: Supporting coverage and reimbursement through information

Background:
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 assist these parties to fairly consider extending coverage to CAM practices and products.

The "players" in developing benefit packages, including health benefits consultants, have well-established methods. In addition to routine approaches, purchasers and payers have inducements to maintain more traditional packages of benefits, especially from consumers. Generally, those persons covered under a benefit package are disinclined to give up or have any significant change made to existing benefits. If a new benefit is added, it is difficult to reduce, replace, or modify an "old" benefit -- and maintain member satisfaction. Thus, it is difficult for purchasers and providers to make significant changes to benefit packages without sufficient, high-confidence information.

- Surveys have been conducted to assess the user's experience with CAM services. A high percentage of users report that chiropractic, acupuncture, massage and naturopathy are "helpful." [JWeeks 5/14/01 based on work by Alternare Health Services, 1997, 1998, 1999; Integrator May 2001] In addition, other reports indicate that users experience a positive change through CAM interventions. [Tzu Chi Institure, Vancouver, B.C. and ChiroAlliance, Jacksonville, FL; Integrator Jan – Feb 2001]

- A survey of physicians with the Group Health Cooperative (HMO) found a belief that coverage of massage, acupuncture, and chiropratic was usually or always beneficial. [JWeeks 5/14/01, Integrator May 2001] A survey of Kaiser (HMO) physicians in California found a high perception of value for CAM interventions [Jweeks 5/14/01; Integrator November 1998].

Challenges:
The paucity of clinical and health services research, as well as publication and dissemination issues, have created an information need. Insurers, managed care organizations, public purchasers, and other sponsors are increasingly willing to consider coverage of safe, cost-effective CAM interventions but are challenged in building an valid information base and evaluating available information in order to make coverage policy decisions.

Draft Recommendations:

11. DHHS should sponsor, or co-sponsor with external partners, an easily accessible, continuously updated website that would provide information on CAM practices and products proven to be safe, clinically efficacious, and cost effective. Information should be provided for both consumer and professional use. An out reach effort should be made to inform purchasers, such as employers and community health centers, of the availability of this website.

12. DHHS, DOD, and VA should periodically report to Congress, the President, and each other the status of research, coverage, access and

availability of CAM services for their respective beneficiaries or through their respective sponsorships.

13. Purchasers (such as employers), health benefits experts, health care associations, providers, medical educational institutions, health policy bodies, foundations, etc. should integrate CAM topics into their informational and development meetings, such as annual meetings,

Groft, Stephen (WHCCAMP)

From: Miller, Maureen (WHCCAMP)
Sent: Thursday, September 13, 2001 11:13 PM
To: camio@ashn.com; cmapaz@totacc.com; deanornish@aol.com; georged@ashn.com; jjfins@mail.med.cornell.edu; linnealarson@mac.com; marjorie49@aol.com; mingtian@aol.com
Cc: 'gbernier@utmb.edu'; 'drpizzono@qwest.net'; 'tierney334@yahoo.com'; 'dosreis@msn.com'; Corinne Axelrod; Doris Kingsbury; Geraldine Pollen; Joseph Kaczmarczyk; jsgordon@mindspring.com; Ken Fisher; Michele Chang; Stephen Groft
Subject: Coverage/Reimbursement Paper for Call

Dear Group D --
Attached is the latest draft of the Coverage and Reimbursement paper, revised today to reflect Steve's format changes (they look good) and incorporate edits. It is a work in progress, as the Background and Challenges sections will be further developed over the next several weeks. And you make decide to add, modify, or delete issues and recommendations. Comments can be provided during the call, or if you prefer or cannot make this late-scheduled call, as soon as possible and no later than 3 p.m. Friday afternoon. All materials must go to the meeting contractor by close of business.

I appreciate you patience and efforts in providing comments, and participating in the call as we each deal with the fall-out of this week's tragedies. (Let's hope for no more bomb threats here or in San Diego, or anywhere.)

Maureen Miller
301-435-2211

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