The AAN's role in the development of health insurer coverage policy

Saty Satya-Murti, MD, FAAN

Katie M. Shepard, BA

Summary

Scientific, evidence-based clinical practice guidelines (CPGs) differ from coverage/policy statements. The latter incorporate values and priorities and translate evidence into human benefit. They assist provider and payer decisions, and abide by extant laws and regulations. Payers have set internal processes for balancing and integrating the intent of CPGs into their coverage/payment policies. Recently, however, their efforts to reach out to respected medical specialty societies for input are increasing. In response, the American Academy of Neurology (AAN) has taken the following steps: 1) it is reacting to, and providing input to, payer requests for policy reviews; 2) it is taking a proactive approach by developing AAN guideline companion documents that describe potential provider impacts and policy implications; and 3) it is commencing an initiative to write its own template policies. This new involvement has met with initial positive outcomes. The AAN will continue to expand efforts to fulfill a growing need in this area.

Academic and specialty societies like the American Academy of Neurology (AAN) have been publishing high-quality evidence-based systematic reviews and corresponding clinical practice guidelines (CPG) for nearly 2 decades. CPGs are comprehensive, scientific evaluations that address the utility of a technology or a treatment and are developed to provide information for health care practitioners without an overt intention to affect payer reimbursement decisions. CPGs are valued not only by practicing neurologists, but also by the Centers for Medicare and Medicaid Services (CMS) and other insurers (payers) in the development of their coverage/payment policies.

The scientific method behind CPGs is rigorous, descriptive, and explanatory. Though they become important in driving clinical care and are useful for populations of patients, CPGs

Health Policy Consultant (SS-M), Santa Maria, CA; American Academy of Neurology (KMS), Minneapolis, MN.

Correspondence to: kshepard@aan.com

Reimbursement for services rendered is a wobbly balance that depends on the evidence underlying a technology or procedure as a base, layered by coverage/payment policies and extant laws and regulations.

may require mindful alteration in certain circumstances to serve the needs of individual patients. Some guidelines, having been written based on restricted availability of evidence, may have “limited relevance to clinicians and patients,” and could be “incompatible with the norms and values of target users.”¹

For example, it is estimated that chronic low back pain affects 2%–8% of the population and that Americans spend at least \$50 billion each year overall on back pain, both acute and chronic.² Guidelines for treating this condition by panels of experts, while offering outstanding summaries of scientific evidence, “do little to guide clinical practice and leave many questions unanswered.”³

In contrast to evidence-based guidelines, coverage/payment policies fulfill a more specific role. They incorporate values based on extant societal “moral, religious, ethical and legal norms.”^{1,4} Prescriptive procedure (Current Procedural Terminology [CPT®]) and diagnosis (ICD-9-CM) coding instructions and claims submission guidelines are usually included in policies. CPT codes range from temporary, emerging technology (category III) codes to accepted and standardized code sets (category I and II). The existence of a CPT code only describes what is being done and does not have any bearing on the safety, effectiveness, or cost-effectiveness of the service or procedure. Though coverage/payment determinations do not, in and of themselves, describe what may be medically appropriate, the documents are generally developed to address how a treatment or technology may be used under average circumstances in order for providers to receive reimbursement. They are not meant to eliminate provider autonomy in the treatment of unusual circumstances and variant patient presentations.

Reimbursement for services rendered is a wobbly balance that depends on the evidence underlying a technology or procedure as a base, layered by coverage/payment policies and extant laws and regulations. Coverage policies take into account values, costs, and priorities for patients and providers, which in turn translate into human benefit. In this context, specialty societies are becoming an increasingly important resource that informs payers, coverage/policy developers, and decision-makers.

Situations in which coverage policies are helpful

Several general instances, outlined below, show where coverage/payment policy development is likely and helpful.

Evidence of benefit for a traditional/accepted treatment is under scrutiny In some cases, high-quality scientific evidence sufficient to reach a conclusion and make a strong evidence-based recommendation for a treatment or technology is lacking. In some others only a weak recommendation can be made based on the available evidence. Independent of the availability of evidence, a treatment or technology may already be in general use. Traditionally, in such instances cost concerns have not widely been taken into consideration. This climate, however, is undoubtedly changing under an unsustainable health care system.

For example, thymectomy for myasthenia gravis (MG) has been performed for more than

In some cases, high-quality scientific evidence sufficient to reach a conclusion and make a strong evidence-based recommendation for a treatment or technology is lacking.

70 years and the procedure is generally believed to be associated with improvement or remission of symptoms; yet methodologic flaws and baseline patient heterogeneity in available studies have limited the conclusions about the benefit of thymectomy and the strength of recommendations on its use.⁵ Thus, by evidence standards, the role of thymectomy remains unclear because indications for this procedure based on randomized trial data are lacking. Multicenter, international randomized controlled trials are under way now to address this gap.^{5–7} In the meantime, a coverage/payment policy developed by a medical specialty society highlighting all currently available evidence would aid in decision-making for individual instances where coverage or payment is questioned by payers.

Strong evidence of lack of benefit exists For some procedures or therapies, the available evidence shows a clear lack of superiority of the treatment over a placebo or an existing practice pattern. In these cases, payers must make decisions about whether or not to cover the cost of a procedure or therapy, even though strong (Class I) evidence goes against common current practice.

For example, both the 2011 AAN guideline and Cochrane database reviews concluded that, based on Class I randomized controlled clinical trials, transcutaneous electrical nerve stimulation (TENS) was not of benefit in the treatment of chronic low back pain.^{8,9} As a consequence of this emergent evidence, coverage and payment for TENS, especially in home settings, became a focus for policymakers among private payers and the Centers for Medicare and Medicaid Services (CMS).

CMS, based on significant input from stakeholders during a public comment period, expressed its willingness to leave its analysis of this treatment option open and not issue a blanket noncoverage decision. At the time of this publication, TENS will be available for coverage, according to CMS, under their “Coverage with Evidence Development” (CED) initiative. This mechanism encourages a conditional payment that requires adherence to explicit patient selection and clinical data generation with a view to demonstrating the impact on health outcomes. Under such a CED “paradigm,” other topics (e.g., PET scans for dementia and cochlear implantations) have received a conditional coverage status (National Coverage Analysis [NCA] Tracking Sheet for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain [CAG-00429N]).

Evidence is weak, but practice is harmful The value of a policy is perhaps most evident when there are severe adverse events associated with particular therapies, but statistical data are lacking.

For example, use of aspirin for children with fever or chicken pox is strongly discouraged for fear of inducing Reye syndrome, even though the quality of evidence linking Reye syndrome and aspirin use is low because only observational case reports make such an association.¹⁰ In this case, a provider specialty society may decide to issue a cautionary policy proscribing aspirin for children with fever. In neurology, even if such instances are infrequent, it is important to be alert to such possibility in the future.

New technology is encountering slow adoption When a technology is emerging, its adoption into standard practice is not widespread. Because of its infrequent use—and paucity of evidence—at this stage, specialty societies are not likely to offer guidelines on the technol-

ogy nor do payers view the technology as a high priority for policy development, unless it is unusually expensive.

For example, deep brain stimulation (DBS) was emerging in the mid-1990s as a treatment for essential tremor and Parkinson disease (PD). Payers, including CMS, had been hesitant to cover the treatment, but a few Medicare contractors who employed physician medical directors with a neurologic background developed the earliest affirmative local coverage policies.¹¹ Since then, DBS has become an accepted treatment, and is now covered by most payers for several movement disorders. Vagus nerve stimulation (VNS) for refractory epilepsy followed a similar path.

More recently, magnetoencephalography (MEG) encountered a similar resistance to coverage. As an emerging diagnostic technology, MEG, in contrast to surface EEG or MRI, is not currently widely used. Therefore, coverage has been either limited or unavailable even though a category I CPT code for MEG (95965) was assigned by the AMA CPT Editorial Panel in 2002. Following a 2009 AAN coverage policy describing the technology, along with its distinct benefits as well as its shortcomings and the existence of positive coverage by some Medicare carriers, MEG received recognition as a diagnostic test for conditional coverage by several payers.¹²

Claims submission or coding guidance is unclear or controversial Whereas CPGs do not incorporate related rules and regulations, policy statements usually include specific rules, coverage parameters, and regulatory language associated with a service or procedure.

For instance, coverage policies for PD set qualifying criteria for DBS surgery. Some policies place a rigid pass-fail threshold score on the Unified Parkinson's Disease Rating Scale (UPDRS), while others depend on multiple qualifiers without requiring rigid threshold scores. The UPDRS is a robust and respected index, but is limited in its assessment of certain key elements of PD.¹³ Thus, strict adherence to only a UPDRS score may lead to the coverage of DBS in one region of the country, but to noncoverage for the same patient in another region. In this instance, the expertise within a specialty society such as the AAN is well positioned to craft a policy that clarifies whether a UPDRS score is, or should be, an absolute requirement toward patient eligibility for DBS.

Role of specialty societies in coverage/payment policy development

Specialty Society CPGs arrive at conclusions based exclusively on scientific merits. The purely evaluative focus of CPGs does not accommodate the values and the pragmatic needs of patient-physician preferences. Their objectivity, while extremely useful in many domains, may vary from practice patterns at large. The disconnection between scientific evidence and clinical practice identifies a clear need for the development of coverage/payment policies.

Generally, payers are adept at balancing and integrating the intent of CPGs into their policies. There are times, however, when payers do depend heavily on a guideline that finds an absence of evidence in support of a technology. As a result, they may institute a noncoverage policy for that technology. Although payers' internal medical staff members have worthy expertise, they still seek a balanced and neutral input from respected specialty societies also for crafting their policy drafts. Balanced policy statements from specialty societies could result in savings from payment for ineffective therapies.

Policies are aimed at providing guidance to payers as they make decisions in the development of their coverage documents. They advise practitioners broadly on conditions for coverage as they weigh their diagnostic and treatment options. Policies merge aspects of CPGs with values, statutes, codes, and regulations. Policymakers and physicians alike may rely on them to bridge the "gap between coverage decisions and research."¹⁴ As priorities are determined, payers and practitioners alike must consider how widely a treatment or technology is used in the setting of a particular disease and its prevalence.¹⁵ If written thoughtfully, policies could be used to moderate the "focal point for conflicts between the desire to speed the adoption of new medical technologies and

the need to keep health insurance affordable.”¹⁶ Therefore, policies reflect an amalgam of science and values set by practitioners, patients, and society.

Payers have started reaching out to specialty societies for help. When definitive evidence is not available and more than 1 treatment option can be used, reasonable physicians may choose differing treatment paths for patients with similar clinical presentations.¹⁷ Similarly, even when good evidence is available, “different expert panels may interpret data differently and emphasize different results in making their decisions.”¹⁸ When payers uncover lack of data to determine the effectiveness of therapy, they have an option to stall or deny affirmative payment decisions. This results in an unsatisfactory situation for patients, their providers, and payers. If a resolution is available, it could be time- and resource-intensive to realize.

In an attempt to minimize this type of situation, a respected specialty society can take one of several actions:

- Stipulate conditional coverage for a modality and delineate explicit patient selection criteria, narrow the diagnostic eligibility, require failure of other treatments as a coverage prerequisite, and establish credentialing for providers.
- Take a stand against coverage of a long practiced modality altogether.
- Develop policy language urging payers to allow, pro tem, individual case-based consideration instead of a blanket denial of claims. Such policies may be revised or retired as new evidence for effectiveness emerges.

The existence of evidence gaps, such as those noted above, is common in clinical sciences. CMS has undertaken a systematic effort to identify these gaps through their technology assessments, open advisory panel meetings, and public domain coverage documents in their Medicare Coverage Center data repositories (<http://www.cms.gov/center/coverage.asp>). The data and contents within this center are frequently the basis for coverage policies and decisions by payers. Another example is the policy-setting initiatives of the Washington State Health Technology Assessment (HTA), a government-sponsored program which relies on critical appraisals of devices, procedures, medical equipment, and diagnostic tests. HTA assessments lead to coverage recommendations.¹⁹

Meeting a growing need

To meet a growing need, the AAN's Medical Economics and Management Committee created the Payment Policy Subcommittee (PPS) in 2007, a group of volunteer members devoting their time to developing relationships with payers and examining coverage/payment policies. Since its formation, the number of requests from policy developers, the majority of whom are insurers, for input on draft policies has increased steadily. When requests are made, staff and volunteer members screen them for their relevance to practice of neurology, and pass appropriate policies to volunteer subject matter experts—identified through AAN sections—to complete an in-depth review of the policy and provide feedback to the requester. AAN experts may agree, disagree, suggest modifications to the proposed policy, or offer citations for studies that may have been overlooked during the policy development process.

In 2009, members of the Academy reviewed a total of 41 coverage/payment policies from 7 of the largest national private insurers including UnitedHealthcare (UHC), WellPoint, Humana, and Aetna. In 2010, the AAN reviewed more than 50 policies. National and local policies developed by various CMS Contractors are always available publicly online for comment.

The infrastructure is growing such that the AAN PPS now receives regular feedback from 2 of the largest insurers on actions taken, if any, based on AAN review. One large insurer with 33 million enrollees sought input from 37 different specialty medical societies, including the AAN, in 2011 (American Academy of Neurology, personal communication, 2012). Their overall annual response rate from all specialties was 35% (reviews requested 386, completed 137). The AAN response rate was 60% (reviews requested 20, completed 12). These numbers include policies for which the AAN or other societies responded that the policy fell outside of the purview of the specialty. Importantly, the average turnaround time from the AAN was

lower (28 days) when compared to that of all specialty societies (36 days). Timeliness helps ensure the feedback is heard during insurer coverage/payment policy committee meetings. Of the 12 reviews the AAN provided to WellPoint in 2011, 2 policies were revised as a direct result of information received from the AAN during the review process.

At the same time, the AAN is taking a more proactive approach by releasing companion policy impact statements on current AAN guidelines and, in a limited number of cases, developing its own template coverage policies to serve as a possible model for payers.^{20,21} Such documents do not have a statutory or obligating authority, as do federal or state agency documents; however, if they are well-written and generated by respected sources based on sound, balanced evidence and values, it is difficult to disregard their recommendations routinely. Such documents would draw attention and offer potential solutions for controversial coverage issues. During the development process the policies should be sensitive to divergent or alternative views by allowing for open comment and response prior to finalization. In addition, the AAN requires that volunteer authors with subject matter expertise complete conflict of interest and disclosure forms.

There may also come a day when policy issues act as a catalyst for the development of a clinical practice guideline on a given issue.

DISCUSSION

Specialty society-developed CPGs serve as a strong base for all coverage/payment policies. Guideline development of the future may take into account a host of other factors including cost implications of a given therapy or technology. Coverage/payment policies, however, are needed to fulfill a separate, narrower role. Traditionally, federal and state agencies such as CMS, Washington State HTA, and private insurers have been the only groups active in formulating coverage/payment policies. In recent years, specialty societies have also become a participant as both a reviewer and as a developer. The AAN's involvement in this arena has led to initial positive outcomes. Efforts will continue to be expended to fulfill this growing need.

REFERENCES

1. Grol R. Has guideline development gone astray? Yes. *BMJ* 2010;340:c306.
2. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Chronic Low Back Pain Background. 2010. Available at: http://www.niams.nih.gov/News_and_Events/Meetings_and_Events/Sci_Retreats/2010/chronic_lbp.asp. Accessed April 30, 2012.
3. Furlan AD, Pennick V. Limitations of guidelines for low back pain therapy. *Nat Rev Rheumatol* 2009;5:473–474.
4. Kraemer J, Gostin L. Science, politics, and values: the politicization of professional practice guidelines. *JAMA* 2009;301:665–667.
5. Gronseth GS, Barohn RJ. Practice parameter: thymectomy for autoimmune myasthenia gravis (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2000;55:7–15.
6. Newsom-Davis J, Cutter G, Wolfe GI, et al. Status of the thymectomy trial for nonthymomatous myasthenia gravis patients receiving prednisone. *Ann NY Acad Sci* 2008;1132:344–347.
7. Cochrane Reviews. Thymectomy for non-thymomatous myasthenia gravis (Internet) (cited 2010 Apr 29). Available at: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008111/abstract;jsessionid=865988808C2DF96B997F62B8CD92F0A7.d03t03>. Accessed April 30, 2012.
8. Dubinsky R, Miyasaki J. Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2010;74:173–176.
9. Khadilkar A, Odebiyi D, Brosseau L, Wells G. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain (Review). *Cochrane Database Syst Rev* 2008;4:CD003008.
10. Guyatt G, Oxman A, Vist G, et al. GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008;336:924–926.
11. United States General Accounting Office, Congress, House Committee on Ways and Means, Subcommittee on Health. Medicare: divided authority for policies on coverage of procedures and devices results in inequities: report to the chairman, Subcommittee on Health, Committee on Ways and Means,

House of Representatives: 2003. Available at: <http://www.gao.gov/new.items/d03175.pdf>. Accessed April 30, 2012.

12. American Academy of Neurology. Magnetoencephalography (MEG) Model Policy. Available at: <http://www.aan.com/globals/axon/assets/7052.pdf>. Accessed April 21, 2010.
13. Goetz CG, Fahn S, Martinez-Martin P, et al. Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): process, format, and clinimetric testing plan. *Mov Disord* 2007;22:41–47.
14. Chalkidou K, Lord J, Fischer A, Littlejohns P. Evidence-based decision making: when should we wait for more information? Coverage decisions that are conditional on gaining more evidence are a powerful tool for informed decision making. *Health Aff* 2008;27:1642–1653.
15. Guyatt G, Helfand M, Kunz R. Comparing the USPSTF and GRADE approaches to recommendations. *Ann Intern Med* 2009;151:363–364.
16. Garber A. Evidence-based coverage policy. *Health Aff* 2001;20:62–82.
17. French J, Gronseth G. Lost in a jungle of evidence: we need a compass. *Neurology* 2008;11:71:1634–1638.
18. Feldman S. Making sense of the new cervical-cancer screening guidelines. *N Engl J Med* 2011;365:2145–2147.
19. Franklin GM, Budenholzer BR. Implementing evidence-based health policy in Washington State. *N Engl J Med* 2009;361:1722–1725.
20. American Academy of Neurology. Canalith Repositioning Model Policy. Available at: <http://www.aan.com/globals/axon/assets/7053.pdf>. Accessed April 2010.
21. American Academy of Neurology Professional Association. Principles of Coding for Intraoperative Neurophysiologic Monitoring and Testing Model Policy. Available at: <http://www.aan.com/globals/axon/assets/9339.pdf>. Accessed April 2012.

ACKNOWLEDGMENT

The authors thank the AAN Payment Policy Subcommittee members Joel M. Kaufman, MD, FAAN (Chair); Terry D. Fife, MD, FAAN; Joseph V. Fritz, PhD; Heidi Moawad, MD; Sandra L. Helmers, MD, MPH, FAAN; and Constantine Moschonas, MD, for their engagement and dedication to payment policy activities; and Julie Cox, MFA (AAN staff), for copyediting an early draft of the manuscript.

DISCLOSURES

Dr. Satya-Murti reports no disclosures relevant to the manuscript. Ms. Shepard is a full time employee of the American Academy of Neurology (AAN).

Related articles from other AAN physician and patient resources

Neurology® • www.neurology.org

Editorial: The AAN: A data-driven organization?

November 22, 2011;77:1864–1865.

AAN Board of Directors recommends formation of a companion association to establish a political action committee

April 24, 2007;68:1425–1427.

Neurology Today® • www.neurotodayonline.com

In Practice: What is the AAN Doing to Protect Your Practice? President-elect Bruce Sigsbee, MD, Answers Your Tough Questions

March 3, 2011;11:28–29.