

# Health Plans' Coverage Determinations for Technology-based Interventions: The Case of Electrical Bone Growth Stimulation

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**Objectives:** To determine (1) whether commercial health plans' coverage criteria for a costly technology-based medical intervention are consistent with recent clinical effectiveness evidence, (2) whether medical directors adhere to planwide coverage criteria when making coverage determinations for individual patients, and (3) if any organizational characteristics are associated with having more stringent coverage criteria or making more frequent coverage denials.

**Study Design:** Case-based survey of medical directors of US commercial health plans.

**Methods:** A close-ended survey was mailed to 346 medical directors meeting eligibility criteria, asking about the criteria specified in their plans' coverage policies for electrical bone growth stimulation (EBGS) and whether they would cover this intervention for a hypothetical patient with abnormal union of long-bone fracture.

**Results:** Responses from 228 (66%) of the 346 directors indicated that approximately 72% of plans have a formal coverage policy for EBGS for long-bone fractures. More than 30% of plans specify that longer than 4 months must elapse before EBGS is attempted, although clinical studies do not support absolute waiting times. Directors of approximately 61% of plans with policies requiring extended waiting periods would nevertheless authorize EBGS for patients who did not meet this criterion.

**Conclusions:** Health plans apply varied criteria in coverage policies for technology-based treatments such as EBGS, but do not always adhere to stated criteria when determining coverage for individual patients. For-profit status, accreditation status, geographic location, and size of plan are not associated with being more or less likely to authorize EBGS.

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Since managed care emerged as the dominant mode of healthcare delivery in the United States, there has been widespread concern about the way health plans make coverage determinations about technologically advanced medical interventions. One strategy used by plans to regulate use of these often costly interventions is to issue coverage policies containing specific criteria for determining whether interventions are medically necessary for patients with particular indications.

Although some see coverage policies primarily as a tool for restricting access to care, others argue that they can be used to promote more consistent and evidence-based practice across plans.<sup>1</sup> At least in theory, these

utilization review tools can provide the means by which individual physicians' clinical judgments are subjected to more systemwide standards.

To date, there are limited data to indicate whether coverage criteria promote consistency or the application of evidence-based standards. Previous work suggests that medical directors rely to varying extents on coverage policies, published scientific evidence, expert opinion, community standards, personal experiences, and patient preferences when making individual coverage determinations.<sup>2</sup>

To investigate this issue, we presented medical directors of commercial health plans with a hypothetical request for authorization for a costly technology-based intervention. We sought to determine (1) whether plans' coverage criteria for this intervention are consistent with the most recent clinical effectiveness evidence and (2) whether plans apply criteria consistently when faced with the ambiguities and exigencies of individual cases. We also examined whether organizational characteristics such as plan size, tax status, and accreditation status are predictive of plan behavior in this area.

Our research group, after consultation with experts, selected electrical bone growth stimulation (EBGS) as the focus of our study. We considered EBGS to be an ideal technology for a study of coverage decision making because it raises many of the issues that can lead to variable coverage policy. Despite its use for more than 2 decades to promote healing in fractures that fail conservative therapy, EBGS has long been in an "evidence limbo," as the medical community did not reach consensus about appropriate selection of fractures for this treatment until recently.

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Although early research was conducted in patients in whom conservative measures had been attempted for 9 months or longer,<sup>3</sup> investigations after 1990 began to rely on serial radiographs to confirm nonunion rather than absolute waiting times.<sup>4,5</sup> In 1999, the Health Care Financing Administration revised Medicare criteria to stipulate that EBGs was appropriate for patients in whom serial x-ray films confirm that fracture healing has ceased for 3 months or longer.<sup>6</sup> Therefore, EBGs has had proponents and opponents for many years, with potential for the introduction of new evidence about clinical effectiveness to lead to agreement on covered indications.

In addition, like many other technologically advanced medical interventions, EBGs is costly. Retail prices for external, noninvasive devices range from \$3500 to more than \$4000; worldwide sales of these devices reached nearly \$200 million in 1998.<sup>7</sup> The cost of EBGs is likely to be at least an implicit consideration among payers.

Finally, EBGs has not figured widely in public debates about medical cost cutting and managed care. Many other technologies for which there is limited evidence have been the subject of controversy, which might inhibit medical directors from candidly expressing their views.

We expected different health plans to develop different coverage criteria for EBGs. We anticipated that few plans would include criteria that were no longer consistent with recent evidence on the appropriate indications for EBGs. Plans that were affiliated with national or multistate organizations were expected to specify criteria that were more consistent with recent evidence. Tax status, accreditation status, and plan size were not expected to be predictors of having more evidence-based criteria.

We expected that variability in the clinical criteria listed in plans' coverage policies would translate into variability in their approach to day-to-day coverage determinations. That is, we expected medical directors to adhere to written coverage criteria when deciding whether to cover EBGs for the patient in our study case, with 80% adherence being our threshold for considering medical directors to be consistently adherent.

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## METHODS

### Sample Selection

We identified a set of characteristics that defined a "commercial managed healthcare organization" for the purposes of studying coverage decision making. To be eligible, organizations needed to (1) provide and finance a comprehensive range of general healthcare services, (2) offer and include enrollment in at least 1 managed

care product line (ie, health maintenance organization [HMO], preferred provider organization, or point of service plan), (3) have been continuously marketing for at least a year (ie, since January 1, 2000), (4) assume financial risk for the medical services they provide, and (5) have at least 10% commercially sponsored beneficiaries.

Preliminary review of published directories of managed care organizations suggested that many multistate organizations could be subdivided into several "plan units" that made independent coverage decisions for beneficiaries in different states or regions.<sup>8-10</sup> In such cases, we considered each plan unit (hereafter referred to as a "plan") to be a separate decision-making entity for the purposes of our analysis. We relied on organizations' self-report to identify all of their affiliated plans; if an organization indicated that decision making was made centrally for all regions in which it operated, we considered the entire organization to be a single plan. We identified plans that were affiliated with national or multistate organizations to assess whether their behavior differed from that of nonaffiliated plans.

Within each plan, we identified a single individual to answer questions about decision making for all products offered for that plan. We generally sought the most senior-level medical director who was responsible for decision making for the largest product in the largest state within that plan and who had the authority to evaluate medical interventions for coverage on a daily basis. We asked medical directors to indicate whether their answers to our questions would have differed if they were responding on behalf of a different product or state in the plan. Medical directors were encouraged to consult with other staff members when necessary to provide accurate information.

Names and addresses of the medical directors were verified by telephone before mailing of the survey in mid January 2001, and ineligible plans were removed during the telephoning process. A reminder postcard was sent 3 weeks after the initial mailing, and 3 subsequent rounds of reminder telephone calls were made until early May 2001.

### Questionnaire Development

Survey questions were developed in consultation with 20 members of the managed care industry, including several former medical directors of health plans. The first part of the survey elicited information about general organizational characteristics of plans, including geographic area of operation, number of covered lives, range of products, physician payment methods, tax status, accreditation status, affiliation with a national or multistate organization, and use of quality and utilization management strategies.

Medical directors were also presented with a hypothetical case involving a request for EBGs for a patient with a long-bone fracture that had not healed with conservative management:

A 55-year-old man suffered a partially displaced fracture of the right tibia after falling down the stairs. Shortly afterward, he was seen by an orthopedic surgeon in a local emergency room. The surgeon felt that open reduction and internal fixation was not medically indicated and applied a cast to the patient's right leg. The patient initially appeared to recover well, but follow-up x-rays over the next several weeks revealed very little callus formation at the site of the fracture. After 3 months, the surgeon determined that healing was delayed and not progressing at a satisfactory rate. She recommended an external (noninvasive) electrical bone growth stimulator because she felt it was clear that satisfactory union would not be achieved in 6 months based on the clinical course of the first 3 months.

Participants were asked to indicate whether their plans would consider the intervention to be medically necessary for the patient described.\* Participants could indicate whether the decision would be made by a medical director or whether the treating physician would be allowed to make this decision as a matter of policy.

We avoided incorporating any details that would force medical directors to reject the request for obvious inconsistencies with widely established standards of care for long-bone fractures (eg, conservative measures not attempted or no radiographic evaluation of healing performed). At the same time, the case was designed to reflect some of the ambiguities that might characterize a real-life case (eg, the treating physician makes estimates about future healing based on a shorter trial period).

Through a review of 8 different EBGs coverage policies posted on health plan Web sites, we identified 5 clinical criteria that are commonly used to guide coverage determinations for EBGs. We asked medical directors whether their plans had any coverage policies for EBGs and, if so, whether these policies required any of the following: (1) minimum period to have elapsed after fracture, (2) serial radiographic evidence of delayed healing, (3) fracture gap within a defined range, (4) presence of clinical signs or symptoms of nonunion at the fracture site, or (5) absence of infection at the fracture site.

\*At the start of the survey, we defined *medically necessary* for participants as the contractual standard applied to decisions about coverage of an intervention for an individual patient and decisions about coverage of an intervention for a group of patients with specific medical indications.

### Statistical Analysis

We created variables to describe plans' organizational characteristics; continuous variables such as enrollment were translated into categorical variables, in which plans were separated into mutually exclusive and collectively exhaustive groups. Univariate analysis was used to uncover any simple associations between organizational characteristics of the plans and their responses to our questions about EBGs decision making, using the  $\chi^2$  test to assess statistical significance. We then developed multivariate logistic regression models to evaluate the independent effect of each organizational variable as a predictor of plan behavior and used a stepwise elimination approach to simplify models. We only report results for variables for which  $P < .05$  in the final regression model.

## RESULTS

Of 479 health plans initially identified, 133 (28%) did not qualify for inclusion based on information obtained from telephone screening and further investigation. Forty-four of these plans had closed or converted to rehabilitation care, 29 had merged with another plan, 26 were equivalent to another plan under a different name, 19 had greater than 90% of their enrollment covered by Medicaid, 13 were in non-risk-bearing networks only, and 2 did not have active enrollment in any managed care products. Of the remaining 346 plans, we obtained complete or partial responses from 228 (66%). Survey responses represented covered lives in all 50 states and the District of Columbia. The total number of covered lives represented was approximately 119 million, or 77% of the covered lives represented by our universe of eligible plans (estimated at 155 million).

### Organizational Characteristics of Participating Organizations

Table 1 gives the characteristics of the responding plans. More than half of participating directors represented plans with more than 100 000 covered lives, and almost a quarter of directors represented plans with fewer than 50 000 lives. A third of plans reported their greatest enrollment in independent practice association or network HMO products. Responding plans were fairly evenly distributed across census regions, with proportionately decreased representation of regions with low HMO penetration.<sup>8-10</sup> Most medical directors believed that their responses also applied to other products and states in their plan; only 8% thought that the results did not apply universally, and in our analysis we

**Table 1.** Characteristics of Health Plans Responding to the Survey\*

Characteristic	No. (%)
<b>Size of plan by covered lives (n = 228)</b>	
Small (< 49 999)	55 (24.1)
Medium (50 000-99 999)	45 (19.7)
Large (100 000-249 999)	37 (16.2)
Very large (> 250 000)	91 (39.9)
<b>Primary product type (n = 228)<sup>†</sup></b>	
Group or staff-model HMO	35 (15.4)
Independent practice association or network-model HMO	75 (32.9)
Point of service	19 (8.3)
Preferred provider organization	42 (18.4)
Indemnity or traditional	10 (4.4)
Mixed	47 (20.6)
<b>Region of primary state (n = 227)<sup>‡</sup></b>	
Northeast	38 (16.7)
Midwest	61 (26.9)
South	71 (31.3)
West	57 (25.1)
<b>HMO penetration level of primary state (n = 227)<sup>‡</sup></b>	
Low (0%-11.1%)	22 (9.7)
Medium low (11.2%-23.4%)	65 (28.6)
Medium high (23.5%-35.1%)	64 (28.2)
High (≥ 35.2%)	76 (33.5)
<b>Primary care physician payment method (n = 218)</b>	
Primarily fee for service	138 (63.3)
Primarily salary	17 (7.8)
Primarily capitation	52 (23.9)
Other or mixed approach	11 (5.0)
<b>Tax status (n = 223)</b>	
For profit	123 (55.2)
Not for profit	100 (44.8)
<b>Accreditation status (n = 216)<sup>§</sup></b>	
Not accredited by any organization	79 (31.2)
Accredited by National Committee for Quality Assurance	106 (41.9)
Accredited by Joint Commission on Accreditation of Healthcare Organizations, URAC, or Accreditation Association for Ambulatory Health Care	68 (26.9)
<b>Affiliation with a system of health plans (n = 228)</b>	
Yes	88 (38.6)
No	140 (61.4)
<b>Use of preauthorization requirements (n = 224)</b>	
Yes, in some cases	204 (91.1)
No	20 (8.9)

\*Sample size varies because of missing survey responses.

<sup>†</sup>A health plan was assigned a specific "primary product type" if at least two thirds of its enrollment was in a single product type. Plans with enrollment divided more evenly between different products were classified as "mixed."

<sup>‡</sup>One multi-region organization indicated that it could not be subdivided into smaller region-specific plans.

<sup>§</sup>Some plans were accredited by more than one organization.

HMO indicates health maintenance organization.

applied their answers to only those covered lives in the relevant state and product.

More than half of the responding plans reimburse their primary care physicians primarily on a fee-for-service basis, with slightly fewer than a quarter paying mainly by capitation. Slightly more than half of the plans are for profit, one third are not accredited by any organization, and one third are affiliated with a national system of plans operating in more than 5 states. More than 90% of plans use preauthorization requirements to manage use.

We compared several organizational characteristics of respondents and nonrespondents using previously published sources about health plans.<sup>8-10</sup> Our review suggested that plans with a larger number of covered lives are slightly overrepresented among our respondents; 56% of respondents represent plans with more than 100 000 covered lives, as opposed to 46% of nonrespondents. However, respondents and nonrespondents do not differ significantly in terms of geographic region, product type, accreditation status, or HMO penetration of the primary state.

**Health Plans' Responses to the Case**

Only 14% of medical directors, representing 8% of covered lives, indicated that EBGs would not be considered medically necessary for the patient described in the case. Approximately 77% of medical directors indicated that their plans would approve the request. The remaining 9% of medical directors indicated that they did not know how their plans would respond to the case. Of note, plans' decisions to cover or not to cover EBGs in this case



were not associated with any particular health plan characteristics.

**Criteria Specified in Coverage Policies**

Slightly more than 72% of plans, representing slightly more than 82% of covered lives, have a formal coverage policy for EBGs for nonunion of long-bone fractures. On multivariate regression analysis, we found that the 2 health plan characteristics associated with being more likely to have a coverage policy are affiliation with a multistate managed care system ( $P < .01$ ) and the use of preauthorization for certain interventions ( $P < .05$ ). Tax status, accreditation, size of plan, and geographic region do not appear to be significantly associated with having an EBGs policy.

Of those plans with coverage policies for EBGs, approximately 23% of plans, representing 37% of covered lives in this category, do not require serial radiographic confirmation of nonunion (Table 2), although the clinical literature and Medicare policy support the use of this method of confirming nonunion over more subjective measures.<sup>6</sup> Slightly fewer than 84% of plans with coverage policies, representing 80% of covered lives in this category, require that a specific amount of time must elapse after initial fracture. No measured organizational characteristics predict having either of these requirements.

Actual time frames specified in coverage policies vary among our data. Of those plans that require that a specific amount of time must elapse after initial fracture, 69% (90% of covered lives in this category) specify a period shorter than 4 months, as is consistent with Medicare coverage policies for EBGs, and 31% (10% of covered lives in this category) specify a period of 4 months or longer.\* A few (3%) medical directors say that their coverage policies require that patients must wait longer than 9 months before EBGs can be considered as an intervention. No health plan characteristics are predictive of having more restrictive time frames.

In addition, a few plans include coverage criteria that are not included in the 1999 Medicare EBGs coverage policy revisions. Slightly fewer than 45% of plans with coverage policies require that the fracture site not be infected, slightly fewer than 17% require that specific clinical signs or symptoms of nonunion be present (eg, pain or motion at the fracture site), and slightly more

**Table 2.** Criteria Included in Electrical Bone Growth Stimulation Coverage Policies

Criterion	Health Plans (%)	Covered Lives (%)
Specific time frames specified	83.8	79.9
Serial radiographs required	76.6	63.4
Fracture gap range specified	36.4	37.6
Clinical signs of nonunion required	16.6	5.4
Noninfected fracture site required	44.7	24.5

than 36% set a maximum limit on the size of the fracture gap.

**Comparison Between Coverage Criteria and Case Responses**

We compared medical directors' responses to the case with the information they provided us about their health plans' coverage policies for EBGs. Of those medical directors representing plans with waiting periods of 4 months or longer in their coverage policies, slightly more than 60% (52% of covered lives in this category) indicated that they would consider EBGs to be medically necessary for the patient described in the case, despite the fact that only 3 months had elapsed. In addition, of those medical directors representing plans that specify limits on fracture gap size, 90% (98% of covered lives in this category) reported that they would consider EBGs to be medically necessary, despite the fact that no fracture gap measurement was provided.

**Validation of Medical Directors' Responses**

As a rough assessment of the validity of medical directors' responses to our questions, we compared the information we obtained about coverage policies through our review of plans' Web sites with the information provided to us by medical directors of those same plans in their answers to our survey questions. The overall consistency of medical directors' responses to our questions about EBGs coverage policies (compared with posted health plan coverage policies) was 87%, with consistency rates for individual questions varying from 80% to 100%.

DISCUSSION

To our knowledge, this is the first study to collect national data about the way health plans apply coverage criteria to day-to-day decisions about technology-based interventions. Our results indicate that there is signifi-

\*As noted earlier, Medicare's coverage policy manual emphasizes the time elapsed between serial radiographs documenting failed healing, rather than total time elapsed since initial fracture. However, this implies a minimum waiting time after initial fracture, because it would not be possible for patients to obtain serial radiographs performed 90 days apart if 90 days had not yet elapsed since initial fracture.

cant variation in plans' coverage criteria, and these criteria are not always consistent with the most recent clinical effectiveness evidence. If medical directors were to adhere rigidly to planwide criteria, almost a third would compel patients with fractures to wait for extended periods before authorizing a treatment that clinical studies have shown to be effective when applied earlier.

At the same time, this variation in plans' coverage criteria does not appear to translate into variation in coverage determinations about individual patients. More than 60% of medical directors from plans with extended waiting times in their policies indicated that they would authorize EBGs in a case in which this criterion was not met. Therefore, regardless of whether criteria are consistent with available clinical effectiveness evidence, they do not appear to have a major effect on decisions about individual patients.

The closed format of the survey did not permit participants to explain why they might approve EBGs in a case in which their plans' written coverage criteria were not met. However, our findings were robust enough that it is unlikely that this discrepancy between planwide criteria and individual decision making is due to random error. Given the close juxtaposition of questions about coverage criteria and questions about the case, we believe that directors were fully cognizant of their plans' coverage criteria when answering questions about our hypothetical patient.

Previous studies have suggested that different health plan characteristics may be associated with different approaches to coverage decision making. Research on coverage of laser-based technologies, for example, indicated that staff-model HMOs were likely to cover more technologies than independent practice association-model HMOs.<sup>11</sup> A 2001 study of plans participating in Medicaid concluded that for-profit plans are more likely to use aggressive utilization review techniques and deny preauthorization than not-for-profit plans.<sup>12</sup>

Our results do not support the argument that organizational characteristics such as plan size, for-profit status, or accreditation status predict whether plans impose more restrictive coverage policies or use preauthorization more aggressively. Although we found that plans that are affiliated with a national or multistate system are more likely to have a coverage policy for EBGs, none of the characteristics that we measured were predictive of plans' responses to our case or their coverage criteria.

To the extent that we could verify them, such as by examining their consistency with written plan criteria,

medical director responses to our survey appeared accurate. There will always be uncertainty, however, about the validity of self-responses. Furthermore, the findings for EBGs do not necessarily generalize to other interventions. Interpretation of criteria might be different in the emotion-laden context of a potentially life-saving procedure for a serious illness, for example, or for an inexpensive preventive intervention.

This study is of interest in part because it represents decision making regarding a large fraction of commercially insured Americans. The survey incorporated a diverse, national cross section of plans, with representation from all geographic regions and plan sizes. By considering the complex organizational structure of managed care organizations, we were able to capture differences in the way different plan units affiliated with a single multistate organization might approach coverage decisions. A key advantage of incorporating a specific case containing detailed clinical information, despite limits on its generalizability, is that it enabled us to explore subtle differences in plans' coverage.

In this case, existing coverage policies did not uniformly promote consistency, nor did they all limit coverage criteria to evidence standards. Not only do many plans' policies contain non-evidence-based criteria, but most medical directors appear to ignore planwide policies when faced with complex patients.

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