ECRI
A NONPROFIT AGENCY

January 23, 1998

Ms. Betty S. Burrier
Health Insurance Specialist
Coverage and Analysis Group
Office of Clinical Standards and Quality
Health Care Financing Administration
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Burrier:

ECRI appreciates receiving a copy of the decision of the United States District Court for the District of Massachusetts (Civil Action No. 97-1 1726-GAO) and also a copy of selected pages from the Administrative Record (AR) from this legal action in which ECRI's technology assessment, Electrical Stimulation for the Treatment of Chronic Wounds, is referred to in the text and footnotes. The case refers to HCFA's national coverage decision not to reimburse for use of electrical stimulation (ES) for wound healing and to the successful arguments of the individual plaintiffs and the American Physical Therapy Association.

The Court Order refers, for the most part, to HCFA's interpretation and use of our technology assessment. We assume you do not require or desire comment on these issues since you are not planning an appeal. However, there are two points at which the Court Order refers to possible flaws in our assessment. These are referred to in footnotes 14 and 15 of the Court Order. We would like to discuss these below, and then offer some broader thoughts on how assessments can be used more effectively in national coverage decision making.

We begin with addressing two specific technical issues contained in the court's decision. The first of these relates to footnote 7 on page 14 of that decision, which is about a telephone conversation with ECRI initiated by HCFA staff on May 14, 1997. HCFA's telephone notes (AR at 253A) state that ECRI "confirmed that the studies they classified as ES compared with sham or minimal therapy did provide only gauze soaked saline solution for the control. Conventional therapy includes topical agents, oral meds and pressure devices. In fact, there were no comparative studies of ES vs. conventional."

Issue One

It appears that, either we were not sufficiently precise in this conversation about the distinction we were drawing between no therapy and minimal therapy, or that we failed to make certain that HCFA staff know what we meant. This problem may also exist in the technology assessment,

5200 Butler Pike
Plymouth Meeting, PA 19462-1298, U.S.A.
Telephone (610) 825-6000
Fax (610) 834-1275
E-mail ecri@hslc.org

where we use the terms "passive therapy," "concomitant standard therapy," and "minimal herapy" to all mean the same thing.

On page 11, paragraph 2, of the technology assessment we define the term "passive therapy" as per Weingarten, and note that passive therapies "enhance, but do not alter, natural wound healing processes." They include "antibacterial and antiseptic agents, debriding agents, and various dressings," and stand in contradistinction to active therapies, which "are defined as agents applied to a wound site to directly stimulate the sound healing process." Among the therapies we defined as "active" are electrical stimulation and application of growth factors.

We described what we meant by the term "minimal therapy" on page 81, line 4, of the technology assessment. Here, we parenthetically note that we are using the terms "concomitant standard" and "minimal" therapy synonymously. We then give "debridement ..., use of topical and/or cleansing agents, applications of dressings, use of pressure-relieving devices or regiments, and administration of topical or systemic antibiotics" as examples of concomitant therapy.

Section 4.3 of the technology assessment (pages 86-95) notes which studies used concomitant therapies, and the description of the studies we examined (see Section 5 of the assessment, pages 104-131) describes the therapies given to the control groups in each study. Both Section 4.3 and Section 5 note that the control groups did receive some treatment other than saline-soaked gauze. Similar information can be found in Section 7 of the assessment, pages 170 to 194.

Perhaps as a result of our imprecision in our telephone conversation with HCFA, the court decision suggests that the statement made in AR at 822 (page 195 of the assessment) is incorrect, and notes that the Kloth and Feedar article demonstrates that this statement is incorrect. In retrospect, the wording of our passage is unfortunate. It would have been better to have very explicitly stated in the conversation and in the assessment that, for the purpose of the analysis we undertook, "no therapy" and "minimal" are functionally equivalent. We were, however, at the time unaware of any confusion or lack of clarity surrounding this issue. HCFA did not ask for additional verbal or written clarification in the telephone conversation. Dr. Kloth reviewed the assessment prior to its completion, and did not mention that he found the statement to be inaccurate. (See his review, which appears in Appendix IV to the assessment).

We cannot help but note that in an assessment of this length and complexity, it is often possible to discover a single sentence or issue that can be presented better. This is especially true in the context of a legal dispute.

Issue Two

There also appears to be some confusion about the statement "there were no comparative studies of ES vs. conventional therapy." Our statement is true, which is illustrated, in large part, by the text in Sections 4.3 and 5. The point here is that if one wants to determine whether patients fare better after electrical stimulation or after conventional treatment, one's study must contain a group of patients that received *only* electrical stimulation and a group that received *only* conventional therapy. No such studies exist. Kloth and Feedar, cited by the court, compares conventional therapy plus ES with conventional therapy, but not ES alone vs. conventional therapy.

This point is also related to a comment made by one reviewer of the technology assessment, and which is discussed in footnote 8 of the court decision. Here, the reviewer suggests that "you would not volunteer to be treated by placebo for six months while your leg stinks and deteriorates." We wish to point out that at no time did ECRI suggest that patients should receive placebo treatment. To the contrary, on page 195 of the technology assessment, we explicitly stated that "The best way to determine whether ES therapy is effective is to conduct RCTs that compare ES therapy to common therapies." We reiterated this point in the assessment's general summary on page 219. Thus, we neither explicitly not implicitly stated that some patients should go untreated.

Having addressed the technical issues above, we turn now to our thoughts on how technology assessments (TAs) can be used more effectively in the national coverage decision-making process. TAs can, of course, be used to determine whether there is enough information for a national coverage decision. If HCFA feels that the evidence is too weak to support a positive coverage decision, it could provide a copy of the TA and guidance to the requesting party-in this case it would have been the American Physical Therapy Association-on the type of study or studies that need to be done to provide definitive evidence, which would lead to either a positive or negative national coverage decision. (ECRI's assessment stated what needed to be done on pp. 195 and 219 of the assessment; namely, an RCT comparing ES with conventional therapy.) We recommend that, after receipt of a TA, HCFA could meet with the requestor to discuss the results of the assessment and gaps in the research literature. They could agree on the study design or at least what the study design must prove. When complete, the study could be reviewed by the TA organization to ensure that the original intent was complied with or that study design variations were made for good reasons. At that point, the scientific basis for a national coverage decision should be clear.

In our opinion, coverage decision making in the public sector may need to be strengthened. The case of ES is symptomatic. Determining whether technology is better than the functional equivalent of doing nothing should have been taking place at the FDA level when safety and

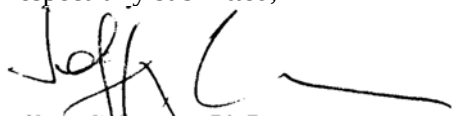
efficacy' are supposed to be examined, not at the HCFA national coverage decision-making level. HCFA coverage decision making should focus on effectiveness, in our opinion. A mechanism needs to be devised so that FDA approval and HCFA coverage decision making are working together more efficiently (we have, by the way, discussed this with FDA). If this is not done, eventually all devices or drugs approved by FDA will have to be covered by HCFA. In effect, there will be no distinction between FDA marketing approval and coverage decision making.

What should be the standard for achieving coverage? Should it be that a technology is "clinically meaningful," and if so, how is this term defined? One way is to insist on a well designed RCT to determine effectiveness. Another route, far more controversial, is through cost-effectiveness analysis. However, this is not formally acceptable under HCFA's coverage decision-making powers (the draft regulations from 1989 that were not excepted as final regulations). The issues of cost effectiveness, clinically meaningful results, and the criteria to demonstrate these qualities could be taken into account in designing the studies that would be necessary to achieve a national coverage decision. But the nature of the studies, as stated above, would have to be agreed upon between the parties requesting a national coverage decision and HCFA.

It might be useful to have a meeting over this subject between HCFA, FDA, NIH, the Blue Cross TEC, and ECRI. It is possible that HCFA's carriers should also be present.

We hope that our thoughts on the coverage decision-making process are useful to you, and that our specific response to technical issues raised in the electrical stimulation case is satisfactory. We are always ready to work constructively with you in serving the interests of the Medicare population.

Respectfully submitted,



Jeffrey C. Lerner, Ph.D.
Vice President
for Strategic Planning

JCL/kr
380267.WLE
Cc: Charles Turkelson, Ph.D., ECRI
Joel J. Nobel, M.D., ECRI

The FDA often uses the term “effectiveness” to mean “efficacy”.