Transmyocardial Revascularization for Severe Angina (#CAG-00004N)
Meeting Report

Subject: Transmyocardial revascularization for severe angina
Purpose: Meet with PLC Medical systems to discuss their FDA status and HCFA reaction to their current data
Date: 07/09/98
Place: 1:30, HCFA conference room
Participants:

HCFA: Grant Bagley, M.D., Vilis Kilpe, M.D., Mitch Burken, M.D., Tom Marciniak, M.D., Frank Emerson, Ron Milhorn, Joyce Eng,

NON-HCFA: Paul Radensky, M.D., J.D., Hurley Consulting Associates; Steven Boyce, M.D., Washington Hospital Center; Brack Hattler, M.D., Ph.D., University of Pittsburgh Medical Center; Xavier Lefebvre, Ph.D., PLC Medical Systems; Vince Puglisi, PLC Medical Systems.

Summary:

Presentation/Discussion:

PLC requested meeting in order to present data from randomized controlled clinical trials on TMR using PLC Medical Systems product, "The Heart Laser." The company claims that the data presented will indicated their product meets HCFA's standards for demonstrated medical effectiveness, appropriately furnished and is cost-effective.

Data unpublished, essentially developed 1995-96 during Phase III FDA process, which is not complete. Trial limited to patients with severe angina pain, used only as pain relief, no evidence of improved mortality, symptomatic relief only. Claims medical effectiveness for a very limited group of patients, perhaps less than 50,000.

Company claims FDA approval imminent, but check with FDA indicates unspecified questions regarding post-market surveillance remain. When asked if use would be limited to labeled indications, company replied their Investigational Device Exemption (IDE) would be "open." In response to whether this procedure should be limited to certain specialized facilities, the company stated is should be available to any "broad spectrum heart surgery facility."

Evaluation:

Data presented were not convincing enough to plan changes in current non-coverage policy. There is essentially no long-term follow up of these patients, with few being followed beyond one year and a very high percentage lost to follow up. Subgroup analyses, particularly for the Medicare-aged patients are not given, nor are the total number of cases in the Medicare age range. The extensive use of cross-overs (patients moved from the medical management to the treatment arm of the study) raises questions about the ability of this study to provide long-term analysis of the effect of this treatment.

The lack of intent to control the IDE use, either with respect to treatment or sites, raises serious questions of whether even these insufficient data would be relevant to any attempt to provide Medicare coverage.

Some of these problems may be better defined following final FDA action and acceptance of these data for journal publication. However, any further action should wait until both of those steps are complete.

Next steps/follow-up items: None. Await FDA action and journal publication of studies before re-review.

Prepared by: Ron Milhorn, CAG, OCSQ, HCFA; (410) 786-5663