

From: steven whitfield
Sent: Monday, December 10, 2007 10:00 PM
To: CMS CAGInquiries
Subject: Renal artery intervention

I agree with strict criteria for renal angioplasty and stenting for renal artery stenosis(RAS).

I hope the definition of "malignant" hypertension includes "refractory" hypertension ie patients who are difficult to control on multiple medications (usually at least 3 drugs) and patients who were previously well controlled but who now require more medication due to RAS.

The diastolic blood pressures of these patients are often less than 100 but systolic blood pressures remain elevated.

Confining the definition to diastolic blood pressure control will eliminate too many patients who primarily have systolic hypertension.

Please keep in mind that renal angioplasty (PTA) without stenting is appropriate for fibromuscular dysplasia.

Also, CMS should consider coverage for evaluation of gradients in "borderline" lesions. This is being done and is not reimbursed.

The measurement of gradients and an FFR (analogous to coronary flow wire) would prevent inappropriate stenting on borderline lesions.

Steven S Whitfield MD,FACC
Medical Directory of the Cardiac Catheterization Laboratory
Olathe Medical Center
Olathe, Kansas

From: Edward Wolf
Sent: Tuesday, December 18, 2007 6:58 PM
To: CMS CAGInquiries
Subject: Medicare proposals regarding renal artery stenting

I am in favor of continuing coverage for renal artery stenting as proposed by CMS. Although this is a vascular bed for which clear treatment guidelines are difficult to identify, I believe that there is enough potential to conserve renal function and assist in reducing blood pressure that further efforts to evolve an appropriate patient treatment paradigm are justified.

Edward A. Wolf, Jr. M.D.

December 20, 2007

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Comments on the Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) and Stenting of the Renal Arteries (CAG 00085R4)

Dear Dr. Phurrough:

Abbott appreciates the opportunity to comment on the Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) and Stenting of the Renal Arteries.

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies. The company employs 65,000 people and markets its products in more than 130 countries. Abbott is presently conducting the HERCULES clinical trial to assess the safety and performance of its Herculink® Elite™ Renal Stent System. This trial will enroll 202 subjects who have uncontrolled hypertension in the presence of *de novo* or restenotic atherosclerotic renal artery disease. The primary endpoint is the binary restenosis rate at 9 months as determined by duplex ultrasound.

Abbott supports the CMS proposal to make no change in the current national coverage decision for percutaneous transluminal angioplasty and stenting of the renal arteries. We agree that further reconsideration of national coverage for renal stenting should be based on peer-reviewed publication and evaluation of convincing new evidence from randomized controlled trials. Maintaining current coverage will permit continued access to endovascular treatment for Medicare beneficiaries with renal artery stenosis while new evidence is generated to further define the best treatment options for such patients. We support additional research to enhance clinical decision making for the treatment of renal artery stenosis.

Maintaining Beneficiary Access to Treatment

Abbott believes that maintaining current coverage will assure that Medicare beneficiaries with renal artery stenosis will continue to have access to a full range of treatment options including renal stenting. The American College of Cardiology/American Heart Association (ACC/AHA) have created practice guidelines to guide physicians treating patients with renal artery stenosis. These

practice guidelines recommend renal stenting for: 1) treatment of resistant hypertension, 2) preservation of renal function, and 3) amelioration of congestive heart failure and unstable angina. By following the AHA/ACC Guidelines, Abbott believes that physicians will be able to select the best treatment option for individual patients.

Relationship of Coverage to Clinical Research Studies

Abbott believes that additional clinical research would be helpful in further defining the best treatment options for Medicare beneficiaries with renal artery stenosis and supports ongoing and future clinical studies in this therapy area. In the proposed decision, CMS notes the discussion at the July 2007 Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting regarding the possibility of limiting coverage for non-medical treatments of renal artery stenosis to patients enrolled in qualified clinical research studies. We support the CMS proposal to not restrict coverage and beneficiary access in such a manner.

According to the clinicaltrials.gov website, there currently are only two renal stent clinical trials enrolling in the U.S. - HERCULES and CORAL. If coverage for renal stenting were limited solely to participants in clinical trials, patient access would be severely restricted as a result of the limited geographical location of trial sites, the limited number of participating sites, inclusion and exclusion criteria that disqualify potential subjects, and limited sample sizes. For example, subjects with a recent (<30 days) myocardial infarction, recent or severe congestive heart failure, or elevated serum creatinine would be excluded from both the HERCULES and the CORAL clinical trials. Additionally, enrollment in the HERCULES trial is limited to 202 subjects at a maximum of 50 U.S. sites; in CORAL, 1080 evaluable subjects will be enrolled at a maximum of 100 U.S. sites. Per the CORAL website, initial enrollment was in the first quarter of 2005 and is estimated to be complete in the first quarter of 2009. If coverage were limited to clinical trials, access to treatment could be restricted for long periods of time. Thus, we believe that restricting coverage only to clinical trials would significantly limit patient access to care.

CMS Recommendations on Clinical Trial Conduct and Informed Patient Consent

In the proposed decision memo, CMS makes recommendations regarding the content of patient informed consent forms both within and outside clinical trials for renal artery stenting. The recommendations include: 1) specific information to be provided to patients as part of the informed consent process and 2) the disclosure of information to prospective patients regarding a 2004 FDA Class I recall for a transhepatic biliary stent.

In response to the first recommendation, Abbott notes that regulations and guidelines currently exist with respect to obtaining informed patient consent. For clinical trials performed under an FDA investigational device exemption (IDE), the Code of Federal Regulations contains specific required elements for informed consent forms, including those listed in CMS's recommendation. For renal stent procedures performed outside of a clinical trial, hospitals currently have processes and guidelines in place that govern patient informed consent.

Regarding the second recommendation, Abbott does not believe that it is appropriate to include information on the May 2004 recall as part of an informed consent for renal stent clinical trials or general patient therapy. The May 2004 Class I recall cited in the proposed decision is device specific and should not be generalized to other devices. We believe that the device information that is provided in the informed consent process should be related only to the stent being implanted.

In the proposed decision memo, CMS also presents 3 recommendations for randomized controlled trials (RCTs) or other clinical research performed at any hospital facility. Recommendation 1 – a full review of the study protocol by an IRB – is already required for any study that involves human subjects. Recommendation 2 – international registration of the clinical study – is not the role of a hospital but, rather, the role of the study's Principal Investigator or the study sponsor. Generally, clinical trials are registered on clinicaltrials.gov in order to assure publication in peer-reviewed journals and the FDA Amendments Act of 2007 established new requirements for the posting of clinical trial information on clinicaltrials.gov. Recommendation 3 addresses specific study design issues. Again, it is not the role of the hospital to develop a specific study protocol and endpoint(s) – that is the role of the study protocol author, e.g. study sponsor or the Principal Investigator. The trial purpose and design dictate the type of primary endpoint that should be incorporated into a study protocol.

Abbott appreciates the opportunity to comment on the proposed coverage decision for renal artery stenting. We look forward to continuing to work with CMS to assure appropriate access to this therapy for Medicare beneficiaries.

Sincerely,



Barbara J. Calvert
Director, Medical Products Reimbursement

cc Sarah McClain, MHS
Marcel Salive, MD, MPH



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**ex officio*

Chief Executive Officer

John C. Lewin, M.D.

December 20, 2007

Steve E. Phurrough, M.D., M.P.A.
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Re: Draft NCD Memorandum on Percutaneous Transluminal Angioplasty (PTA) and Stenting of the Renal Arteries (CAG-00085R4).

Dear Dr. Phurrough:

The American College of Cardiology (ACC; the College) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' draft National Coverage Decision Memorandum on Percutaneous Transluminal Angioplasty (PTA) and Stenting of the Renal Arteries (CAG-00085R4).

The ACC is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. Our goal is to assist CMS in making appropriate coverage decisions based on scientific evidence.

The ACC commends CMS' excellent summary of the available data in the draft decision memorandum, and is especially grateful to CMS for its draft decision proposing no changes to the current NCD for PTA and stenting of the renal arteries. The College strongly supports CMS' position against taking additional policy actions on this procedure at this time, and echoes the comments submitted by SCAI in their letter on this draft Decision Memorandum.

Again, the ACC is thankful for CMS' willingness to work collaboratively with physicians and other health care providers to strengthen Medicare's coverage policies. We appreciate your attention to this letter, and remain eager to assist you and your staff as it finalizes this NCD. If you have any questions, please contact Sergio A. Santiviago, Senior Specialist, Regulatory Affairs at 202.375.6392, or by e-mail at ssantivi@acc.org.

Sincerely,

James T. Dove, M.D., F.A.C.C.
President

cc: Jack Lewin, M.D., C.E.O.