

CMS Maintains *Status Quo* for Medicare Coverage for Renal Artery Angioplasty and Stenting

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The Centers for Medicare and Medicaid Services (CMS) announced on Thursday, February 14, 2008 that it will maintain current coverage for renal artery percutaneous transluminal angioplasty (PTA) and stenting.

Boston Scientific is conducting the RENAISSANCE Trial, a prospective, multi-center trial designed to study the safety and effectiveness of the Express[®] SD Renal Stent in the treatment of renal artery disease. Boston Scientific has submitted results from the RENAISSANCE Trial to the United States Food and Drug Administration (FDA) and is currently seeking FDA approval of its Express SD Renal Stent.*


What Did CMS Decide Regarding Coverage for Renal Artery PTA and Stenting?

- CMS will make no change in the national coverage determination addressing PTA of the renal arteries, and it will continue to allow for local contractor discretion related to coverage of renal artery stenting. In other words, CMS is proposing to maintain the *status quo*.
- CMS states that it continues to support the collection of randomized, controlled trial (RCT) data, however it does not make RCT participation a condition of coverage.
- CMS also recommends that for all renal artery revascularization procedures, whether performed within or outside of RCTs or other clinical research studies, physicians should obtain informed patient consent after:

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* Caution - Investigational device. Limited by federal law to investigational use.
Not available for sale in the United States.

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- Describing all possible treatment alternatives;
 - Disclosing that in May, 2004 there was an FDA Class I recall for a transhepatic biliary stent;
 - Describing the uncertainty expressed by the July 2007 Medicare Coverage Advisory Committee (MedCAC) panelists regarding safety and clinical effectiveness of surgical and endovascular renal artery interventions for the treatment of patients with atherosclerotic renal artery stenosis, whether published results are applicable to Medicare patients, and whether there are improved health outcomes associated with surgical and endovascular co-interventions as compared to medical treatment alone; and
 - Describing CMS' coverage decision regarding renal artery revascularization and making it available to Medicare patients to be read and discussed.

Other Information for Your Consideration

- Currently, there are no stents approved by the FDA for use in the renal artery on the market in the United States.
- Medicare covers PTA of the renal arteries “for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. The PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.”¹

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¹ Centers for Medicaid and Medicare Services. Medicare NCD Manual, 20.7 B1.

- Medicare coverage of renal artery stenting is at the discretion of local Medicare contractors and coverage policies for renal stenting can vary.

For additional questions, please feel free to contact Maria Stewart in Health Economics and Reimbursement at Maria.Stewart@bsci.com .

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