

Percutaneous Renal Revascularization and Medicare Coverage

The Society of Interventional Radiology's position on the current CMS coverage of renal interventions.

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The Centers for Medicare & Medicaid Services (CMS) has recently solicited input to revise the National Coverage Decision (NCD) for treating atherosclerotic renal artery stenosis (RAS) with percutaneous revascularization (balloon angioplasty and/or stenting, [PTA/S]). Through an NCD, CMS provides a list of appropriate indications for treatment. This list is then used to determine if CMS will reimburse for a procedure. It is possible that some physicians may not realize that CMS limits reimbursement according to approved indication. Certainly, this is the case for carotid stenting, for which CMS currently will reimburse only if the procedure is performed on a symptomatic patient at high surgical risk with at least an 80% diameter stenosis. All other patients insured by CMS are not covered for reimbursement unless they are part of an approved trial. It was recently announced that the carotid stent NCD will not be expanded.

PRESENT CMS POLICY

As of April 2007, renal artery interventions are covered under the NCD for percutaneous transluminal angioplasty (Medicare NCD Manual, 20.7). The indications in that policy for renal interventions are limited to "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."

Medicare coverage of renal artery stenting is at the discretion of local Medicare contractors. To our knowledge, only one carrier—Blue Cross and Blue Shield of Arkansas—has a detailed Local Carrier Decisions specifically for renal artery angioplasty and stent placement

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(LCD L8678). Because most regions are covered by the generic NCD, the standard for reimbursement seems to have been covered by Title XVIII of the Social Security Act, section 1862(a)(1)(A), which allows coverage and payment only for services that are considered "medically reasonable and necessary."

Most commonly, the range of indications for reimbursement would include severe hypertension refractory to multiple medications, renal salvage in an azotemic patient, and "prophylaxis" in a currently asymptomatic patient with normal renal function. The Society of Interventional Radiology (SIR) is not aware of the benchmark of consideration for surgery having been used as a litmus test for reimbursement; in fact, such a prerequisite would be difficult to implement without individual filing of paper claims and chart reviews. Such a standard is also difficult to rationalize. Because surgery is known to be more invasive than angioplasty or stent placement, it is not reasonable to consider them as alternatives; the risk-benefit analysis that routinely determines medical decision making would favor angioplasty or stent placement for many more patients than the inherently risky alternative—surgery.¹ The use of renal PTA/S has grown tremendously in a short period of time.² Among interventional radiologists, the annual growth in use of renal PTA/S was 10% between 1996

Traditional indications for RAS placement are hypertension, renal failure, congestive heart failure, and complications of renal transplant. In our view, the way to make certain that RAS placement procedures are performed appropriately is to ensure that appropriate clinical and angiographic indications are present. In funding the CORAL Trial, which is a randomized trial of renal stenting compared to best medical therapy, the NIH has established reasonable criteria and technical protocols for renal artery stent placement. As a minimum, the CORAL eligibility criteria represent a standard for the appropriate performance of renal artery stent procedures. These will be addressed here.

Atherosclerotic RAS Indications for Renal Artery Stent Placement

At least one clinical indication and one angiographic indication should be present to justify a renal artery interventional procedure.

Clinical Indications:

1. Hypertension: If hypertension is the indication, patients must have "resistant" hypertension, defined in the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure⁶ as inability to achieve goal blood pressure (<140/90 mm Hg, or <130/80 mm Hg for patients with diabetes or chronic kidney disease) despite an appropriate three-drug regimen that includes a diuretic. CORAL hypertension indications for stenting are documented history of hypertension on two or more antihypertensive medications. The blood pressure reading should be based on the average of two or more properly measured, seated blood pressure readings on each of two or more office visits. There may be some patients who are intolerant of medications, and in these cases, angioplasty or stent treatment of an underlying RAS should be reimbursed. It may be helpful to have a nephrologist involved in the care of these patients to ensure that they are truly "resistant" to medical management and require renal revascularization.

2. Renal failure: As recommended in CORAL, the renal failure indication should be stage 3 or higher chronic kidney disease (CKD) (estimated glomerular filtration rate <60 mL/min per 1.73 m² calculated by the modified Modification of Diet in Renal Disease formula) and should only be reimbursed when "global" renal disease is present. This means that an angiographically significant (see below) stenosis is present in all renal arteries (bilaterally severe for people with two functional kidneys and unilaterally severe for people with only one functional kidney, including individuals with unilateral RAS and intrinsic renal disease in the kidney contralateral to the side with RAS). Unilateral RAS with a contralateral normally perfused and nondiseased kidney is not consistent with a renovascular cause of CKD and should not be accepted as an indication for revascularization.

3. Congestive heart failure (CHF): CHF can occur due to diastolic dysfunction in people with renal artery hypertension, especially when compounded by volume overload and is characterized by good community-based function (New York Heart Association Class 1 Heart Failure) with intermittent bouts of "flash" pulmonary edema requiring hospital admission. As an indication, CHF is supported only when "global" renal ischemia is present as described above.⁷

RAS placement should not be indicated as prophylaxis for renal preservation, to prevent future kidney damage or renal dysfunction, or to prevent loss of renal mass unless the above clinical indications are present.

Angiographic Indications for Renal Artery Stent Placement

At least one angiographic indicator should be present to support reimbursement for renal artery intervention. The angiographic indicators should be:

1. Stenosis $\geq 60\%$ by diameter using digital automated or digital manual caliper systems: RAS placement is indicated only for stenoses that are clinically important. RAS usually do not cause clinical symptoms until they are severe, at least 60% by diameter.⁸ For patients with duplex or MRA evidence for a hemodynamically significant RAS, coverage for intervention should be extended for angiographic finding of a lesser degree (50% to 60%) stenosis, recognizing the limitations of angiography in fully defining stenosis severity. CORAL non-invasive duplex and MRA criteria should be used.

2. Invasive pressure measurements: As an alternative to digital caliper measurements, a trans-stenotic pressure gradient should be measured and documented with a tracing in the patient record showing a systolic pressure gradient of at least 20 mm Hg. Pressures should be measured using the techniques recommended by the American Heart Association.⁵

Technical Considerations

Approximately 80% of atherosclerotic stenoses are ostial, and these respond poorly to balloon angioplasty. In this population, "primary" or "direct" RAS placement is the standard technique. Attempts at balloon angioplasty alone with provisional stenting reserved for those with suboptimal results of balloon angioplasty are not the standard of care and are not justifiable either medically or for coding and billing purposes. One randomized clinical trial showed better patient outcomes with RAS placement compared with balloon angioplasty.⁹

For nonostial atherosclerotic RAS, some interventional physicians will attempt balloon angioplasty as a definitive therapy. If angioplasty is successful and a stent is not placed, this should be a reimbursable service.

If bilateral renal artery interventional procedures are required, it is usually in the patient's best interest if they are performed at the same time. If angiographic and clinical indicators are present, we support payment for both sides treated on the same day. However, there may be valid reasons to delay treatment of the second renal artery, such as risk of contrast nephrotoxicity or length of the procedure. In these small number of cases, reimbursement for procedures on separate days is appropriate.

Coverage should not be linked to use of an FDA-approved stent device for the renal arteries. There are currently only three devices approved (Genesis and Palmaz stents, Cordis Corporation, a Johnson & Johnson company, Miami, FL; AVE Bridge stent, Medtronic, Inc., Santa Rosa, CA) but there are many suitable devices in clinical practice, and FDA approval is not feasible for many companies and not a reasonable standard.

Use of distal embolic protection devices should not be required.

Credentialing and Quality Assurance Considerations

Physicians performing renal artery stenting must meet the training criteria of the American Heart Association for unrestricted competency for peripheral interventions¹⁰ and participate in a facility Quality Assurance program in which the physician outcomes meet national quality assurance thresholds.¹¹

and 2000.² Among interventional cardiologists over the same time period, annual growth was 31%.²

Unfortunately, it is unclear if the growth in percutaneous renal interventions represents overuse or appropriate use of medical care. Surgical revascularization of

RAS is associated with a tenfold greater risk of 30-day mortality compared with stent placement³ and a much higher risk of systemic complications, such as myocardial infarction, heart failure, respiratory failure, and kidney failure.¹ But the lower risk from renal PTA/S does

TABLE 1. ELIGIBILITY CRITERIA FOR THE CORAL STUDY

Inclusion Criteria

1. Either:

- a. Documented history of hypertension on two or more antihypertensive medications OR
- b. Renal dysfunction defined as stage 3 or greater CKD based on the new National Kidney Foundation classifications (estimated glomerular filtration rate <60 mL/min per 1.73 m² calculated by the modified Modification of Diet in Renal Disease formula)

2. One or more severe renal artery stenoses by any of the following pathways:

- a. Angiographic: $\geq 60\%$ and <100% by renal angiogram

OR

- b. Duplex: systolic velocity of >300 cm/s

OR

- c. Core lab approved MRA demonstrating:

- Stenosis >90% OR
- Stenosis >75% with spin dephasing on three-dimensional phase contrast MRA

OR

- Stenosis >75% and two of the following:
 - Ischemic kidney is >1 cm smaller than contralateral kidney
 - Ischemic kidney enhances less on arterial phase
 - Ischemic kidney has delayed gadolinium excretion
 - Ischemic kidney hyperconcentrates the urine
 - Two-dimensional phase contrast flow waveform shows delayed systolic peak

Exclusion Criteria

1. Unable to provide informed consent
2. Unable or unwilling to comply with study protocol or procedures
3. Age <18
4. Fibromuscular dysplasia or other nonatherosclerotic RAS known to be present before randomization
5. Pregnancy or unknown pregnancy status in female of childbearing potential

6. Participation in any drug or device trial during the study period, unless approved by the Steering Committee

7. Previous enrollment in the CORAL study

8. History of stroke within 6 months, if associated with a residual neurologic deficit

9. Any major surgery, major trauma, revascularization procedure, unstable angina, or myocardial infarction 30 days before study entry

10. Any planned major surgery or revascularization procedure, outside of the randomly allocated renal stenting dictated by this protocol, after randomization

11. Hospitalization for heart failure within 30 days

12. Comorbid condition causing life expectancy ≤ 3 years

13. Allergic reaction to intravascular contrast, not amenable to pretreatment

14. Allergy to stainless steel

15. Allergy to all of the following: aspirin, clopidogrel, and ticlopidine

16. Known untreated aneurysm of the abdominal aorta >5 cm

17. Previous kidney transplant

18. Stenosis of >50% of a previously treated revascularized renal artery or treatment of any RAS within the past 9 months (roll-in patients can have previous treatment on the contralateral side)

19. Kidney size <7 cm supplied by target vessel

20. Hydronephrosis, nephritis, or other known cause of renal insufficiency not due to large-vessel RAS

21. Visualized stenosis of only an accessory renal artery supplying less than half of the ipsilateral renal parenchyma, without stenosis in a dominant renal artery

22. Local lab serum creatinine >3 mg/dL on the day of randomization

23. Presence of RAS not amenable for treatment with a stent, known to be present before randomization

24. Abrupt vessel closure or dissection after diagnostic angiography (Note: patients with abrupt vessel closure or dissection as a result of diagnostic angiography will not be randomized but will undergo stent revascularization, receive optimal medical therapy, and will be followed for the full study period.)

TABLE 2. CORAL STUDY ENDPOINTS

Primary Endpoint:

Event-free survival from cardiovascular and renal adverse events defined as a composite of cardiovascular or renal death, stroke, myocardial infarction, hospitalization for congestive heart failure, progressive renal insufficiency, or need for permanent renal replacement therapy.

Secondary Endpoints:

1. Rate of all-cause mortality
2. Subgroup interaction in critical subgroups:
 - Men versus women
 - African Americans versus non-African Americans

- Diabetes versus non-diabetes mellitus
- Global versus partial renal ischemia
- 3. Longitudinal renal function
- 4. Systolic blood pressure response
- 5. Durability of renal artery patency after stenting
- 6. Evaluation of renal resistive index: a measure of preservation of microvascular renal artery function
- 7. Correlation between stenosis severity and kidney function
- 8. Quality of life
- 9. Cost effectiveness

not guarantee clinical benefit, and patients can be harmed from the revascularization by contrast nephrotoxicity, arterial injury, or cholesterol embolization. There have been several randomized trials, which have evaluated the outcomes from renal PTA/S, with variable results. These trials have been criticized.⁴ Many of the recommendations for renal revascularization in a recent multispecialty guideline⁵ are based heavily on expert consensus rather than trial evidence. The Agency for Health Care Research and Quality commissioned a review (<http://effectivehealthcare.ahrq.gov/synthesize/reports/execSummary.cfm?Topic=42>) that concluded that there is no good evidence to support renal artery interventional therapy for any indication. There is currently a large-scale randomized clinical trial designed to assess the value of renal artery stent placement for atherosclerotic obstruction and hypertension or chronic kidney disease funded primarily by the National Heart, Lung, and Blood Institute of the National Institutes of Health—the Cardiovascular Outcomes with Renal Atherosclerotic Lesions (CORAL) trial (www.coralclinicaltrial.org). Until the results of well-designed randomized clinical trials, such as the CORAL trial, are available, there will remain uncertainty as to who needs and benefits from renal PTA/S. It is in this context that CMS has opened the NCD for renal revascularization. The comments in the sidebar indicate the opinion of SIR on this issue and have been submitted to CMS for review.

CLOSING COMMENTS

Some readers may be surprised that SIR is not advocating unrestricted reimbursement for renal PTA/S. The mission of SIR is improving public health through disease management and minimally invasive, image-guided

therapeutic interventions. We take this mission seriously. We do not improve public health by providing medical care that does not make people better. In the situation where we do not know, we support and help create trials to determine what is the best care. We do not always have Class 1 evidence (large, randomized, controlled trials) to rely upon, in which case we make our recommendations as listed based on the best available evidence, weighing the risk of immediate harm from intervention versus the potential benefit from revascularization. At the same time, we are creating trials to produce Class 1 evidence.

One of the authors of this article, Dr. Tim Murphy, is a principal investigator in the CORAL trial, which is a multicenter, NIH-funded trial of renal stents plus best medical therapy versus medical therapy alone to treat hypertension due to RAS. Eligibility requirements are listed in Table 1. Study endpoints are listed in Table 2. At this time, 183 patients have been randomized, with a goal of enrolling a total of 1,080 patients. The expected date of completion of the study is 2011. However, changes in reimbursement that make it easier or harder to be reimbursed for renal PTA/S for routine clinical care may affect the ability to enroll patients.

The future of medicine will be more data driven both for clinical care and reimbursement. The revision of the renal NCD by CMS is part of a process that is likely to be repeated for many high-volume and high-growth procedures that lack Class 1 evidence for all indications. We believe that interventionists are better off being part of the process, offering our expertise in a credible and constructive way, and helping to create and perform the research that will provide the necessary evidence to justify the effectiveness and cost effectiveness of our care. ■

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1. Weibull H, Bergqvist D, Bergentz SE, et al. Percutaneous transluminal renal angioplasty versus surgical reconstruction of atherosclerotic renal artery stenosis: a prospective randomized study. *J Vasc Surg.* 1993;18:841-850; discussion 850-852.
2. Murphy TP, Soares G, Kim M. Increase in utilization of percutaneous renal artery interventions by medicare beneficiaries, 1996-2000. *AJR Am J Roentgenol.* 2004;183:561-568.
3. Lawrie GM, Morris GC Jr, Glaeser DH, et al. Renovascular reconstruction: factors affecting long-term prognosis in 919 patients followed up to 31 years. *Am J Cardiol.* 1989;63:1085-1092.
4. Sacks D, Rundback JH, Martin LG. Renal angioplasty/stent placement and hypertension in the year 2000. *J Vasc Interv Radiol.* 2000;11:949-953.
5. Hirsch AT, Haskal ZJ, Hertzner NR, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease); endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *Circulation.* 2006;113:e463-654.
6. Chobanian AV, Bakris GL, Black HR, et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension.* 2003;42:1206-1252.
7. Bloch MJ, Trost DW, Pickering TG, et al. Prevention of recurrent pulmonary edema in patients with bilateral renovascular disease through renal artery stent placement. *Am J Hypertens.* 1999;12:1-7.
8. Schoenberg SO, Bock M, Kallinowski F, et al. Correlation of hemodynamic impact and morphologic degree of renal artery stenosis in a canine model. *J Am Soc Nephrol.* 2000;11:2190-2198.
9. van de Ven PJ, Kaatee R, Beutler JJ, et al. Arterial stenting and balloon angioplasty in ostial atherosclerotic renovascular disease: a randomised trial. *Lancet.* 1999;353:282-286.
10. Creager MA, Goldstone J, Hirshfeld JW Jr, et al. ACC/ACP/SCAI/SVMB/SVS clinical competence statement on vascular medicine and catheter-based peripheral vascular interventions: a report of the American College of Cardiology/American Heart Association/American College of Physician Task Force on Clinical Competence (ACC/ACP/SCAI/SVMB/SVS Writing Committee to develop a clinical competence statement on peripheral vascular disease). *J Am Coll Cardiol.* 2004;44:941-957.
11. Rundback JH, Gray RJ, Rozenblit G, et al. Renal artery stent placement for the management of ischemic nephropathy. *J Vasc Interv Radiol.* 1998;9:413-420.