PriorityHealth

MEDICAL POLICY
No. 91561-R1

RENAL ARTERY STENOSIS

Effective Date: December 25, 2014	**Review Dates: 12/08, 12/09, 12/10, 12/11, 12/12, 12/13, 11/14, 11/15, 11/16, 11/17, 11/18**
Date Of Origin: December 10, 2008	**Status: Current**

I. POLICY/CRITERIA

A. Medical management is the preferred treatment for Atherosclerotic Renal Artery Stenosis (ARAS). Priority Health will cover, however, angioplasty with or without stenting for ARAS for either of the following conditions:

1. Contraindications (e.g. intolerance to medical regimen, clinically proven medication allergy) to an aggressive regimen of medications (antihypertensive combinations +/- statins +/- antiplatelets) for either refractory hypertension or worsening renal function.

2. For members with unusual presentations of ARAS, e.g., malignant hypertension, rapidly worsening disease (moderate to severe hypertension in patients with recurrent episodes of flash pulmonary edema)

B. Angioplasty, without stenting, is a covered benefit for:

1. Fibromuscular dysplasia

C. Angioplasty with or without stenting is **not** a covered benefit for the following:

1. Renal transplant recipients except with medical director review.

2. Previous failed revascularization.

3. Refractory hypertension, as defined by hypertension not responding (or worsening) to an aggressive regimen of medications (antihypertensive combinations +/- statins +/- antiplatelets), over a period of 6 months or more.

4. Chronic kidney disease, or

5. Worsening renal function, as defined by increasing serum creatinine not responding (or worsening) to an aggressive regimen of medications

II. MEDICAL NECESSITY REVIEW

☐ Required ☒ Not Required ☐ Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN/MICHILD:** ***For Medicaid/Healthy Michigan Plan/MIChild members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

Renal artery stenosis (RAS) is defined as the narrowing of the lumen of the renal artery. Atherosclerosis accounts for 90 percent of cases of RAS. Atherosclerotic renal artery stenosis (ARAS) is a progressive disease that may occur alone or in combination with hypertension and ischemic kidney disease. The prevalence of ARAS ranges from 30 percent among patients with coronary artery disease to 50 percent among elderly or those with diffuse atherosclerotic vascular diseases. In the United States 12 to 14 percent of new patients entering dialysis programs have been found to have ARAS, although the contribution of ARAS to end stage renal disease is unclear.

Most authorities consider the goals of therapy to be improvement in uncontrolled hypertension, preservation or salvage of kidney function, and improvement in symptoms and quality of life. Treatment alternatives include medications alone or

revascularization of the stenosed renal artery or arteries. Combination therapy with multiple antihypertensive agents, usually including angiotensin converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs), calcium channel blockers, and or beta blockers, are frequently prescribed with a goal of normalizing blood pressure. Some clinicians also recommend statins to lower low-density lipoprotein (LDL) cholesterol and antiplatelet agents, such as aspirin or clopidogrel, to reduce thrombosis.

The current standard for revascularization in most patients is percutaneous transluminal angioplasty with stent placement across the stenosis. Angioplasty without stent placement is less commonly employed. Revascularization by surgical reconstruction is generally used only for patients with complicated renal artery anatomy or for patients who require pararenal aortic reconstructions for aortic aneurysms or severe aortoiliac occlusive disease.

A 2007 AHRQ Update on the Comparative Effectiveness of Management Strategies for Renal Artery Stenosis summarized the evidence of two types of management – medical management vs. angioplasty with stenting – as follows:

- Overall, the evidence does not currently support one treatment approach over the other for the general population of people with ARAS.
- The evidence on this topic is generally inconclusive due to small numbers of RCTs with few patients comparing angioplasty to medical therapy, questions of relevance of trials to current practice due to lack of stent placement and relative lack of ACE inhibitor use, and poor quality and limited applicability of many of the remaining, primarily cohort, studies. No trials comparing interventions commonly in use have been published.
- Weak evidence suggests no difference in mortality rates with medical treatment alone or with angioplasty.
- There is acceptable evidence that overall there is no difference in kidney outcomes between patients treated medically only or those receiving angioplasty without stent; though the relevance of this finding to current practice is questionable due to changes in treatment options. However, improvements in kidney function were only reported among patients receiving angioplasty.
- There is acceptable evidence that combination antihypertensive treatment results in large decreases in blood pressure. The evidence regarding the relative effect of angioplasty and medication on blood pressure control is inconsistent. The RCTs did not find a consistent effect; other comparative studies mostly found no difference; cohorts of medical treatment generally found larger decreases in blood pressure than cohorts of angioplasty with stent. However, cohort studies of angioplasty with stent did report that up to 18 percent of patients had cure of hypertension.
- There is weak evidence suggesting similar rates of cardiovascular events between interventions; however, it is likely that the studies were too small to detect different rates of cardiovascular events.

- Weak evidence suggests no difference in quality of life with medical treatment alone or with angioplasty.
- The evidence does not adequately assess the relative harms due to adverse events and complications of medical treatment and angioplasty.
- There is weak evidence that patients with bilateral RAS may have more favorable outcomes with angioplasty than with medical therapy compared to patients with unilateral disease.
- Weak or inconsistent evidence does not support whether any other clinical features or diagnostic tests predict outcomes after angioplasty or with medical therapy.
- There is no evidence regarding the value of interventions done at the time of angioplasty.

Of note, the 2007 AHRQ Update reviewed 60 studies from an earlier report and 8 new studies; the studies included those that looked at two or more interventions for ARAS as well as prospective cohort (single arm) studies of angioplasty with stent placement, prospective cohort studies of medical interventions, cohort studies of RAS natural history, and prospective or large retrospective studies of surgical bypass. The Update did not address the management of fibromuscular dysplasia, renal transplant recipients, or patients who have a previous failed revascularization.

While the Update included studies on angioplasty without stenting, the authors recognized that practices have evolved so that angioplasty with stenting is more commonly employed. This policy, however, will consider ARAS angioplasty with and without stenting.

The Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL) trial, a large, multi-center trial published 43 month follow-up data in 947 patients who had atherosclerotic renal-artery stenosis and either systolic hypertension while taking two or more antihypertensive drugs or chronic kidney disease to medical therapy plus renal-artery stenting or medical therapy alone. Renal-artery stenting did not confer a significant benefit with respect to the prevention of clinical events when added to comprehensive, multifactorial medical therapy in people with atherosclerotic renal-artery stenosis and hypertension or chronic kidney disease. (Cooper, C. et.al. 2014)

V. CODING INFORMATION

ICD-10 Codes that may support medical:

I12.0 – I12.9	Hypertensive chronic kidney disease
I13.0 – I13.2	Hypertensive heart and chronic kidney disease
I15.0 – I15.9	Secondary hypertension
I70.1	Atherosclerosis of renal artery

I77.3	Arterial fibromuscular dysplasia
I77.89	Other specified disorders of arteries and arterioles
N28.0	Ischemia and infarction of kidney

CPT/HCPCS Codes:

37236	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery
37237	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (List separately in addition to code for primary procedure)
37246	Transluminal balloon angioplasty (except lower extremity artery (ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery
37247	Transluminal balloon angioplasty (except lower extremity artery (ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; each additional artery (List separately in addition to code for primary procedure)
0234T	Transluminal peripheral atherectomy, including radiological supervision and interpretation; renal artery

VI. REFERENCES

1. Aetna Clinical Policy Bulletin. Peripheral Artery Stents. http://www.aetna.com/cpb/medical/data/700_799/0785.html (Retrieved October 23, 2012 , October 30, 2013, October 8, 2014, October 6, 2017, October 5, 2018).
2. Agency for Healthcare Research and Quality Review No. 5. (Prepared by Tufts-New England Medical Center Evidence-based Practice Center under Contract No. 290-02-0022). Dec 2006. Rockville, MD: Available at www.effectivehealthcare.ahrq.gov/reports/final.cfm.
3. Balk, E., Raman, G., Chung, M., Ip, S., Tatsioni, A., Alonso, A., Kupelnick, B., Chew, P., DeVine, D., Gilbert, S., and Lau, J. Comparative Effectiveness of Management Strategies for Renal Artery Stenosis. Comparative Effectiveness
4. Balk E, Raman G, Chung M et al. Effectiveness of management strategies for renal artery stenosis: a systematic review. Ann Intern Med. 2006; 145:901-912.

5. Bax L, Wolttlez AJ, Kouwenberg HJ, et al. Stent placement in patients with atherosclerotic renal artery stenosis and impaired renal function: a randomized trial. Ann Intern Med. 2009; 150(12):840-848.
6. Cooper CJ, Murphy TP, Matsumoto A et al. Stent revascularization for the prevention of cardiovascular and renal events among patients with renal artery stenosis and systolic hypertension: rationale and design of the CORAL trial. Am Heart J. 2006; 152:59-66.
7. Cooper C.J., Murphy T. P. et. al. Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis The CORAL Trial , N Engl J Med 2014; 370:13-22
8. Curry TK, Messina LM. Fibromuscular dysplasia: when is intervention warranted? *Semin Vasc Surg*. 2003 Sep; 16(3):190-9.
9. Davies MG, Saad WE, Peden EK, Mohiuddin IT, Naoum JJ, Lumsden AB. The long-term outcomes of percutaneous therapy for renal artery fibromuscular dysplasia. *J Vasc Surg*. 2008 Oct; 48(4):865-71. Epub 2008 Aug 09.
10. Harding MB, Smith LR, Himmelstein SI et al. Renal artery stenosis: prevalence and associated risk factors in patients undergoing routine cardiac catheterization. J Am Soc Nephrol. 1992; 2:1608-1616.
11. Hayes, Inc. Endovascular Stents for the Treatment of Atherosclerotic Renal Artery Stenosis. 2009 and annual updates.
12. Hirsch AT, Haskal ZJ, Hertzer NR et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic). Circulation. 2006; 113:e463-e654.
13. Hirsch AT, Haskal ZJ, Hertzer NR et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic). J Am Coll Cardiol. 2006; 47:1239-1312.
14. Humana Medical Coverage Policy. Peripheral Artery Stenting http://apps.humana.com/tad/tad_new/Search.aspx?searchtype=beginswith&docbegin=P (Retrieved September 2012 & October 30, 2013)
15. Missouris CG, Buckenham T, Cappuccio FP, MacGregor GA. Renal artery stenosis: a common and important problem in patients with peripheral vascular disease. Am J Med. 1994; 96:10-14?
16. National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7) @ http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=201&ncdver=10&DocID=20.7&list_type=ncd&bc=gAAAAAgAAAAAAA%3d%3d& (Retrieved October 8, 2014 & October 6, 2017)
17. Olin JW, Pierce M. Contemporary management of fibromuscular dysplasia *Curr Opin Cardiol*. 2008 Nov; 23(6):527-36.
18. Olin JW. Recognizing and managing fibromuscular dysplasia. *Cleve Clin J Med*. 2007 Apr; 74(4):273-4, 277-82.
19. Safian RD, Textor SC. Renal-artery stenosis. N Engl J Med. 2001; 344:431-442.

United States Renal Data System (USRDS) 1997 Annual Data Report. Bethesda, Maryland, US Department of Health and Human Services/National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases. 1997.
