



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Radiofrequency Ablation (RFA) of Renal Masses

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Hyperlink to Related Coverage Policies

Cryoablation of Renal Tumors
Stem-Cell Transplant for Renal Cell Carcinoma

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Coverage Policy

CIGNA covers radiofrequency ablation (RFA) therapy as medically necessary for the treatment of renal masses for individuals with renal cell carcinoma who are not appropriate candidates for surgical intervention.

General Background

The majority of newly discovered solid renal masses are malignant renal cell carcinomas (RCCs). Radical or partial nephrectomy via an open or laparoscopic approach is the standard treatment for renal masses. Tumor size and location, as well as patient age and comorbidities influence the type of surgery performed (Bhayani, et al., 2003; Gattinoni, et al., 2003).

Radiofrequency ablation (RFA) is an accepted minimally invasive treatment option for a renal mass in individuals who are not surgical candidates (e.g., due to age or comorbid conditions). RFA, which can be performed laparoscopically or percutaneously, involves the passage of high-frequency electrical current into the renal mass. Guided by images from intraoperative computed tomography (CT) or ultrasound, the surgeon inserts a small electrode into the tumor. Applying a high-frequency electrical current generates heat within the renal mass and ablates tissue around the electrode. RFA of a renal mass may require multiple cycles of current application with the electrode placed at different sites within the mass. For renal tumors larger than three centimeters, re-treatment may be required on subsequent days with multiple cycles of renal tissue ablation on

each day of treatment. In the months following RFA, patients undergo periodic evaluations by CT or magnetic resonance imaging to monitor for regrowth of the ablated mass (Gervais, et al., 2003; Roy-Choudhury, et al., 2003; Hwang, et al., 2004; Johnson and Cadeddu, 2004).

U.S. Food and Drug Administration (FDA)

Ablation systems are approved by the FDA under the 510(k) process as a Class II electrosurgical cutting and coagulation accessory device. The devices are approved for use as a “percutaneous, laparoscopic, intraoperative coagulation and ablation tissue, such as partial or complete ablation of non-resectable liver lesions and osteoma tumors”. Examples of these devices include the Cool-tip™ RF Ablation System (Valleylab, Boulder, CO) and the Rita® System (Rita Medical Systems, Inc., Mountain View, CA) (FDA, 2006).

Literature Review

Meta-analyses (Hui, et al., 2008; Kunkle and Uzzo, 2008), systematic reviews (Kutikov, et al., 2008), case series (Arima, et al., 2007; Breen, et al., 2007; Arzola, et al., 2006; Memarsadeghi, et al., 2006; Park, et al., 2006; Hwang, et al., 2004; Lewin, et al., 2004; Gervais, et al., 2003; Jacomides, et al., 2003; Roy-Choudhury, et al., 2003; Su, et al., 2003; Ogan, et al., 2002; Rendon, et al., 2002) and retrospective reviews (Zagoria, et al., 2007; Salagierski, et al., 2006; Gervais, et al., 2005; Matsumoto, et al., 2005; Varkarakis et al., 2005; Farrell, et al., 2003; Mayo-Smith, 2003) support the safety and efficacy of RFA as a minimally invasive treatment option for patients with renal masses who are poor surgical candidates.

Other studies have compared RFA to cryoablation and/or to radical and/or partial nephrectomy. In a systematic review of renal tumor ablation including RFA and cryotherapy, Hui et al. (2008) stated that there are “no comparative data to suggest that cryoablation is more effective than RF ablation in the treatment of RCC”. In a retrospective review, Hegarty et al. (2006) reported a three-year median follow-up cancer-specific survival rate following cryoablation of 98% compared to a median one-year follow-up of 100% following RFA. In a retrospective comparative review, Lucas et al. (2008) reported on renal function following radical nephrectomy (RN) (n=71), partial nephrectomy (PN) (n=85), and RFA (n=86) in patients with renal masses less than four centimeters in size (stage T1a). Following treatment, new onset of chronic kidney disease and a decrease in glomerular filtration rate were significantly more prevalent in the RN group compared to the PN or RFA group (p<0.001 for each). In a retrospective review, Stern, et al. (2007) reported that there was not a statistically significant difference (p=0.674) in the three-year recurrence-free rate following treatment of renal masses with RFA (n=40) (93.4%) compared to partial nephrectomy (n=37) (95.8%).

In an interventional guidance on RFA for renal cancer, the National Institute for Clinical Excellence (United Kingdom) (2004) states that RFA may be used in patients who have small renal tumors and are unsuitable for surgery. Even though the evidence is limited, RFA is adequately safe and reduces tumor bulk.

Professional Societies/Organizations

The American Urological Association (2009) guideline for the management of stage I renal mass states that although standard technique is lacking and follow-up criteria are not well defined, RFA is an alternative therapy to partial nephrectomy in individuals with a localized renal mass, especially those individuals who represent a high surgical risk. They do note however, that compared to surgical excision recurrence is more likely to occur following RFA. Measures of success following RFA are not well defined, and surgical salvage is difficult following recurrence after treatment with RFA.

In their practice guidelines for kidney cancer, the National Comprehensive Cancer Network (2009) recommends that patients with stage I–III tumors undergo surgical excision. They state that “though a rigorous comparison with surgical resection (i.e. total or partial nephrectomy by open or laparoscopic techniques) has not been done”, RFA is “currently considered an option by some experts for selected small tumors”. RFA can be considered for patients who are not surgical candidates (e.g., elderly or infirm patients).

The European Association of Urology (2009) (EAU) guidelines on the diagnosis and management of renal cell carcinoma list RFA as an alternative treatment for surgery. Possible advantages of RFA include: “reduced morbidity, outpatient therapy, and the ability to treat high-risk surgical candidates”. The indications for RFA include “small, incidentally found, renal cortical lesions in elderly patients, patients with genetic predisposition to multiple tumors, or patients with a solitary kidney, or bilateral tumors”. The EAU also notes that the efficacy of RFA should be further evaluated in clinical trials.

The Society of Interventional Radiologists (SIR) (Clark, et al., 2006) published reporting standards for the use of percutaneous ablation (e.g., RFA) for the treatment of renal cell carcinoma (RCC). The guidelines state that nephron-sparing technology (i.e., partial nephrectomy, wedge resection and thermal ablation) is becoming more popular due to the increased incidence of RCC. Cryoablation and RFA are “currently the most widely used techniques for in situ RCC destruction”. Candidates for RFA include patients who are poor surgical candidates due to poor renal function (e.g., RCC detected in an anatomical or functional solitary kidney when resection would result in the need for dialysis) and/or comorbid disease, and “patients at high risk for the development of additional RCC in the future in whom the least invasive nephron-sparing approach is desirable” (e.g., patients with hereditary diseases; patients with synchronous RCC). SIR recommends that “tumor size, proximity to the collecting system, and proximity to adjacent viscera” be taken into consideration when selecting thermal ablation candidates.

Summary

Evidence in the published peer-reviewed literature and professional societies supports the use of radiofrequency ablation (RFA) for the treatment of renal masses in individuals with renal cell carcinoma who are poor surgical candidates.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT ^{®*} Codes	Description
50542	Laparoscopy, surgical; ablation of renal mass lesion(s)
50592	Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
189.0	Malignant neoplasm of kidney, except pelvis
198.0	Secondary malignant neoplasm of kidney
233.9	Carcinoma in situ; other and unspecified urinary organs

*Current Procedural Terminology (CPT[®]) © 2008 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	11/1/2007	0216	Radiofrequency Ablation (RFA) of Renal Masses

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