OVERVIEW
This policy has been written to document the use of cryosurgical ablation or radiofrequency ablation in the treatment of localized renal cell carcinoma (RCC). Radiofrequency ablation is a percutaneously performed procedure that utilizes a small needle electrode which is placed directly into a tumor. Cryosurgical ablation (hereafter, cryosurgery) involves the use of extreme cold to destroy abnormal tissue. Cryosurgical ablation or radiofrequency ablation of RCC is reported to be beneficial for patients who are not candidates for surgery due to co-morbidities; patients who have only one kidney, or if nephrectomy would lead to dialysis dependency; patients with small tumors; and patients who are at risk for complications following kidney removal if the risk would not be present by other methods.

PRIOR AUTHORIZATION
Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products

POLICY STATEMENT
Cryosurgery or radiofrequency ablation of tumors located in the kidney, are covered for patients who meet the medical criteria listed below; all other indications are considered not medically necessary due to lack of peer-reviewed literature which support improved health outcomes.

MEDICAL CRITERIA
Cryosurgery or radiofrequency ablation of tumors located in the kidney is considered medically necessary when one of the following criteria is met:

- In order to preserve kidney function in patients with significantly impaired renal function (i.e., the patient has one kidney)
- Has renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min per m2 and the standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen existing kidney function;
- The patient is not considered a surgical candidate.

BACKGROUND
Traditional methods of treating localized renal cell carcinoma (RCC) include radical nephrectomy or nephron-sparing surgery. Cryosurgical ablation or radiofrequency ablation of RCC is reported to be beneficial for patients who are not candidates for surgery due to co-morbidities; patients who have only one kidney, or if nephrectomy would lead to dialysis dependency; patients with small tumors; and patients who are at risk for complications following kidney removal if the risk would not be present by other methods.

Radiofrequency ablation (RFA) is being evaluated to treat various tumors, including inoperable tumors, or to treat patients ineligible for surgery due to age, presence of comorbidities, or poor general health. Goals of RFA may include 1) controlling local tumor growth and preventing recurrence; 2) palliating symptoms; and 3) extending survival duration for patients with certain tumors. The effective volume of RFA depends on the frequency and duration of applied current, local tissue characteristics, and probe configuration (e.g., single vs.
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Potential complications associated with RFA include those caused by heat damage to normal tissue adjacent to the tumor (e.g., intestinal damage during RFA of kidney), structural damage along the probe track (e.g., pneumothorax as a consequence of procedures on the lung), or secondary tumors if cells seed during probe removal.

RFA was initially developed to treat inoperable tumors of the liver (see policy No. 7.01.91). Recently, reports have been published on use of RFA to treat renal cell carcinomas, breast tumors, pulmonary cancers (including primary and metastatic lung tumors), bone, and other tumors. For some of these, RFA is being investigated as an alternative to surgery for operable tumors. Well-established local or systemic treatment alternatives are available for each of these malignancies. The hypothesized advantages of RFA for these cancers include improved local control and those common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Renal cell carcinoma (RCC). Radical nephrectomy remains the principal treatment of RCC, however, partial nephrectomy or nephron-sparing surgery has been shown to be as effective as radical nephrectomy, with comparable long-term recurrence-free survival rates, in a select group of patients. (8, 9) Alternative therapy such as RFA is of interest in patients with small renal tumors when preservation of renal function is necessary (e.g., in patients with marginal renal function, a solitary kidney, bilateral tumors) and in patients with comorbidities that would render them unfit for surgery. Another consideration would be in patients at high risk of developing additional renal cancers (as in von Hippel-Lindau disease). (8)

Based on the scientific data (large numbers of patients treated with follow-up) and the clinical input (see below) received, radiofrequency ablation of small (i.e., 4 cm or less) renal cancers may be considered medically necessary in those patients who are not surgical candidates due to comorbid conditions or who have baseline renal insufficiency such that standard surgical procedures would impair their kidney function.

Cryosurgical ablation (hereafter referred to as cryosurgery or cryoablation) involves freezing of target tissues, most often by inserting into the tumor a probe through which coolant is circulated. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

The hypothesized advantages of cryosurgery include improved local control and benefits common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization). Potential complications of cryosurgery include those caused by hypothermic damage to normal tissue adjacent to the tumor, structural damage along the probe track, and secondary tumors, if cancerous cells are seeded during probe removal.

Cryosurgical treatment of various tumors including renal cell carcinomas, malignant and benign breast disease, pancreatic cancer, and lung cancer has been reported in the literature.
The available evidence supports a role for cryoablation for patients with small renal tumors less than 4 cm in size. Since longer-term cancer-specific outcomes are unknown, cryoablation of renal tumors should be limited to patients considered to be poor candidates for the standard surgical approach.

**COVERAGE**
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for the applicable surgery services benefits/coverage.

**CODING**
BlueCHIP for Medicare and Commercial
The following CPT Codes are medically necessary when medical criteria is met:

50250:
50542:
50592:
50593:

**RELATED POLICIES**
None

**PUBLISHED**
Provider Update  May 2014
Provider Update  May 2012
Provider Update  May 2011
Provider Update  May 2010
Provider Update  Sept 2009
Provider Update  Sept 2008
Policy Update  Dec  2007
Policy Update  Oct  2004

**REFERENCES**

Cryoablation of Renal Tumors in Patients with Solitary Kidneys. W.B. Shingleton and P.E. Sewell, Jr.


http://online.liebertpub.com/doi/abs/10.1089/089277902761402961


http://www.uabmedicine.org/conditions-and-services/ablation-kidney-tumors


Nguyen CT, Lane BR, Kaouk JH et al. Surgical salvage of renal cell carcinoma recurrence after thermal ablative therapy. J Urol 2008; 180(1):104-9; discussion 09
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