



CIGNA MEDICAL COVERAGE POLICY

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Subject Cryoablation of Renal Tumors

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Hyperlink to Related Coverage Policies

- Genetic Testing for von Hippel-Lindau Disease
- Radiofrequency Ablation (RFA) of Renal Masses
- Stem-Cell Transplantation for Renal Cell Carcinoma

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Coverage Policy

CIGNA covers cryoablation as medically necessary as a treatment option for renal tumors in an individual with renal cell carcinoma (RCC) who is not an appropriate candidate for surgical intervention.

General Background

Renal cell carcinoma (RCC), also referred to as kidney cancer or renal adenocarcinoma, is a disease in which cancer cells are found in the lining of tubules in the kidney. Approximately 90% of renal tumors are RCCs. Risk factors for RCC development include smoking and obesity. Several hereditary types of RCC also exist, the most common form being von Hippel-Lindau (VHL) disease. The most important determining factors for five-year survival are the tumor grade, local extent of the tumor, presence of regional nodal metastases, and evidence of metastatic disease at presentation. RCC primarily metastasizes to the lung, bone, brain, liver, and adrenal gland (National Comprehensive Cancer Network Guidelines™ [NCCN Guidelines™], 2011).

Symptoms of RCC may include: blood in the urine, loss of appetite, pain in the side that doesn't subside, weight loss, and anemia. Tests used in the detection of RCC may include: urinalysis, blood tests, liver function tests, computed axial tomography (CAT) scan, MRI and biopsy (National Cancer Institute [NCI], 2008). Standard treatment available for patients with RCC includes surgery, chemotherapy, external or internal radiation therapy, and immunotherapy. Surgical excision in the form of a simple or radical nephrectomy is the accepted, often curative, treatment for stages I, II and III of RCC. The estimated five-year survival rate is 96% for patients presenting with stage I disease, 82% for stage II disease, 64% for those with stage III disease (NCCN, 2011).

The prognosis of stage IV RCC is poor, and treatment generally consists of palliative methods, such as tumor embolization or external beam irradiation. Chemotherapy or radiation therapy may also be given as adjuvant therapy after surgery. There has been a concomitant development of minimally invasive, nephron-sparing surgical procedures (Johnson, Cadeddu, 2004), such as radiofrequency ablation (RFA) and cryoablation. This is particularly useful for patients who are not surgical candidates due to age or comorbid conditions.

Cryoablation

Cryoablation, also referred to as cryosurgery, has been evaluated in the treatment of RCC as a minimally invasive, nephron-sparing alternative to open or laparoscopic partial nephrectomy. Cryoablation is a method of in situ tumor ablation performed by inserting a probe into the tumor; the probe then delivers a coolant (cryogen) at subfreezing temperatures. Cell death is caused by direct freezing, cell dehydration and ischemic hypoxia. Cryoablation may be performed as an open surgical technique or as a closed procedure, under either laparoscopic or percutaneous approach, using ultrasound (US) or MRI to monitor probe placement. The maximum recommended lesion size for cryoablation of RCC is 4.0 cm (i.e., small stage I tumors). In general, cryoablation is indicated for small unresectable tumors in patients with a solitary kidney, those with compromised renal function, or patients who are poor surgical candidates (NCCN, 2011; National Institute for Health and Clinical Excellence [NICE], 2007). Follow-up with either MRI or computed tomography (CT) scan is necessary to monitor outcomes of cryosurgery (Gill, 2000). Potential complications of cryoablation include hypothermic damage to normal tissue adjacent to the tumor, laceration of the liver, structural damage along the probe track, and the development of secondary tumors if cancerous cells are seeded during probe removal.

U.S. Food and Drug Administration (FDA)

Examples of cryosurgical devices approved by the U.S. FDA under the 510(k) approval process include the SeedNet™ Family (Galil Medical Ltd., Shaar Yokneam, Israel), the CryoHit® (Galil Medical Ltd., Tel Aviv, Israel), and the CRYOcare™ Surgical System, Model Cryo 20 device (Endocare, Inc., Irvine, CA). These devices are indicated for use in open, minimally invasive, or endoscopic surgical procedures in the areas of: general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary, and thoracic surgery (U.S. FDA, 2005; U.S. FDA, 2002; U.S. FDA, 1999).

Literature Review

Kunkle and Uzzo (2008) performed a metaanalysis of 47 case series evaluating cryoablation and RFA as primary treatment for small renal masses (n=1375). The rates of local tumor progression were significantly higher for RFA compared to cryoablation (12.9% versus 5.2%; $p < 0.0001$). Repeat ablation was performed more often after RFA ($p < 0.0001$), Metastasis was reported less frequently for cryoablation (1.0%) than RFA (2.5%), but this difference did not reach statistical significance (Kunkle and Uzzo, 2008).

A number of case series and comparative studies with patient populations ranging from 32–85 have examined and support the safety and effectiveness of cryosurgery for the treatment of renal cancer (Bandi, et al., 2007; Weld, et al., 2007; O'Malley, et al., 2007; Schwartz, et al., 2006; Lawatsch, et al., 2006; Davol, et al., 2006; Hegarty, et al., 2006; Matin, et al., 2006; Gill, et al., 2005; Cestari, et al., 2004; Johnson and Cadeddu, 2004; Rukstalis, et al., 2001). In general, patients included in the studies were those with renal masses under 4 cm in diameter, located on the periphery of the kidney. Average local recurrence-free and total recurrence-free survival rates of 90.6% and 87.6% respectively at a median follow-up of 18 months have been reported. Cancer-specific survival rates at five and 10 years have been reported to be 93% and 81% respectively (Berger, et al., 2009). In comparison, patients who undergo partial nephrectomy demonstrate five- and 10-year cancer-specific survival rates of 92% and 80%, respectively, across all tumor stages and 96% and 90%, respectively, for tumors < 4 cm (Kunkle and Uzzo, 2008). A major complication rate of 5% has been documented in the literature, which is lower than the overall complication rate of laparoscopic partial nephrectomy (Levy, et al., 2010).

Professional Societies/Organizations

The NCCN practice guidelines for kidney cancer state that “patients in satisfactory medical condition should undergo surgical excision of stage I through III tumors. However, a small set of elderly or infirm patients with small tumors may be offered surveillance alone or energy ablative techniques, such as RFA or cryoablation” (NCCN, 2011).

According to the American Urological Association (AUA), renal cryoablation may be a treatment option for the patients at high surgical risk who are not candidates for observation or for those who want proactive treatment, and accept the need for repeat biopsy after treatment and ongoing radiographic surveillance. The AUA also

states that “active surveillance is a reasonable option for the management of localized renal masses that should be discussed with all patients and should be a primary consideration for patients with decreased life expectancy or extensive comorbidities that would make them high risk for intervention” (AUA, 2009) .

The European Association of Urology recommends non-surgical alternative techniques such as cryoablation for patients with smaller peripheral tumors who are not suitable for open or laparoscopic surgery due to a poor performance status (Ljungberg, et al., 2009).

The National Institute for Health and Clinical Excellence (NICE) guidance on cryoablation for renal cancer describes the procedure as a possible treatment option for small tumors, and for patients with a solitary kidney, those with compromised renal function, or patients who are not surgical candidates (NICE, 2007).

Summary

There is sufficient evidence in the peer-reviewed scientific literature demonstrating that cryoablation provides short-term tumor control or improves survival in patients with renal cell carcinoma (RCC). The overall body of literature indicates that cryoablation is associated with low morbidity in patients who are poor surgical candidates and those with small, early-stage tumors located at the periphery of the kidney. Ongoing evaluation is needed to determine long-term outcomes and to compare cryoablation to other nephron-sparing procedures.

Coding/Billing Information

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

Covered when medically necessary:

CPT ^{®*} Codes	Description
50250	Ablation, open, one or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50542 [†]	Laparoscopy, surgical; ablation of renal mass lesion(s) , including intraoperative ultrasound guidance and monitoring, when performed
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy

†Note: Covered when medically necessary and when used to report laparoscopy, surgical ablation of renal mass lesion(s) by cryoablation.

ICD-9-CM Diagnosis Codes	Description
189.0	Malignant neoplasm of kidney, except pelvis
198.0	Secondary malignant neoplasm of kidney

***Current Procedural Terminology (CPT[®]) © 2010 American Medical Association: Chicago, IL.**

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	04/15/2008	0326	Cryoablation of Renal Tumors

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