



# 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)  
for Primary and Metastatic  
Cancers of the Liver**

**Effective Date ..... 8/15/2009  
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Coverage Policy Number ..... 0145**

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## Hyperlink to Related Coverage Policies

Cryoablation of Liver Tumors  
 Percutaneous Ethanol Injection (PEI) for Liver Cancer  
 Radioembolization with Yttrium-90 (90Y) Microspheres  
 Transcatheter Arterial Chemoembolization (TACE)

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

## Coverage Policy

**CIGNA covers radiofrequency ablation (RFA) as medically necessary for the treatment of unresectable primary liver cancer and unresectable liver metastases.**

## General Background

Hepatic tumors can be caused by primary liver cancer, also referred to as hepatocellular carcinoma (HCC), or by metastasis to the liver from other tissues. The most common extrahepatic primary cancer associated with liver metastases is colorectal cancer (CRC). The only potentially curative treatments are surgical resection or liver transplantation. However the majority of patients with primary or metastatic liver cancers are not suitable candidates for surgical resection at the time of diagnosis due to the size, site and number of tumors, perivascular and extra-hepatic involvement, advanced or decompensated liver cirrhosis, poor hepatic reserve, and/or poor general health. In addition, chemotherapy and radiotherapy rarely produce a complete or sustained response in patients with advanced disease. HCC is associated with liver cirrhosis in 50–80% of patients; 5% of cirrhosis patients develop HCC. Other causes of the disease include hepatitis B and C infection, particularly in conjunction with alcohol abuse.

For treatment purposes, primary liver cancer patients are classified as having localized resectable, localized unresectable or advanced disease. Surgery with curative intent is not appropriate for patients who have

multifocal disease, or poor hepatic reserve associated with cirrhosis, or if the tumor is in close proximity to major vascular or biliary structures that precludes margin-negative resection. Partial hepatectomy has been reported to result in five-year survival rates ranging from 10–30%. Liver transplantation is also considered for patients with localized disease that is unresectable. Even among patients who undergo resection with curative intent, recurrence is common. Despite treatment, many patients die of liver failure related to parenchymal replacement, from biliary obstruction, or from extrahepatic disease. Various locoregional therapies have been investigated for the treatment of primary and metastatic liver cancers including radiofrequency ablation (RFA), percutaneous ethanol injection (PEI); laser surgery; focused ultrasound (US); and thermal ablation by cryoprobes. These local ablative therapies also offer palliation for some patients who are not candidates for curative resection or liver transplantation (Roberts, 2003).

### **Radiofrequency Ablation (RFA)**

RFA involves the delivery of alternating current through an electrode which is inserted in the center of the tumor. Only those areas through which RF current passes are heated to a cytotoxic temperature; thus, surrounding normal tissues are spared (Siperstein, et al., 2000). The percutaneous approach is generally used when the tumor burden is limited to one or two small (<3.0 cm in diameter) liver tumors, while the intraoperative or laparoscopic approaches are used for multiple tumors, bilobar tumors for which surgical resection may also be performed, large tumors (> 3.0 cm), or tumors that abut a major intrahepatic blood vessel (Curley and Izzo, 2000). Patients may receive adjunct or adjuvant therapy with chemotherapy, radiotherapy, immunotherapy or embolization to enhance the effects of RFA. Serious treatment-related complications, though generally rare, include needle tract seeding, subcapsular hematoma, portal thrombosis, hemoperitoneum, gastrointestinal bleeding, pneumothorax, symptomatic pleural effusion, ventricular fibrillation, and infection of the ablated tumor (ECRI, 2003).

### **Literature Review**

A large number of clinical studies of RFA for the treatment of primary and metastatic tumors of the liver have been published in the peer-reviewed medical literature heterogeneity (Baldan, et al., 2006; Chow, et al., 2006; van Duijnhoven, et al., 2006; Lermite, et al., 2006; Hildebrand, et al., 2006; Chen, et al., 2005; Lam, et al., 2004; Berber, et al., 2002). Colorectal metastasis is most commonly reported in the literature. Outcome measures have included tumor response, survival rates; local tumor control and recurrence and complications and mortality after RFA alone or in combination with adjunct or adjuvant therapy. In general, results of these studies indicate that RFA is an effective and relatively safe alternative for patients with HCC and liver metastases. RFA has been reported to be more effective for tumors < 5.0 cm in diameter compared to larger tumors with recurrence more likely in tumors measuring > 6.0 cm (Solbiati, et al., 2001; Livraghi, et al., 2003).

**Systematic Reviews:** RFA has been compared to other interventions for liver tumors in several systematic reviews. Cho et al. (2009) analyzed four RCTs including 652 patients that compared RFA to PEI for the treatment of unresectable HCC. A meta-analysis of these RCTs demonstrated a significant improvement in 3-year survival favoring RFA over PEI ( $p < 0.001$ ).

Lau and Lai (2009) included RCTs ( $n=10$ ), nonrandomized controlled trials ( $n=8$ ) and cohort studies ( $n=26$ ) in their systematic review. According to these authors, the evidence showed “RFA was more effective than other local ablative therapies, and supported its use in the treatment of unresectable small HCC, recurrent small HCC, and as bridging therapy before liver transplantation, and as a primary treatment in competition with partial hepatectomy for resectable small HCC. However, insufficient evidence was found to determine if RFA improves outcomes” (Lau and Lai, 2009).

Lopez and colleagues (2006) conducted a systematic review of RCTs ( $n=16$ ) published from 2002 to 2005 assessing percutaneous ablation and other locoregional therapies as well as systemic therapies. Of these trials, four demonstrated a better local HCC control in tumors > 2 cm treated by RFA compared to ethanol injection. It was noted that Child-Pugh A patients with nonsurgical small tumors that are expected to achieve complete response are the ideal candidates for percutaneous treatments such as RFA. However, the use of RFA in patients with larger (i.e., 3–5 cm) or multiple tumors, and advanced liver failure may be reasonable on an individual basis (Lopez, et al., 2006).

Sutherland et al. (2006) examined studies comparing RFA with other therapies for HCC and CRC liver metastases. It was stated that few studies with comparable interventions were identified, which made it difficult to objectively assess and compare outcomes. In terms of the safety of RFA for the treatment of HCC, no distinct

differences were found in the complication rates between RFA and the other comparative procedures such as TACE and PEI. Despite the limitations of the data, it was concluded that RFA generally resulted in larger and more complete areas of ablation and may also be associated with higher survival rates than the other ablative techniques assessed. There was insufficient evidence to determine the safety and efficacy of RFA for the treatment of CRC liver metastases (Sutherland, et al., 2006).

Galandi and Antes (2004) conducted a Cochrane review of the literature on RFA compared to other interventions for HCC. Only two randomized trials were identified that met inclusion criteria for the review. The authors stated that based on the available evidence, RFA seems to achieve higher recurrence-free survival rates compared to PEI. No difference in overall survival was found. It was concluded that although RFA seems to be a promising technique for the treatment of HCC, more randomized clinical trials are needed to further define the role of this procedure.

### Professional Societies/Organizations

The Society of Interventional Radiology (SIR) position on percutaneous radiofrequency ablation for the treatment of liver tumors states that percutaneous RFA of hepatic tumors is a safe and effective treatment for selected patients with HCC and colorectal carcinoma metastases (Gervais, et al., 2009).

According to NCI, surgical resection is the standard curative modality. RFA may be considered for tumors smaller than 5 cm in patients with localized but unresectable liver cancer or for those with concomitant medical considerations such as cirrhosis or limited bilateral tumors (NCI, 2009). For patients with unresectable CRC hepatic metastases, RFA has emerged as a safe technique that may provide for long-term tumor control. There is no standard therapy for patients with advanced metastatic liver cancer (NCI, 2008).

The National Comprehensive Cancer Network (NCCN) guidelines for HCC state that patients who are not candidates for curative therapies (i.e., resection, transplantation) may be treated with locoregional approaches such as ablation (e.g., RFA, PEI cryosurgery) and transarterial embolization. For ablative therapies, all tumors should be amenable to ablation and accessible for percutaneous, laparoscopic, and open approaches. Tumors ≤ 3 cm are optimally treated with ablation (NCCN, 2009a). Similarly, the NCCN guidelines for colon cancer recommend considering ablative therapy of liver metastases only when disease is judged to be completely amenable to ablation (NCCN, 2009b). Ablative therapies (i.e., RFA or cryotherapy) are also among the recommended options for unresectable neuroendocrine liver metastases (NCCN, 2009c).

### Summary

The results of the available clinical studies demonstrate that radiofrequency ablation (RFA) of unresectable hepatocellular carcinoma (HCC) and metastatic liver cancers is a relatively safe and efficacious procedure for the short-term local control of single or multiple tumors. Histopathological examination of cancer specimens and normal liver tissues following RFA demonstrates that the procedure induces well-circumscribed areas of coagulative necrosis and adequate tumor-negative margins. There is some evidence from comparative studies that RFA may provide procedural morbidity and survival that is equivalent or superior to other minimally invasive or percutaneous techniques, such as transcatheter arterial chemoembolization (TACE) or percutaneous ethanol injection (PEI), in patients with small lesions. In addition, there are some limited data to suggest that RFA may provide similar outcomes as surgery in some patients; however, these findings must be confirmed in prospective, randomized trials. Although not curative, RFA may slow tumor progression and can provide palliation in patients with unresectable hepatic malignancies.

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## Coding/Billing Information

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

**Covered when medically necessary:**

CPT®* Codes	Description
47370	Laparoscopy, surgical, ablation of one or more liver tumor(s); radiofrequency
47380	Ablation, open, of one or more liver tumor(s); radiofrequency

47382	Ablation, one or more liver tumor(s), percutaneous, radiofrequency
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ICD-9-CM Diagnosis Codes	Description
155.0	Malignant neoplasm of liver, primary
155.2	Malignant neoplasm of liver, not specified as primary or secondary
197.7	Secondary malignant neoplasm of liver

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

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	8/15/2007	0145	Radiofrequency Ablation (RFA) for Primary and Metastatic Cancers of the Liver
Great-West Healthcare	3/14/2006	04.223.02	Radiofrequency Ablation (RFA) of Hepatic Tumors

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.