KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Radiofrequency Ablation

- Barrett's Esophagus
- Lung Cancer
- Renal Tumors
- Primary HCC and Metastatic Liver Cancer
- Uterine Fibroids

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "***Radiofrequency Ablation***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria Used
Barrett's Esophagus	Radiofrequency ablation is considered medically necessary for the treatment of members with Barrett's esophagus (BE) who have histological confirmation of low-grade dysplasia by two or more endoscopies three or more months apart.
Lung Cancer	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Renal Tumors Primary HCC and Metastatic Liver Cancer	Medical necessity review is no longer required for this service.
Transcervical Ablation Uterine Ablation of Leiomyomas (58580)	MCG* A-1039 This is not covered per MCG* For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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Laparoscopic Radiofrequency Ablation of Uterine Fibroids (58674)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Evidence and Source Documents

Radiofrequency Ablation for the Treatment of Barrett's Esophagus
Radiofrequency Ablation in the Treatment of Lung Cancer
Radiofrequency Ablation of Renal Tumors
Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer
Radiofrequency Volumetric Thermal Ablation (RFVTA) of Uterine Fibroids Using the AcessaTM System

Medical Technology Assessment Committee (MTAC)

Radiofrequency Ablation for the Treatment of Barrett's Esophagus

BACKGROUND

Barrett's esophagus is a disease wherein the stratified squamous epithelium lining the esophagus gets replaced by metaplastic columnar epithelium. The disease affects more Caucasians than Blacks and is diagnosed around 55 years (Spechler & Goyal, 1996) and its prevalence varied widely from 0.4% to 20% (Gerson, Shetler, & Triadafilopoulos, 2002; Ormsby et al., 2000; Ward et al., 2006). Barrett's esophagus is caused by chronic gastro esophageal reflux disease (GERD). While Body mass index (BMI), is believed to be associated with increased risk of Barrett's esophagus (Kamat, Wen, Morris, & Anandasabapathy, 2009), studies have found that abdominal obesity is a risk factor for Barrett's esophagus (Corley et al., 2007; Edelstein, Farrow, Bronner, Rosen, & Vaughan, 2007; Kramer et al., 2013). It is not well known if germline mutations are associated with the disease.

Initially, Barrett's esophagus manifests with no symptoms or patients show signs of GERD. The most common symptoms of GERD are pyrosis (heart burn), regurgitation and dysphagia. Other manifestations of GERD are chronic cough, bronchospasm and laryngitis, chest pain resembling angina pectoris. GERD is complicated by erosive esophagitis, esophageal ulceration, stricture and hemorrhage (Spechler & Goyal, 1996), and Barrett's esophagus. The annual cancer incidence varied from 0.1 to 0.4% (Desai et al., 2012; Hvid-Jensen, Pedersen, Drewes, Sørensen, & Funch-Jensen, 2011; Rugge, Fassan, Cavallin, & Zaninotto, 2012; Shakhatreh et al., 2014). Studies have shown that the risk of developing cancer is proportional to dysplasia status and length of Barrett's esophagus (Pohl et al., 2016; Sikkema et al., 2011; Thota et al., 2015; Van der Veen, Dees, Blankensteijn, & Van Blankenstein, 1989). Patients with high-grade dysplasia have higher risk (4-8%) of progression to adenocarcinoma while patients with Barrett's esophagus, low-grade dysplasia and indefinite for dysplasia have a risk ranging from 0.2 to 1.2% (Singh et al., 2014; Verbeek et al., 2012). However, mortality due to esophageal adenocarcinoma is lower than that of other causes (Sikkema, De Jonge, Steyerberg, & Kuipers, 2010). Diagnostic is based on endoscopy and biopsy showing columnar epithelium and intestinal metaplasia respectively. Histology classification has described four types of Barrett's esophagus (BE); these include non-dysplastic (ND), low-grade for dysplasia (LGD), indefinite for dysplasia (ID), high-grade dysplastic (HGD).

General management includes proton pump inhibitor (PPI). Fundoplication may be an alternative for PPI resistance. Aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) that inhibit cyclooxygenase (COX) have been described; however, these drugs have potential side effects. Surveillance has been

promoted by many guidelines (Association, 2011; Fitzgerald et al., 2014; Shaheen, Falk, Iyer, & Gerson, 2016) but its benefit is not well documented. In addition, surveillance modality depends on the type of dysplasia. Treatment of dysplasia is of greatest importance. Several approaches have been described and include endoscopic ablative therapies, endoscopic resection or the combination of both, and esophagectomy. Endoscopic resection encompasses removal of both mucosa and submucosa (Pech, May, Gossner, Rabenstein, & Ell, 2004) and can lead to stricture. Endoscopic ablative therapies consist of radiofrequency ablation (RFA), photodynamic therapy, and endoscopic spray cryotherapy.

RFA uses radiofrequency energy and produces thermal injury to destroy the mucosa. Energy used comes from a balloon equipped with a series of electrodes to ablate the mucosa (Sharma et al., 2007). The radiofrequency energy can either be delivered circumferentially or focally. There are two different devices and accessories, both manufactured by BARRX. The balloon based HALO360 device is used to treat circumferential areas of BE. The system includes a high-power energy generator, a sizing balloon catheter and several balloon-based ablation catheters. There are 60 tightly spaced, bipolar independent electrodes encircling the balloon through which the energy is delivered. A preselected amount of energy is delivered in less than a second at 350 W. This allows for full thickness ablation of the epithelium without damage to the submucosa. The HALO [90] ablation system is used to treat more focal areas and uses a radiofrequency generator and an endoscope mounted electrode. Both procedures can be done on an outpatient basis. Barrx90 ULTRA, Barrx60, and Channel RFA device are alternative options for focal ablations.

02/01/2010: MTAC REVIEW
Radiofrequency ablation for the treatment of Barrett's Esophagus
Evidence Conclusion:
Conclusion:

- There is fair evidence from one RCT with short-term follow-up that radiofrequency ablation using the HALO systems is superior to sham therapy (no therapy) in the treatment of BE with dysplasia.
- There is insufficient evidence to determine that RFA to has better outcomes and less harms than alternative therapies with curative intent for BE with dysplasia.
- There is insufficient evidence to determine the long-term efficacy, and safety of radiofrequency ablation therapy in the management of patients with Barrett's esophagus with dysplasia, and whether the risk of ablation is less than the risk of progression of BE.
- There is insufficient evidence to determine that radiofrequency ablation therapy eliminates the necessity for of further endoscopic surveillance of patients with Barrett's esophagus with dysplasia.
- There is insufficient evidence to determine that radiofrequency ablation therapy reduces or eliminates cancer risk in patients with Barrett's esophagus with dysplasia.

Articles: The search yielded around forty articles. Many were reviews, letters, and editorials. There was one randomized controlled trial and number of case series and reports. The RCT and the majority of the case series were conducted by the same group of investigators. The RCT with the following citation was critically appraised. Shaheen NJ, Sharma P, Overholt B, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. N Engl J Med 2009; 360:2277-2288. See Evidence Table

The use of Radiofrequency ablation for the treatment of Barrett's esophagus with dysplasia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

09/19/2016: MTAC REVIEW
Radiofrequency ablation for the treatment of Barrett's Esophagus
Evidence Conclusion:
Conclusion:

- Fair evidence shows that Radio frequency ablation (RFA) and endoscopic mucosal resection are both effective in managing HGD BE but RFA has less adverse events.
- Fair evidence supports efficacy of RFA over endoscopic surveillance for low grade dysplasia.
- Low evidence supports similar efficacy between endotherapy and surgery in the treatment of early Barrett's neoplasia
- There is fair evidence that RFA is effective and safe for the treatment of low-grade dysplasia; however, studies with long follow-up are needed.

- There is sufficient evidence to determine whether RFA is effective and safe for the treatment of high-grade dysplastic Barrett's esophagus.

Articles: The literature revealed a number of articles, but the following articles were selected for critical appraisal: Systematic review comparing radiofrequency ablation and complete endoscopic resection in treating dysplastic Barrett's esophagus: a critical assessment of histologic outcomes and adverse events (Chadwick et al, 2014) See Evidence Table 1. Radiofrequency ablation vs endoscopic surveillance for patients with Barrett's esophagus and low-grade dysplasia a randomized clinical trial (Phoa et al 2014) See Evidence Table 2. Efficacy and durability of radiofrequency ablation for Barrett's esophagus: systematic review and meta-analysis (Orman et al, 2013) See Evidence Table 3. Meta-analysis of endoscopic therapy for low-grade dysplasia in Barrett's oesophagus (Almond et al 2014) See Evidence Table 4. Endotherapy versus surgery for early neoplasia in Barrett's esophagus: a meta-analysis (Wu, Pan, Wang, Gao, & Hu, 2014) See Evidence Table 5.

The use of Radiofrequency ablation for the treatment of Barrett's esophagus with dysplasia does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Radiofrequency Ablation in the Treatment of Lung Cancer

BACKGROUND

Lung cancer is the leading cause of cancer related mortality in the United States. It has two main types; the non-small cell lung cancer (NSCLC) which accounts for approximately 80-85% of cases, and the small cell lung cancer (SCLC). After the initial diagnosis of the disease is made, it is essential to have an accurate TNM staging in order to determine the appropriate therapy. The standard treatment of patients with stage I or II NSCLC is surgical resection, and in order to achieve a potential cure from the disease, the cancer must be completely resectable through pneumonectomy or lobectomy, and the patient should be able to tolerate the surgery and have adequate pulmonary function. Patients with more advanced or metastatic lung disease, or who cannot tolerate surgery, due to age or the presence of other co-morbidities, are poor surgical candidates. They are traditionally offered treatment with conventional external beam radiotherapy which is considered the most reasonable alternative. However, its results have not been satisfactory, and it has lower overall long-term survival than complete surgical resection. This radiation therapy may also be associated with regional complications as radiation pneumonitis, fibrosis, and esophagitis, and is not indicated for pulmonary metastases. Chemotherapy was found to have only a modest therapeutic effect and is usually used as palliative therapy. This has led the researchers to develop minimally invasive techniques as stereotactic radiotherapy, brachytherapy, photodynamic therapy, bronchial artery infusion of chemotherapy, cryotherapy and radiofrequency ablation (RFA) (D'Amico 2003, Qiao 2003, Pennathur 2007). Radiofrequency ablation is a relatively new minimally invasive therapy that potentially leads to localized tissue destruction. It works by transferring radiofrequency (RF) energy from a generator through an electrode, to the target tissues. The waves are converted into heat, resulting in thermal damage, and coagulative necrosis of the tissues. For solid organ tumor ablation, thin RF electrodes are introduced laparoscopically or percutaneously to the target lesion under ultrasound, CT, or MRI guidance. A power of 5-120W is delivered to the electrodes, and an alternating current of 450-1,200 kHz passes from the tip to the surrounding tissue. When the temperature of the tumor cells is raised above 70oC cell destruction occurs. Several radiofrequency ablation devices were cleared by the FDA as tools for general ablation of soft tissue by thermal necrosis. The devices were also cleared for ablation of liver lesions, and bone metastases. According to the FDA, they have not been cleared for lung tumor ablation as their safety and effectiveness have not been fully established. In December 2007, the FDA issued a public health notification to alert the health practitioners of the deaths associated with lung tumor ablation using the radiofrequency devices (FDA Web site).

06/04/2008: MTAC REVIEW

Radiofrequency Ablation in the Treatment of Lung Cancer

Evidence Conclusion: There is limited evidence on the efficacy and safety of radiofrequency ablation for the treatment of lung cancer in patients who are not candidates for surgical resection. The body of evidence consists of small observational case series with no control or comparison groups that compare the RF ablation with conventional or other noninvasive techniques used for the treatments of patients with non-operable lung cancer, or those who cannot tolerate surgery. The published studies were heterogeneous; there were differences in the eligibility criteria of the studies, patient characteristics, stage of the disease, cancer type, number and sizes of the lesions, as well as other tumor characteristics. There were also

variations in the ablation approaches, types of devices used to deliver the therapy, follow-up, endpoints, and outcome measures. Moreover, the follow-up duration in the majority of the studies was too short to determine the long-term safety and effectiveness of the therapy. Overall, the results of the published studies indicate that the median survival of patients receiving the therapy ranged from 8.6 months to 33 months. The one-year survival rate ranged from 63-85%, the two-year survival was 55-65% and the three-year survival rate was 15-46%. Complete tumor necrosis ranged from 38% to 95%, and local disease recurrence varied from 3% to 38.1%. The studies indicate the RF ablation has better outcomes with tumors smaller than 3 cm in diameter vs. those >3cm in diameter, as this would allow oversizing of the ablation areas. The adverse effects associated with FR ablation included pneumothorax that often-needed aspiration, pleural effusion, hemoptysis, pain, as well as other complications some of which required hospitalization of the patients. The authors of the published studies presented the results for all patients combined, with no adjustments for confounding factors as age of the patients, presence of other co-morbidities and/or malignancies, or the use of other adjuvant therapy. Moreover, in the absence of comparison groups, it is hard to determine whether radiofrequency ablation leads to better local control or improved survival outcomes than external beam radiation therapy or any other noninvasive treatment. In conclusion there is insufficient published evidence to determine the efficacy and safety of radiofrequency ablation for the treatment of lung cancer.
Articles: The search yielded over 300 articles. Many were review articles or publications not related to the current review. No meta-analyses of empirical studies randomized, or non-randomized controlled studies were identified. The majority were observational prospective case series with population sizes ranging from <10 to 60 patients. There was a larger (N=153) retrospective observational study that evaluated the long-term efficacy and safety of the therapy. Prospective series with at least 50 patients, and/or with longer-term follow-up, as well as the larger retrospective series were selected for critical appraisal. *The following studies were critically appraised:* DE Baire T, Palussiere J, Auperin A, et al. Midterm local efficacy and survival after radiofrequency ablation of lung tumors with minimum follow-up of 1 year. Prospective evaluation. Radiology 2006.240:587-596. See Evidence Table. Ambrogi MC, Lucchi M, Dini P, et al. Percutaneous radiofrequency ablation of lung tumors: results in mid-term. Eur J Cardiothorac Surg. 2006. 30:177-183. See Evidence Table. Gadaleta C, Catino A, Mattioli V. Radiofrequency thermal ablation in the treatment of lung metastases. In Vivo. 2006; 20:765-768. See Evidence Table. Simon CJ, Dupuy DE, DiPetrillo TA, et al. Pulmonary radiofrequency ablation: Long-term safety and efficacy. Radiology 2007.243:268-275. See Evidence Table.

> The use of Radiofrequency ablation in the treatment of lung cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Radiofrequency Ablation of Renal Tumors
BACKGROUND
With the widespread use of body imaging techniques as magnetic resonance imaging (MRI), computed tomography (CT), there is an increasing number of pre-symptomatic, incidentally detected small renal masses or lesions with unclear clinical significance. The standard treatment for renal masses is radical nephrectomy. Other available treatment options for these small, incidentally discovered masses include watchful waiting or partial nephrectomy. Recently, with the current trend of minimally invasive surgery, nephron-sparing approaches have gained more acceptance. Among these are radiofrequency (RF) ablation, cryoablation, microwaves, and high intensity focused ultrasonography (HIFU). These techniques are still under development and only target selected, small renal tumors with a diameter of 4 cm or less. RF ablation works by transferring RF energy from a generator through an electrode, to the target tissues. The waves are converted into heat, resulting in thermal damage, and coagulative necrosis of the tissues. For solid organ tumor ablation, thin RF electrodes are introduced laparoscopically, or percutaneously to the target lesion under ultrasound, CT, or MRI guidance. A power of 5-120W is delivered to the electrodes, and an alternating current of 450-1,200 kHz passes from the tip to the surrounding tissue. When the temperature of the tumor cells is raised above 70^{o}C cell destruction occurs. The size of the lesion depends on the thermal properties of the tissue, the time, and the amount of the energy delivered. Radiofrequency ablation has been used for selected liver and bone tumors. It is approved by the FDA for ablation of aberrant atrioventricular conduction pathways in patients with Wolf-Parkinson-White syndrome, and for treating soft-tissue lesions in the liver. Its use for human renal tumors is still under investigation, and its efficacy and safety as well as its dosimetry have not been fully established.

12/11/2002: MTAC REVIEW

Radiofrequency Ablation of Renal Tumors
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of radiofrequency ablation for the treatment of renal tumors.
Articles: The search yielded one review article, two case reports and three case series with 10-15 patients each. There were no meta-analyses or randomized controlled studies.

> The use of radiofrequency ablation in the treatment of renal tumors does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer
BACKGROUND
The liver is a common site for primary and secondary malignancies. Hepatocellular carcinoma (HCC), the most common primary tumor is the fifth most common cancer in the world, and the third most common cause of cancer-related mortality. It is responsible for more than half a million deaths across the globe each year. Treatment options for patients diagnosed with primary and secondary malignancies are limited. Less than 15% are candidates for surgical resection at presentation because of inadequate liver functional reserve, extrahepatic disease, anatomic constraints of the tumor, or medical comorbidities. The use of external beam radiation is limited due to the intolerance of normal liver parenchyma to tumoricidal radiation doses (the dose required to destroy solid tumors (>70 Gy) is much higher than the liver tolerance dose of 35 GY). In addition, systematic chemotherapy was found to have little impact on survival, and negative impact on the health-related quality of life due to the toxicity to other organs and systems. These limitations have led to the emergence of other therapies, such as radiofrequency ablation (RFA), cryosurgical ablation (CSA), percutaneous ethanol injections (PEI), hepatic arterial infusion chemotherapy, transarterial chemo-embolization (TACE), and selective intrarterial radioembolization therapy (Steel 2003, Salem 2005, Ibrahim 2008, Bult 2009, Riaz 2009, Bhardwaj 2010). Ablative techniques improve the ability to treat patients with unresectable hepatic tumors. Thermal ablative techniques, such as RFA, destroy tumors via a source that changes temperature to levels that are associated with cell death while causing minimal damage to adjacent, normal tissue. Chemical ablative techniques, such as PEI, involve the injection of cancer killing chemicals such as pure alcohol (ethanol) or acetic acid directly into the tumor. The choice of technique depends on equipment availability and physician preference. PEI is a chemical ablative technique where absolute or 95% ethanol is injected into tumor tissue resulting in coagulative necrosis through cytoplasmic dehydration, denaturation of cellular proteins, and small vessel thrombosis. When the consistency of the tumor is ‘soft’ within a ‘hard’ cirrhotic liver (most HCCs), the distribution of ethanol is relatively uniform; however, when the tumor is ‘hard’ within a ‘soft’ normal liver (most metastases), the distribution is not as uniform. For this reason, PEI works better for HCC than for metastases. Complications of PEI include: hyperthermia, pain, elevated serum liver function tests, needle-tract seeding, pleural effusion, biliary stricture, portal vein thrombosis, and bleeding in the biliary tract (Clark 2007, Yamane 2009). The most commonly used ablative technique in the United Stated is RFA. RFA causes tumor destruction through the use of alternating high-frequency electric current in the radiofrequency range (460-500 kHz). This current is delivered through an electrode placed in the center of a lesion. Ions within the cell follow the alternating current creating frictional heat producing local tissue temperatures that can exceed 100°C. This ionic agitation leads to tissue destruction via tissue boiling and creation of water vapors. Once temperatures greater than 60°^{C} are reached, protein denaturation, tissue coagulation, and vascular thrombosis result in a zone of complete ablation. Partial tissue destruction can occur up to 8 mm in diameter from the zone of complete ablation. RFA can be delivered either percutaneously, laparoscopically, or through open approaches (laparotomy). Complications from RFA include pleural effusion, hepatic abscess, biliary injury, liver failure, intra-abdominal hemorrhage, pneumothorax, and hypoxemia. The most troubling complications arise when a probe is placed too close to the diaphragm or intra-abdominal organ, resulting in ablation of the surrounding viscera with the accompanying complications of perforation, diaphragmatic injury, or pulmonary damage. Limitations of RFA include: treating lesions in perihilar areas or near large vascular structures, and real time monitoring of the ablative zone is difficult due to air released during heating (Yamane 2009, Arciero 2006). RFA has received FDA approval for generic tissue ablation and the ablation of unresectable colorectal cancer metastases.

08/11/1999: MTAC REVIEW
Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer

Evidence Conclusion: The best published scientific evidence evaluating percutaneous radiofrequency (RF) ablation of liver cancer consists of one case series of 39 patients with primary hepatocellular carcinoma and 11 patients with other primary tumors who had liver metastases. The majority of patients had 3-4 treatments with one or more nodules being ablated at each session. Five patients experienced mild pain during the procedure; no other complications were reported. The 5-year survival rate among those with primary hepatocellular carcinoma was 40%; the period of follow-up for persons with liver metastases was too short for the calculation of a 5-year survival rate. Because the survival rate of patients treated with RF ablation was not directly compared to that of a control group, it is not possible to determine whether this treatment improves survival among patients with liver cancer.
Articles: Rossi S, DiStasi M, Buscarini E, Quartetti P, Garbagnati F, Squassante L, Paties CT, Silverman DE, Buscarini L. Percutaneous RF interstitial thermal ablation in the treatment of hepatic cancer. AJR Am J Roentgenol 1996; 167: 759-68. See Evidence Table.

The use of radiofrequency ablation in the treatment of primary HCC does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/08/2001: MTAC REVIEW
Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer
Evidence Conclusion: Only one study on radiofrequency ablation was a controlled trial. The remainder were case series. The trial reported on a clinically intermediate outcome, liver necrosis, not survival. The case series reports had survival information, but this was not presented in a standardized format (e.g. 1-year survival, 3-year survival). Instead, they reported on survival after a certain mean or median follow-up time (patients had different amounts of follow-up time) which is more difficult to interpret. For primary HCC, in the one trial comparing RF ablation to an alternative technique, PEI, both techniques resulted in high rates of complete necrosis and the difference in rates was not statistically significant (Livraghi). PEI required more sessions and RF ablation had more adverse effects (there was 1 major and 4 minor complications with RF ablation, none with PEI). In the case series reviewed (Curley), there was a 72% survival rate after a median of 19 months of follow-up (all patients had at least 12 months follow-up). Livraghi (2001) (not critically appraised for this review) reported on a case series of patients with HCC treated with PEI. The 1-year survival rate for patients with a single HCC 5 cm or smaller was 98, 93 and 64%, respectively for Child's A, B and C cirrhosis. For metastatic hepatic cancer, de Barre found that 81% patients survived after a mean follow-up of 14 months; 62% of these who survived had hepatic disease or distant metastases. 2-year or longer follow-up data were not available. This does not appear to be a dramatic increase in survival compared to untreated metastatic liver cancer (mean survival 6 to 21 months), but there is not strong evidence to support this claim. No studies compared RF ablation treatment to another treatment for metastatic liver cancer such as cryosurgery. In a case series on cryosurgery for hepatic colorectal metastases (Ruers, 2001) (not critically appraised for this review), the 1-year survival was 76% and the 2-year survival was 61%. The effectiveness of RF ablation may differ depending on the type of metastatic tumor.
Articles: The search yielded 85 articles, many of which were review articles, opinion pieces, dealt with technical aspects of the procedures or addressed other, similar treatments. There were no randomized controlled trials or meta-analysis. There was one non-randomized controlled trial and the rest of the empirical articles were case series. Articles on HCC and metastatic liver cancer were analyzed separately. Two studies on primary hepatocellular carcinoma were reviewed (the non-randomized trial and a recent case series with a moderate sample size by a different research group): Livraghi T, Goldberg SN, Lazzaroni S, Meloni F, Solbiati L, Gazelle GS. Small hepatocellular carcinoma: Treatment with radiofrequency ablation versus ethanol injection. Radiology 1999; 210: 655-661. See Evidence Table. Curley SA, Izzo F, Ellis LM, Vauthey JN, Vallone P. Radiofrequency ablation of hepatocellular cancer in 110 patients with cirrhosis. Ann Surg 2000; 232: 381-91. *One study on metastatic liver cancer was reviewed (the largest case series with the longest follow-up):* de Barre T, Ellas D, Dromain C, El Din MG, Kuoch V, Ducreux M. et al. Radiofrequency ablation of 100 hepatic metastases with a mean follow-up of more than 1 year. AJR 2000; 175: 1619-25. See Evidence Table.

The use of radiofrequency ablation in the treatment of primary HCC does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

06/21/2010: MTAC REVIEW

Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer

Evidence Conclusion: There is fair evidence that overall and disease-free survival rates were not statistically different for patient with solitary HCC <5 cm in diameter treated with either RFA or surgical resection. There is fair evidence that patients with HCC treated with RFA have better survival and lower recurrence rates than patients treated with PEI. There is fair evidence that for patients with HCC and tumors between 3.1 and 5.0 cm in diameter the combined treatment of PEI plus RFA versus RFA alone increases survival; however, long term follow-up is needed. There is insufficient evidence to determine the efficacy of RFA compared to surgical resection for patients with liver metastases. **Articles:** The literature search yielded around 250 articles pertaining to the use of RFA. The majority of these articles were case series and cohort studies. Only one randomized controlled trial (Chen 2006) was identified that compared RFA with resection for small HCC. There were several RCTs and meta-analyses comparing RFA with PEI. The two most recent meta-analyses (Bouza 2009, Germani 2010) were selected for review. There were several studies comparing the combined use of PEI and RFA. Many of these studies did not have a control group or did not assess survival as an outcome. An RCT that compared PEI + RFA with RFA alone was selected for review (Zhang 2007). No randomized controlled trials or meta-analyses were found pertaining to the use of RFA for metastatic liver cancer. The literature consisted mainly of case series and cohort studies. A retrospective cohort study (Abdalla 2004) that compared resection to RFA was selected for review. The following studies were critically appraised. Chen MS, Li JQ, Zheng Y et al. A prospective randomized trial comparing percutaneous local ablative therapy and partial hepatectomy for small hepatocellular carcinoma. *Ann Surg 2006;* 243:321-328. See Evidence Table. Bhardwaj N, Strickland AD, Ahmad F et al. Liver ablation techniques: a review. *Surg Endosc 2010;* 24:254-265. Bouza C, López-Cuadrado T, Alcázar R et al. Meta-analysis of percutaneous radiofrequency ablation versus ethanol injection in hepatocellular carcinoma. *BMC Gastroenterol 2009;* 9:31-39. See Evidence Table. Germani G, Pleguezuelo M, Gurusamy K et al. Clinical outcomes of radiofrequency ablation, percutaneous alcohol ablation and acetic acid injection for hepatocellular carcinoma: A meta-analysis. *J Hepatol 2010;* 52:380-388. See Evidence Table. Zhang YJ, Liang HH, Chen MS et al. Hepatocellular carcinoma treated with radiofrequency ablation with or without ethanol injection: A prospective randomized controlled trial. *Radiology 2007;* 244:599-607. See Evidence Table. Abdalla EK, Vauthey JN, Ellis LM et al. Recurrence and outcomes following hepatic resection, radiofrequency ablation, and combined resection/ablation for colorectal liver metastases. *Ann Surg 2004;* 239:818-827. See Evidence Table.

The use of radiofrequency ablation in the treatment of primary HCC does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Laparoscopic Radiofrequency Volumetric Thermal Ablation (RFVTA) of Uterine Fibroids Using the AcessaTM System

BACKGROUND

Uterine fibroids, also known as uterine myomas or leiomyomas, are non-cancerous tumors that grow within the wall of the uterus. They are the most common pelvic neoplasms in women, occurring among 20-40% of those in the reproductive age and 70%-80% by the age of 50. Uterine myomas are commonly classified into 3 subgroups according to their location: subserosal (projecting outside the uterus), intramural (within the myometrium) and submucosal (projecting into the cavity of the uterus. (A more recent classification was developed by International Federation of Gynecology and Obstetrics [FIGO]). Uterine fibroids also vary in size and number ranging from one tiny seedling to multiple bulky mases that can significantly enlarge the uterus. The majority of uterine leiomyomas are asymptomatic and can go unnoticed or are incidentally detected on clinical examination or imaging. However, 20-50% are symptomatic causing abnormal uterine bleeding (AUB) including menorrhagia, dysmenorrhea, pelvic pressure, back pain, and fertility issues (Brucker 2014, Chittawar 2015, Vilos 2015, Lee 2016).

Uterine fibroids are currently the leading indication of hysterectomy worldwide. Hysterectomy is the most effective and definitive treatment for symptomatic fibroids, however, many women desire to preserve their fertility and/or conserve their uterus. Myomectomy is the alternative procedure for these women; it can be performed by conventional laparotomy or by minimal access techniques such as laparoscopy, robotic-assisted laparoscopy, hysteroscopy, or other modified techniques depending on the number, size, and location of the fibroids. Each technique has its benefits and associated harms, but myomectomy in general carries the risk of fibroid recurrence and potential need for future hysterectomy. The recurrence rate ranges from 10-50% depending on age, number of fibroids, uterine size, and childbirth after myomectomy.

Conventional laparotomy has been the approach of choice for many surgeons, but it is associated with intra- and post-operative blood loss requiring blood transfusion in approximately 20% of cases. Laparoscopic myomectomy performed by a highly skilled laparoscopic surgeon is associated with less blood loss, diminished postoperative pain, faster recovery, and shorter hospital stay compared to abdominal myomectomy. However, the multilayer suturing may be challenging, and the procedure takes longer to perform and requires surgical expertise and specialized equipment. In addition, there may be a limit to the size and number of lesions removed laparoscopically. There is also a concern about the risk of uterine rupture occurring in the second or third trimester of pregnancy after laparoscopic myomectomy. A recently raised concern is the risk of power morcellation in cases of undiagnosed uterine malignancy while removing the fibroids laparoscopically as this may result in disruption and wide dissemination of an unrecognized sarcoma (Brucker 2014, Chittawar 2015, Vilos 2015 Kramer 2016).
Alternative non-surgical or minimally invasive management options for uterine fibroids include medical treatment (hormonal and non-hormonal); magnetic resonance guided focused ultrasound surgery (MRgFUSD), uterine artery embolization (UAE), laparoscopic occlusion of uterine arteries, and radiofrequency (RF) myolysis or ablation of the myomas (Chittawar 2015, Vilos 2015).

Myolysis was introduced in the 1980s as a conservative option for treating myomas. It uses a focused energy to cause tissue destruction. Energy sources include laser, bipolar, monopolar, cryoprobe, or thermal radiofrequency ablation (RFA). In general, a radiofrequency system consists of a generator, an electrode, electrode return pads, and cables connecting these elements. The generator produces high frequency, low voltage, alternating current that is transmitted via an electrode with an insulated shaft. Placing the electrode into the target tissue results in transmission of the current through the tissue. The current then travels to the electrode return pads and back to the generator completing the circuit. The heat produced by ionic movement within the cells adjacent to the exposed portion of the electrode, spreads and produces volumetric ablation through coagulative necrosis (Lee 2016)

In 2002 Lee BB, first reported on the use of RF ablation under laparoscopic intraabdominal ultrasound guidance to treat patients with symptomatic myomas. A number of observational small feasibility studies using different systems were published along the years (Chudnoff 2013, Chittawar 2015, Kramer 2016, and FDA website accessed April 2017). The Acessa™ System (Halt Medical, Inc., Brentwood, CA) is an ultrasound guided system for performing radiofrequency volumetric thermal ablation (RFVTA) of fibroids in the outpatient setting. The system consists of several components including a dual function RF generator, a disposable 3.4 mm diameter hand piece with a deployable 7-needle electrode array, a handpiece cable, two disposable dispersive electrode pads, pad cable, power cord, and a foot pedal. It is designed to deliver up to 200W of RF power in 3 operational modes: Temperature Control, Manual Control, and Coagulation Mode. Additional equipment needed for the RFA procedure using the Acessa™ system include a standard laparoscopic tower (insufflator, camera box, light source and printer), laparoscope 5 or 10 mm, ultrasound machine with laparoscopic transducer, and two video monitors one for the laparoscopic image and one for the ultrasound image (Chudnoff 2013, lee 2016 and Acessa website accessed April 2017).

The procedure is performed under general anesthesia and laparoscopic intra-abdominal ultrasound guidance. The laparoscopic ultrasound probe is used to determine the location and size of all fibroids present. The RFA handpiece tip is then inserted percutaneously through a 2-mm skin incision and directed into each myoma with laparoscopic and ultrasound guidance to verify the appropriate placement of the device within each myoma. The electrode array is then deployed, the appropriate duration of ablation is determined, and the treatment applied. Once the ablation is completed, the generator is switched to coagulation mode to seal the tract during withdrawal of the handpiece and provide hemostasis. Irregular myomas and those ≥ 4 cm in diameter require multiple overlapping ablations to ensure adequate ablation of the myoma periphery. After ablation, the myomas are not replaced by fibrous tissue, but are gradually reabsorbed by the surrounding myometrium. Complete reabsorption depends on the completeness of ablation, location of the myoma and weal as its size (Vilos 2015, Lee 2016).

More recently a transvaginal approach was introduced for delivering the energy without the need for general anesthesia. The procedure was examined in an observational study in China and used a different radiofrequency generator (Jiang 2014).

06/21/2017: MTAC REVIEW
Evidence Conclusion:
Conclusion

- There is insufficient published evidence to determine that laparoscopic ultrasound guided radiofrequency volumetric thermal ablation (RFVTA) of symptomatic uterine myoma has superior or equivalent results as other therapies/interventions used among women with symptomatic fibroids who desire to conserve their uterus. The only comparative study published to date, was small, unblinded, and only powered to detect significant difference in the length of post procedural hospital stay with RFVTA versus laparoscopic myomectomy. It was not powered to detect differences in the clinical outcomes or quality of life. A lack of significant differences does not necessarily indicate equivalence.
- There is insufficient evidence to determine the safety of the laparoscopic ultrasound RFVTA or the durability of the observed benefit over the years. The comparative study was too small and with insufficient follow-up period. The other studies examining the safety of the procedure were all observational; the largest and longest of which was the pivotal Halt trial which reported significant benefit and durability of the effect of the intervention for up to three years. However, similar to the other published observational studies on this technology, it had its limitations; had no control or comparison group, and the majority of outcomes were subjective. The three-year follow-up of Halt trial shows an increasing rate of repeat surgeries along the years. By the end of the third year, 14 (12%) of the women who entered the 3-year follow-up had repeat surgeries 11 (79%) of which were hysterectomies

Articles: The literature search for studies on laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids identified 4 studies with population sizes ranging from 31 to135, reported in 9 publications. Only one study was randomized and controlled with its results were published in three articles (Brucker 2014, Hahn 2015, and Kramer 2016). The others were observational, non-comparative studies including a very small short feasibility study (Garza 2011), a small study (N-35) with 12 months follow-up (Robles 2013) and the pivotal Halt trial (published in 4 articles (Chudnoff 2013, Guido 2013, Galen 2013, and Berman 2014). The RCT and the HALT trial were selected for critical appraisal. Berman JM, Guido RS, Garza Leal JG, et al. Three-year outcome of the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas. *J Minim Invasive Gynecol*. 2014 Sep-Oct; 21(5):767-774. Brucker SY, Hahn M, Kraemer D, et al. Laparoscopic radiofrequency volumetric thermal ablation of fibroids versus laparoscopic myomectomy. *Int J Gynaecol Obstet*. 2014 Jun; 125(3):261-265.Chudnoff SG, Berman JM, Levine DJ, et al. Outpatient procedure for the treatment and relief of symptomatic uterine myomas. *Obstet Gynecol*. 2013 May; 121(5):1075-1082. Galen DI, Isaacson KB, Lee BB. Does menstrual bleeding decrease after ablation of intramural myomas? A retrospective study. *J Minim Invasive Gynecol*. 2013 Nov-Dec; 20(6):830-835. Guido RS, Macer JA, Abbott K, et al. Radiofrequency volumetric thermal ablation of fibroids: a prospective, clinical analysis of two years' outcome from the Halt trial. *Health Qual Life Outcomes*. 2013 Aug 13; 11:139. Hahn M, Brucker S, Kraemer D, et al. Radiofrequency Volumetric Thermal Ablation of Fibroids and Laparoscopic Myomectomy: Long-Term Follow-up from a Randomized Trial. *Geburtshilfe Frauenheilkd.* 2015 May; 75(5):442-449. Krämer B, Hahn M, Taran FA, et al. Interim analysis of a randomized controlled trial comparing laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids with laparoscopic myomectomy. *Int J Gynaecol Obstet*. 2016 May; 133(2):206-211.

The use of Laparoscopic Radiofrequency Volumetric Thermal Ablation (RFVTA) of Uterine Fibroids Using the AcessaTM System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Barrett's Esophagus- Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)

With Diagnosis Codes	
K22.70	Barrett's esophagus without dysplasia
K22.710	Barrett's esophagus with low grade dysplasia
K22.711	Barrett's esophagus with high grade dysplasia
K22.719	Barrett's esophagus with dysplasia, unspecified

Lung Cancer - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
32998	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency

Transcervical Uterine Ablation of Leiomyomas - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
58580	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency

Laparoscopic Radiofrequency Ablation of Uterine Fibroids—Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Date Created	Dates Reviewed	Date Last Revised
07/17/2008	Added to annual review on 04/04/2011 MDCRPC, 02/07/2012 MDCRPC,12/04/2012 MDCRPC, 10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC ,11/06/2018MPC, 11/05/2019MPC, 11/03/2020MPC, 11/02/2021MPC, 11/01/2022MPC, 11/07/2023MPC, 04/02/2024MPC , 04/01/2025MPC	08/09/2024

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
05/03/2016	Combined RFA Barrett's Esophagus and Lung Cancer into one policy
10/04/2016	Added MTAC Review
11/01/2016	MPC approved criteria of medical necessity for Barrett's Esophagus
08/01/2017	Added MTAC Review for RFVTA
12/05/2017	Adopted KPWA Policy for Barrett's Esophagus and Uterine Fibroids for Medicare
08/28/2018	Removed non-covered LCD for lung cancer

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11/17/2020	Removed references to vertebral augmentation for painful spinal metastases as there is already separate criteria for vertebroplasty
04/05/2022	MPC approved to adopt MCG* A-1039 Transcervical Uterine Ablation of Leiomyomas. This service continues to be considered not medically necessary.
10/03/2023	MPC approved to maintain a position of noncoverage for Laparoscopic RFA by adopting KP criteria of insufficient evidence (CPT 58674). 60-day notice not required.
04/17/2024	Removed termed code 0404T, replaced with 58580
08/09/2024	Removed termed code C9771

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