Clinical Policy Title: Radiofrequency ablation of tumors

AmeriHealth Caritas considers the use of radiofrequency ablation to be clinically proven and, therefore, medically necessary in members aged 18 years and older for treatment of tumors that are accessible to the procedure and at least 1 cm from major organs or structures that could be injured by thermal conduction, including:

- Hepatocellular carcinoma confirmed by biopsy or imaging (National Comprehensive Care Network [NCCN], 2017a; Interqual, 2016; American College of Radiology [ACR], 2015):
  - Bridge therapy to maintain candidacy for liver transplantation.
  - When a member is medically inoperable, ineligible for liver transplantation, or refuses resection, and has either:
    - Barcelona Clinic Liver Cancer early-stage (defined as a single tumor < 5 cm at its longest axis, or two or three tumors each ≤ 3 cm, Child-Pugh A-B, and performance status 0) with no extrahepatic disease.
• Barcelona Clinic Liver Cancer intermediate stage (defined as a single large tumor or multinodular disease, preserved liver function, and no extrahepatic spread or macrovascular invasion) and tumors have been downsized to a single tumor ≤ 5 cm or two to three tumors each ≤ 3 cm following transarterial therapy.

• Liver metastases confirmed by biopsy or imaging when all of the following criteria are met (NCCN, 2017a, b, c, f; ACR, 2015; Interqual, 2016):
  - Tumors ≤ 5 cm.
  - Ineligible for surgical resection.
  - For members with colorectal cancer, metastases are confined to the liver.
  - For members with neuroendocrine tumor involvement, persistent symptoms after medical treatment with somatostatin analogs.

• Renal cell carcinoma when all of the following criteria are met (NCCN, 2018; Interqual, 2017):
  - Stage I (T1a).
  - Confirmed by biopsy.
  - Single tumor > 1 cm and ≤ 4 cm.
  - No metastasis.

• Symptomatic osteolytic bone metastases in members who have failed, or are poor candidates for, standard pain treatments such as radiation or opioids (Rosian, 2017; Rosenthal, 2012; Warmuth, 2012).

• Primary or secondary lung cancers (NCCN, 2018; National Institute for Health and Care Excellence [NICE], 2010a):
  - Early-stage, resectable (stage I-II, N0) non-small cell lung cancer in members who are medically inoperable or refuse surgery (Bi, 2016; Sher, 2011).
  - For members: who are not candidates for stereotactic ablative radiotherapy, external beam radiation therapy, or sublobar resection; who have failed stereotactic ablative radiotherapy; or for whom local control may not be the highest priority (NCCN, 2018).

• Primary therapy for:
  - Intestinal metaplasia (Barrett’s esophagus) (Almeida, 2016; NICE, 2014; NICE, 2010b).
  - Early-stage esophageal or esophagogastric cancer (pTis, pT1a, pTibNO) with or without endoscopic resection (NCCN, 2017d).

• After esophageal resection for residual or recurrent high-grade or low-grade esophageal dysplasia (NCCN, 2017d; Evans, 2013).

• Thyroid cancer for locoregional control when standard therapy (e.g., surgery or local therapies) is contraindicated, has failed, or is refused (NCCN, 2017e; NICE, 2016).

• Metastatic (synchronous stage IV) soft tissue sarcoma of the trunk, extremity, head, or neck (NCCN, 2018c; Gronchi, 2016):
  - Primary local therapy when confined to a single organ and limited tumor bulk.
  - Palliative therapy for symptomatic disseminated disease.
AmeriHealth Caritas considers the use of radiofrequency ablation to be clinically proven and, therefore, medically necessary for treatment of osteoid osteomas that cannot be managed successfully with medical treatment, are accessible to the procedure, and at least 1 cm from major organs or structures that could be injured by thermal conduction (Rosenthal, 2012; Warmuth, 2012).

**Limitations:**

The effectiveness of radiofrequency ablation for indications other than the ones listed above has not been established. Radiofrequency ablation may be considered on a case-by-case basis for removal of other primary or metastatic malignant neoplasms when either:

- Removal of the neoplasm may be curative and the member is unable to tolerate or refuses surgical resection or radiation therapy.
- Palliative debulking or complete removal may relieve symptoms.

Relative contraindications include (NCCN, 2017a, b, c; Interqual, 2016):

- Ablative margins measuring less than 1 cm (i.e., tumors should be located at least 1 cm from critical structures or vessels to achieve complete tumor destruction), except in cases of palliation or debulking.
- More than three tumors per organ. However, the number of lesions should not be considered an absolute contraindication to radiofrequency ablation if successful treatment of all metastatic deposits can be accomplished.

Untreatable or unmanageable coagulopathy is an absolute contraindication to radiofrequency ablation.

**Alternative covered services:**

Standard of care specific to each tumor.

**Background**

Radiofrequency ablation applies heat using high-frequency alternating current via electrodes placed within the tissue to induce tissue coagulation and cell death (Friedman, 2004). It is one of several types of ablative therapies used to treat a wide range of cardiac, neurologic, vascular, and oncologic conditions. The U.S. Food and Drug Administration (FDA) classifies radiofrequency ablation as an electrosurgical, cutting, and coagulation device with 510(k) marketing submission requirements (FDA, 2017).

Radiofrequency ablation can be applied percutaneously, laparoscopically, or at open surgery. The choice of technique will depend on: the patient’s condition; tumor size, number, location, and growth pattern;
and operator and local practice patterns. It may be performed in outpatient or inpatient settings under
general anesthesia, conscious sedation, or deep sedation (Friedman, 2004).

Percutaneous radiofrequency ablation is a minimally invasive, repeatable procedure performed under
radiologic guidance. The percutaneous approach requires that tumors not lie adjacent to other organs
or vessels that could be injured by thermal conduction. Surgical approaches allow a more accurate
evaluation of disease in and around the organ and present less risk to adjacent structures. The open
approach allows for concurrent combination therapies, such as resection and placement of pumps for
regional chemotherapy (Friedman, 2004).

This policy will focus on radiofrequency ablation as treatment for tumors and pre-malignant conditions,
excluding treatment of uterine fibroids. See Clinical policy #12.03.04 Radiofrequency ablation of uterine
fibroids.

Searches

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other
evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on January 8, 2018. Search terms were: "Catheter Ablation" (MeSH),
"Neoplasms" (MeSH), and the free text terms “radiofrequency ablation” and “RFA.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes
  and greater precision of effect estimation than in smaller primary studies. Systematic
reviews use predetermined transparent methods to minimize bias, effectively treating the
review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple
cost studies), reporting both costs and outcomes — sometimes referred to as efficiency
studies — which also rank near the top of evidence hierarchies.

Findings

Radiofrequency ablation was initially indicated as a treatment option for inoperable hepatic tumors. The
liver is a common site for metastasis from solid tumors, and many are unsuitable for surgical excision
because of their number, distribution, or the presence of extrahepatic spread (NCCN, 2017a).
Increasingly, radiofrequency ablation is becoming an attractive treatment option for locoregional control, palliation, and, in some circumstances, cure of other solid tumors, including some operable tumors for which well-established local or systemic treatment alternatives are available. For patients who present with significant surgical risks or who have significant competing comorbidities, radiofrequency ablation balances potential cure, locoregional control, or palliation with treatment toxicity and benefits common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Existing evidence and clinical experience supports radiofrequency ablation as a safe procedure in the hands of an experience specialist and effective in tumor destruction, which may be associated with higher survival rates for some cancers. The most common complications include post-procedural pain, fever, and burns. An absolute contraindication is uncontrolled coagulopathy. Other relative contraindications primarily relate to tumor location and underlying organ function.

To be amenable to ablation, typically a 1 cm margin of tumor-free tissue is needed, except in cases of palliation or debulking, and the tumor must be in an accessible location and away from major organs and vessels. Currently, there is no standard tumor size or number of tumors appropriate for ablation; however, studies have found improved outcomes when tumors 4 cm or smaller are treated (NCCN, 2017a, b, c; Interqual, 2016). Typically, choice of ablative technique is based on tumor size (radiofrequency ablation is most effective for treating tumors < 3 cm at their longest axis) and location and underlying organ function (NCCN, 2017a). Except for studies of osteoid osteoma, most studies included patients older than 17 years.

Radiofrequency ablation is an established treatment alternative for the following hepatic indications (NCCN, 2017a, b, c; ACR, 2015):

- Early-stage hepatocellular carcinoma:
  - Curative therapy for isolated tumors ≤ 3 cm (in select cases, up to 5 cm).
  - Locoregional therapy in medically inoperable patients.
- Neoadjuvant therapy as a bridge to transplant.
- Isolated colorectal liver metastasis < 3 cm to 5 cm.

There is sufficient evidence to support radiofrequency ablation as a locoregional treatment option for the following extrahepatic indications:

- Early-stage renal cell carcinoma without metastasis (NCCN, 2018a).
- Symptomatic osteolytic bone metastases in persons who have failed, or are poor candidates for, standard treatments such as radiation or opioids (Rosian, 2017; Rosenthal, 2012; Warmuth, 2012).
- Osteoid osteomas that cannot be managed successfully with medical treatment (Rosenthal, 2012; Warmuth, 2012).
- Primary or secondary lung cancers (NCCN, 2018b; NICE, 2010a):
- Early-stage, resectable (stage I-II, N0) non-small cell lung cancer in patients who are medically inoperable or refuse surgery (Bi, 2016; Sher, 2011).
- For patients who are not candidates for stereotactic ablative radiotherapy, external beam radiation therapy, or sublobar resection; who have failed stereotactic ablative radiotherapy; or for whom local control may not be the highest priority (NCCN, 2018b).

- Primary therapy for intestinal metaplasia (Barrett’s esophagus) (NCCN, 2017d; Almeida, 2016; NICE, 2014; NICE, 2010b).
- Residual or recurrent high-grade or low-grade esophageal dysplasia after esophageal resection (NCCN, 2017d; Evans, 2013).
- Thyroid cancer for locoregional control when standard therapy (e.g., surgery or local therapies) is contraindicated, has failed, or is refused (NCCN, 2017e).
- Metastatic (synchronous stage IV) soft tissue sarcoma of the trunk, extremity, head, or neck (NCCN, 2018c):
  - Primary local therapy when confined to a single organ and limited tumor bulk.
  - Palliative therapy for symptomatic disseminated disease.

There is insufficient evidence to support the use of radiofrequency ablation for treatment of any other malignant primary tumor or benign tumor, such as Morton’s neuroma (American Orthopaedic Foot and Ankle Society, 2018; Valerio, 2017; Peek, 2016; Association of Extremity Nerve Surgeons, 2014; Fegrachi, 2014; Fischer, 2012b).

**Policy updates:**

None.

**Summary of clinical evidence:**

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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Rosian (2017) for the Ludwig Boltzmann Institut für Health Technology Assessment (LBIHTA) Radiofrequency ablation for metastatic spinal lesions | **Key points:**
| | • Systematic review of four prospective single-arm studies and five retrospective single-arm studies with at least 30 patients. Data on safety and efficacy were evaluated in 471 and 112 patients, respectively.
| | • Significant improvement in pain relief (three prospective studies) and health-related quality of life (two studies) after treatment with radiofrequency ablation and vertebroplasty.
| | • No recurrence of vertebral metastases during follow-up (one study).
| | • No major radiofrequency ablation-related complications were reported.
<p>| | • Adverse event rate (procedure-related or not procedure-related) = 18% (105/583 patients); most frequent radiofrequency ablation-related adverse events were increased pain and numbness (7.8%, 6/77 patients); most frequent adverse event reported related to vertebroplasty was cement extravasation (18.7%, 67/358 patients). |</p>
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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td>Valerio (2017)</td>
<td>Key points:</td>
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| New and established technology in focal ablation of the prostate | • Systematic review of 37 studies (3,230 total patients) of focal therapy using seven sources of energy in single-arm retrospective and prospective development studies, including one case series on radiofrequency.  
• Focal therapy seems to have a minor impact on quality of life and genito-urinary function.  
• Oncological effectiveness is yet to be defined against standard of care. |
| Almeida (2016, update of Xie, 2009) for the Technology Assessment Unit of McGill University Health Centre | Key points:                       |
| Radiofrequency ablation for treatment of Barrett’s esophagus | • Systematic review and cost analysis of two randomized controlled trials (RCTs), eight single-arm cohort studies, and one systematic review for high-grade dysplasia, and two RCTs, one single-arm cohort study, and two meta-analyses for low-grade dysplasia.  
• Considered standard of care for treatment of high-grade dysplasia based on good-quality evidence of effectiveness and safety in eliminating dysplastic tissue and higher morbidity associated with esophagectomy.  
• More controversial for low-grade dysplasia based on lower quality evidence of diagnostic accuracy, uncertainty surrounding the progression rates to cancer, and the spontaneous reversion in some patients. Routine use not recommended but may be considered in patients with risk factors suggestive of higher risk of progression to high-grade dysplasia/cancer (e.g., multifocal, long segment, or persistent Barrett’s esophagus). |
| Bi (2016)                                    | Key points:                       |
| Comparison of the effectiveness of radiofrequency ablation with stereotactic body radiation therapy in inoperable stage I non-small cell lung cancer | • Systematic review and pooled analysis of 31 primarily case series of stereotactic body radiation therapy (2,767 patients) and 13 studies of radiofrequency ablation (328 patients).  
• Local tumor control rates (95% confidence interval) at 1, 2, 3, and 5 years:  
  - Radiofrequency ablation = 77% (70% to 85%), 48% (37% to 58%), 55% (47% to 62%), and 42% (30% to 54%), respectively.  
  - Stereotactic body radiation therapy = 97% (96% to 98%), 92% (91% to 94%), 88% (86% to 90%), and 86% (85% to 88%) (P < .001).  
• Differences remained significant after correcting for stage IA and age (P < .001 at 1 year, 2 years, and 3 years; P = .04 at 5 years).  
• No statistically significant difference in overall survival between modalities (P > .05).  
• Most frequent complication of radiofrequency ablation was pneumothorax (31%) and of stereotactic body radiation therapy was (grade ≥ 3) radiation pneumonitis (2%) |
| Chen (2016)                                  | Key points:                       |
| Radiofrequency ablation for treatment of benign thyroid nodules | • Systematic review and meta-analysis 20 single-arm studies comprising data from 1,090 patients with 1,406 benign thyroid nodules.  
• Overall quality: low with significant publication bias.  
• Radiofrequency ablation significantly decreased nodule volume at 1, 3, 6, 12, and the last follow-up months compared to baseline, including a decline by cold and hot nodules.  
• Radiofrequency ablation decreased the largest diameter, symptom score, cosmetic score, triiodothyronine level, and vascular scale, had no effect in free thyroxine, and increased thyrotropin level. |
<p>| Peek (2016)                                  | Key points:                       |</p>
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<th>Content, Methods, Recommendations</th>
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| **Minimally invasive ablative techniques in the treatment of breast cancer** | - Systematic review and meta-analysis of 63 studies, including 1,608 patients with breast tumors treated with radiofrequency ablation, high-intensity focused ultrasound, and cryo-, laser-, or microwave-ablation.  
- Highest rate of complete ablation was achieved with radiofrequency ablation (87.1%, 491/564 patients) and microwave ablation (83.2%, 89/107 patients).  
- Microwave ablation had the highest rate of short-term complications (14.6%, 21/144 patients).  
- Overall recurrence rate = 4.2% (24/570 patients) and most often with laser ablation (10.7%, 11/103 patients).  
- Radiofrequency ablation had the shortest treatment times (15.6 ± 5.6 min) and high-intensity focused ultrasound the longest (101.5 ± 46.6 min).  
- Adequately powered and prospectively conducted cohort trials are needed to confirm complete pathological ablation in all patients. |
| **Fegrachi (2014)** | **Key points:**  
- Systematic review of five non-comparative studies (158 total patients).  
- Overall quality: low with high risk of bias and heterogeneous study populations and outcomes.  
- Median survival after radiofrequency ablation = three months to 33 months.  
- Procedure-related morbidity = 4% to 37%, overall mortality = 0% to 19%, overall morbidity = 10% to 43%. Pooling of data was not done due to heterogeneous study populations and outcomes.  
- Radiofrequency ablation appears safe when used with the correct temperature and at an appropriate distance from vital structures, but multi-center RCTs are needed to determine the true effect size of radiofrequency ablation and to minimize bias. |
| **Fischer (2012a) for the LBIHTA** | **Radiofrequency ablation for the treatment of benign and malignant nodules of endocrine organs (thyroid gland and adrenal gland)**  
**Key points:**  
- Systematic review of three case series of benign thyroid nodules, one case series of thyroid cancer, and two case series of adrenal tumors.  
- Overall quality: very low.  
- Thyroid tumors: radiofrequency ablation is safe and improves tumor-related symptoms.  
- Adrenal tumors: radiofrequency ablation is safe and possibly improves aldosteronism and reduces recurrence.  
- Higher-quality studies are needed to confirm these findings. |
| **Fischer (2012b) for the LBIHTA** | **Radiofrequency ablation for the treatment of head and neck cancer**  
**Key points:**  
- Systematic review identified one case series of 21 patients with various recurrent or unresectable/inoperable head and neck cancer aged around 63 years. Follow up = approximately 44 days; drop-out rate = 38%.  
- Marginal improvement in quality of life, median survival was four months, 45% with serious complications, and 5% procedure-related mortality. |
| **Rosenthal (2012)** | **Critical review and state of the art in interventional oncology: benign and**  
**Key points:**  
- Percutaneous radiofrequency ablation is an important treatment for both benign bone tumors and palliation of metastases involving bone and soft-tissue sites beyond the liver and lung. |
Image-guided radiofrequency ablation is now the standard treatment for osteoid osteoma, as the procedure can be performed with higher rates of technical success, decreased morbidity, and lower cost than those with open surgery.

Several ablation methods can effectively treat focal metastatic skeletal disease, primarily with the goal of durable palliation of pain, particularly when conventional therapies, including chemotherapy and external-beam radiation, have failed.

Warmuth (2012) for the LBIHTA
Radiofrequency ablation of bone tumors (osteoid-osteoma and osseus metastases)

Key points:
- Systematic review of four prospective case series (175 total patients aged 15 years to 23 years) of radiofrequency ablation for osteoid osteomas with a maximum tumor size = 15 mm, and two prospective case series (79 total patients aged 58 years to 62 years) with osseous metastases with a mean tumor size of 5 cm.
- Osteoid osteomas: residual and recurrent symptoms (pain) in 5% to 26% and 0% to 8% of patients, respectively. Procedure-associated morbidity varied from 0% to 26%.
- Painful osseous metastases: statistically significant reduced pain and improved mood at one and three months following radiofrequency ablation. The local recurrence rate was 42% after 6 months. Intervention-associated pain was observed in 11% to 75% of patients, other adverse events were seen in 2% to 13% of patients.

Sher (2011)
Cost-effectiveness analysis of stereotactic body radiation therapy and radiofrequency ablation for medically inoperable, early-stage non-small cell lung cancer

Key points:
- Markov model describes health states of 65-year-old men with medically inoperable non-small cell lung cancer after treatment with three-dimensional conformal radiation therapy, stereotactic body radiation therapy, and radiofrequency ablation. Patients were assumed to receive supportive care after recurrence. Utility values, recurrence risks, and costs were adapted from the literature, and sensitivity analyses performed.
- Stereotactic body radiation therapy was the most cost-effective treatment over a wide range of treatment and disease assumptions. On the basis of efficacy and cost, stereotactic body radiation therapy should be the primary treatment approach for this disease.

References

Professional society guidelines/other:

American College of Radiology ACR Appropriateness Criteria®:


- Gastric cancer. Version 5.2017.(g)
- Rectal cancer. Version 3.2017.(c)
- Soft tissue sarcoma. Version 1.2018.(c)
- Thyroid carcinoma. Version 2.2017.(e)

National Institute for Health and Care Excellence (NICE):
- Radiofrequency ablation for symptomatic interdigital (Morton's) neuroma [IPG539]. Evidence-based recommendations on radiofrequency ablation for symptomatic interdigital


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.


**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.
Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>20982</td>
<td>Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency</td>
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<tr>
<td>32998</td>
<td>Ablation therapy for reduction or eradication of one or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral</td>
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<td>43270</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre-hyphen and post-hyphendilation and guide wire passage, when performed)</td>
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<tr>
<td>44369</td>
<td>Small intestinal endoscopy, enteroscopy, beyond second portion of duodenum, not including ileum; with ablation of tumor(s), polyp(s) or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique</td>
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<td>47381</td>
<td>Cryosurgical</td>
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<td>50592</td>
<td>Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency</td>
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<td>53850</td>
<td>Transurethral destruction of the prostate tissue; by microwave thermotherapy</td>
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<td>53852</td>
<td>by radiofrequency thermotherapy</td>
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<tr>
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<th>Description</th>
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<tr>
<td>C16.0 - C18.9</td>
<td>Malignant neoplasm of stomach, small intestine, and colon [metastatic gastrointestinal stromal tumors (GIST) with limited progression]</td>
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<td>C34.00 - C34.92</td>
<td>Malignant neoplasm of bronchus and lung</td>
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<td>C49.0 - C49.9</td>
<td>Malignant neoplasm of other connective and soft tissue of upper limb, including shoulder, lower limb, including hip, and trunk unspecified [in symptomatic persons with disseminated metastases]</td>
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<td>C64.1 - C64.9</td>
<td>Malignant neoplasm of kidney, except renal pelvis</td>
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<td>C78.00 - C78.02</td>
<td>Secondary malignant neoplasm of lung</td>
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<td>D02.20 - D02.22</td>
<td>Carcinoma in situ bronchus and lung</td>
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<td>D16.00 - D16.9</td>
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<td>Q60.0</td>
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<td>Z90.5</td>
<td>Acquired absence of kidney</td>
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<tr>
<td>HCPCS Level II Code</td>
<td>Description</td>
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<tr>
<td>C1886</td>
<td>Catheter, extravascular tissue ablation, any modality</td>
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