



Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Radiofrequency Ablation for Lung Cancer		
MNG #: 091	<input checked="" type="checkbox"/> SCO <input checked="" type="checkbox"/> One Care <input checked="" type="checkbox"/> MAPD-MA Medicare Preferred <input checked="" type="checkbox"/> MAPD-MA Medicare Value <input checked="" type="checkbox"/> MAPD-RI Medicare Preferred <input checked="" type="checkbox"/> MAPD-RI Medicare Value <input checked="" type="checkbox"/> DSNP-RI Medicare Maximus	Prior Authorization Needed? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Clinical: <input checked="" type="checkbox"/>	Operational: <input type="checkbox"/>	Informational: <input type="checkbox"/>
Medicare Benefit: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Approval Date: 11/04/2021;	Effective Date: 2/06/2022;
Last Revised Date:	Next Annual Review Date: 11/04/2022;	Retire Date:

OVERVIEW:

In the United States, *lung cancer* is the second most common cancer and the second most frequent site of metastatic disease. The preferred treatment for early stage lung cancer and lung metastases is surgery, however, only a small minority of patients may meet the criteria. Specifically, surgical resection may be inappropriate for patients with poor cardiopulmonary function, who have insufficient pulmonary reserve, and who have multiple medical comorbidities that place them at high risk for complications. Alternative non-surgical options for these patients are radiation and percutaneous ablative therapies.

Radiofrequency ablative (RFA) therapy is a technique for the treatment of lung malignancies by using electromagnetic energy to induce frictional heating to destroy the targeted cancer cells. These cells are not removed and will be gradually replaced by fibrosis and scar tissue. The goal of RFA therapy is to control local tumor growth, prevent recurrence, and palliate symptoms. Compared to surgical resection, RFA therapy has similar overall survival, mortality, and procedure-related complication rates. The hypothesized advantages of RFA over surgery are improved local control, the ability to perform multiple sessions, and improvements related to minimally invasive procedures (such as preservation of normal organ tissue, decreased morbidity, decreased complications, and decreased length of hospitalization).

DEFINITIONS:

Computed Tomography (CT): Imaging procedure that uses specialized x-ray equipment to create scans of areas inside the body. The x-ray source produces a fan shaped beam that passes through the section of the patient’s body to obtain snapshots at various angles. The image data is sent to a computer to reconstruct all of the individual snapshots into cross-sectional images of the internal organs and tissues.

Lung Cancer: Refers to the proliferation of malignant cells that originate in the airways and pulmonary parenchyma. There are two types of lung cancers: *non-small cell lung cancer* and *small cell lung cancer*.



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Non-Small Cell Lung Cancer (NSCLC): Malignant tumor of the lung that is characterized by genetic mutations (in oncogenes, tumor suppressor genes, and chromatin modifying genes), gene rearrangements, gene amplifications, gene deletions, and epigenetic changes. NSCLC accounts for approximately 85% to 90% of lung cancer cases. The subtypes include non-squamous cell carcinoma (adenocarcinoma and large cell carcinoma) and squamous cell carcinoma.

Radiofrequency Ablative (RFA) Therapy: minimally invasive procedure in which a needle electrode is inserted by image guidance (via *computed tomography*) into the center of a lesion or tumor. The radiofrequency generator oscillates in a closed-loop circuit between the applicator and the grounding pad(s) placed on the patient's skin to induce frictional heating resulting in temperatures of greater than 60°C. This creates a zone of tissue necrosis that encompasses the tumor and the margin of normal parenchyma.

Small Cell Lung Cancer (SCLC): Malignant tumor of the lung that is characterized by mutations that cause autocrine growth loops, activation of proto-oncogenes, and the loss or inactivation of tumor-suppressor genes. SCLC is described as having a rapid doubling time, high growth fraction, and can result in widespread metastases early in the disease. The subtypes include neuroendocrine tumor, pure small cell lung cancer, and combined small cell lung cancer.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance may cover and consider radiofrequency ablation (RFA) therapy as medically necessary when all of the following criteria are met:

- For the treatment of isolated peripheral non-small cell lung cancer lesion, OR
- For the treatment of malignant non-pulmonary tumor(s) metastatic to the lung, AND
 - The size of the lesion or tumor is ≤ 3 cm in size,
 - The tumor is at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery, and/or heart,
 - There is ≤ 3 tumors per lung,
- The member has a medical comorbidity that renders them unfit for surgical resection or radiation treatment OR the member is unable to tolerate OR declines surgical or radiation treatment,
- Based on medical consultation with a specialist, surgical resection or radiation treatment is likely to substantially worsen the member's pulmonary status, AND
- The provider has discussed the risks and complications of the proposed treatment, and has obtained informed consent from the member

LIMITATIONS/EXCLUSIONS:

Commonwealth Care Alliance will limit the following:

- Repeat RFA therapy may be considered after 12 months have elapsed from the initial treatment,
 - Subsequent RFA therapy requests may be reviewed on a case-by-case basis by CCA Medical Director upon receipt of clinical documentation that substantiates medical necessity
- Tumors within the same lung may be treated with RFA therapy in the same session
 - Bilateral lung tumors should not be treated with RFA therapy in the same session



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Commonwealth Care Alliance will not cover and does not consider radiofrequency ablation therapy as medically necessary for the following:

- If the member has a life expectancy of < 1 year,
- If the member has an untreatable coagulopathy,
- If RFA therapy is used as a curative treatment of the following:
 - Primary or metastatic malignant neoplasms in persons who are able to tolerate surgical resection,
 - Initial treatment of painful bony metastases,
 - Osteoid osteomas that can be managed with medical treatment,
 - Hepatic metastases from non-colonic primary cancers or those > 5 cm,
 - All other tumors outside of the liver including but not limited to: head and neck, thyroid, adrenal gland, ovary, pelvic or abdominal metastases of unspecified origin, and tumors of the breast

AUTHORIZATION:

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not signify that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider’s agreement with the Plan (including complying with Plan’s Provider Manual specifications).

CPT Code	Description
32998	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

REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.



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Disclaimer:

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

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ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION



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APPROVALS:

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11/04/2021

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