Radiofrequency Ablation for Lung Cancer
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Radiofrequency Ablation for Lung Cancer		
MNG #: 091	**☒SCO ☒One Care** **☒ MA Medicare Premier** **☒ MA Medicare Value** **☒ RI Medicare Preferred** **☒ RI Medicare Value** **☒ RI Medicare Maximum**	**Prior Authorization Needed?** **☒ Yes (always required)** **☐ Yes (only in certain situations. See this MNG for details)** **☐ No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Benefit Type: **☐ Medicare** **☒ Medicaid**	**Approval Date:** 11/04/2021;	**Effective Date:** 2/06/2022;
Last Revised Date: 3/28/2023;	**Next Annual Review Date:** 11/04/2022; 3/28/2024;	**Retire Date:**

OVERVIEW:

Non-small cell lung cancer (NSCLC) is a malignant tumor that arises from the epithelial cells of the lung of the central bronchi to terminal alveoli. Patients with NSCLC tend to have disease that is limited to one lung, do not involve the mediastinum, or may involve more distant sites that have localized stage I or II disease. The treatment of lung cancer depends on the tumor histology, extent, and patient-specific factors (e.g., age, pulmonary function, and comorbidities). Surgery remains to be the standard first-line treatment for medically operable patients with clinical stage I and II NSCLC, 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 that are currently being studied and used for these patients are chemotherapy, stereotactic body radiation therapy (SBRT), proton beam or carbon ion therapy, thermal ablation (e.g., radiofrequency ablation, cryoablation, microwave ablation, laser ablation), irreversible electroporation, or a combination of these treatment modalities.

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. The goal of RFA therapy is to control local tumor growth, prevent recurrence, and palliate symptoms. The hypothesized advantages of RFA over surgery are improved local control, the ability to perform multiple sessions, preservation of normal organ tissue, decreased morbidity, decreased complications, and decreased length of hospitalization.

DEFINITIONS:

Non-Small Cell Lung Cancer (NSCLC): Malignant tumor of the lung that arises from the epithelial cells of the lung in the central bronchi to the terminal alveoli. The subtypes include non-squamous cell carcinoma (adenocarcinoma and large cell carcinoma) and squamous cell carcinoma. They correlate with the site of origin and reflect the variation in the respiratory tract epithelium. It is hypothesized that tobacco use, environmental exposures, and genetic predisposition causes genetic mutations (in oncogenes, tumor suppressor genes, and chromatin modifying

genes), gene rearrangements, gene amplifications, gene deletions, and epigenetic changes.

Radiofrequency Ablative (RFA) Therapy: Image-guided treatment that applies electromagnetic thermal energy into the center of a lesion or tumor to produce irreversible and immediate cell death. 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. Cells killed by the RFA approach are not removed but will be gradually replaced by fibrosis and scar tissue.

Stereotactic Body Radiation Therapy (SBRT): Type of external radiation therapy that uses special equipment to position a patient and precisely deliver a limited number (one to five) high-dose fractions of radiation to tumors in the body (with the exception of the brain) over several days. SBRT is the primary alternative to surgery for patients with clinical stage I or II NSCLC. This therapy has been shown to provide disease control for early-stage NSCLC and spare normal tissue.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses InterQual Smart Sheets, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists.

Clinical Coverage Criteria:

1. Commonwealth Care Alliance may cover and consider radiofrequency ablation (RFA) therapy as medically necessary for the treatment of an **isolated peripheral non-small cell lung cancer lesion** or **malignant non-pulmonary tumor(s) metastatic to the lung** when all of the following criteria are met:
   a. The size of the lesion or tumor is ≤ 3 cm in size; *and*
   b. The tumor is at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery, and/or heart; *and*
   c. There is ≤ 3 tumors per lung; *and*
   d. The member has a medical comorbidity that renders them unfit for surgical resection, *stereotactic body radiation therapy* (SBRT) or definitive radiation treatment (RT) OR the member is unable to tolerate or declines surgery, SBRT or RT; *and*
   e. Based on medical consultation with a specialist, surgical resection, SBRT, or RTIs likely to substantially worsen the member's pulmonary status; *and*
   f. The provider has discussed the risks and complications of the proposed treatment and has obtained informed consent from the member.

LIMITATIONS/EXCLUSIONS:

1. Commonwealth Care Alliance will limit the following:
   a. Tumors within the same lung may be treated with RFA therapy in the same session, however, bilateral lung tumors should not be treated in the same session due to the relative risk of bilateral pneumothorax.

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b. Requests for RFA therapy for indications other than those listed above are reviewed on a case-by-case basis by a CCA Medical Director upon receipt of clinical documentation that substantiates medical necessity.

2. Commonwealth Care Alliance will not cover and does not consider radiofrequency ablation therapy as medically necessary for the following:
   a. If the member has a life expectancy of < 1 year,
   b. If the member has an untreatable coagulopathy or an end-stage lung disease and/or respiratory failure,
   c. If RFA therapy is used as a curative treatment of the following:
      i. Small cell lung cancer (SCLC),
      ii. Primary or metastatic malignant neoplasms in persons who are able to tolerate surgical resection,
      iii. Initial treatment of painful bony metastases,
      iv. Osteoid osteomas that can be managed with medical treatment,
      v. Hepatic metastases from non-colonic primary cancers or those > 5 cm,
      vi. Brunner's gland hyperplasia,
      vii. Renal cysts, renal allograft neoplasms, or sporadic renal angiomyolipomas,
      viii. 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	Coverage	
		SCO/One Care	Medicare Advantage
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	Yes	No

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 by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

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This MNG references the specific regulations, coverage, limitations, service conditions, and/or prior authorization requirements in the following:

1. MassHealth, 101 CMR 316.05: Maximum Allowable Fees – Surgical Services, Effective date: 8/11/2017

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
12/31/23	Utilization Management Committee approval
3/28/2023	Annual policy review. Overview, definitions, clinical coverage criteria, limitations, and references updated. Removed the criteria for "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…" Added that "requests for RFA for indications other than those listed…be reviewed on a case-by-case basis…" Added to the exclusions list to include indications where the effectiveness has not been established.

APPROVALS:

David Mello	Senior Medical Director, Utilization Review and Medical Policy
CCA Senior Clinical Lead [Print]	**Title [Print]**
	12/31/23
Signature	**Date**

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Click here to enter text.	
CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**
Nazlim Hagmann	Chief Medical Officer
CCA CMO or Designee [Print]	**Title [Print]**
	3/28/2023
Signature	**Date**