Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Medicare Advantage Medical Policy #MA-126
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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Stereotactic Radiosurgery and Stereotactic Body Radiotherapy is addressed separately in medical policy MA-011.

Note: The use of Radiofrequency Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy MA-127.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Osteoid Osteomas

Based on review of available data, the Health Plan may consider radiofrequency ablation (RFA) of osteoid osteomas to be **eligible for coverage.****

Osteolytic Bone Metastases

Based on review of available data, the Health Plan may consider radiofrequency ablation (RFA) of painful bony metastases in individuals who have failed or who are poor candidates for standard treatments such as opioids or radiation therapy to be **eligible for coverage.****

Localized Renal Malignancy

Based on review of available data, the Health Plan may consider radiofrequency ablation (RFA) for clinically localized, suspected renal malignancy for individuals with peripheral lesions that are less than or equal to 4 cm in diameter to be **eligible for coverage.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Non-Small Cell Lung Cancer

Based on review of available data, the Health Plan may consider radiofrequency ablation (RFA) of non-small cell lung cancer (NSCLC) to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for RFA of NSCLC will be considered when **ALL** of the following criteria are met:

- Surgical or radiation treatment with curative intent is considered appropriate based on stage of disease, however medical co-morbidity renders the individual unfit for those interventions; **AND**
- No tumor has a maximum diameter of greater than 3.0 cm; **AND**
- Tumors are located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

Metastatic Malignant Tumor(s) to the Lung
Based on review of available data, the Health Plan may consider radiofrequency ablation (RFA) to treat malignant nonpulmonary tumor(s) metastatic to the lung to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for RFA to treat malignant nonpulmonary tumor(s) metastatic to the lung will be considered when **ALL** of the following criteria are met:

- When it is necessary to preserve lung function because surgical resection or radiotherapy is likely to worsen pulmonary status substantially, OR when the individual is not considered a surgical candidate; **AND**
- There is no evidence of extra-pulmonary metastases; **AND**
- No more than 3 tumors per lung should be ablated; **AND**
- No tumor has a maximum diameter greater than 3.0 cm; **AND**
- Tumors are located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart; **AND**
- If a repeat procedure, at least 12 months have elapsed since the prior ablation.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers radiofrequency ablation (RFA) of tumors outside the liver to be **investigational*** when the above criteria are not met and for all other tumors, including but not limited to:

- Breast, the head and neck, thyroid, pancreas, adrenal gland, ovary, and pelvic/abdominal metastases of unspecified origin.

Background/Overview

Health Disparities in Certain Solid Tumor Types
Based on data from 2014 through 2018, age-adjusted breast cancer mortality is approximately 40% higher among Black women compared to non-Hispanic White women in the United States (27.7 vs

20.0 deaths per 100,000 women), despite a lower overall incidence of breast cancer among Black women (125.8 vs 139.2 cases per 100,000 women). Experts postulate that this divergence in mortality may be related to access issues– Black women are more likely than White women to lack health insurance, limiting access to screening and appropriate therapies. Socioeconomic status is also a driver in health and health outcome disparities related to breast cancer. Women with low incomes have significantly lower rates of breast cancer screening, a higher probability of late-stage diagnosis, and are less likely to receive high-quality care, resulting in higher mortality from breast cancer.

Based on data from 2016 through 2020, kidney cancer is more common in men than women and occurs more often in American Indian and Alaskan Native individuals, followed by Black and Hispanic individuals. American Indians and Alaska Natives have higher death rates from kidney cancer than any other racial or ethnic group. A cohort study by Howard et al (2021) included 158,445 patients with localized kidney cancer from the National Cancer Database between 2010 and 2017. Investigators found that female patients were treated more aggressively compared with male patients, with lower adjusted odds of undertreatment and higher adjusted odds of overtreatment. They also found that Black and Hispanic patients had higher adjusted odds of undertreatment and overtreatment compared to White patients, and uninsured status was associated with lower adjusted odds of overtreatment and higher adjusted odds of undertreatment. These results suggest that sex, race and ethnicity, and socioeconomic status are associated with disparities in guideline-based treatment for localized kidney cancer, specifically, with increased rates of non-guideline-based treatment for women and Black and Hispanic patients.

Radiofrequency Ablation
Radiofrequency ablation (RFA) was initially developed to treat inoperable tumors of the liver (see medical policy 00182). Recently, studies have reported on the use of RFA to treat other tumors. For some of these, RFA is being investigated as an alternative to surgery for operable tumors. Well-established local or systemic treatment alternatives are available for each of these malignancies. The hypothesized advantages of RFA for these cancers include improved local control and those common to any minimally invasive procedure (eg, preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Goals of RFA may include (1) controlling local tumor growth and preventing recurrence; (2) palliating symptoms; and (3) extending survival duration for patients with certain tumors. The effective volume of RFA depends on the frequency and duration of applied current, local tissue characteristics, and probe configuration (eg, single vs. multiple tips). RFA can be performed as an open surgical procedure, laparoscopically or percutaneously, with ultrasound or computed tomography guidance.

Potential complications associated with RFA include those caused by heat damage to normal tissue adjacent to the tumor (eg, intestinal damage during RFA of kidney), structural damage along the probe track (eg, pneumothorax as a consequence of procedures on the lung), and secondary tumors (if cells seed during probe removal).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) issued a statement in September 2008, concerning the regulatory status of RFA. The FDA has cleared RFA devices for the general indication of soft tissue cutting, coagulation, and ablation by thermal coagulation necrosis. Under this general indication, RFA can be used to ablate tumors, including lung tumors. Some RFA devices have been cleared for additional specific treatment indications, including partial or complete ablation of nonresectable liver lesions and palliation of pain associated with metastatic lesions involving bone. The FDA has not cleared any RFA devices for the specific treatment indication of partial or complete ablation of lung tumors, citing lack of sufficient clinical data to establish safety and effectiveness for this purpose. The FDA has received reports of death and serious injuries associated with the use of RFA devices in the treatment of lung tumors.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

In radiofrequency ablation (RFA), a probe is inserted into the center of a tumor; then, prong-shaped, non-insulated electrodes are projected into the tumor. Next, heat is generated locally by an alternating, high-frequency current that travels through the electrodes. The localized heat treats the tissue adjacent to the probe, resulting in a 3 cm to 5.5 cm sphere of dead tissue. The cells killed by RFA are not removed but are gradually replaced by fibrosis and scar tissue. If there is a local recurrence, it occurs at the edge and can sometimes be retreated. RFA may be performed percutaneously, laparoscopically, or as an open procedure.

Summary of Evidence

For individuals who have painful osteolytic bone metastases who have failed or are poor candidates for standard treatments who receive RFA, the evidence includes a prospective cohort study and case series. Relevant outcomes are symptoms, change in disease status, quality of life (QOL), medication use, and treatment-related morbidity. A prospective cohort study and case series have shown clinically significant pain relief (defined as a decrease of 2 units from baseline on the Brief Pain Inventory scale) or reduction in opioid use following treatment of painful osteolytic metastases. A multicenter, prospective study reported significant reductions in pain through the 6-month follow-up period, with 59% of patients achieving immediate improvement in pain within 3 days of RFA. The population is comprised of patients with few or no treatment options, for whom short-term pain relief is an appropriate clinical outcome. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have painful osteoid osteomas who receive RFA, the evidence includes numerous observational studies and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. In a systematic review of thermal ablation techniques, clinical success (pain-free) was achieved in 94% to 98% of patients. Most patients (89% to 96%) remained pain-free when assessed during longer-term follow-up. Another systematic review reported similar success rates noting an average 8.3% failure rate among patients receiving computed tomography-guided RFA. Although no randomized trials of RFA for osteoid osteomas have been performed, the uncontrolled studies have demonstrated RFA can provide adequate symptom relief with minimal complications, for a population for whom short-term symptom relief and avoidance of invasive procedures are appropriate clinical outcomes. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have localized renal cell carcinoma (RCC) that is no more than 4 cm in size who receive RFA, the evidence includes a randomized controlled trial (RCT), numerous observational studies, and systematic reviews of these studies. Relevant outcomes are overall survival (OS), change in disease status, QOL, and treatment-related morbidity. A recent meta-analysis that included only an RCT and cohort studies found that RFA was as effective as nephrectomy for small renal tumors, with a reduction in complications. Another recent meta-analysis found that partial nephrectomy (PN) was superior to ablative techniques (the study included RFA but also cryoablation and microwave ablation) in overall mortality and local recurrence but not in cancer-specific mortality. It also found fewer complications and improved renal function with ablation. A meta-analysis from 2022 found that PN was superior to ablation (RFA, cryoablation, and microwave ablation) in local recurrence. Overall complications, decline in renal function, and cancer-specific mortality rates did not differ between ablation and PN. Although inconsistent, the evidence does suggest that, for small renal tumors, RFA may result in a similar rate of disease progression with a lower complication rate than nephrectomy. However, comparative trials are needed to determine with greater certainty the effects of these treatments in the same patient population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have inoperable primary pulmonary tumors or nonpulmonary tumors metastatic to the lung who receive RFA, the evidence includes prospective observational studies and systematic reviews of these studies. Relevant outcomes are OS, change in disease status, QOL, and treatment-related morbidity. A multicenter study found that for tumors less than 3.5 cm in size, RFA can lead to a complete response in as many as 88% of patients for at least 1 year. Two-year survival rates have been reported to range from 41% to 75% in case series, with 5-year survival rates of 20% to 27%. In general, the evidence suggests that RFA results in adequate survival and tumor control in patients who are not surgical candidates, with low morbidity rates. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have breast tumors who receive RFA, the evidence includes observational studies and systematic reviews of these studies. Relevant outcomes are OS, change in disease status, QOL, and treatment-related morbidity. Evidence has reported varied and incomplete ablation rates with concerns about postablation tumor cell viability. Long-term improvements in health outcomes have not been demonstrated. Additionally, available studies do not permit comparisons with conventional breast-conserving procedures. Further prospective studies, with long-term follow-up, should focus on whether RFA of the breast for small tumors can provide local control and survival rates compared with conventional breast-conserving treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have benign thyroid tumors who receive RFA, the evidence includes RCTs, prospective studies, case series, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. Systematic reviews have demonstrated that RFA results in a significant reduction in thyroid nodule size, with a 2020 review showing that these changes remain durable through at least 36 months. Complication rates are generally low, but include voice changes. The data are limited by significant heterogeneity in meta-analyses, a lack of generalizability to populations outside Republic of Korea and Italy, and a lack of comparators more relevant to practice in the United States. Further studies comparing RFA to percutaneous ethanol injection (PEI) or surgery would be more informative in determining the potential utility of RFA in patients with symptomatic or large benign thyroid tumors as these are the recommended treatment options per the American Thyroid Association. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have miscellaneous tumors (eg, head and neck, thyroid cancer, pancreas) who receive RFA, the evidence includes a few case series, prospective observational studies, and retrospective comparative studies. Relevant outcomes are OS, change in disease status, QOL, and treatment-related morbidity. There is a limited evidence base for these tumor types. Reporting on outcomes or comparisons with other treatments is limited. These studies do not permit conclusions on the health benefits of RFA. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Clinical input obtained in 2010 supported use of RFA for localized RCC that is no more than 4 cm in size when preservation of kidney function is necessary, and a standard surgical approach is likely to worsen kidney function substantially or when the patient is not considered a surgical candidate. Thus, absent other treatment options, RFA for small renal cell tumors was judged to be medically necessary.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

2010 Input

In response to requests, input was received from 2 physician specialty societies (4 reviewers) and 2 academic medical centers (4 reviewers) while this policy was under review in 2010. Input was similar to that received in 2009, except support for the use of radiofrequency ablation (RFA) to treat lung tumors was declined (only 1 respondent indicated this was an option in tumors metastatic to lung). One respondent also indicated a potential use for adrenal tumors. Input supported RFA for localized renal cell carcinoma no more than 4 cm in size when preservation of kidney function is necessary and a standard surgical approach would likely substantially worsen kidney function or when the patient is not considered a surgical candidate.

2009 Input

In response to requests, input was received from 1 physician specialty society (4 reviews) and from 2 academic medical centers (3 reviews) while this policy was under review in 2009. All reviewers supported the use of RFA in the treatment of painful bone metastases that have failed standard treatment and in the treatment of osteoid osteomas. Reviewers were divided over the use of RFA for lung tumors, although several agreed that, while it may be useful in a select population of patients, it should be used in the clinical trial setting. Reviewers were also split with regard to RFA in the treatment of renal tumors, with some supporting its use in a select population of patients. With the exception of 1 disagreement and 1 nonresponse, the reviewers agreed to the investigational statement on the use of RFA in all other tumors outside the liver that are addressed in this policy.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Chest Physicians

The American College of Chest Physicians (2013) guidelines on the treatment of stage I and II non-small-cell lung cancer (NSCLC) have indicated RFA has been used effectively in clinical stage I NSCLC. Therefore, in medically inoperable patients, peripheral NSCLC tumors less than 3 cm may be treated with RFA. The College also collaborated with the Society of Thoracic Surgeons to develop consensus guidelines on the treatment of high-risk patients with stage I NSCLC. These 2012 consensus guidelines indicated RFA is an alternative treatment option for patients who are not surgical candidates due to severe medical comorbidity.

American Head and Neck Society - Endocrine Surgery Section
An international, multidisciplinary consensus statement on RFA and related ultrasound-guided ablation technologies for the treatment of benign and malignant thyroid disease was released in 2022 through a collaboration of international professional societies, including the Endocrine Surgery Section of the American Head and Neck Society. Select relevant recommendations from the guideline are listed in Table 1.

Table 1. Summary of RFA Recommendations for Treatment of Benign and Malignant Thyroid Disease*

Recommendation 1	US-guided ablation procedures may be used as a first-line alternative to surgery for patients with benign thyroid nodules contributing to compressive and/or cosmetic symptoms.
Recommendation 2	Although less efficacious than surgery or RAI in normalizing thyroid function, thermal ablation procedures can be a safe therapeutic alternative in patients with an autonomously functional thyroid nodule and contraindications to first-line techniques.
Recommendation 3a	US-guided ablation procedures may be considered in patients with suitable primary papillary microcarcinoma who are unfit for surgery or decline surgery or active surveillance
Recommendation 3b	US-guided ablation procedures may be considered in patients with suitable recurrent papillary thyroid carcinoma who are unfit for surgery or decline surgery or active surveillance
Recommendation 3c	Repeat ablation of a benign nodule can be considered for remnant nodular tissue contributing to unresolved symptomatic or cosmetic concerns

*This is not a comprehensive list of recommendations from the guideline.
RAI: radioactive iodine; RFA: radiofrequency ablation; US: Ultrasound.

American Urological Association
The American Urological Association (AUA; 2017) guideline on renal masses and localized renal cancer affirms that partial nephrectomy should be prioritized for the management of cT1a renal masses when intervention is indicated. Thermal ablation should be considered "as an alternate approach for the management of cT1a renal masses <3 cm in size." The guidelines were updated in 2021 and recommendations are generally consistent with what was published in the 2017 guideline. The 2021 AUA guideline explicitly states that RFA and cryoablation may be offered as options to patients who elect thermal ablation.

American Thyroid Association
The American Thyroid Association (2015) guideline on the management of thyroid nodules and differentiated thyroid cancer provides recommendations for management. Patients with a benign cytology diagnosis or those very unlikely to be malignant (eg, purely cystic nodule) should undergo

surveillance with the frequency determined by the level of suspicion for a missed malignancy. Medical or surgical intervention is considered if the nodules are large (>4 cm), causing compressive or structural symptoms, or if there is clinical concern. Recurrent cystic thyroid nodules with benign cytology should be considered for surgical removal or percutaneous ethanol injection. For differentiated thyroid cancer, "localized treatments with thermal (radiofrequency or cryo-) ablation, ethanol ablation, or chemoembolization may be beneficial in patients with a single or a few metastases and in those with metastases at high risk of local complications."

National Comprehensive Cancer Network
The National Comprehensive Cancer Network (NCCN) guidelines for the treatment of NSCLC (v.3.2023) state: "For medically operable disease, resection is the preferred local treatment modality (other modalities include SABR [stereotactic ablative radiotherapy], thermal ablation such as radiofrequency ablation, and cryotherapy)." For patients who are not amenable to surgery, image-guided thermal ablation therapy (IGTA; includes RFA, microwave ablation, and cryoablation) may be considered. The guidance states "IGTA is an option for the management of NSCLC lesions <3 cm. Ablation for NSCLC lesions >3 cm may be associated with higher rates of local recurrence and complications."

The NCCN guidelines for thyroid carcinoma (v.3.2023) indicate that local therapies such as RFA may be considered for locoregional recurrence of thyroid carcinoma-papillary carcinoma in select patients with limited burden nodal disease. Additionally, local therapies, including RFA, can be considered in those with metastatic disease.

The NCCN guidelines (v.1.2024) for renal cancer indicate that “thermal ablation (eg, cryosurgery, radiofrequency ablation, microwave ablation) is an option for the management of clinical stage T1 renal lesions. Thermal ablation is an option for clinical T1b masses in select patients not eligible for surgery. Biopsy of lesions is recommended to be done prior to or at time of ablation. Ablative techniques may require mutiple treatments to achieve the same oncologic outcomes as conventional surgery."

The NCCN colon cancer guidelines (v.2.2023) state that “resection is the standard approach for the local treatment of resectable metastatic disease. However, patients with liver or lung oligometastases can also be considered for tumor ablation therapy, particularly in cases that may not be optimal for resection. There is extensive evidence on the use of RFA as a reasonable treatment option for non-surgical candidates and for recurrent disease after hepatectomy with small liver metastases that can be treated with clear margins.”

The NCCN guidelines for head and neck cancers (v.2.2023), breast cancer (v.4.2023), bone cancer (v.1.2024), and pancreatic adenocarcinoma (v.2.2023) do not mention RFA.

National Institute for Health and Care Excellence
The NICE guidance (2004) on osteoid osteoma indicated that "current evidence on the safety and efficacy of computed tomography (CT)-guided thermocoagulation of osteoid osteoma appears adequate to support its use...."

Updated NICE guidance (2010) on renal cancer has indicated that "evidence on the safety and efficacy of percutaneous radiofrequency ablation (RFA) … in the short and medium term appears adequate to support the use of this procedure provided that patients are followed up in the long term."

The NICE guidance (2010) on RFA for primary and secondary lung cancers has stated: "Current evidence on the efficacy of percutaneous radiofrequency ablation (RFA) … is adequate in terms of tumor control." The NICE also indicated RFA might "be used in patients with small, early-stage lung cancers or small numbers of lung metastases who are unsuitable for, or prefer not to undergo, surgery. It may also have a place in multi-modality treatment of more advanced primary lung cancers." The guidance warned of serious complications (eg, pneumothorax) among lung cancer patients.

The NICE guidance (2016) on benign thyroid nodules stated: "Current evidence on the safety and efficacy of ultrasound-guided percutaneous radiofrequency ablation … is adequate to support the use of this procedure…."

Society of Interventional Radiology
The Society of Interventional Radiology (2020) published a position statement on the role of percutaneous ablation in renal cell carcinoma. Their relevant recommendations are as follows:

- "In patients with small renal tumors (stage T1a), percutaneous thermal ablation is a safe and effective treatment with fewer complications than nephrectomy and acceptable long-term oncological and survival outcomes. (Level of Evidence: C; Strength of Recommendation: Moderate)"
- "In selected patients with suspected T1a renal cell carcinoma, percutaneous thermal ablation should be offered over active surveillance. (Level of Evidence: C; Strength of Recommendation: Moderate)"
- "In high-risk patients with T1b renal cell carcinoma who are not surgical candidates, percutaneous thermal ablation may be an appropriate treatment option; however, further research in this area is required. (Level of Evidence: D; Strength of Recommendation: Weak)"
- "Radiofrequency ablation, cryoablation, and microwave ablation are all appropriate modalities for thermal ablation, and method of ablation should be left to the discretion of the operating physician. (Level of Evidence: D; Strength of Recommendation: Weak)"

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05189821	RFA Treatment for Papillary Thyroid Microcarcinoma Cohort	50	Nov 2026
NCT05189808	Radiofrequency Ablation for Indeterminate Bethesda III Thyroid Nodules	50	Aug 2024
NCT03808779	A Multicenter, Randomized and Controlled Trial of Radiofrequency Ablation vs. Conventional Surgery as Treatment of Papillary Thyroid Microcarcinoma (PTMC)	200	Feb 2024
NCT04619472	A Multicenter, Single Group Target Value Clinical Study to Evaluate Safety and Effectiveness of Radiofrequency Ablation System in the Treatment of Peripheral Lung Tumors	126	May 2023
Unpublished			
NCT01051037	Phase II Study Evaluating Safety and Efficacy of Stereotactic Body Radiotherapy and Radiofrequency Ablation for Medically Inoperable and Recurrent Lung Tumors Near Central Airways	17	Dec 2017 (completed)

NCT: national clinical trial.

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Policy History

Original Effective Date: 10/01/2025
Current Effective Date: 10/01/2025
07/15/2025 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 07/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	20982, 32998, 50542, 50592, 60699, 76940, 77013, 77022, 60660, 60661
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.