Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Policy # 00175
Original Effective Date: 08/24/2005
Current Effective Date: 08/10/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), 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 00045.

Note: The use of Radiofrequency Ablation (RFA) of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00182.

Note: Cryosurgical Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00220.

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.*

Osteolytic Bone Metastases
Based on review of available data, the Company may consider radiofrequency ablation (RFA) to palliate pain in patients with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as radiation or opioids to be **eligible for coverage.****

Based on review of available data, the Company may consider radiofrequency ablation (RFA) to treat osteoid osteomas that cannot be managed successfully with medical treatment to be **eligible for coverage.****

Localized Renal Cell Carcinoma
Based on review of available data, the Company may consider RFA to treat localized renal cell carcinoma (RCC) that is no more than 4 cm in size to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for RFA to treat localized renal cell carcinoma (RCC) that is no more than 4 cm in size will be considered when EITHER of the following is met:

- In order to preserve kidney function in patients with significantly impaired renal function (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min/m^2); AND
- The standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function; OR
- Patient is not considered a surgical candidate.

Isolated Peripheral Non-Small Cell Lung Cancer Lesion

Based on review of available data, the Company may consider RFA to treat an isolated peripheral non-small cell lung cancer (NSCLC) lesion that is no more than 3 cm in size to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for RFA to treat an isolated peripheral NSCLC lesion that is no more than 3 cm in size will be considered when ALL of the following criteria are met:

- Surgical resection 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
- Tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

Malignant Non-Pulmonary Tumor(s) Metastatic to the Lung

Based on review of available data, the Company may consider RFA to treat malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size to be **eligible for coverage**. **

Patient Selection Criteria

Coverage eligibility for RFA to treat malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size when ALL of the following criteria are met:

- In order to preserve lung function when surgical resection or radiation treatment is likely to substantially worsen pulmonary status; OR
- The patient is not considered a surgical candidate; AND
- There is no evidence of extrapulmonary metastases; and the tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart; and

(See Policy Guidelines section for additional criteria.)

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 Company considers radiofrequency ablation to be **investigational*** as a technique for ablation of:

- Breast tumors;
- Lung cancer not meeting the criteria above;
- Renal cell cancer not meeting criteria above;
- Osteoid osteomas that can be managed with medical treatment;
- Painful bony metastases as initial treatment; and
- All other tumors outside the liver including, but not limited to, the head and neck, thyroid, adrenal gland, ovary, and pelvic/abdominal metastases of unspecified origin.

Policy Guidelines

The following are additional criteria developed by clinical judgment or consensus and existing guidelines for the use of radiofrequency ablation to treat metastatic tumors to the lung:

- No more than 3 tumors per lung should be ablated;
- Tumors should be amenable to complete ablation; AND
- Twelve months should elapse before a repeat ablation is considered.

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Background/Overview

Radiofrequency Ablation

RFA was initially developed to treat inoperable tumors of the liver (see evidence review 7.01.91). 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

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.

Bone Tumors

For individuals who have painful osteolytic bone metastases who have failed or are poor candidates for standard treatments who receive RFA, the evidence includes case series. The relevant outcomes are symptoms, change in disease status, quality of life (QOL), medication use, and treatment-related morbidity. Case series have shown clinically significant pain relief and reduction in opioid use following treatment of painful osteolytic metastases. 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 a meaningful improvement in the net health outcome.

For individuals who have painful osteoid osteomas who receive RFA, the evidence includes numerous observational studies and a systematic review of these studies. The 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%-96%) remained pain-free when assessed during longer-term follow-up. 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 a meaningful improvement in the net health outcome.

Localized Renal Cell Carcinoma
For individuals who have localized renal cell carcinoma 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. The 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 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. 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 the effects of the technology on health outcomes.

Clinical input obtained in 2010 supported use of RFA for localized renal cell carcinoma 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 may be considered medically necessary.

Inoperable Primary Pulmonary and Nonpulmonary Tumors
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. The 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 a meaningful improvement in the net health outcome.

Breast Tumors
For individuals who have breast tumors who receive RFA, the evidence includes observational studies and systematic reviews of these studies. The 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 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 the effects of the technology on health outcomes.

Benign Thyroid Tumors
For individuals who have benign thyroid tumors who receive RFA, the evidence includes RCTs, prospective studies, case series, and systematic reviews of these studies. The relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. A systematic review that included four RCTs and five observational studies found significant reductions in nodule size and withdrawal from methimazole following treatment with RFA when compared with a variety of local treatment. Reports of complications vary. The most frequent major complication in a large multicenter series of specialty centers was voice change. The evidence is insufficient to determine the effects of the technology on health outcomes.

Miscellaneous Solid Tumors
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. The 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 the impact of technology on health outcomes.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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 one disagreement and one 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

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.

National Comprehensive Cancer Network
The NCCN guidelines for the treatment of non-small cell lung cancer (v.5.2019) state: "For medically operable disease, resection is the preferred local treatment modality (other modalities include SABR, thermal ablation such as radiofrequency ablation and cryotherapy)."

The NCCN guidelines for thyroid carcinoma (v.1.2019) indicate that local therapies such as RFA may be considered for locoregional recurrence of thyroid carcinoma-papillary carcinoma.

The NCCN guidelines (v.1.2020) for renal cancer indicate that "[t]hermal ablation (eg, cryosurgery, radiofrequency ablation) is an option for the management of patients with clinical stage T1 renal lesions. Thermal ablation is an option for masses <3 cm, but it may also be an option for larger masses in select patients. Ablation in masses >3 cm is associated with higher rates of local recurrence/persistence and complications."

The NCCN colon cancer guidelines (v.2.2019), which are currently under discussion, state that "for the local treatment of resectable metastatic disease, patients with liver or lunch oligometastases can be considered for tumor ablation therapy….Evidence on the use of RFA as a reasonable treatment option for non-surgical candidates and those with recurrent disease after hepatectomy with small liver metastases that can be treated with clear margins is growing."

The NCCN guidelines for head and neck cancers (v.2.2019) and pancreatic adenocarcinoma (v.3.2019) 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: "[C]urrent 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…."

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 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01051037	Phase II Study Evaluating Safety and Efficacy of Stereotactic Body Radiotherapy and Radiofrequency	17	Dec 2017 (completed)

	Ablation for Medically Inoperable and Recurrent Lung Tumors Near Central Airways		
NCT00776399	Radiofrequency Ablation in Resectable Colorectal Lung Metastasis: A Phase-II Clinical Trial	70	Aug 2018 (completed)

NCT: national clinical trial.

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Policy History

Original Effective Date: 08/24/2005
Current Effective Date: 08/10/2020

07/13/2005	Medical Director review
07/19/2005	Medical Policy Committee review
08/24/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/08/2006	Medical Director review
08/09/2006	Medical Policy Committee approval.
07/10/2007	Medical Director review
07/18/2007	Medical Policy Committee approval. Policy Statement added for osteoid osteoma and rationale/source updated.
07/02/2008	Medical Director review
07/16/2008	Medical Policy Committee approval. Coverage eligibility unchanged.
07/02/2009	Medical Director review
07/22/2009	Medical Policy Committee approval. Coverage statement added to indicate that use of radiofrequency ablation as treatment of osteoid osteomas that cannot be managed successfully with medical treatment may be considered eligible for coverage. Coverage statement added that treatment of localized renal cell carcinoma no more than 4cm in size may be considered eligible for coverage when specific criteria are met. Added that radiofrequency ablation for the treatment of osteoid osteomas that can be managed with medical treatment is considered to be investigational.
08/05/2010	Medical Policy Committee review

08/18/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2011	Medical Policy Committee review
08/17/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. Added options for primary and metastatic pulmonary tumors to be eligible for coverage with criteria.
12/12/2013	Medical Policy Committee review
12/18/2013	Medical Policy Implementation Committee approval. Reformatted investigational statement and added thyroid as investigational.
06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/30/2016	Medical Policy Committee review
07/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis codes
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2018	Coding update
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/31/2018	Coding update
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/13/2019	Coding update
01/14/2020	Coding update
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Added an eligible for coverage statement for RFA to treat osteoid osteomas that cannot be managed

successfully with medical treatment. Added a reference to the Policy Guidelines after the eligible for coverage criteria for treatment of malignant nonpulmonary tumor(s) metastatic to the lung.

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 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 Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana 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 Blue Cross Blue Shield of Louisiana 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 Blue Cross Blue Shield of Louisiana 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, 20983, 32998, 50542, 50592, 60699, 76940, 77013, 77022
HCPCS	No codes

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ICD-10 Diagnosis	C34.90-C34.92, C40.00-C40.92, C50.11-C50.919, C64.1-C64.9, C65.1-C65.9, C66.1-C66.9, C68.1-C68.9, C73, D09.3, D16.00-D16.9, D34, D44.0, E04.0-E04.9

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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 BCBSLA 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 Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.