



Louisiana

Microwave Tumor Ablation

Policy # 00569

Original Effective Date: 10/01/2017

Current Effective Date: 05/11/2020

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: Cryosurgery Ablation of Miscellaneous Solid Tumors other than Liver or Prostate Tumors or Breast Fibroadenomas is addressed separately in medical policy 00023.

Note: Radioembolization for Primary and Metastatic Tumors of the Liver is addressed separately in medical policy 00110.

Note: Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors is addressed separately in medical policy 00175.

Note: Radiofrequency Ablation 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.

Note: Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies is addressed separately in medical policy 00227.

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.*

Hepatic Tumors

Based on review of available data, the Company may consider microwave ablation of primary or metastatic hepatic tumors to be **eligible for coverage**.**

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Patient Selection Criteria

Coverage eligibility for microwave ablation of primary or metastatic hepatic tumors will be considered when ALL criteria are met:

- The tumor is unresectable due to location of lesion[s] and/or comorbid conditions AND
- A single tumor of ≤ 5 cm or up to 3 nodules ≤ 3 cm each.

Lung Tumors

Based on review of available data, the Company may consider microwave ablation of primary or metastatic lung tumors to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for microwave ablation of primary or metastatic lung tumors will be considered when ALL criteria are met:

- The tumor is unresectable due to location of lesion[s] and/or comorbid conditions; AND
- A single tumor of ≤ 3 cm.

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 microwave ablation of primary or metastatic tumors other than liver or lung to be **investigational.***

Based on review of available data, the Company considers microwave ablation of more than a single primary or metastatic tumor in the lung to be **investigational.***

The use of microwave ablation when patient selection criteria are not met is considered to be **investigational.***

Background/Overview

Microwave Ablation

MWA uses microwave energy to induce an ultra-high-speed, 915 MHz or 2.450 MHz (2.45 GHz), alternating electric field, which causes water molecule rotation and creates heat. This results in

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thermal coagulation and localized tissue necrosis. In MWA, a single microwave antenna or multiple antennas connected to a generator are inserted directly into the tumor or tissue to be ablated; energy from the antennas generates friction and heat. The local heat coagulates the tissue adjacent to the probe, resulting in a small, 2 cm to 3cm elliptical area (5x3 cm) of tissue ablation. In tumors greater than 2 cm in diameter, two to three antennas may be used simultaneously to increase the targeted area of MWA and shorten the operative time. Multiple antennas may also be used simultaneously to ablate multiple tumors. Tissue ablation occurs quickly, within one minute after a pulse of energy, and multiple pulses may be delivered within a treatment session, depending on tumor size. The cells killed by MWA are typically not removed but are gradually replaced by fibrosis and scar tissue. If there is a local recurrence, it occurs at the margins. Treatment may be repeated as needed. MWA may be used for the following purposes: (1) to control local tumor growth and prevent recurrence; (2) to palliate symptoms; and (3) to prolong survival.

MWA is similar to radiofrequency (RFA) and cryosurgical ablation. However, MWA has potential advantages over RFA and cryosurgical ablation. In MWA, the heating process is active, which produces higher temperatures than the passive heating of RFA and should allow for more complete thermal ablation in less time. The higher temperatures reached with MWA (>100°C) can overcome the “heat sink” effect in which tissue cooling occurs from nearby blood flow in large vessels, potentially resulting in incomplete tumor ablation. MWA does not rely on the conduction of electricity for heating and, therefore, does not flow electrical current through patients and does not require grounding pads, therefore there is no risk of skin burns. Additionally, MWA does not produce electric noise, which allows ultrasound guidance during the procedure without interference, unlike RFA. Finally, MWA can take less time than RFA, because multiple antennas can be used simultaneously.

Adverse Events

Complications from MWA may include pain and fever. Other complications associated with MWA include those caused by heat damage to normal tissue adjacent to the tumor (eg, intestinal damage during MWA of the kidney or liver), structural damage along the probe track (eg, pneumothorax as a consequence of procedures on the lung), liver enzyme elevation, liver abscess, ascites, pleural effusion, diaphragm injury, or secondary tumors if cells seed during probe removal. MWA should be avoided in pregnant women because potential risks to the patient and/or fetus have not been established, and in patients with implanted electronic devices (eg, implantable pacemakers) that may be adversely affected by microwave power output.

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Applications

MWA was first used percutaneously in 1986 as an adjunct to liver biopsy. Since then, MWA has been used to ablate tumors and tissue to treat many conditions including hepatocellular carcinoma, breast cancer, colorectal cancer metastatic to the liver, renal cell carcinoma, renal hamartoma, adrenal malignant carcinoma, non-small-cell lung cancer, intrahepatic primary cholangiocarcinoma, secondary splenomegaly and hypersplenism, abdominal tumors, and other tumors not amenable to resection. Well-established local or systemic treatment alternatives are available for each of these malignancies. The potential advantages of MWA for these cancers include improved local control and other advantages common to any minimally invasive procedure (eg, preserving normal organ tissue, decreasing morbidity, shortening length of hospitalization). MWA also has been investigated as a treatment for unresectable hepatic tumors, as both primary and palliative treatment, and as a bridge to a liver transplant. In the latter setting, MWA is being assessed to determine whether it can reduce the incidence of tumor progression while awaiting transplantation and thus maintain a patient's candidacy while awaiting a liver transplant.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Multiple devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for MWA. The indications for use are labeled for soft tissue ablation, including partial or complete ablation of nonresectable liver tumors. Some devices are cleared for use in open surgical, percutaneous ablation or laparoscopic procedures. Table 1 is a summary of selected MWA devices cleared by the FDA.

The FDA used determinations of substantial equivalence to existing radiofrequency and MWA devices to clear these devices. FDA product code: NEY.

This evidence review does not address MWA for the treatment of splenomegaly, ulcers, or for cardiac applications or as a surgical coagulation tool.

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Table 1. Selected Microwave Ablation Devices Cleared by FDA

Device	Indication	Manufacturer	Date Cleared	510(k) No.
VivaWave™ Microwave Ablation System	Coagulation of soft tissue	Vivant Medical, Inc.	6/2002	K011676
	Probe modification	ValleyLab	4/2006	K053535
Microsoulis Tissue Ablation System	Intraoperative coagulation of soft tissue	Microsoulis Americas, Inc	1/2006	K052919
MicroSurgeon Microwave Soft Tissue Ablation MTAD-100 MTD-200	Surgical ablation of soft tissue	MicroSurgeon, Inc.	8/2007	K070023
	Probe/design modifications		2/2009	K082565
MedWaves Microwave Coagulation/Ablation System	General surgery use in open procedures for the coagulation and ablation of soft tissues	MedWaves Incorporated	12/2007	K070356
Acculis Accu2i pMTA Microwave Tissue Ablation Applicator	Intraoperative coagulation of soft tissue	Microsoulis Holdings, Ltd	8/2010	K094021
	Software addition		11/2012	K122762

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Acculis Accu2i pMTA Applicator and SulisV ^{pMTA} Generator				
MicroThermX Microwave Ablation System	Coagulation (ablation) of soft tissue. May be used in open surgical as well as percutaneous ablation procedures.	BSD Medical Corporation	8/2010	K100786
Emprint TM Ablation System	Percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.		4/2014	K133821
Emprint TM Ablation System	Same with design modification of device antenna for percutaneous use	Covidien LLC	12/2016	K163105
Emprint TM SX Ablation Platform with Thermosphere TM Technology	3-D navigation feature assists in the placement of antenna using real-time image guidance during intraoperative and		9/2017	K171358

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	laparoscopic ablation procedures.			
	Ablation (coagulation) of soft tissue.			
	Ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings.			
Certus 140 2.45 GHz Ablation System and Accessories			10/2010	K100744
Certus 140™ 2.45 GHz Ablation System and Accessories	Surgical coagulation (including Planar Coagulation) in open surgical settings.	NeuWave Medical, Inc.	01/2012	K113237
CertuSurg ^{GT} Surgical Tool			7/2013	K130399
Certus 140™ 2.45 GHz Ablation System and Accessories			5/2016	K160936
Certus 140 2.45GHz Ablation System	Same indication with probe redesign		10/2018	K173756
	Ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the			

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	partial or complete ablation of non-resectable liver tumors.			
NEUWAVE Flex Microwave Ablation System (FLEX)	Ablation (coagulation) of soft tissue. Design evolution of Certus 140 2.45GHz Ablation System (K160936)	NeuWave Medical, Inc.	3/2017	K163118
Solero Microwave Tissue Ablation (MTA) System and Accessories	Ablation of soft tissue during open procedures	Angiodynamics, Inc.	5/2017	K162449
Microwave Ablation System	Coagulation (ablation) of soft tissue	Surgnova Healthcare Technologies (Zhejiang) Co., Ltd	7/2019	K183153

Rationale/Source

Microwave ablation (MWA) is a technique to destroy tumors and soft tissue using microwave energy to create thermal coagulation and localized tissue necrosis. MWA is used to treat tumors not amenable to resection and to treat patients ineligible for surgery due to age, comorbidities, or poor general health. MWA may be performed as an open procedure, laparoscopically, percutaneously, or thoracoscopically under image guidance (eg, ultrasound, computed tomography, magnetic resonance imaging) with sedation, or local or general anesthesia. This technique is also referred to as microwave coagulation therapy.

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For individuals who have unresectable primary or metastatic breast cancer who receive MWA, the evidence includes case series and a systematic review of feasibility and pilot studies conducted prior to 2010. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have an unresectable primary or metastatic hepatic tumor who receive MWA, the evidence includes randomized controlled trials (RCTs), comparative observational studies, case series, and systematic reviews comparing MWA to radiofrequency ablation (RFA) and to surgical resection. The relevant outcomes are overall survival (OS), disease-specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. The body of evidence indicates that MWA is an effective option in patients for whom resection is not an option. Although studies had methodological limitations, they consistently showed that MWA and RFA had similar survival outcomes with up to five years of follow-up in patients with a single tumor <5 cm or up to three nodules <3 cm each. In meta-analyses of observational studies, patients receiving MWA had higher local recurrence rates and lower survival than those who received resection, but the patient populations were not limited to those who had unresectable tumors. MWA was associated with lower complications, intraoperative blood loss, and hospital length of stay. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who have an unresectable primary or metastatic lung tumor who receive MWA, the evidence includes one RCT, retrospective observational studies, and systematic reviews of these studies. The relevant outcomes are OS, disease-specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. The body of evidence indicates that MWA is an effective option in patients for whom resection is not an option. In the RCT, direct comparison of MWA and RFA in patients with primary or metastatic lung cancer (mean tumor size 1.90 cm [\pm 0.89] at baseline) found similar mortality rates up to 12 months of follow-up. In the first of three systematic reviews that included 12 retrospective observational studies, local recurrence rates were similar for MWA and RFA at a range of 9 to 47 months of follow-up. In the second systematic review with a meta-analysis, there was lower OS with MWA compared to RFA but studies were not directly comparable due to clinical and methodological heterogeneity. However, the authors concluded that percutaneous RFA and MWA were both effective with a high safety profile. In the third systematic review using a network meta-analysis, the weighted average OS rates for MWA were 82.5%, 54.6%, 35.7%, 29.6%, and 16.6% at 1, 2, 3, 4, and 5 years, respectively. Limitations of the body of evidence included a lack of controlled studies and heterogeneity across studies. The RCT did not report results by tumor size or the number of metastases. The observational studies included in the systematic

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reviews did not report sufficient information to assess the effectiveness or safety of MWA in subgroups based on the presence of multiple tumors or total tumor burden. Therefore, conclusions about the evidence sufficiency can only be made about patients with single tumors. For this population, the evidence is sufficient to determine the effects of the technology on health outcomes. For individuals who have an unresectable primary or metastatic renal tumor who receive MWA, the evidence includes one RCT that compared MWA to partial nephrectomy and case series. The relevant outcomes are OS, disease-specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. In the RCT, overall local recurrence-free survival at 3 years was 91.3% for MWA and 96.0% for partial nephrectomy ($p=0.54$). This positive outcome should be replicated in additional RCTs. There are also no controlled studies comparing MWA to other ablation techniques in patients with renal tumors. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have unresectable primary or metastatic solid tumors other than breast, hepatic, lung, or renal who receive MWA, the evidence includes case series. The evidence is insufficient to determine the effects of the 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.

2016 Input

In response to requests, input was received from 2 physician specialty societies and 1 academic medical center while this policy was under in 2016. This number of responses was less than optimal. Input overall was mixed. There was some support for the medical necessity of microwave ablation (MWA) in each category, with some reviewers indicating that it was standard of care for certain tumors. However, there were no indications for which all three reviewers agreed that MWA should be medically necessary.

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2011 Input

In response to requests, input was received from two physician specialty societies (three reviews) and four academic medical centers (six reviews) while this policy was in development. Eight reviewers considered MWA investigational to treat primary tumors such as hepatocellular carcinoma, benign and malignant renal tumors, lung tumors, adrenal tumors, or cholangiocarcinoma. The reviewers noted insufficient evidence and a need for further studies on MWA. However, one reviewer indicated MWA for primary tumors, including, but not limited to hepatocellular carcinoma, benign and malignant renal tumors, lung tumors, adrenal tumors, and cholangiocarcinoma, may be considered a treatment option, and another reviewer indicated that MWA for renal tumors may be considered a treatment option.

Four reviewers considered MWA investigational to treat liver metastases, and two reviewers indicated MWA for liver metastases may be considered a treatment option. One reviewer noted MWA may be appropriate for tumors not amenable to radiofrequency ablation or other local treatments. This reviewer also suggested MWA may be more appropriate for tumors located near large blood vessels.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

The National Comprehensive Cancer Network guidelines on hepatobiliary cancers (v.3.2019) list MWA (along with radiofrequency ablation, cryoablation, and percutaneous alcohol injection) as a treatment option for hepatocellular carcinoma (HCC) tumors in patients who are not candidates for potential curative treatments (eg, resection and transplantation) and do not have large-volume extrahepatic disease. Ablation should only be considered when tumors are accessible by percutaneous, laparoscopic, or open approaches. The guidelines indicate “ablative therapies are most effective for [HCC] tumors less than 3 cm....” HCC tumors between 3 cm and 5 cm may also be treated with ablation to prolong survival when used in combination with arterial embolization. Additionally, the tumor location must be accessible to permit ablation of the tumor and tumor margins without ablating major vessels, bile ducts, the diaphragm, or other abdominal organs. However, only one RCT of MWA compared to radiofrequency ablation was cited in the guidelines to support recommendations for MWA.

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The guidelines on non-small cell lung cancer (v.6.2019) do not mention MWA and state, "for medically operative disease, resection is the preferred local treatment modality (other modalities include SABR, thermal ablation such as radiofrequency ablation, and cryotherapy)." Guidelines on small-cell lung cancer (v.2.2019) state, "stereotactic ablative radiotherapy is an option for certain patients with medically inoperable stage I to IIA small-cell lung cancer."

The Network guidelines on neuroendocrine tumors (v.1.2019) state that: "Cytoreductive surgery or ablative therapies (including radiofrequency, microwave, and cryotherapy) may be considered if near-complete treatment of tumor burden can be achieved (category 2B). For unresectable liver metastases, hepatic regional therapy (arterial embolization, chemoembolization, or radioembolization [category 2B]) is recommended."

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2016) updated its guidance on MWA for treatment of metastases in the liver. The revised guidance states:

- Current evidence on microwave ablation for treating liver metastases raises no major safety concerns and the evidence on efficacy is adequate in terms of tumour ablation. Therefore this procedure may be used provided that standard arrangements are in place for clinical governance, consent, and audit.
- Patient selection should be carried out by a hepatobiliary cancer multidisciplinary team.
- Further research would be useful for guiding the selection of patients for this procedure. This should document the site and type of the primary tumour being treated, the intention of treatment (palliative or curative), imaging techniques used to assess the efficacy of the procedure, longterm outcomes and survival.

The Institute (2007) also published guidance on MWA for HCC. This guidance indicated: "Current evidence on the safety and efficacy of microwave ablation of hepatocellular carcinoma appears adequate to support the use of this procedure..." The guidance also stated there are no major concerns about the efficacy of MWA, but noted that limited, long-term survival data are available.

American College of Chest Physicians

The American College of Chest Physicians' (2013) evidence-based guidelines on the treatment of non-small-cell lung cancer noted that the role of ablative therapies in the treatment of high-risk

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patients with stage I non-small-cell lung cancer is evolving. The guidelines deal mostly with radiofrequency ablation.

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 ongoing and 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			
NCT02896166	Microwave Ablation in the Treatment of stage Non-Small Cell Lung Cancer	150	Sep 2019
		2000	December 2019
NCT03045952	Percutaneous Microwave Ablation Under Ultrasound		

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	Guidance for Liver Cancer: A Multicenter Analysis		
NCT03981497	Microwave Ablation for Treatment of Small Renal Tumors and Primary and Secondary Liver Neoplasms	250	February 2024

NCT: national clinical trial.

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07/06/2017 Medical Policy Committee review

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- 07/19/2017 Medical Policy Implementation Committee approval. New policy.
 - 01/01/2018 Coding update
 - 07/05/2018 Medical Policy Committee review
 - 07/11/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 - 07/03/2019 Medical Policy Committee review
 - 07/17/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 - 11/07/2019 Medical Policy Committee review
 - 11/13/2019 Medical Policy Implementation Committee approval. Coverage changes from investigational position only to may be eligible for hepatic and lung tumors with specific criteria. For Hepatic tumors conditions for may be eligible for coverage include: the tumor is unresectable due to location of lesion[s] and/or comorbid conditions and a single tumor of ≤ 5 cm or up to 3 nodules < 3 cm each. For Lung tumors conditions include: the tumor is unresectable due to location of lesion and/or comorbid conditions and a single tumor of ≤ 3 cm.
 - 04/02/2020 Medical Policy Committee review
 - 04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- Next Scheduled Review Date: 04/2021

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.

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

Code Type	Code
CPT	19499, 32998, 47382, 50592, 76940, 77499
HCPCS	C9751
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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);

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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.

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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.

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