



Radiofrequency Ablation of Primary or Metastatic Liver Tumors

Policy # 00182

Original Effective Date: 09/22/2005

Current Effective Date: 05/08/2023

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

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.

Note: Radiofrequency Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00182.

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.*

Based on review of available data, the Company may consider radiofrequency ablation (RFA) of primary, inoperable (eg, due to location of lesion[s] and/or comorbid conditions), hepatocellular carcinoma to be **eligible for coverage**** under the following conditions:

Patient Selection Criteria

Coverage eligibility will be considered when any of the following criteria are met:

- As a primary treatment of hepatocellular carcinoma meeting the Milan criteria (a single tumor of ≤ 5 cm or up to 3 nodules < 3 cm); or

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- As a bridge to transplant, where the intent is to prevent further tumor growth and to maintain an individual's candidacy for liver transplant.

Based on review of available data, the Company may consider radiofrequency ablation (RFA) as a primary treatment of inoperable hepatic metastases to be **eligible for coverage**** under the following conditions:

Patient Selection Criteria

Coverage eligibility will be considered when any of the following criteria are met:

- Metastases are of colorectal origin and meet the Milan criteria (a single tumor of ≤ 5 cm or up to 3 nodules < 3 cm); or
- Metastases are of neuroendocrine in origin and systemic therapy has failed to control symptoms.

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 (RFA) of primary, inoperable, hepatocellular carcinoma to be **investigational*** under the following conditions:

- When there are more than 3 nodules or when not all sites of tumor foci can be adequately treated.
- When used to downstage (downsize) hepatocellular carcinoma in individuals being considered for liver transplant.

Based on review of available data, the Company considers radiofrequency ablation (RFA) of primary, operable hepatocellular carcinoma to be **investigational.***

Based on review of available data, the Company considers radiofrequency ablation (RFA) for hepatic metastasis to be **investigational*** for:

- Hepatic metastases from colorectal cancer or neuroendocrine tumors that do not meet the criteria above; and

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- For hepatic metastases from other types of cancer except colorectal cancer or neuroendocrine tumors.

Background/Overview

Hepatic and Neuroendocrine Tumors

Hepatic tumors can arise as primary liver cancer (hepatocellular cancer) or by metastasis to the liver from other tissues. Local therapy for hepatic metastasis may be indicated when there is no extrahepatic disease, which rarely occurs for individuals with primary cancers other than colorectal carcinoma or certain neuroendocrine malignancies. A study from 2016 determined that the incidence of liver cancer was higher among White individuals, Black individuals, and Hispanic individuals born after 1938. The incidence of hepatocellular carcinoma was twice as high for US-born Hispanic men compared to Hispanic men born outside of the US. This may be due to the increased risk of smoking, hepatitis B or C infection, and diabetes among US-born Hispanic individuals.

Neuroendocrine tumors are tumors of cells that possess secretory granules and originate from the neuroectoderm. Neuroendocrine cells have roles both in the endocrine system and in the nervous system. They produce and secrete a variety of regulatory hormones, or neuropeptides, which include neurotransmitters and growth factors. Overproduction of the specific neuropeptides produced by the cancerous cells causes various symptoms, depending on the hormone produced. They are rare, with an incidence of 2 to 4 per 100,000 per year.

Treatment

Treatment options for hepatocellular carcinoma (HCC) range from potentially curative treatments, such as resection or liver transplantation, to nonsurgical options, which include ablative therapies (RFA, cryoablation, microwave ablation, percutaneous ethanol, or acetic acid injection), transarterial chemoembolization, radiation therapy, and systemic therapy. Choice of therapy depends on the severity of the underlying liver disease, size, and distribution of tumors, vascular supply, and individual overall health. Treatment of liver metastases is undertaken to prolong survival and reduce endocrine-related symptoms and hepatic mass-related symptoms.

At present, surgical resection with adequate margins or liver transplantation constitutes the only treatments available with demonstrated curative potential for hepatic tumors. However, most hepatic tumors are unresectable at diagnosis, due either to their anatomic location, size, number of lesions,

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or underlying liver reserve. Comorbid conditions may also make individuals unqualified for surgical resection.

Radiofrequency Ablation

Radiofrequency ablation is a procedure in which a needle electrode is inserted into a tumor either percutaneously, through a laparoscope, or through an open incision. The electrode is heated by a high-frequency, alternating current, which destroys tissue in a 3 to 5 cm sphere of the electrode. 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 of the treated tissue and, in some cases, is retreated. Radiofrequency ablation has been investigated as a treatment for unresectable hepatic tumors, both as a primary intervention and as a bridge to a liver transplant. In the latter setting, RFA is being tested to determine whether it can reduce the incidence of tumor progression in individuals awaiting transplantation and thus maintain individuals' candidacy for liver ablation, transhepatic arterial chemoembolization, microwave coagulation, percutaneous ethanol injection, and radioembolization (yttrium-90 microspheres).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Radiofrequency ablation devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Food and Drug Administration product code: GEI.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA 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.

Radiofrequency ablation is a procedure in which a probe is inserted into the center of a tumor and heated locally by a high-frequency, alternating current that flows from electrodes. The local heat treats the tissue adjacent to the probe, resulting in a 3 to 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

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recurrence, it occurs at the edge of the treated tissue and, in some cases, is retreated. Radiofrequency ablation may be performed percutaneously, laparoscopically, or as an open procedure.

Summary of Evidence

For individuals who have primary, operable HCC who receive RFA, the evidence includes meta-analyses of randomized controlled trials (RCTs) and/or retrospective observational studies and additional observational studies. Relevant outcomes are overall survival (OS), disease-specific survival, change in disease status, and morbid events. The majority of data found that individuals undergoing surgical resection experienced longer survival outcomes and lower recurrence rates than individuals receiving RFA, though complication rates were higher with surgical resection. Some meta-analyses of specifically selected populations (eg, small tumor sizes or Child-Pugh Class A liver function or HCC within the Milan criteria) found that OS and disease-free survival (DFS) rates were not significantly different between RFA and surgical resection. Results from observational studies have suggested that RFA alone or RFA plus percutaneous ethanol injection (PEI) could be as effective as a resection for small HCC tumors, as OS and DFS rates were not significantly different between RFA and surgical resection. An exact tumor cutoff size has not been established. Some studies found that OS was similar in individuals receiving RFA or resection when tumor size was 3 cm or less; however, OS was significantly longer in individuals undergoing resection if the tumor size was between 3.1 cm and 5 cm. Further study in a multicenter RCT would permit greater certainty whether RFA, with or without other ablative or arterial-directed therapies, is as effective as surgical resection in treating HCC tumors 3 cm or smaller. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have inoperable HCC who receive RFA, the evidence includes RCTs and several systematic reviews and meta-analyses. Relevant outcomes are OS, disease-specific survival, change in disease status, and morbid events. When resection is not an option, nonsurgical options include RFA, PEI, transarterial chemoembolization (TACE), cryoablation, microwave ablation, and systemic therapy. Meta-analyses comparing RFA to other local ablative therapies have found that RFA and microwave ablation are similarly effective, that RFA is more effective than PEI, and that RFA may be better than cryoablation. The evidence comparing RFA with TACE is limited, and no conclusions can be drawn. RFA has also been shown to improve survival in individuals with unresectable HCC as an adjunct to chemotherapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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For individuals who have inoperable HCC awaiting liver transplant who receive RFA, the evidence includes small case series. Relevant outcomes are OS, disease-specific survival, and change in disease status. A number of approaches are used in this patient population, including RFA and other locoregional therapies, particularly TACE. Locoregional therapy has reduced the dropout rate of individuals with HCC awaiting a liver transplant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have inoperable hepatic metastases of colorectal origin who receive RFA, the evidence includes RCTs and several systematic reviews and meta-analyses. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are no RCTs comparing RFA with alternative treatments for individuals who have unresectable colorectal liver metastases. However, an RCT assessing RFA plus chemotherapy found improved survival at 8 years compared with chemotherapy alone. In addition, prospective studies have demonstrated that OS following RFA is at least equivalent to and likely better than currently accepted systemic chemotherapy in well-matched individuals with unresectable hepatic metastatic colorectal cancer who do not have extrahepatic disease. Results from a number of uncontrolled case series also have suggested that RFA of hepatic colorectal cancer metastases produces long-term survival that is at a minimum equivalent to but likely superior to historical outcomes achieved with systemic chemotherapy. Evidence from a comparative study has indicated that RFA has fewer deleterious effects on quality of life than chemotherapy and that RFA individuals recover their quality of life significantly faster than chemotherapy recipients. It should be noted that individuals treated with RFA in different series might have had better prognoses than those who had chemotherapy, suggesting patient selection bias might at least partially explain the better outcomes observed following RFA. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have inoperable hepatic metastases of neuroendocrine origin who receive RFA, the evidence includes case series and a systematic review of case series. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Most reports of RFA treatment for neuroendocrine liver metastases have assessed small numbers of individuals or subsets of individuals in reports of multiple ablative methods or very small subsets of larger case series of individuals with various diagnoses. The available evidence has indicated that durable tumor and symptom control of neuroendocrine liver metastases can be achieved using RFA in individuals whose symptoms are not controlled by

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systemic therapy or who are ineligible for resection. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have hepatic metastases not of colorectal or neuroendocrine origin who receive RFA, the evidence includes small nonrandomized comparative studies and small case series. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Similar to primary HCC, resection appears to have the most favorable outcomes. For individuals who are ineligible for resection, RFA may provide a survival benefit. However, the evidence is limited by study designs with a high-risk of bias and small sample sizes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

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 Association for the Study of Liver Diseases

The American Association for the Study of Liver Diseases (2018) published a guideline on the treatment of hepatocellular carcinoma. For adults with Child-Pugh class cirrhosis and resectable T1 or T2 HCC, the guideline suggests using resection over radiofrequency ablation (RFA; moderate quality/certainty of evidence; conditional strength of recommendation). Technical remarks in the guideline note that "Stage T1 and T2 HCC include a wide range of tumor sizes from <1 cm to 5 cm, and the effectiveness of available therapies depend in large part on the size, number, and location of the tumors. Whereas smaller, single tumors (<2.5 cm) that are favorably located may be equally well treated by either resection or ablation, tumors larger than 2.5-3 cm, multifocal, or near major vascular or biliary structures may have limited ablative options." Additionally, the guideline highlighted that "randomized trials performed to date comparing RFA to resection have been performed primarily in East Asian individuals, in whom there is a higher etiologic prevalence of HBV [hepatitis B virus] (including noncirrhotic HBV-associated HCC) and a lower prevalence of other liver diseases such

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as NAFLD [non-alcoholic fatty liver disease] or HCV [hepatitis C virus] compared with Western individuals. The impact of these demographic differences on oncologic outcomes of different therapies is unknown."

National Comprehensive Cancer Network

Several National Comprehensive Cancer Network (NCCN) guidelines are relevant to this review. The NCCN (v1.2022) guidelines on hepatobiliary cancers note that "locoregional therapy should be considered in individuals who are not candidates for surgical curative treatments, or as part of a strategy to bridge individuals for other curative therapies." The guideline further states that "ablation alone may be curative in treating tumors ≤ 3 cm. In well-selected individuals with small, properly located tumors, ablation should be considered a definitive treatment in the context of a multidisciplinary review. Lesions 3 to 5 cm may be treated to prolong survival using arterially directed therapies, or with the combination of an arterially directed therapy and ablation as long as the tumor is accessible for ablation" (category 2A).

The NCCN (v1.2022) guidelines on colon cancer metastatic to the liver state that "ablative techniques may be considered alone or in conjunction with resection. All original sites of disease need to be amenable to ablation or resection" (category 2A). Of all ablative techniques, the guidelines note that RFA has the most supporting evidence.

The NCCN (v1.2022) guidelines for neuroendocrine tumors state that "percutaneous thermal ablation, often using microwave energy (radiofrequency and cryoablation are also acceptable), can be considered for oligometastatic liver disease, generally up to 4 lesions each smaller than 3 cm. Feasibility considerations include safe percutaneous imaging-guided approach to the target lesions, and proximity to vessels, bile ducts, or adjacent non-target structures that may require hydro- or aero-dissection for displacement [category 2B]." Additionally, "cytoreductive surgery or ablative therapies such as RFA or cryoablation may be considered if near-complete treatment of tumor burden can be achieved (category 2B). Ablative therapy in this setting is non-curative. For unresectable liver metastases, hepatic regional therapy (arterial embolization, chemoembolization, or radioembolization [category 2B]) is recommended."

Society of Interventional Radiology

The Society of Interventional Radiology (2009) published a position statement on percutaneous RFA for the treatment of liver tumors. The Society indicated that "percutaneous RF ablation of hepatic

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tumors is a safe and effective treatment for selected individuals with HCC and colorectal carcinoma metastases" and that the current literature does not support any recommendations for or against the use of RFA in other diseases.

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 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03127072	A Prospective, Randomized, One-center Study Assessing Overall Survival Using RFA Plus Chemotherapy ± Target Therapy and Chemotherapy ± Target Therapy Alone in Individuals with Unresectable Colorectal Cancer Liver Metastases	200	Dec 2021
NCT02169765	Hepatic Resection Versus Radiofrequency Ablation for Early-stage Hepatocellular Carcinoma: a Randomized Controlled Trial	120	Dec 2022
NCT03088150 ^a	COLLISION Trial - Colorectal Liver Metastases: Surgery vs Thermal Ablation, a Phase III Single-blind Prospective Randomized Controlled Trial	618	Dec 2022

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NCT02192671	Hepatic Resection Versus Radiofrequency Ablation for Individuals with Hepatocellular Carcinoma and Portal Hypertension	120	Dec 2022
NCT04798898	Improving Survival of Colorectal Liver Metastases by RFA-mediated Immunostimulation	200	Dec 2024
NCT03988998	Radiofrequency Ablation with or Without Radiotherapy for Small Hepatocellular Carcinoma: a Randomized Control Trial	100	Jan 2023
NCT03898921	Radiofrequency Ablation Versus Stereotactic Body Radiotherapy (SBRT) for Small Hepatocellular Carcinoma: A Phase III, Prospective, Open, Parallel Controlled Clinical Trial	270	Mar 2022
<i>Unpublished</i>			
NCT02243384	A Randomized Controlled Trial of Laparoscopic Hepatectomy and Radiofrequency Ablation in the Treatment of Early Hepatocellular Carcinoma	150	Oct 2021
NCT02535117	Laparoscopic Surgery Versus Radiofrequency Ablation for Recurrent Hepatocellular Carcinoma after Initial Partial Hepatectomy: a Multicenter Experience	216	Jul 2020 (last updated Aug 2015)

NCT: national clinical trial.

^aDenotes sponsorship or cosponsorship by manufacturer

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Policy History

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09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review
09/22/2005	Quality 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.
01/10/2006	Medical Director review
01/17/2006	Medical Policy Committee approval. Coverage eligibility updated to include investigational status of RFA as a bridge to liver transplant.
01/09/2008	Medical Director review
01/23/2008	Medical Policy Committee approval. Added "in the absence of extrahepatic metastatic disease" to the patient selection criteria.
01/07/2009	Medical Director review
01/14/2009	Medical Policy Committee approval. No change to coverage eligibility.
01/07/2010	Medical Policy Committee approval
01/20/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/06/2011	Medical Policy Committee review

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01/19/2011	Medical Policy Implementation Committee approval. Extensively revised coverage statements and added policy guidelines.
01/06/2011	Medical Policy Committee review
01/19/2011	Medical Policy Implementation Committee approval. Rationale revised. No change to coverage.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/08/2015	Medical Policy Committee review
01/21/2015	Medical Policy Implementation Committee approval. Added phrase “unless RFA is used as a bridge to transplant” to the medically necessary indication for RFA in those with primary HCC and metastatic colorectal or neuroendocrine tumors for HCC should also not be candidates for liver transplantation.
01/07/2016	Medical Policy Committee review
01/22/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
01/05/2017	Medical Policy Committee review
01/18/2017	Medical Policy Implementation Committee approval. No change to coverage.
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. Policy statements reformatted and edited for clarity and specificity, including the distinction between operable and non-operable tumors and the Milan criteria. The intent of the statements is unchanged. A statement has been added that RFA for operable HCC is considered investigational.
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. No change to coverage.
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. No change to coverage. Three new policies referenced as notes for cross reference including: Cryosurgical Ablation of Primary or Metastatic Liver Tumors medical policy 00220, Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies

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medical policy 00227 and Radiofrequency Ablation of Primary or Metastatic Liver Tumors medical policy 00182.

04/02/2020 Medical Policy Committee review

04/08/2020 Medical Policy Implementation Committee approval. No change to coverage.

04/01/2021 Medical Policy Committee review

04/14/2021 Medical Policy Implementation Committee approval. No change to coverage.

04/07/2022 Medical Policy Committee review

04/13/2022 Medical Policy Implementation Committee approval. No change to coverage.

04/06/2023 Medical Policy Committee review

04/12/2023 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 04/2024

Coding

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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	47370, 47380, 47382, 76940, 77013, 77022
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

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- 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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