Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone

Policy # 00023
Original Effective Date: 01/26/2004
Current Effective Date: 08/14/2023

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: Whole Gland Cryoablation of Prostate Cancer is addressed separately in medical policy 00022.

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.

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 cryosurgical ablation 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.****

Based on review of available data, the Company may consider cryosurgical ablation to treat lung cancer to be **eligible for coverage.****

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Patient Selection Criteria
Coverage eligibility for cryosurgical ablation to treat lung cancer may be considered when **EITHER** of the following criteria is met:

- The individual has early-stage non-small cell lung cancer (NSCLC) and is a poor surgical candidate; **OR**
- The individual requires palliation for a central airway obstructing lesion.

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 cryosurgical ablation to treat localized renal cell carcinoma (RCC) when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers cryosurgical ablation to treat lung cancer when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers cryosurgical ablation as a treatment for benign or malignant tumors of the breast, pancreas, or bone, to be **investigational.***

Policy Guidelines

This policy does not address pediatric indications.

The objective of this review is to determine whether cryoablation of tumors located in the kidney, lung, breast, pancreas, or bone will improve the net health outcome. This review is limited to treatment in adults (age 18 years and older) and does not address pediatric populations.

Background/Overview

Renal Tumors

Localized kidney cancer is treated with radical nephrectomy or nephron-sparing surgery. Prognosis drops precipitously if the tumor extends outside the kidney capsule because chemotherapy is relatively ineffective against metastatic renal cell carcinoma.

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Lung Tumors and Lung Metastases
Early-stage lung tumors are typically treated surgically. Patients with early-stage lung cancer who are not surgical candidates may be candidates for radiotherapy with curative intent. Cryoablation is being investigated in patients who are medically inoperable, with small primary lung cancers or lung metastases from extrapulmonary primaries. Patients with a more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. Treatment is rarely curative; rather, it seeks to retard tumor growth or palliate symptoms.

Breast Tumors
Early-stage primary breast cancers are treated surgically. The selection of lumpectomy, modified radical mastectomy, or another approach is balanced against the patient's desire for breast conservation, the need for tumor-free margins in resected tissue, and the patient's age, hormone receptor status, and other factors. Adjuvant radiotherapy decreases local recurrences, particularly for those who select lumpectomy. Adjuvant hormonal therapy and/or chemotherapy are added, depending on the presence and number of involved nodes, hormone receptor status, and other factors. Treatment of metastatic disease includes surgery to remove the lesion and combination chemotherapy.

Fibroadenomas are common benign tumors of the breast that can present as a palpable mass or a mammographic abnormality. These benign tumors are frequently surgically excised to rule out a malignancy.

Pancreatic Cancer
Pancreatic cancer is a relatively rare solid tumor that occurs almost exclusively in adults, and it is largely considered incurable. Surgical resection of tumors contained entirely within the pancreas is currently the only potentially curative treatment. However, the nature of the cancer is such that few tumors are found at such an early and potentially curable stage. Patients with a more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. Treatment focuses on slowing tumor growth and palliation of symptoms.

Bone Cancer and Bone Metastases
Primary bone cancers are extremely rare, accounting for less than 0.2% of all cancers. Bone metastases are more common, with clinical complications including debilitating bone pain.

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Treatment for bone metastases is performed to relieve local bone pain, provide stabilization, and prevent impending fracture or spinal cord compression.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several cryoablation devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for use in open, minimally invasive, or endoscopic surgical procedures in the areas of general surgery, urology, gynecology, oncology, neurology, dermatology, proctology, thoracic surgery, and ear, nose, and throat. Examples include:

- Cryocare®‡ Surgical System (Endocare);
- CryoGen Cryosurgical System (Cryosurgical);
- CryoHit®‡ (Galil Medical) for the treatment of breast fibroadenoma;
- IceSense3™‡, ProSense™‡, and MultiSense Systems (IceCure Medical);
- SeedNet™‡ System (Galil Medical); and
- Visica®‡ System (Sanarus Medical).

FDA product code: GEH.

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.

Cryosurgical ablation (hereafter referred to as cryosurgery or cryoablation) involves freezing of target tissues; this is most often performed by inserting a coolant-carrying probe into the tumor. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

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Summary of Evidence
For individuals with early stage kidney cancer who are surgical candidates treated with cryoablation, the evidence includes comparative observational studies and systematic reviews. Relevant outcomes are overall survival (OS), disease-specific survival, quality of life, and treatment-related morbidity. Multiple comparative observational studies and systematic reviews of these studies have compared cryoablation to partial nephrectomy for early stage renal cancer. These studies have consistently found that partial nephrectomy is associated with better oncological outcomes than cryosurgery, but cryosurgery was associated with better perioperative outcomes, lower incidence of complications, and less decline in kidney function. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with early stage kidney cancer who are not surgical candidates and who are treated with cryoablation, the evidence includes comparative observational studies of cryoablation compared to partial nephrectomy or other ablative techniques, systematic reviews of these studies, and case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. Although oncological outcomes were better with surgery, in comparative observational studies, cryoablation was associated with less decline in kidney function. Recent case series totaling more than 400 patients showed cryoablation was associated with good oncological outcomes and preservation of renal function. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with non-small cell lung cancer (NSCLC) who are not surgical candidates, the evidence includes uncontrolled observational studies and case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. Medically inoperable patients with early stage primary lung tumors were treated with cryoablation in a consecutive series of 45 patients. Five year survival was 68%; the main complications were hemoptysis in 40% of patients and pneumothorax in 51%. A prospective single arm Phase 2 study of 128 patients reported on cryoablation for treatment of metastases to the lung. Cryoablation for metastatic lung cancer was studied in a single arm trial in 40 patients. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with non-small cell lung cancer who require palliation for a central airway obstructing lesion who are treated with cryoablation, the evidence includes case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. There

are no comparative studies. A series of 521 consecutive patients reported improvement in symptoms in 86% of patients, but multiple study design, conduct, and relevance limitations preclude drawing conclusions about efficacy or safety of cryoablation in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with solid tumors located in the breast, pancreas, or bone who are treated with cryoablation, the evidence includes uncontrolled observational studies and case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. Due to the lack of prospective controlled trials, it is not possible to conclude that cryoablation improves outcomes for any indication better than alternative treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

2017 Input
Clinical input was sought to help determine whether the use of cryoablation for individuals with NSCLC who are either poor surgical candidates or who required palliation for a lesion obstructing the central airway would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 9 respondents, including 2 specialty society-level responses, 3 physician-level responses identified by specialty societies, and 4 physicians identified by 1 health system.

For individuals with NSCLC who are either poor surgical candidates or who required palliation for a lesion obstructing the central airway who receive cryoablation, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice.

Supplemental Information

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.

2017 Input
Clinical input was sought to help determine whether the use of cryoablation for individuals with non small cell lung cancer (NSCLC)who are either poor surgical candidates or who required palliation for a lesion obstructing the central airway would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 9 respondents, including 2 specialty society-level responses, 3 physician-level responses identified by specialty societies, and 4 physicians identified by 1 health system.

For individuals with NSCLC who are either poor surgical candidates or who required palliation for a lesion obstructing the central airway who receive cryoablation, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice.

2009 Input
In response to requests, input was received from 2 physician specialty societies (5 reviews) and from 2 academic medical centers (3 reviews) while this policy was under review in 2009. There was strong support for the use of cryoablation in the treatment of select patients with renal tumors. There also was support for its use in the treatment of benign breast disease. Reviewers generally agreed cryoablation was investigational in the treatment of pancreatic cancer.

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 Radiology
The American College of Radiology Appropriateness Criteria (2009, updated 2019) for post-treatment follow-up and active surveillance of renal cell carcinoma [RCC] indicated that "Ablative therapies, such as radiofrequency ablation, microwave ablation, and cryoablation, have been shown to be an effective and safe alternative [to surgical resection] for the treatment of small, localized RCCs." These recommendations are based on a review of the data and consensus.

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American Urological Association
The American Urological Association (2017) updated its guidelines on the evaluation and management of clinically localized sporadic renal masses suspicious for renal cell carcinoma. The guideline statements on thermal ablation (radiofrequency ablation, cryoablation) are listed in Table 1.

Table 1. Guidelines on Localized Masses Suspicious for Renal Cell Carcinoma

Recommendations	LOR	LOE
Guideline statement 24		
Physicians should consider thermal ablation (TA) as an alternate approach for the management of cT1a renal masses <3 cm in size. For patients who elect TA, a percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity.	Conditional	C
Guideline statement 25		
Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation	Conditional	C
Guideline statement 27		
Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical extirpation, which may be addressed with repeat ablation if further intervention is elected	Strong	B

LOE: level of evidence; LOR: level of recommendation.

National Comprehensive Cancer Network

Kidney Cancer
The NCCN (v.4.2021) guidelines on kidney cancer state that "thermal ablation (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 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. Biopsy of small lesions confirms a diagnosis of malignancy for surveillance, cryosurgery, and radiofrequency ablation strategies. Ablative techniques are associated with a higher local recurrence rate than conventional surgery and may require multiple treatments to achieve the same local oncologic outcomes. The NCCN guidelines also note that "ablative techniques such as cryo- or radiofrequency ablation are alternative strategies for selected patients, particularly the elderly and those with competing health risks." Additionally, the guidelines note that "randomized phase III comparison with surgical resection (ie, radical or partial nephrectomy by open or laparoscopic techniques) has not been done" and "ablative techniques are associated with a higher local recurrence rate than conventional surgery."

Non-Small Cell Lung Cancer
The NCCN (v. 4.2021) guidelines for NSCLC made the following relevant recommendations:

- Resection is the preferred local treatment modality for medically operable disease.
- Image-guided thermal ablation (IGTA) techniques include radiofrequency ablation, microwave ablation, and cryoablation.
- IGTA may be an option for select patients not receiving stereotactic ablative radiotherapy or definitive radiotherapy.
- IGTA may be considered for those patients who are deemed "high risk"- those with tumors that are for the most part surgically resectable but rendered medically inoperable due to comorbidities. In cases where IGTA is considered for high-risk or borderline operable patients, a multidisciplinary evaluation is recommended.
- 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 guidelines do not separate out recommendations by ablation technique and note that "each energy modality has advantages and disadvantages. Determination of energy modality to be used for ablation should take into consideration the size and location of the target tumor, risk of complication, as well as local expertise and/or operator familiarity."

Cancer Pain
The NCCN Guidelines on Adult Cancer Pain (v.2.2021) do not address cryoablation specifically for pain due to bone metastases, but note that "ablation techniques may...be helpful for pain management in patients who receive inadequate relief from pharmacological therapy.

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			
Renal cancer			
NCT02399124[a]	ICESECRET PROSENSE™‡ Cryotherapy for Renal Cell Carcinoma Trial	120	Jan 2025
Unpublished			
NCT01117779[a]	Tracking Renal Tumors After Cryoablation Evaluation (TRACE) Registry		Nov 2020 Terminated (Boston Scientific acquisition of BTG/Galil Medical - business decision made to stop follow-up early)

NCT: national clinical trial.

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[a] Denotes industry-sponsored or cosponsored trial.

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Original Effective Date: 01/26/2004
Current Effective Date: 08/14/2023
10/21/2003 Medical Policy Committee review
01/26/2004 Managed Care Advisory Committee approval

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12/07/2005	Medical Director review
12/20/2005	Medical Policy Committee review. Format revision. FDA approval information added to policy.
02/23/2006	Quality Care Advisory Council approval
10/10/2007	Medical Director review
10/17/2007	Medical Policy Committee approval. No change to coverage eligibility.
03/04/2009	Medical Director review
03/18/2009	Medical Policy Committee approval. Changed localized renal cell carcinoma from investigational to eligible for coverage with criteria. Breast fibroadenomas removed from this policy and made into a separate policy.
03/05/2010	Medical Policy Committee review
03/19/2010	Medical Policy Implementation Committee approval. Added benign tumors of the breast to be investigational.
03/03/2011	Medical Policy Committee review
03/16/2011	Medical Policy Implementation Committee approval. Renal cell carcinomas in patients who are surgical candidates was added as investigational.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Title changed from "Cryosurgery Ablation of Miscellaneous Solid Tumors other than Liver or Prostate" to "Cryosurgery Ablation of Miscellaneous Solid Tumors Other than Liver or Prostate Tumors or Breast Fibroadenomas". Removed the second criteria bullet for treatment of renal cell carcinoma requiring that the patient not be considered as a surgical candidate due to co-morbid disease. Lung cancer added to investigational statement. The investigational statement was revised for clarification.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review

09/23/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/08/2016 Medical Policy Committee review
09/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017 Medical Policy Committee review
12/20/2017 Medical Policy Implementation Committee approval. Added a criteria bullet to localized renal cell carcinoma that states "the patient is not considered a surgical candidate." Added that cryosurgical ablation to treat lung cancer may be considered eligible for coverage with criteria. Added an investigational statement for lung cancer when criteria are not met. Replaced the investigational statement regarding cryosurgical ablation for malignant tumors with an investigational statement indicating that cryosurgical ablation as a treatment for benign or malignant tumors of the breast, pancreas, or bone and other solid tumors or metastases outside the liver, prostate and breast fibroadenomas is considered to be investigational.
01/01/2018 Coding update
08/31/2018 Coding update
12/06/2018 Medical Policy Committee review
12/19/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019 Medical Policy Committee review
12/11/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2020 Medical Policy Committee review
05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/06/2021 Medical Policy Committee review
05/12/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021 Medical Policy Committee review
07/14/2021 Medical Policy Implementation Committee approval. Title changed from "Cryosurgery Ablation of Miscellaneous Solid Tumors other than Liver or Prostate Tumors or Breast Fibroadenomas" to "Cryosurgical Ablation of Miscellaneous

	Solid Tumors other than Liver, Prostate, or Dermatologic Tumors". Revised the When Services May be Eligible and When Services Are Investigational sections.
07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. Title changed from "Cryosurgery Ablation of Miscellaneous Solid Tumors other than Liver, Prostate, or Dermatologic Tumors" to "Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone.". "…and other solid tumors or metastases outside the liver and prostate" was removed from the investigational statement. Added Policy Guidelines.
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. Replaced "patients" with "individuals" in the coverage section. Added a suspected renal mass to be eligible for coverage with criteria for localized renal cell carcinoma. Changed a criteria bullet for cryosurgical ablation of a renal mass suspected to be localized renal cell carcinoma from "not considered a surgical candidate" to "considered a high-risk surgical candidate".
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Replaced renal mass section with "Based on review of available data, the Company may consider cryosurgical ablation 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."

Next Scheduled Review Date: 07/2024

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 2022 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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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	0581T, 19105, 20983, 32994, 50250, 50542, 50593
HCPCS	C2618
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:

Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone

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Current Effective Date: 08/14/2023

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 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.