

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

Policy # 00023

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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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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 of renal cell carcinoma (RCC) to be **eligible for coverage**** when **BOTH** of the following criteria are met:

- Clinically localized, suspected renal malignancy; **AND**
- For individuals with peripheral lesions that are less than or equal to 4 cm in diameter.

Based on review of available data, the Company may consider cryosurgical ablation to treat lung cancer to be **eligible for coverage**** when **EITHER** of the following criteria is met:

- The individual has non-small cell lung cancer (NSCLC) and meets **ALL** of the following criteria:
 - Early-stage NSCLC; **AND**
 - Tumor diameter is less than or equal to 3.0 cm; **AND**
 - Individual is poor surgical candidate; **OR**
- The individual requires palliation for a central airway obstructing lesion.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers cryosurgical ablation to treat localized renal cell carcinoma (RCC) in all other situations to be **not medically necessary**.**

The use of cryosurgical ablation to treat lung cancer when criteria are not met is considered to be **not medically necessary**.**

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 as a treatment for benign or malignant tumors of the breast, pancreas, or bone to be **investigational**.*

Policy Guidelines

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.

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.

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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. 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.

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Description

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.

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 500 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 NSCLC 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.

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For individuals with low-risk, early-stage breast cancer who are treated with cryoablation, the evidence includes systematic reviews, uncontrolled observational studies, and case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. The available evidence has shown that complete ablation can be achieved in most cases for variably defined small tumors, but studies have not included control groups or compared outcomes of cryosurgery with alternative strategies for managing similar patients. Due to the lack of prospective controlled trials, it is not possible to conclude that cryoablation improves outcomes better than alternative treatments. 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 pancreas or bone who are treated with cryoablation, the evidence includes systematic reviews, 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.

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.

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

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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 2021) 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 effective and safe alternatives [to surgical resection] for the treatment of small, localized RCCs." These recommendations are based on a review of the data and expert consensus.

American Urological Association

The American Urological Association (2021) 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
<i>Guideline statement 25</i>		
Clinicians 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.	Moderate	C
<i>Guideline statement 26</i>		
Both radiofrequency ablation (RFA) and cryoablation may be offered as options for patients who elect thermal ablation.	Conditional	C
<i>Guideline statement 28</i>		
Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical excision, which may be addressed with repeat ablation if further intervention is elected	Strong	B

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

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National Comprehensive Cancer Network

Breast Cancer

The National Comprehensive Network (NCCN) guideline on breast cancer does not include information on the use of cryoablation for breast cancer, except for ovarian ablation.

Kidney Cancer

The National Comprehensive Network (NCCN) (v.2.2026) guidelines on kidney cancer state that "percutaneous ablation (cryosurgery, radiofrequency ablation, microwave ablation) is an option for the management of clinical stage T1 renal lesions. Percutaneous ablation is suitable for renal masses ≤ 3 cm. Percutaneous ablation is an option for clinical T1b masses in select patients not eligible for surgery. Biopsy of lesions is recommended to be done prior to or at time of ablation. Percutaneous ablation may require retreatment to achieve the same local oncologic outcomes as conventional surgery.

The NCCN guidelines also note that "active surveillance and percutaneous ablation such as cryotherapy, microwave ablation, or radiofrequency ablation are alternative strategies for selected patients, particularly for those who are older, those with competing health risks, and those with T1b masses not eligible for surgery." Additionally, the guidelines note that "randomized phase III comparison of percutaneous ablation with surgical resection (ie, radical or partial nephrectomy by open or laparoscopic techniques) has not been performed."

Non-Small Cell Lung Cancer

The NCCN (v.5.2026) 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 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.
- There is evidence on the use of IGTA for selected patients with stage IA NSCLC, those who present with multiple lung cancers, or those who present with locoregional recurrence of symptomatic local thoracic disease.
- 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."

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Cancer Pain

The NCCN Guidelines on Adult Cancer Pain (v.1.2026) 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 ^{TM†} Cryotherapy for Renal Cell Carcinoma Trial	120	Mar 2026 (active, not recruiting)
Breast cancer			
NCT05505643	COOL-IT: Cryoablation vs Lumpectomy in T1 Breast Cancers: A Randomized Controlled Trial With Safety Lead-in	256	Apr 2033 (recruiting)
NCT07483996	Cryoablation as Alternative for Lumpectomy in Early-Stage Breast Cancer: The CRYSTAL Trial	938	Dec 2038 (not yet recruiting)
NSCLC			
NCT07272356	Investigation of the Efficacy of Local Minimally Invasive Ablative Therapy for Pulmonary Tumors and Its Impact on Respiratory Function	68	Jun 2026 (active, not recruiting)
Unpublished			
NCT04506671	A Prospective, Non-randomized, in Parallel Groups Study Evaluating the Efficacy and Safety of	142	Jun 2025 (unknown)

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	Percutaneous Cryoablation and Partial Nephrectomy in Localized T1b Renal Tumor		
NCT04334785	Evaluation for the Effectiveness and Safety of Cryo-ablation in the Treatment of Early Invasive Breast Cancer	186	May 2025 (unknown)
NCT05615545	Safety and Efficacy of Cryoablation in the Treatment of Advanced Bone and Soft Tissue Tumors: a Single-center Retrospective Study	30	Oct 2024 (unknown)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy # 00023

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Current Effective Date: 08/01/2026

Policy History

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10/21/2003	Medical Policy Committee review
01/26/2004	Managed Care Advisory Committee approval
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

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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

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	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.”
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Moved coverage for renal malignancy to a “When Services Are Eligible for Coverage” section for clarity. Revised the investigational statement for cryosurgical ablation to treat localized renal cell carcinoma for clarity. Updated NCCN Guidelines to Version 4.2024 for Kidney Cancer in the Supplemental Information section. Coverage eligibility unchanged.
07/03/2025	Medical Policy Committee review
07/09/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2026	Medical Policy Committee review
07/08/2026	Medical Policy Implementation Committee review
07/16/2026	Medical Quality Management Committee approval. Added early-stage NSCLC and tumor diameter less than or equal to 3.0 cm as coverage criteria for cryosurgical ablation to treat lung cancer. Cryosurgical ablation to treat localized renal cell carcinoma (RCC) in all other situations and when criteria are not met changed from investigational to not medically necessary.

Next Scheduled Review Date: 07/2027

Coding

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

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue 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 Louisiana Blue 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 Louisiana Blue Medical

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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	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:
 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.

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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.

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

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.