



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 09/19/22
LAST REVIEW DATE: 09/03/24
CURRENT EFFECTIVE DATE: 09/03/24
LAST CRITERIA REVISION DATE: 09/21/23
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 3RD QTR 2025

CRYOABLATION OF TUMORS LOCATED IN THE KIDNEY, LUNG, BREAST, PANCREAS, OR BONE

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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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.

The U.S. Food and Drug Administration (FDA) has cleared several cryoablation devices 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, including, *but not limited to*:

- 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)

Definitions:

Adult: Age 18 years and older

Criteria:

- Cryosurgical ablation to treat localized renal cell carcinoma that is no more than 4 cm in size in adults is considered **medically necessary** with documentation of **ANY** of the following:
 1. Preservation of kidney function is necessary (e.g., the individual has 1 kidney or renal insufficiency defined by a glomerular filtration rate of <60 mL/min/m²), and standard surgical approach (e.g., resection of renal tissue) is likely to worsen kidney function substantially; or
 2. The individual is not considered a surgical candidate.
- Cryosurgical ablation to treat lung cancer in adults is considered **medically necessary** with documentation of **ANY** of the following:
 1. The individual has early-stage non-small-cell lung cancer and is a poor surgical candidate; or
 2. The individual requires palliation for a central airway obstructing lesion.

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- Cryosurgical ablation as a treatment for benign or malignant tumors of the breast, lung (other than defined above), pancreas, or bone, and to treat renal cell carcinomas in individuals who are surgical candidates is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 09/03/24. We do not include marketing materials, poster boards and non-published literature in our review.

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10. Kaufman CS, Bachman B, Littrup PJ, et al. Cryoablation treatment of benign breast lesions with 12-month follow-up. *Am J Surg*. Oct 2004;188(4):340-8. doi:10.1016/j.amjsurg.2004.06.025
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12. Kaufman CS, Littrup PJ, Freeman-Gibb LA, et al. Office-based cryoablation of breast fibroadenomas with long-term follow-up. *Breast J*. Sep-Oct 2005;11(5):344-50. doi:10.1111/j.1075-122X.2005.21700.x
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17. Lee SH, Choi WJ, Sung SW, et al. Endoscopic cryotherapy of lung and bronchial tumors: a systematic review. *Korean J Intern Med*. Jun 2011;26(2):137-44. doi:10.3904/kjim.2011.26.2.137
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Coding:

CPT: 19105, 20983, 32994, 50250, 50542, 50593, 0581T

History:

Date:

Activity:

Medical Policy Panel	09/03/24	Review with revisions
Medical Policy Panel	09/21/23	Review with revisions
Medical Policy Panel	08/01/23	Review with no revisions
Medical Policy Panel	08/16/22	Approved guideline (Effective 09/19/22)



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Policy Revisions:

09/03/24	Updated:	Resources section.
09/21/23	Added:	“Insufficient evidence to support improvement of the net health outcome; or”, and “Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or” to experimental or investigational criteria.
09/21/23	Revised:	“Insufficient evidence to support improvement outside the investigational setting” from #3 to #5 in experimental or investigational criteria.
09/21/23	Updated:	Resources section.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

