

**EVIDENCE-BASED CRITERIA
SECTION: MEDICINE**

**ORIGINAL EFFECTIVE DATE: 09/19/22
LAST REVIEW DATE: 08/16/22
CURRENT EFFECTIVE DATE: 09/19/22
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:**

NEXT ANNUAL REVIEW DATE: 3RD QTR 2023

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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CRYOABLATION OF TUMORS LOCATED IN THE KIDNEY, LUNG, BREAST, PANCREAS, OR BONE (cont.)

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 (i.e., the individual has 1 kidney or renal insufficiency defined by a glomerular filtration rate of <60 mL/min/m²), and standard surgical approach (i.e., 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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CRYOABLATION OF TUMORS LOCATED IN THE KIDNEY, LUNG, BREAST, PANCREAS, OR BONE (cont.)

Criteria: (cont.)

- 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 outside the investigational setting.

Resources:

Literature reviewed 08/16/22. We do not include marketing materials, poster boards and non-published literature in our review.

1. Andrews JR, Atwell T, Schmit G, et al. Oncologic Outcomes Following Partial Nephrectomy and Percutaneous Ablation for cT1 Renal Masses. *Eur Urol*. Aug 2019;76(2):244-251. doi:10.1016/j.eururo.2019.04.026
2. Callstrom MR, Dupuy DE, Solomon SB, et al. Percutaneous image-guided cryoablation of painful metastases involving bone: multicenter trial. *Cancer*. Mar 1 2013;119(5):1033-41. doi:10.1002/cncr.27793
3. Callstrom MR, Woodrum DA, Nichols FC, et al. Multicenter Study of Metastatic Lung Tumors Targeted by Interventional Cryoablation Evaluation (SOLSTICE). *J Thorac Oncol*. Jul 2020;15(7):1200-1209. doi:10.1016/j.jtho.2020.02.022
4. Campbell S, Uzzo RG, Allaf ME, et al. Renal Mass and Localized Renal Cancer: AUA Guideline. *J Urol*. Sep 2017;198(3):520-529. doi:10.1016/j.juro.2017.04.100
5. Cronan J, Dariushnia S, Bercu Z, et al. Systematic Review of Contemporary Evidence for the Management of T1 Renal Cell Carcinoma: What IRs Need to Know for Kidney Cancer Tumor Boards. *Semin Intervent Radiol*. Aug 2019;36(3):194-202. doi:10.1055/s-0039-1693119
6. de Baere T, Tselikas L, Woodrum D, et al. Evaluating Cryoablation of Metastatic Lung Tumors in Patients--Safety and Efficacy: The ECLIPSE Trial--Interim Analysis at 1 Year. *J Thorac Oncol*. Oct 2015;10(10):1468-74. doi:10.1097/JTO.0000000000000632

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Resources: (cont.)

7. Expert Panel on Urological I, Purysko AS, Nikolaidis P, et al. ACR Appropriateness Criteria(R) Post-Treatment Follow-up and Active Surveillance of Clinically Localized Renal Cell Cancer. *J Am Coll Radiol*. Nov 2019;16(11S):S399-S416. doi:10.1016/j.jacr.2019.05.022
8. Jennings JW, Prologo JD, Garnon J, et al. Cryoablation for Palliation of Painful Bone Metastases: The MOTION Multicenter Study. *Radiol Imaging Cancer*. Mar 2021;3(2):e200101. doi:10.1148/rycan.2021200101
9. 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
10. Kaufman CS, Bachman B, Littrup PJ, et al. Office-based ultrasound-guided cryoablation of breast fibroadenomas. *Am J Surg*. Nov 2002;184(5):394-400. doi:10.1016/s0002-9610(02)01010-3
11. 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
12. Kaufman CS, Littrup PJ, Freeman-Gibb LA, et al. Office-based cryoablation of breast fibroadenomas: 12-month followup. *J Am Coll Surg*. Jun 2004;198(6):914-23. doi:10.1016/j.jamcollsurg.2004.02.014
13. Keane MG, Bramis K, Pereira SP, Fusai GK. Systematic review of novel ablative methods in locally advanced pancreatic cancer. *World J Gastroenterol*. Mar 7 2014;20(9):2267-78. doi:10.3748/wjg.v20.i9.2267
14. Klatte T, Shariat SF, Remzi M. Systematic review and meta-analysis of perioperative and oncologic outcomes of laparoscopic cryoablation versus laparoscopic partial nephrectomy for the treatment of small renal tumors. *J Urol*. May 2014;191(5):1209-17. doi:10.1016/j.juro.2013.11.006
15. Kovach SJ, Hendrickson RJ, Cappadona CR, et al. Cryoablation of unresectable pancreatic cancer. *Surgery*. Apr 2002;131(4):463-4. doi:10.1067/msy.2002.121231
16. 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
17. Li J, Chen X, Yang H, et al. Tumour cryoablation combined with palliative bypass surgery in the treatment of unresectable pancreatic cancer: a retrospective study of 142 patients. *Postgrad Med J*. Feb 2011;87(1024):89-95. doi:10.1136/pgmj.2010.098350

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Resources: (cont.)

18. Littrup PJ, Freeman-Gibb L, Andea A, et al. Cryotherapy for breast fibroadenomas. *Radiology*. Jan 2005;234(1):63-72. doi:10.1148/radiol.2341030931
19. Maiwand MO, Asimakopoulos G. Cryosurgery for lung cancer: clinical results and technical aspects. *Technol Cancer Res Treat*. Apr 2004;3(2):143-50. doi:10.1177/153303460400300207
20. Manenti G, Perretta T, Gaspari E, et al. Percutaneous local ablation of unifocal subclinical breast cancer: clinical experience and preliminary results of cryotherapy. *Eur Radiol*. Nov 2011;21(11):2344-53. doi:10.1007/s00330-011-2179-2
21. Meller I, Weinbroum A, Bickels J, et al. Fifteen years of bone tumor cryosurgery: a single-center experience of 440 procedures and long-term follow-up. *Eur J Surg Oncol*. Aug 2008;34(8):921-927. doi:10.1016/j.ejso.2007.11.001
22. Moore W, Talati R, Bhattacharji P, Bilfinger T. Five-year survival after cryoablation of stage I non-small cell lung cancer in medically inoperable patients. *J Vasc Interv Radiol*. Mar 2015;26(3):312-9. doi:10.1016/j.jvir.2014.12.006
23. Morin J, Traore A, Dionne G, et al. Magnetic resonance-guided percutaneous cryosurgery of breast carcinoma: technique and early clinical results. *Can J Surg*. Oct 2004;47(5):347-51.
24. Morkos J, Porosnicu Rodriguez KA, Zhou A, et al. Percutaneous Cryoablation for Stage 1 Renal Cell Carcinoma: Outcomes from a 10-year Prospective Study and Comparison with Matched Cohorts from the National Cancer Database. *Radiology*. Aug 2020;296(2):452-459. doi:10.1148/radiol.2020192325
25. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer. Version 2.2022. Accessed June 8, 2022. http://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf
26. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 3.2022. Accessed June 9, 2022. http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
27. National Comprehensive Cancer Network (NCCN). Adult Cancer Pain. Version 1. 2022. Accessed June 10, 2022. https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf
28. Niu L, Mu F, Zhang C, et al. Cryotherapy protocols for metastatic breast cancer after failure of radical surgery. *Cryobiology*. Aug 2013;67(1):17-22. doi:10.1016/j.cryobiol.2013.04.004

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Resources: (cont.)

29. Niu L, Xu K, Mu F. Cryosurgery for lung cancer. *J Thorac Dis.* Aug 2012;4(4):408-19. doi:10.3978/j.issn.2072-1439.2012.07.13
30. Nurko J, Mabry CD, Whitworth P, et al. Interim results from the FibroAdenoma Cryoablation Treatment Registry. *Am J Surg.* Oct 2005;190(4):647-51; discussion 651-2. doi:10.1016/j.amjsurg.2005.06.033
31. Pecoraro A, Palumbo C, Knipper S, et al. Cryoablation Predisposes to Higher Cancer Specific Mortality Relative to Partial Nephrectomy in Patients with Nonmetastatic pT1b Kidney Cancer. *J Urol.* Dec 2019;202(6):1120-1126. doi:10.1097/JU.0000000000000460
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38. Stacul F, Sachs C, Giudici F, et al. Cryoablation of renal tumors: long-term follow-up from a multicenter experience. *Abdom Radiol (NY).* Sep 2021;46(9):4476-4488. doi:10.1007/s00261-021-03082-z

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Resources: (cont.)

39. Suzuki Y. Cryosurgical treatment of advanced breast cancer and cryoimmunological responses. *Skin Cancer*. 1995; 10:19-26.
40. Tanaka S. Cryosurgical treatment of advanced breast cancer. *Skin Cancer*. Jan 1995; 10:9-18.
41. Tang K, Yao W, Li H, et al. Laparoscopic renal cryoablation versus laparoscopic partial nephrectomy for the treatment of small renal masses: a systematic review and meta-analysis of comparative studies. *J Laparoendosc Adv Surg Tech A*. Jun 2014;24(6):403-10. doi:10.1089/lap.2013.0550
42. Tao Z, Tang Y, Li B, Yuan Z, Liu FH. Safety and effectiveness of cryosurgery on advanced pancreatic cancer: a systematic review. *Pancreas*. Jul 2012;41(5):809-11. doi:10.1097/MPA.0b013e318243a503
43. Uhlig J, Strauss A, Rucker G, et al. Partial nephrectomy versus ablative techniques for small renal masses: a systematic review and network meta-analysis. *Eur Radiol*. Mar 2019;29(3):1293-1307. doi:10.1007/s00330-018-5660-3
44. Xu KC, Niu LZ, Hu YZ, et al. A pilot study on combination of cryosurgery and (125)iodine seed implantation for treatment of locally advanced pancreatic cancer. *World J Gastroenterol*. Mar 14 2008;14(10):1603-11. doi:10.3748/wjg.14.1603
45. Yan S, Yang W, Zhu CM, Yan PM, Wang ZC. Comparison among cryoablation, radiofrequency ablation, and partial nephrectomy for renal cell carcinomas sized smaller than 2 cm or sized 2-4 cm: A population-based study. *Medicine (Baltimore)*. May 2019;98(21):e15610. doi:10.1097/MD.00000000000015610
46. Zhao Z, Wu F. Minimally-invasive thermal ablation of early-stage breast cancer: a systemic review. *Eur J Surg Oncol*. Dec 2010;36(12):1149-55. doi:10.1016/j.ejso.2010.09.012

Coding:

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

History:

Medical Policy Panel

Date:

08/16/22

Activity:

Approved guideline (Effective 09/19/22)



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Policy Revisions:



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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 nílínígíí Blue Cross Blue Shield of Arizona haada yit'éego bína'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'idíílkidgo beehaz'áanii hółq díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. 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.



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