NANOKNIFE®

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms “experimental” and “investigational” are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

Description:

The NanoKnife System or irreversible electroporation (IRE) is a minimally invasive technology that uses IRE, a non-thermal technology, to ablate soft tissue lesions through permeabilization of the cell membrane. Imaging techniques such as ultrasound or computed tomography (CT) are used to guide two or more NanoKnife IRE disposable electrodes in or around the targeted lesions. A series of short electric pulses are then sent from the electrodes directly into the lesions where cell death is caused. The FDA has approved the NanoKnife only for treatment of soft tissue tumors.
NANOKNIFE (cont.)

Criteria:

- Nanoknife is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 05/23/17. We do not include marketing materials, poster boards and non-published literature in our review.

Resources published prior to 04/30/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. CADTH Rapid Response Reports. Irreversible Electroporation for Tumors of the Pancreas or Liver: A Review of Clinical and Cost-Effectiveness. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health. Copyright (c) 2016 Canadian Agency for Drugs and Technologies in Health.; 2016.


NANOKNIFE (cont.)

**Resources:** (cont.)


NANOKNIFE (cont.)

Resources: (cont.)


NANOKNIFE (cont.)

Resources: (cont.)


29. UpToDate. Image-guided ablation of lung tumors. 09/10/2015.

30. UpToDate. Radiofrequency ablation and cryoablation for renal cell carcinoma. 07/01/2015.


NANOKNIFE (cont.)

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 85001-3466, (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 interprete, llame al 602-864-4884.

Navajo: Díí kwe’ é atah niilíngíí Blue Cross Blue Shield of Arizona haada yit’éégo bina’idílkiigo éí doodago Háida biíí aniyeéédíí t’áadoo le’é yina’idílkiigo bee haz’a’háníi hóló díí t’aí haazadí’éh’é háká a’dooowolgo bee haz’a doo bááh bilinígóó. Ata’halné’ígíí kojí‘ bich’í’ hodíílnih 877-475-4799.

Chinese: 如果您，或您正在協助的對象，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 thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viễn, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تسامح أسئلة بخصوص ضروريات اللغة، فهناك الحق في الحصول على المساعدة والمعلومات Blue Cross Blue Shield of Arizona لتحديد الحق في التوصل إلى مترجم. التحدث مع مترجم التصلب 877-475-4799.
NANOKNIFE (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuiangan, ay mga maya mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karatangan ka na makakuhang tululog at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관련해서 질문이 있다면 귀하의 그러한 도움과 정보를 귀하의 연어로 비용 무담없이 얻을 수 있는 권리가 있습니다. 그렇게 돕시다와 매기기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

روش سه، یا کسی که شما به آن کمک می‌کنید، سوال در مورد اطلاعات به زبان خود را به طور رایگان دروافت نمایید 877-475-4799.

Assyrian:

قەنەبە، یا چەندەیەکە کە وەکوو یەوە، سەڵەکە بێتەوە بە بۆبەرکە لە خۆبەکە بە نەوەی 877-475-4799.

Serbo-Croatian: Ukoliko vi ili neko kome vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevoditeljem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณช่วยเหลือถามคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้ความช่วยเหลือและข้อมูลภาษา ของคุณได้โดยไม่ค่าเงิน ที่หมายเลขโทรศัพท์ 877-475-4799.