RADIOFREQUENCY ABLATION OF MISCELLANEOUS SOLID TUMORS EXCLUDING LIVER TUMORS

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.

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Description:

Radiofrequency Ablation (RFA):
An electrode is inserted into a tumor to deliver an alternating current, causing protein denaturation, coagulation and ultimately cell death. This surgical procedure may be performed as an open or percutaneous procedure or under laparoscopic guidance. RFA has been investigated as a treatment for inoperable tumors or for an individual who is ineligible for surgery due to age, comorbidities or poor health.
MEDICAL COVERAGE GUIDELINES

SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/21/13
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RADIOFREQUENCY ABLATION OF MISCELLANEOUS SOLID TUMORS EXCLUDING LIVER TUMORS (cont.)

Definitions:

Renal Cell Carcinoma:
Cancer of the lining of the renal (kidney) tubules.

Renal Carcinoma:
Cancer that forms in the center of the kidney.

Wilms’ Tumor:
A type of kidney cancer that generally develops in children under 5 years of age.

Criteria:

- Radiofrequency ablation for osteoid osteoma is considered *medically necessary* with documentation of **BOTH** of the following:
  
  1. Failure to respond to a **three month** trial of non-steroidal anti-inflammatory drugs (NSAIDs) **and**
  2. Osteoid osteoma is not located in the spine **or** hand

- Radiofrequency ablation to palliate pain in osteolytic bone metastases is considered *medically necessary* for individuals who have failed or are poor candidates for standard treatments such as radiation.

- Radiofrequency ablation for the treatment of lung cancer is considered *medically necessary* with documentation of **ONE** of the following:
  
  1. Individual with isolated, peripheral non-small cell lung cancer with documentation of **ALL** of the following:
     
     • Tumor size is 3 cm or less
     • Surgical resection or radiation treatment with curative intent is considered appropriate based on stage of disease, however, individual is not a candidate for these interventions due to medical comorbidity
     • Tumor located at least 1 cm from trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and heart
RADIOFREQUENCY ABLATION OF MISCELLANEOUS SOLID TUMORS EXCLUDING LIVER TUMORS (cont.)

Criteria: (cont.)

- Radiofrequency ablation for the treatment of lung cancer is considered *medically necessary* with documentation of ONE of the following: (cont.)

  2. Individual with malignant non-pulmonary tumor(s) metastatic to the lung with documentation of ALL of the following:
     - Tumor size is 3 cm or less
     - Procedure is intended to preserve lung function when surgical resection or radiation treatment is likely to substantially worsen pulmonary status or Individual is not a candidate for surgical resection
     - No evidence of extrapulmonary metastases and tumor located at least 1 cm from trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and heart
     - No more than 3 tumors per lung will be ablated
     - Tumors are amenable to complete ablation
     - If repeat ablation, at least 12 months have elapsed since prior ablation

- If the above criteria are not met, radiofrequency ablation for the treatment of lung cancer 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.

- Radiofrequency ablation for the treatment of localized renal cell carcinoma is considered *medically necessary* for tumors less than or equal to 4 cm in size with documentation of ANY of the following:
  1. Individual has a solitary kidney
  2. Surgery is contraindicated and specific contraindication is documented
  3. Renal insufficiency with glomerular filtration rate less than 60mL/min per m$^2$
RADIOFREQUENCY ABLATION OF MISCELLANEOUS SOLID TUMORS EXCLUDING LIVER TUMORS (cont.)

Criteria: (cont.)

- Radiofrequency ablation for the following indications 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.

These indications include, but are not limited to:

- Breast cancer
- Breast fibroadenomas
- Osteolytic bone metastases as initial treatment
- Osteoma other than osteoid osteoma MPRM states
- All other tumors outside the liver (e.g., adrenal gland, head and neck, thyroid, ovary and pelvic/abdominal metastases of unspecified origin)
- Renal cell carcinoma not meeting the above criteria
- Wilms’ tumor

Resources:

Literature reviewed 10/04/17. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 08/21/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

RADIOFREQUENCY ABLATION OF MISCELLANEOUS SOLID TUMORS EXCLUDING LIVER TUMORS (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 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:
RADIOFREQUENCY ABLATION OF MISCELLANEOUS SOLID TUMORS EXCLUDING LIVER TUMORS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyang tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuhang tulong at impormasyon sa iyang 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 Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 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:

انگار شما، یا کسی که شما به آن کمک می‌کنید، سوال در مورد اطلاعات به زبان انگلیسی یا به زبان عربی دارید، تماس حاصل نمایید.

Assyrian:

،تاماس حاصل نمایید.

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 prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคุณรู้ใจคนด้วยแบบสอบถาม Blue Cross Blue Shield of Arizonaคุณสมบัติจะได้รับคำแนะนำและข้อมูลที่มีประโยชน์ของคุณโดยไม่ต้องใช้เงิน ติดต่อเราได้ที่ 877-475-4799