



MEDICAL COVERAGE GUIDELINES  
SECTION: RADIOLOGY

ORIGINAL EFFECTIVE DATE: 03/17/15  
LAST REVIEW DATE: 04/03/18  
LAST CRITERIA REVISION DATE: 08/29/16  
ARCHIVE DATE:

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## ELASTOGRAPHY

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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:

Elastography refers to the measurement of elastic properties of tissues and is based on the principle that malignant tissue is harder than benign tissue. Elastography examines the viscoelastic properties of tissue and has been investigated as a technique to increase ultrasound (US) and magnetic resonance (MR) specificity. Elastography has been investigated in a variety of clinical applications, including, but not limited to, breast imaging, endoscopic, vascular and prostate imaging as well as assessment of thyroid, skin, brain tumors and liver fibrosis.



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## **ELASTOGRAPHY (cont.)**

### **Description: (cont.)**

Elastography imaging techniques include the following:

#### **Acoustic Radiation Force Impulse Imaging (ARFI):**

ARFI uses an ultrasound probe to produce an acoustic 'push' pulse, which generates shear waves that propagate in tissue to assess liver stiffness. ARFI elastography evaluates the wave propagation speed to assess tissue stiffness. The faster the shear wave speed, the harder the object. ARFI elastography can be performed at the same time as a liver sonographic evaluation, even in individuals with a significant amount of ascites. ARFI technologies include Virtual Touch™ Quantification and Siemens Acuson S2000™ system.

#### **Magnetic Resonance Elastography (MRE):**

MRE combines MR imaging (MRI) with sound waves to create a visual map (elastogram) showing the stiffness of body tissues. MRE advantages over ultrasound elastography include: 1) analyzing larger liver volumes; 2) analyzing liver volumes of obese individuals or individuals with ascites; and 3) precise analysis of viscoelasticity using a 3-dimensional displacement vector.

#### **Real-Time Tissue Elastography (RTE):**

RTE is a type of strain elastography which uses a combined autocorrelation method to measure tissue strain caused by manual compression or an individual's heartbeat. The relative tissue strain is displayed on conventional color B mode ultrasound images in real time. This technology does not perform as well in severely obese individuals. RTE technologies includes HI VISION™ Preirus™.

#### **Shear Wave Elastography:**

Shear wave elastography uses ultrasound beams that are transmitted continuously to tissue at different depths at high speed. The restorative force of the tissue propagates laterally, generating shear waves. The velocity of the waves is measured and a two-dimensional image is created. The waves propagate quickly through hard tissue and more slowly through soft tissue, which allows for the calculation of tissue elasticity. Shear wave technologies include the Aixplorer® MultiWave™ Ultrasound System.

#### **Tactile Breast Imaging:**

Tactile breast imaging consists of a breast examination and subsequent image documentation, by computer-aided tactile sensors and documentation utilizing elastography to quantitatively measure and record the presence or absence, the size, shape, hardness and location of breast lesions. Breast lesion documentation systems include a hand-held device comprised of miniature pressure sensors to electronically palpate the breast for use in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast exam. These systems include, but are not limited to: the Breast View® Visual Mapping System, the SureTouch™ System and the iBreastExam™.

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## **ELASTOGRAPHY (cont.)**

### **Description:** (cont.)

#### Transient Elastography:

Vibration controlled transient elastography (VCTE) uses a mechanical vibrator to produce mild amplitude and low-frequency (50 Hz) waves, inducing an elastic shear wave that propagates throughout the liver. Ultrasound tracks the wave, measuring its speed, which correlates with liver stiffness. Increases in liver fibrosis also increase liver stiffness and resistance of liver blood flow. Transient elastography technologies include FibroScan.

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### **Criteria:**

**For elastography for liver disease, see BCBSAZ Medical Coverage Guideline #O495, “Noninvasive Techniques for Evaluation and Monitoring of Chronic Liver Disease”.**

- Elastography for all indications other than chronic liver disease 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.

Elastography imaging techniques include, *but are not limited to:*

- Acoustic radiation force impulse imaging
- Magnetic resonance elastography
- Real-time tissue elastography
- Shear wave elastography
- Tactile breast imaging
- Transient elastography

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## **ELASTOGRAPHY (cont.)**

### **Resources:**

**Literature reviewed through 04/03/18. We do not include marketing materials, poster boards and non-published literature in our review.**

**Resources prior to 03/21/17 may be requested from the BCBSAZ Medical Policy and Technology Research Department.**

1. Cheng R, Li J, Ji L, Liu H, Zhu L. Comparison of the diagnostic efficacy between ultrasound elastography and magnetic resonance imaging for breast masses. *Exp Ther Med*. Mar 2018;15(3):2519-2524.
2. Coombes BK, Tucker K, Vicenzino B, et al. Achilles and patellar tendinopathy display opposite changes in elastic properties: A shear wave elastography study. *Scand J Med Sci Sports*. Mar 2018;28(3):1201-1208.
3. Creze M, Marc S, Long Yue J, Gagey O, Maitre X, Marie-France B. Magnetic resonance elastography of the lumbar back muscles: A preliminary study. *Clin Anat*. Feb 15 2018.
4. DeJong HM, Abbott S, Zelesco M, Kennedy BF, Ziman MR, Wood FM. The validity and reliability of using ultrasound elastography to measure cutaneous stiffness, a systematic review. *Int J Burns Trauma*. 2017;7(7):124-141.
5. Dirrachs T, Quack V, Gatz M, et al. Shear Wave Elastography (SWE) for Monitoring of Treatment of Tendinopathies: A Double-blinded, Longitudinal Clinical Study. *Acad Radiol*. Mar 2018;25(3):265-272.
6. Gilbert F, Klein D, Weng AM, et al. Supraspinatus muscle elasticity measured with real time shear wave ultrasound elastography correlates with MRI spectroscopic measured amount of fatty degeneration. *BMC Musculoskelet Disord*. Dec 28 2017;18(1):549.
7. Hu X, Liu Y, Qian L. Diagnostic potential of real-time elastography (RTE) and shear wave elastography (SWE) to differentiate benign and malignant thyroid nodules: A systematic review and meta-analysis. *Medicine*. Oct 2017;96(43):e8282.
8. Jayaraman J, Indiran V, Kannan K, Maduraimuthu P. Acoustic Radiation Force Impulse Imaging in Benign and Malignant Breast Lesions. *Cureus*. Jun 1 2017;9(6):e1301.
9. Marticorena Garcia SR, Guo J, Durr M, et al. Comparison of ultrasound shear wave elastography with magnetic resonance elastography and renal microvascular flow in the assessment of chronic renal allograft dysfunction. *Acta radiologica (Stockholm, Sweden : 1987)*. Jan 1 2017;284185117748488.



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## ELASTOGRAPHY (cont.)

### Resources: (cont.)

10. Serra C, Rizzello F, Pratico C, et al. Real-time elastography for the detection of fibrotic and inflammatory tissue in patients with stricturing Crohn's disease. *J Ultrasound*. Dec 2017;20(4):273-284.
11. UpToDate.com. Transabdominal ultrasonography of the small and large intestine. 02/06/2018.
12. Wang HK, Lai YC, Lin YH, Chiou HJ, Chou YH. Acoustic Radiation Force Impulse Imaging of the Transplant Kidney: Correlation Between Cortical Stiffness and Arterial Resistance in Early Post-transplant Period. *Transplant Proc*. Jun 2017;49(5):1001-1004.
13. Xue Y, Yao S, Li X, Zhang H. Value of shear wave elastography in discriminating malignant and benign breast lesions: A meta-analysis. *Medicine*. Oct 2017;96(42):e7412.
14. Zachrisson H, Svensson C, Dremetsika A, Eriksson P. An extended high-frequency ultrasound protocol for detection of vessel wall inflammation. *Clin Physiol Funct Imaging*. Aug 9 2017.
15. Zhang F, Zhao X, Han R, Du M, Li P, Ji X. Comparison of Acoustic Radiation Force Impulse Imaging and Strain Elastography in Differentiating Malignant From Benign Thyroid Nodules. *Journal of ultrasound in medicine : official journal of the American Institute of Ultrasound in Medicine*. Dec 2017;36(12):2533-2543.
16. Zhang Q, Yao J, Cai Y, et al. Elevated hardness of peripheral gland on real-time elastography is an independent marker for high-risk prostate cancers. *Radiol Med*. Dec 2017;122(12):944-951.



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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](mailto: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 nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bína'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'idíílkidgo beehaz'áanii hólg díí t'áa 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.

