



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 09/18/18
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

NONINVASIVE TECHNIQUES FOR THE MEASUREMENT OF TISSUE OXYGENATION

- Near Infrared Spectroscopy (NIRS)
- Spatial Frequency Domain Imaging (SFDI)

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.

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.

NONINVASIVE TECHNIQUES FOR THE MEASUREMENT OF TISSUE OXYGENATION (cont.)

Description:

Near infrared spectroscopy (NIRS) for the examination of wounds is a technique that has been investigated to measure the level of oxygenated, deoxygenated and total hemoglobin within and under a wound and compare it to the individual's control (non-wound) tissue. The Emuna1000™ device has been proposed as a wound healing prediction tool via quantitative assessment of ischemic tissue. The device has been suggested for use within hyperbaric oxygen chambers.

Spatial Frequency Domain Imaging (SFDI) is a noninvasive transcutaneous measurement of five biomarkers (tissue oxygenation [StO₂], oxyhemoglobin [ctHbO₂], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]) using SFDI and multi-spectral analysis. The Reflect RS® from Modulated Imaging Inc. is an imaging device proposed to help identify potential areas of risk of compromised tissue and areas of elevated risk for ulceration.

Criteria:

- Near infrared (NIR) spectroscopic examination of wounds with the following devices is considered ***experimental or investigational*** based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

These devices include, *but are not limited to:*

- Emuna1000

NONINVASIVE TECHNIQUES FOR THE MEASUREMENT OF TISSUE OXYGENATION (cont.)

Criteria: (cont.)

- Spatial frequency domain imaging (SFDI) with multi-spectral analysis for the measurement of tissue oxygenation and hemoglobin is considered ***experimental or investigational*** based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

These devices include, *but are not limited to:*

- Reflect RS® by Modulated Imaging Inc.

Resources:

Literature reviewed 09/18/18. We do not include marketing materials, poster boards and non-published literature in our review.

1. ClinicalTrials.gov. Non-Invasive Assessment of Wound Healing with Optical Methods NCT0058604. Accessed 07/27/15, 10/15/14, 11/21/2012 & 09/27/2012.
2. ClinicalTrials.Gov. Spatial Frequency Domain Imaging (SFD) for Assessment of Diabetic Foot Ulcer Development and Healing NCT03341559. Accessed 09/08/2018.
3. ClinicalTrials.Gov. Optical Imaging for Assessment of Foot Perfusion NCT03144050. Accessed 09/08/2018.
4. ClinicalTrials.Gov. Assessment of Circulatory Compromise With Ox-Imager Using a Vascular Occlusion Test Protocol NCT03563105. Accessed 09/08/2018.



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 09/18/18
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

NONINVASIVE TECHNIQUES FOR THE MEASUREMENT OF TISSUE OXYGENATION (cont.)

Resources: (cont.)

5. Cole AL, Roskosky M, Chuler MS, Freedman BA. Near Infrared Spectroscopy and Lower Extremity Acute Compartment Syndrome: A Review of the Literature. *Trauma & Treatment, S2: 003 doi:104172/2167-1222S2-003*. 2014.
6. Emunamedica LLC. 2011.
7. Modulated Imaging Inc. Spatial Frequency Domain Imaging (SFDI). Accessed 09/08/2018.
8. Roskosky M, Robinson G, Reisman W, Ziran B, Shuler M, Freedman BA. Subcutaneous depth in a traumatized lower extremity. *Journal of Trauma and Acute Care Surgery*. September 2014 2014;77(3):S190-S193.
9. Wire B. Chronic Wound Diagnostics Company Emunamedica Announces Receipt of U.S. Patent Allowance. 04/22/14 2014.
10. Yafi A, Muakkassa FK, Pasupneti T, et al. Quantitative skin assessment using spatial frequency domain imaging (SFDI) in patients with or at high risk for pressure ulcers. *Lasers Surg Med*. Nov 2017;49(9):827-834.



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 09/18/18
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

NONINVASIVE TECHNIQUES FOR THE MEASUREMENT OF TISSUE OXYGENATION (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:

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 nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idíłkido go éí doodago Háida bíjá anilyeedíí t'áadoo le'é yina'idíłkido beehaz'áanii hółq díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į' hodíłnih 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، ف لديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

