NEAR INFRARED SPECTROSCOPIC EXAMINATION OF WOUNDS

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.

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Description:

Near infrared spectroscopic 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.
NEAR INFRARED SPECTROSCOPIC EXAMINATION OF WOUNDS (cont.)

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

Resources:


2. Emunamedica LLC. 2011.

Emuna1000 is a trademark of Emunamedica, L.L.C., an independent corporation that is not affiliated with BCBSAZ.