Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Near Infrared Spectroscopy for Wound Examination

Description/Background

Wound healing is a complex process that is dependent on multiple factors including adequate nutrition, bacterial load and mechanical forces. Adequate oxygenation of the tissues is vital to healing. Several non-invasive methods of measuring oxygen perfusion have been developed in attempts to predict healing potential.

Near infrared spectroscopy (NIRS) is a newer method of measuring oxygenation of tissues. This technology uses reflected light to calculate perfusion by analyzing subtle color changes that occur in hemoglobin when it is oxygenated. Recording the ratio of oxygenated to deoxygenated hemoglobin provide a measurement of the percentage of oxygenated blood that reaches the skin. The NIRS device transmits wavelengths of light between about 600 nm and 1000 nm; however, this range is not standardized. Most NIRS devices are noncontact systems.[1]

Regulatory Status

In November 2006 the U.S. Food and Drug Administration (FDA) gave 510(k) premarket notification for OxyVu-1™ Hyperspectral Tissue Oxygenation Measurement System (Hypermed, Inc.). OxyVu-1 is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of oxygen saturation (HT-Sat), oxyhemoglobin level (HT-Oxy), and deoxyhemoglobin (HT-Deoxy) level. It is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise. K061848.[2]

The Kent Camera (Kent Imaging, Calgary, AB, Canada) is an FDA approved Class II device indicated for determining oxygenation levels in superficial tissues for patients with potential circulatory compromise. The Kent Camera is a non-invasive tissue oxygenation measurement system that reports an approximate value of: oxygen saturation, oxyhemoglobin and deoxyhemoglobin levels in superficial tissue. Kent Camera displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions; and is indicated for use to determine oxygenation levels in superficial tissues. The Kent Camera was given FDA approval (2012) based on its similarity to the predicate device, OxyVu-1 Hyperspectral Tissue Oxygenation Measurement System (Hypermed, Inc.).[3]

In December 2016, the FDA gave 501(k) premarket notification to Hyperview™ Hyperspectral Tissue Oxygenation Measurement System (Hypermed Imaging, Inc.), which reports an approximate value of oxygen saturation (O2Sat), oxyhemoglobin level (Oxy), and deoxyhemoglobin (Deoxy) level. The device is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise.[4]

In October 2017, the FDA cleared Kent Imaging's $Snapshot_{NIR}$, a handheld device. (K163070)[5] $Snapshot_{NIR}$ is a Canadian-made near-infrared (NIR), reflectance-based technology that measures tissue oxygen saturation (S_tO_2) in superficial tissue. Using multiple wavelengths of NIR light, $Snapshot_{NIR}$ measures relative amounts of oxygenated and deoxygenated hemoglobin in the microcirculation where oxygen exchange is happening. Snapshot provides users with a tissue oxygenation map that can be used in medical decision making, for tracking and trending oxygenation, and for evaluating tissue viability in wound care[6].

There are other devices that are FDA approved for similar indications. Product code: MUD

Medical Policy Statement

The use of a near infrared spectroscopic device to examine wounds is **experimental/ investigational.** There is insufficient evidence of its effectiveness on health outcomes.

Inclusionary and Exclusionary Guidelines

NA

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0640T 0859T 0860T 93998

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Weingarten, et al (2010)[7] examined the effectiveness of diffuse NIR spectroscopy in predicting wound healing in sixteen chronic diabetic wounds. Oxyhemoglobin measurements were recorded weekly until there was wound closure, limb amputation or 20 completed visits without healing. Digital photography measured wound size, and the degree of wound contraction was compared to the NIR measurements. In the 16 patients followed, 7 wounds healed, 6 limbs were amputated and 3 wounds remained open after 20 visits. The initial values in subsurface hemoglobin concentration in all wounds were higher than the non-wound control sites. Healed wounds showed a consistent reduction of hemoglobin concentration several weeks before closure that approached control site values. In wounds that did not heal or resulted in amputation of the limb, the hemoglobin concentration remained elevated. In some cases, these non-healing wounds appeared to be improving. A negative slope for the rate of change of hemoglobin concentration was indicative of healing across all wounds. The authors concluded that evaluation of wound using NIR may provide an effective measurement of wound healing. These preliminary findings need further validation through well-designed studies.

Neidrauer et al (2010)[8] also reported on the above study, and state "In a clinical environment, it will be necessary to be able to predict healing before the end points of this study are reached. An accurate assessment of the capability of the HbO_2 slopes over time to predict healing or nonhealing would need to be determined through a study of more patients with measurements taken at more time points."

Lin et al (2020)[9] reported on a one-year prospective observational study involving 50 patients with diabetic foot ulcers. Patients were divided into groups by their arterial statuses. Group A had no peripheral arterial disease [PAD], group B had PAD without angioplasty, and group C had PAD with angioplasty. The patients in group C were older, more likely to have had an amputation and had more severe wounds than patients in other groups. The requirements of insulin injection for diabetes mellitus control differed significantly (P = .024) among the three groups. A wireless wearable NIRS device was used to assess tissue perfusion to determine the effects of Buerger exercises on wound healing. At the end of the survey, 19 patients (38%) had unhealed DFUs. The NIRS revealed that most nonhealed patients in groups B and C shared higher resting hemoglobin levels and tissue blood volume and lower tissue oxygen concentration, which indicated inflammation accompanied by higher blood flow and oxygen consumption. The nonhealed patients in group C showed paradoxically reduced hemoglobin and tissue blood volume after the exercises. The authors suggested that NIRS may prove valuable in predicting wound healing by identifying risk factors for poor wound prognosis, such as reduced hemoglobin and tissue blood volume after exercise.

Landsman (2020)[1] performed a retrospective study to determine if near infrared spectroscopy can be used to identify patterns involved in tissue oxygenation and wound healing as well as predict which wounds may or may not heal. Twenty-five patients with either diabetic foot ulcers

or venous leg ulcers who were being actively treated in the clinic were reviewed. All wounds were tracked with NIRS at regular intervals. Retrospectively, the de-identified images were reviewed to determine any patterns that might exist. Wound bed and peri-wound oxygenation patterns were observed and classified, including correlation with both the clinical appearance and the NIRS images. Four distinct patterns of tissue oxygenation that appeared to have some value for predicting which wounds would heal, and which would not, were identified among the 25 patients. The reviewer concluded that both qualitative and quantitative data are used to determine what is happening clinically. The study represents an early attempt to understand the role of NIRS and percent oxygenated hemoglobin in the wound healing process. It also lays groundwork for identifying patterns associated with wound closure.

SUMMARY
There are a limited number of studies regarding the usefulness of near infrared spectroscopy on the prediction of wound healing, and the study populations are small. Due to a lack to published studies with larger patient populations, conclusions regarding the efficacy of this technology cannot be made.

Government Regulations National/Local:

National Coverage Determination (NCD) for Infrared Therapy Devices (270.6)
Effective Date of this Version: 10/24/2006
Implementation Date: 01/16/2007

Indications and Limitations of Coverage

B. Nationally Covered Indications N/A

C. Nationally Non-Covered Indications

Effective for services performed on and after October 24, 2006, the Centers for Medicare & Medicaid Services has determined that there is sufficient evidence to conclude the use of infrared therapy devices and any related accessories is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act (the Act). The use of infrared and/or near-infrared light and/or heat, including monochromatic infrared energy, is non-covered for the treatment, including the symptoms such as pain arising from these conditions, of diabetic and/or non-diabetic peripheral sensory neuropathy, wounds and/or ulcers of the skin and/or subcutaneous tissues.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Low Energy Ultrasound for the Treatment of Wounds (retired)
- Low-Level Laser Therapy and High-Power Laser Therapy
- Monochromatic Infrared Energy (MIRE) Device for the Treatment of Cutaneous Ulcers, Diabetic Neuropathy and Miscellaneous Musculoskeletal Conditions
- Non Contact Ultrasound Treatment for Wounds
- Wound Therapy (BCN only)

References

1. Landsman A. Visualization of wound healing progression with near infrared spectroscopy: a retrospective study. Wounds. Oct 2020;32(10):265-271. PMID 33370248
2. U.S. Food and Drug Administration (FDA), 510(k) Summary OxyVu-1 Hyperspectral Tissue Oxygenation Measurement System, November 8, 2006.
3. U. S. Food and Drug Administration (FDA), Centers for Devices and Radiological Health, new device approval, "Kent Camera – K113507," approval date August 12, 2012, https://www.accessdata.fda.gov/cdrh_docs/pdf11/K113507.pdf Accessed 1/9/25.
4. U.S. Food and Drug Administration (FDA), 510(k) Summary HyperView™ Tissue Oxygenation Measurement System, December 16, 2016.
5. U.S. Food and Drug Administration (FDA), 510(k) Summary Kent Camera (handheld). https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163070.pdf Accessed 1/9/25.
6. Kent Imaging web page. SnapshotNIR — Kent Imaging Accessed 1/9/25.
7. Weingarten, MS et al. Prediction of wound healing in human diabetic foot ulcers by diffuse near-infrared spectroscopy: a pilot study. Wound Repair Regen. 2010 Mar-Apr; 18(2): 180-185.
8. Neidrauer, M et al. Near infrared wound monitor helps clinical assessment of diabetic foot ulcers. Journal of Diabetes Science and Technology. Vol 4, Issue 4, July 2010.
9. Lin BS, Chang CC, Tseng YH, et al. Using Wireless Near-Infrared Spectroscopy to Predict Wound Prognosis in Diabetic Foot Ulcers. Adv Skin Wound Care. 2020 Jan, Vol 33, No. 1, pp. 1-12. Doi: 10.1097/01.ASW.0000613552.50065.d5.
10. CMS National Coverage Determination (NCD) for Infrared Therapy Devices (270.6), effective date 10/24/2006. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=315&KeyWord=infrared%20therapy%20devices&KeyWordLookUp=Title&KeyWordSearchType=Exact&bc=CAAAAAAAAAAA Accessed 1/9/25.

The articles reviewed In this research Include those obtained in an Internet based literature search for relevant medical references through 1/9/25, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/13	10/16/12	10/16/12	Joint policy established
7/1/14	4/10/14	4/15/14	Routine review
5/1/16	2/16/16	2/16/16	Routine review
5/1/17	2/21/17	2/21/17	Routine review Policy retired
5/1/18	2/20/18	2/20/18	Policy unretired, addition of new code, routine review
5/1/19	2/19/19		Routine maintenance Updated description, regulatory information, rationale, government regulations and references.
5/1/20	2/18/20		Routine maintenance
5/1/21	2/16/21		Routine maintenance. Ref 1,4,9,10 added
11/1/21	8/17/21		Code update: 0493T revised: added 0640T, 0641T, 0642T
5/1/22	2/15/22		Routine maintenance
5/1/23	2/21/23		Routine maintenance (jf) 0493T – Code is being deleted-remove nomenclature per 2023 code update 93998 code added Vendor Review: NA Added reference 6
5/1/24	2/20/24		Routine maintenance (jf) -2024 Annual CPT Update Add 0859T and 0859T as E/I. - Delete codes 0641T and 0642T from policy per annual CPT code update. - Nomenclature updated for 0640T Vendor Review: NA

5/1/25	2/18/25		Routine maintenance (jf) Vendor Review: NA

Next Review Date: 1st Qtr, 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: NEAR INFRARED SPECTROSCOPY FOR WOUND EXAMINATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.