

Submitted by: Sheila H. Ridner, PhD, RN, FAAN

Name: Sheila H. Ridner, PhD, RN, FAAN

Company/Organization: Vanderbilt University School of Nursing

Address: 525 Godchaux Hall, 461 21st Ave. South, Nashville, TN 37240

Phone: 615-322-0831

E-mail: Sheila. Ridner@Vanderbilt.Edu

Date of Request: 7-19-2019

NCCN Guidelines Panel: NCCN Guidelines® Panel: Breast Cancer

On behalf of Vanderbilt University School of Nursing, Lymphedema Education and Research Network (LE&RN), and the American Society of Breast Surgeons Foundation, we respectfully request the NCCN Breast Cancer Guideline Panel to review the enclosed data to support the request to recommend monitoring for subclinical lymphedema under BINV-17 – Post Surgical Management.

Breast cancer-related lymphedema (BCRL) is a major source of morbidity among breast cancer survivors. Previously, lymphedema was only detected clinically, but the advent of technologies such as bioimpedance spectroscopy (BIS) has allowed for subclinical detection. As a result, emphasis is now placed on earlier detection of BCRL and subsequent intervention with noninvasive measures that are less intensive and less costly than complete decongestive physiotherapy (CDP). Increasing data support that early detection of subclinical BCRL followed by early intervention improves patient outcomes. Feasibility of the incorporation of BIS assessments in breast cancer programs as part of routine follow-up in clinical settings ranging from large institutions to small rural practices is well established.

Specific Changes:

1. Request to add a bullet point under BINV-17 “Post-surgical management: educate, monitor, and refer for lymphedema management” to read:
 - **Establish a surveillance program with bioimpedance spectroscopy (BIS) to detect subclinical breast cancer-related lymphedema (BCRL), initiate early intervention and reduce the need for complete decongestive physiotherapy.**
2. Request to add a footnote under BINV-17 to read:
 - **Pretreatment baseline measures are recommended to facilitate the earliest identification of subclinical lymphedema.**

FDA Status:

BIS technology is FDA-cleared with the following indications for use:

A BIS device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of lymphedema.

The use of the device to obtain an L-Dex score is only indicated for patients who will have or who have had lymph nodes, from the axillary and/or pelvic regions, either removed, damaged or irradiated.

Rationale: A recent publication of the interim analysis from a multisite randomized controlled trial led by Vanderbilt University School of Nursing demonstrated results consistent with recent findings, that patients undergoing surveillance with BIS had reductions in the rates of lymphedema progression

requiring resource-intensive and costly CDP compared with monitoring with tape measure (10% absolute reduction and 67% relative reduction in the rates of CDP), supporting the need for subclinical detection and early intervention for patients with BCRL.

Citation of Articles:

The following articles are submitted in support of this proposed change.

1. FDA_510_K_K180126.pdf https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180126.pdf
Accessed Jul 9, 2019.
2. Ridner, S.H., et al. *A randomized trial evaluating bioimpedance spectroscopy versus tape measurement for the prevention of lymphedema following treatment for breast cancer: Interim analysis*. Ann Surg Oncol, 2019.
3. Soran A, Polat AK, Mager LG. Chapter 47: Breast cancer-related lymphedema. In: Aydiner A, Igci A, Soran A, editors. Breast Disease Management and Therapies. Vol 2. Cham, Switzerland: Springer International Publishing; 2019.
4. Kilgore, L.J., et al. *Reducing breast cancer-related lymphedema (BCRL) through prospective surveillance monitoring using bioimpedance spectroscopy (BIS) and patient directed self-interventions*. Ann Surg Oncol, 2018.
5. Koelmeyer, L.A., et al. Early surveillance is associated with less incidence and severity of breast cancer-related lymphedema compared with a traditional referral model of care. Cancer. 2018; 125(6): 854-62.
6. Coroneos, C.J., et al. *Correlation of L-Dex bioimpedance spectroscopy with limb volume and lymphatic function in lymphedema*. Lymphat Res Biol, 2018.
7. Whitworth, P.W. and Cooper, A. *Reducing chronic breast cancer-related lymphedema utilizing a program of prospective surveillance with bioimpedance spectroscopy*. Breast J. 2018; 24(1): 62-5.
8. Kaufman, D.I., et al. Utilization of bioimpedance spectroscopy in the prevention of chronic breast cancer-related lymphedema. Breast Cancer Res Treat. 2017; 166(3): 809-15.
9. Laidley, A. and Anglin, B. The impact of L-Dex® measurements in assessing breast cancer related lymphedema (BCRL) as part of routine clinical practice. Front Oncol. 2016; 6:192.
10. Soran, A., et al. The importance of detection of subclinical lymphedema for the prevention of breast cancer-related clinical lymphedema after axillary lymph node dissection: A prospective observational study. Lymphat Res Biol. 2014; 12(4): 289-94.
11. Basta, M.N., et al. Complicated breast cancer-related lymphedema: Evaluating health care resource utilization and associated costs of management. Am J Surg. 2016; 211(1): 133-41.
12. Stout, N.L., et al. Breast cancer-related lymphedema: Comparing direct costs of a prospective surveillance model and a traditional model of care. Phys Ther. 2012; 92(1): 152-63.
13. Shih, Y.C., et al. Incidence, treatment costs, and complications of lymphedema after breast cancer among women of working age: A 2-year follow-up study. J Clin Oncol. 2009; 27(12): 2007-14.

Sincerely,



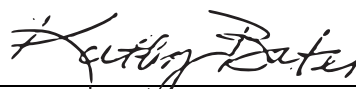
Martha Rivers Ingram Professor
Vanderbilt University
School of Nursing



President & CEO
LE&RN



Director
American Society of Breast
Surgeons Foundation



LE&RN Spokesperson

Enclosures:
Referenced Literature