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.


Sincerely,

Martha Rivers Ingram Professor
Vanderbilt University
President & CEO
School of Nursing
LE&RN

Director
American Society of Breast Surgeons Foundation

Enclosures:
Referenced Literature