



5900 Pasteur Court, Suite 125
Carlsbad, California 92008 USA
— www.impedimed.com —

Submitted by:

Frank Vicini, MD, FACR
Chief Medical Officer
ImpediMed, Inc.
5900 Pasteur Court
Suite 125
Carlsbad, CA 92008
Phone: 760 585 2100
Email: fvicini@impedimed.com

Date of request: July 10, 2017

Joan McClure, MS
Senior Vice President, Clinical Information & Publications
National Comprehensive Cancer Network® (NCCN®)
275 Commerce Dr, Suite 300
Fort Washington, PA 19034

Dear Ms. McClure:

NCCN Guidelines® Panel: Breast Cancer

On behalf of ImpediMed, Inc., we respectfully request the NCCN Breast Cancer Guideline Panel to review the enclosed data for inclusion of the bioimpedance spectroscopy (BIS) for the early detection and management of breast cancer related lymphedema.

Specific Changes:

Request to expand BINV-16, “educate, monitor, and refer for lymphedema management” to read:

Provide education on risk of lymphedema and risk reduction practices; monitor for early stage lymphedema using an objective, reproducible tool, such as bioimpedance spectroscopy (BIS); and refer for early lymphedema management.

FDA Status:

ImpediMed’s Bioimpedance Spectroscopy (BIS) device is FDA-cleared with the following indications for use:

A bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex® ratio that supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of unilateral lymphedema of the arm and leg in women and the leg in men.

Rationale:

Since the inclusion of “educate, monitor, and refer for lymphedema management” in the NCCN Guidelines® for Breast Cancer there has been substantial new evidence to support the request to include bioimpedance spectroscopy (BIS) as an objective, reproducible tool that provides a standardized metric for early detection and management of breast cancer related lymphedema.

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

1. 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): p. 289-94.
2. Laidley, M., Alison and M. Anglin, Beth, *The Impact of L-Dex® Measurements in Assessing Breast Cancer Related Lymphedema (BCRL) as Part of Routine Clinical Practice*. *Frontiers in Oncology*, 2016. **6**(192).
3. Whitworth, P.W., et al., *Reducing chronic breast cancer related lymphedema utilizing a program of prospective surveillance with bioimpedance spectroscopy (BIS)*. *J Clin Oncol* 2017. **35**(suppl; abstr 10117).
4. Reichart, K., *Lymphedema: Improving Screening and Treatment Among At-Risk Breast Cancer Survivors*. *Clin J Oncol Nurs*, 2017. **21**(1): p. 21-25.
5. Levenhagen, K., et al., *Diagnosis of Upper Quadrant Lymphedema Secondary to Cancer: Clinical Practice Guideline From the Oncology Section of the American Physical Therapy Association*. *Phys Ther.*, 2017. **97**: p. 1-17

Sincerely,



Frank Vicini, MD, FACR
Chief Medical Officer, ImpediMed

Enclosures:

Additional supporting documentation
Primary referenced literature