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.


Sincerely,

[Signature]

Frank Vicini, MD, FACR
Chief Medical Officer, ImpediMed

Enclosures:
Additional supporting documentation
Primary referenced literature