PROPOSED/DRAFT Local Coverage Determination (LCD): Bioimpedance Spectroscopy (BIS) Devices for the Detection and Management of Lymphedema (DL36141)

[PROPOSED/DRAFT]

Please note: This is a Proposed/Draft policy.
Proposed/Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed/Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Contractor Information

Contractor Name	Contract Number	Contract Type	Jurisdiction
National Government Services, Inc. opens in new window	13102	A and B and HHH MAC	J - K

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Proposed/Draft LCD Information

Document Information

[PROPOSED/DRAFT]

Source LCD ID
N/A

Proposed LCD ID
DL36141

Original ICD-9 LCD ID
N/A

Proposed LCD Title
Bioimpedance Spectroscopy (BIS) Devices for the Detection and Management of Lymphedema

Jurisdiction
Connecticut

CMS National Coverage Policy Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See Section 1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Code of Federal Regulations:

42 CFR, Section 410.32, indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see Sec. 411.15(k)(1) of this chapter).

CMS Publications:
CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 2:
80–80.2 Required Hospital Notice to Beneficiaries

CMS Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 4:
10 Outpatient Prospective Payment System (OPPS)

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

Bioimpedance spectroscopy (BIS) devices use impedance ratios to measure extracellular fluid volume differences between limbs in the clinical assessment of lymphedema. Use is considered not medically necessary in the assessment, diagnosis, or managemnet of individuals with known or suspected lymphedema.

Lymphedema is swelling from protein-rich fluid due to improper functioning of the lymphatic system. Patients with breast cancer are considered at risk of developing lymphedema following breast conserving surgical procedures. Ridner et al. (2009) noted studies show 6% - 40% will develop lymphedema inlcuding a rate of 6% - 22% in those having sentinel node biopsies. Bar et al. (2010) retrospectively studied the development of arm lymphedema in 1,713 consecutive Stage I or II breast cancer patients who underwent breast conservation therapy, including axillary staging followed by radiation. A difference of 2 cm or less between the measured circumferences of the affected and unaffected arms was used as indicating mild lymphedema was present in 266 (16%) of patients. The course of 109 (6%) of the 1,713 patients with mild lymphedema at the time of diagnosis

was reviewed for the rate of freedom from progression to more severe lymphedema; 79% were free at 1 year, 66% at two years and 52% at 5 years. Treatment methods vary but may involve compression, complex decongestive therapy, manual lymphatic drainage; exercise, and other therapies.

The U.S. Federal Drug Administration (FDA) granted 510(K) market clearance for a BIS device (the ImpediMED L-DEX® U400 BIS Extra Cellular Fluid Analyzer) (ImpediMed Limited, San Diego CA) in 2008. The device was considered an impedance plethysomograph and was approved for the extracellular fluid volume measurement to aid in the assessment of unilateral lymphedema of the arms in women. The application stated the device was not intended to diagnose or predict lymphedema of an extremity. In 2011, the company received FDA clearance for another BIS device, the ImpiMed L-Dex U400® ExtraCellular Flluid Analyzer with an expanded use to include legs in adult human women and men. The device was noted to be indicated for patients who will have or who have had lymph nodes, from the axillary and pelvic regions, either removed, damaged or irradiated.

Ridner et al. (2009) used single-frequency bioelectrical impedance in nonlaboratory settings to measure arm extracellular fluid. Ratios among healthy normal women (n = 60) and breast cancer survivor groups without clinical evidence of lymphedema (n = 75) were very similar, with nearly complete overlap in confidence intervals. Values were very different in breast cancer patients with lymphedema (n = 97) from those in the group without lymphedema ($p < 0.001$).

Czerniec et al. (2010) compared the reliability of physical measurement methods and self-reported swelling. Each arm of the 33 women with lymphedema and 18 women without unilateral lymphedema secondary to breast cancer were measured by self-report, bioimpedance spectroscopy (BIS), perometer, and the truncated cone method (circumference). Measurements were made on two different dates four weeks apart. The authors concluded the physical measurement tools were reliable witih high concordance (0.89 – 0.99) but not interchangeable. Self-report was moderately correlated with physical measurements (0.65 – 0.71). Jain et al. (2010) also studied a comparison between BIS and perometry but only 10 women were included in the investigation.

Czerniec et al. (2011) compared the abilitiy of bioimpedance spectroscopy (BIS) and perometry to detect localized lymphedema. Women with mild to severe upper limb lymphedema (n = 29) and those without a history of lymphedema (n = 11) were studied. The BIS measurements (inter-limb ratios) were higher in the patients with lymphedema compared to perometry measurements but similar in those without lymphedema. The authors concluded that BIS could be used for localized measurements and that it was more sensitive to detect localized lymphedema than perometry. Studies with larger sample size are needed given the small number of participants in this study.

Fu et al. (2013) studied the reliability, sensitivity and specificity of bioimpedance spectroscopy to detect lymphedema. Breast cancer survivors previously diagnosed with lymphedema (n = 42) (16.8%), breast cancer survivors at risk for lymphedema (n = 148) (59.2%) and healthy women (n = 60) (24%) participated (n = 250). Sequential circumferential tape measuremeasurements (a 200 mL differnece in limb volume between the affected and unaffected limb) were used to validate the presence of lymphedema. BIS measurements were obtained in all participants with retests at five-minute intervals. Results showed that an L-Dex ratio was highly reliable among healthy women (ICC= 0.99; 95% CI = 0.99 – 0.99); survivors at-risk for lymphedema (ICC= 0.99; 95% CI = 0.99 – 9.99); and all women (ICC = 0.85; 95% CI = 0.81 – 0.87) but only acceptable for survivors with lympedema (ICC=0.69; 95% CI = 0.54 – 0.80). A cutoff L.-Dex ratio >+7.1 missed 20% of true lymphedema cases. The authors stated that it was important for clnicians to integrate other assessment methods such as self-report, clinical observation, or perometry to ensure the accute detection of lymphedema.

A technology assessment (TA) performed for the Agency for Healthcare Research and Quality (AHRQ, 2010) stated that consistent evidence indicatd that lymphedema could be reliably measured using circumferential measures or volume displacement. Given the frequency of use of different measures of limb volume or circumference the authors concluded these measures are the de afacto 'gold standards' for diagnosing secondary lymphedema. Too little evidence was found to draw conclusions about the reliabiliity of other tests such as tonometry, ultrasound, lymphoscintigraphy, or bioimpedance.

Information to determine the usefulness of bioimpedance sptroscopy to assess the presence of lymphedema is currently inadequate to determine its clinical utility. Numbers of patients studied are small. Trials to examine its effect on clinical outcomes compared to other accepted techniques is lacking. Therefore, its use is considered investigational/not medically necessary in the Medicare population.

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Proposed/Draft Process Information

Associated Information
The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Sources of Information and Basis for Decision
This bibliography presents those sources that were obtained during the development of this policy. National Government Services is not responsible for the continuing viability of Web site addresses listed below.

Aetna- Number 0069: Clinical Policy Bulletin, Lymphedema: http://www.aetna.com/cpb/medical/data/1_99/0069.html Accessed April 21, 2015.

Agency for Healthcare Research and Quality. Diagnosis and treatment of secondary lymphedema. Technology Assessment Report. 2010 May. Project ID LYMT0908. Available at: http://www.ahrq.gov/clinic/techix.htm. Accessed on March 17, 2014.

ANTHEM– MED 00105: https://www.anthem.com/medicalpolicies/policies/mp_pw_c129400.htm Accessed April 21, 2015.

Bar Ad V, Cheville A, Solin LJ, et al. Time course of mild arm lymphedema after breast conservation treatment for early-stage breast cancer. *Int J Radiat Oncol Biol Phys.* 2010; 76(1):85-90.

Berlit S, et al, Comparing Bioelectrical Impedance Values in Assessing Early Upper Limb Lymphedema after Breast Cancer Surgery, *in vivo* 26: 863-868 (2012).

Czerniec SA, Ward LC, Lee MJ, et al. Segmental measurement of breast cancer-related arm lymphoedema using perometry and bioimpedance spectroscopy. *Support Care Cancer*. 2011; 19(5):703-710.

Czerniec SA, Ward LC, Refshauge KM, Beith J, Lee MJ, York S, Kilbreath SL., Assessment of breast cancer-related arm lymphedemacomparison of physical measurement methods and self-report,*Cancer Invest*. 2010 Jan;28(1):54-62. doi: 10.3109/07357900902918494.

Food and Drug Administration 510(k) Premarket Notification Database. ImpediMed L-Dex U400 BIS Extra Cellular Fluid Analysis. No. K080825. Rockville, MD: FDA. October 3, 2008. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080825.pdf. Accessed on March 17, 2014.

Fu MR, Cleland CM, Guth AA, et al. L-dex ratio in detecting breast cancer-related lymphedema: reliability, sensitivity, and specificity. *Lymphology*. 2013; 46(2):85-96.

Hayes S, Janda M, Cornish B, et al. Lymphedema secondary to breast cancer: how choice of measure influences diagnosis, prevalence, and identifiable risk factors. *Lymphology.* 2008; 41(1):18-28.

Humana- Lymphedema – Diagnosis and Treatment Medical Coverage Policy: http://apps.humana.com/tad/tad_new/home.aspx Accessed April 21, 2015.

Jain MS, Danoff JV, Paul SM. Correlation between bioelectrical spectroscopy and perometry in assessment of upper extremity swelling. *Lymphology.* 2010; 43(2):85-94.

Oremus M, Dayes I, Walker K, Raina P. Systematic review: conservative treatments for secondary lymphedema. BMC Cancer. 2012; 12:6. http://www.biomedcentral.com/1471-2407/12/6. Accessed on May 12, 2015.

Ridner SH, Dietrich MS, Deng J, et al. Bioelectrical impedance for detecting upper limb lymphedema in nonlaboratory settings. *Lymphat Res Biol.* 2009; 7(1):11-15.

Up To Date, http://www.uptodate.com/contents/prevention-and-treatment-of-lymphedema.com. Accessed on April 21, 2015

Open Meetings/Part B MAC Contractor Advisory Committee (CAC) Meetings N/A
Comment Period Start Date
06/26/2015

Comment Period End Date
08/09/2015

Released to Final LCD Date
N/A

Reason for Proposed LCD

- Provider Education/Guidance

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Coding Information

[PROPOSED/DRAFT]

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes
Group 1 Paragraph: N/A

Group 1 Codes:

93702	BIOIMPEDANCE SPECTROSCOPY (BIS), EXTRACELLULAR FLUID ANALYSIS FOR LYMPHEDEMA ASSESSMENT(S)

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes	Description
XX000	Not Applicable

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph: All diagnosis codes are considered not reasonable and necessary.

Group 1 Codes:

ICD-10 Codes	Description
XX000	Not Applicable

ICD-10 Additional Information

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Associated Documents

Attachments N/A

Related Local Coverage Documents N/A

Related National Coverage Documents N/A Back to Top

Keywords

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