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PRESS RELEASE

IMPEDIMED STRENGTHENS REIMBURSEMENT POSITION IN THE US WITH THE RELEASE OF CATEGORY III CODE

The American Medical Association (AMA) posted this week a Category III CPT code for release on July 1st. The code is for the use of Bioimpedance Spectroscopy (BIS) in the measurement of extracellular fluid differences of the limbs.

The new code, accepted at the AMA's February CPT Editorial Panel, will become effective on January 1, 2011, following a six month implementation period which begins from its release on July 1, 2010.

"The newly assigned CPT code will cover the use of the L-Dex ® U400 for its present FDA cleared indication for aiding in the clinical assessment of unilateral lymphoedema of the arm in women," said Greg Brown, Chief Executive Officer of ImpediMed. "This code covers the use of the technology in measuring extracellular fluid differences between the limbs. Such a definition for the code allows for both the present cleared claim, and a future potential clearance for other limbs."

Mr. Brown went on to say, "The Company recently announced to the Australian market that it had filed with the FDA an expanded claim for aiding in the clinical assessment of lymphoedema of the limbs. The Company will continue to work towards expanding the coverage for the L-Dex U400 with this new Category III code by educating health insurance providers within the United States as to the potential health economic benefit of a pre-emptive model of care with respect to breast cancer patients."

Category III codes are recognized as emerging technologies and have the advantage of not having a specific payment amount associated with them. Health insurance providers make individual decisions regarding payment for healthcare services based on, among other things, both economic and available clinical data to demonstrate the benefits of the procedure. Patients who develop lymphoedema incur significantly higher medical costs than patients who don't.[1] Lymphoedema impacts on quality of life and has associated longer term medical risks, both of which support the benefit of earlier detection and treatment.

"Survivorship issues are one of the most important things to my patients today. Medicine is identifying their cancer earlier, when it can be more effectively treated. Being able to resume their life without lingering reminders of their cancer is vital to their well being and peace of mind," said Walton Taylor M.D.[2], ImpediMed's Medical Director. "The use of the L-Dex U400 aids surgeons and oncologists to clinically assess and prospectively manage

lymphoedema and to potentially identify it earlier, when it can be most cost effectively treated."

ImpediMed's L-Dex devices are the first FDA, CE and TGA cleared devices that offer simple point of care, standardised and objective metrics to aid in the clinical assessment of lymphoedema of the limbs (female arms only in the US). They enable medical professionals to provide preoperative clinical assessments and ongoing monitoring of patients for the early signs of lymphoedema. This potentially allows for the early, simple, and cost effective treatment that can assist in preventing the progression of lymphoedema to irreversible forms, helping to improve the quality of life of patients while easing the substantial financial burden on patients and governments. At present there are 90 L-Dex U400 devices with medical professionals in the US market.

1. 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.

2. Dr. Walton Taylor is a board certified surgeon with extensive experience in the diagnosis and treatment of breast cancer. He is a Fellow of the American College of Surgeons and member of the American Society of Breast Surgeons.

ENDS

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" L-Dex® values that lie outside the normal range may indicate the early signs of lymphoedema and values that have changed +10 L-Dex units from baseline may also indicate early lymphoedema. The L-Dex scale is a tool to assist in the clinical assessment of lymphoedema by a medical provider. The L-Dex scale is not intended to diagnose or predict lymphoedema of an extremity".

About ImpediMed
ImpediMed Ltd. is the world leader in the development and distribution of medical devices employing Bioimpedance Spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status. ImpediMed's primary product range consists of a number of medical devices that aid surgeons, oncologists, therapists and radiation oncologists in the clinical assessment of patients for the potential onset of secondary lymphoedema. Pre-operative clinical assessment in breast cancer survivors, before the onset of symptoms, may prevent the condition from becoming a lifelong management issue and thus improve the quality of life of the cancer survivor. ImpediMed has the first medical device with an FDA clearance in the United States to aid health care professionals, clinically assess secondary lymphoedema of the arm in female breast cancer patients.
For more information, visit. www.impedimed.com.

CPT Category III codes

This section of CPT codes contains a temporary set of codes for emerging technologies, services, and procedures.

For more information on CPT Category I, II and III codes, see Applying for Codes.

CPT® is a registered trademark of the American Medical Association (AMA).

Concurrent with the development of CPT-5, the CPT Editorial Panel has approved the early release of the new CPT Category III codes. All changes provided as an early release of Category III codes are not intended to take effect until the implementation date.

To assist users in reporting the most recently approved Category III codes, the AMA's CPT Web site features updates of the CPT Editorial Panel actions and early release of the Category III codes in July and January in a given CPT cycle. These dates for early release correspond with the three annual CPT Editorial Panel meetings for each CPT cycle (June, October, and February).

As with CPT Category I codes, inclusion of a descriptor and its associated code number does not represent endorsement by the AMA of any particular diagnostic or therapeutic procedure or service. Inclusion or exclusion of a procedure or service does not imply any health insurance coverage or reimbursement policy.

Background information for Category III codes
CPT Category III codes are a set of temporary codes that allow data collection for emerging technology, services, and procedures. These codes are intended to be used to substantiate widespread usage or to provide documentation for the Food and Drug Administration (FDA) approval process. The CPT Category III codes may not conform to the usual CPT code requirements as follows:

- Services or procedures must be performed by many health care professionals across the country.
- FDA approval must be documented or be imminent within a given CPT cycle.
- The service or procedure has a proven clinical efficacy.
- The service or procedure must have relevance for research, either ongoing or planned.

These codes are assigned an alphanumeric identifier with a letter in the last character (e.g., 1234T) and are located in a separate section of the CPT codebook, following the Medicine section. The introductory language for this code section explains the purpose of these codes.

Because CPT Category III codes are intended to be used for data collection purposes to substantiate widespread usage or to provide documentation for the FDA approval process, they are not intended for services or procedures that are not accepted by the CPT Editorial Panel due to an incomplete proposal, the need for more information, or a lack of CPT Advisory Committee support.

Once approved by the CPT Editorial Panel, the newly added CPT Category III codes are made available on a semi-annual basis via electronic distribution on this Web site. The full set of Category III codes will be included in the next published edition for that CPT cycle.

CPT Category III codes are not referred to the AMA-Specialty RVS Update Committee (RUC) for valuation because no relative value units (RVUs) are assigned to these codes. Payment for these services or procedures is based on the policies of payers and not on a yearly fee schedule.

In general, these codes are archived after five years if the code has not been accepted for placement in the Category I section of the CPT codebook, unless demonstrated that a Category III code is still needed. These codes will not be reused.

Category III codes for CPT 2010
It is important to note that, because future CPT Editorial Panel or Executive Committee actions may affect these items, codes and descriptor language may differ at the time of publication. Also, future Panel actions may result in gaps in code number sequencing. A cross-reference will appear in the Category III section of the CPT codebook to direct users to the newly established CPT Category I code.

The symbol ● indicates new procedure codes that will be added to the CPT codebook in 2010.

Category III codes
The following section contains a set of temporary codes for emerging technology, services, and procedures. Category III codes allow data collection for these services or procedures. Use of unlisted codes does not offer the opportunity for the collection of specific data. If a Category III code is available, this code must be reported instead of a Category I unlisted code. This is an activity that is critically important in the evaluation of health care delivery and the formation of public and private policy. The use of the codes in this section allows physicians and other qualified health care professionals, insurers, health services researchers, and health policy experts to identify emerging technology, services, and procedures for clinical efficacy, utilization, and outcomes.

The inclusion of a service or procedure in this section neither implies nor endorses clinical efficacy, safety, or the applicability to clinical practice. The codes in this section may not conform to the usual requirements for CPT Category I codes established by the Editorial Panel. For Category I codes, the Panel requires that the service or procedure be performed by many health care professionals in clinical practice in multiple locations and that FDA approval, as appropriate, has already been received. The nature of emerging technology, services, and procedures is such that these requirements may not be met. For these reasons, temporary codes for emerging technology, services, and procedures have been placed in a separate section of the CPT codebook, and the codes are differentiated from CPT Category I codes by the use of the alphanumeric characters.

Services or procedures described in this section make use of alphanumeric characters. These codes have an alpha character as the 5th character in the string, preceded by four digits. The digits are not intended to reflect the placement of the code in the Category I section of the CPT nomenclature. Codes in this section may or may not eventually receive a CPT Category I code. In either case, a given Category III code will be archived five years from its date of publication or revision in the CPT code book unless it is demonstrated that a temporary code is still needed. Services or procedures described by Category III codes, which have been archived after five years without conversion, may be reported using the Category I unlisted code. New codes in this section are released semi-annually via the AMA CPT Web site to expedite dissemination for reporting. The full set of temporary codes for emerging technology, services, and procedures are published annually in the CPT codebook.

Category III codes 0208T-0222T were accepted at the June 2009 CPT Editorial Panel meeting for the 2011 CPT production cycle. Therefore, these codes will not appear in the 2010 CPT codebook. However, due to the Category III code early release policy, these codes are effective on January 1, 2010, following the six month implementation period which begins July 1, 2009.

▲0208T Pure tone audiometry (threshold), automated; air only	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
▲0209T air and bone	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
▲0210T Speech audiometry threshold, automated;	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
▲0211T with speech recognition	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
▲0212T Comprehensive audiometry threshold evaluation and speech recognition (0209T, 0211T combined), automated	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
(For audiometric testing using audiometers performed manually by a qualified health care professional, see 92551-92557)		
●0213T Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
(To report bilateral procedures, use 0213T with modifier 50)		
+●0214T second level (List separately in addition to code for primary procedure)	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
(To report bilateral procedures, use 0214T with modifier 50)		

+●0215T third and any additional level(s) (List separately in addition to code for primary procedure)	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
(Do not report 0215T more than once per day)		
(Use 0214T, 0215T in conjunction with 0213T)		
(To report bilateral procedures, use 0215T with modifier 50)		
●0216T Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
(To report bilateral procedures, use 0216T with modifier 50)		
+●0217T second level (List separately in addition to code for primary procedure)	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
(To report bilateral procedures, use 0217T with modifier 50)		
+●0218T third and any additional level(s) (List separately in addition to code for primary procedure)	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
(Do not report 0218T more than once per day)		
(Use 0217T, 0218T in conjunction with 0216T)		
(To report bilateral procedures, use 0218T with modifier 50)		
●0219T Placement of ~~a~~ posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
●0220T thoracic	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***

●0221T lumbar	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
(Do not report 0219T-0221T with any radiological service)		
(Do not report 0219T-0221T with 20930, 20931, 22600-22614, 22840, 22851 at same level)		
✚●0222T each additional vertebral segment (List separately in addition to code for primary procedure)	Released July 1, 2009 Implemented Jan 1, 2010	***CPT 2011***
(Use 0222T in conjunction with 0219T-0221T)		
(For posterior or posterolateral arthrodesis technique, see 22600-22614)		

Category III codes 0223T-0233T were accepted at the October 2009 CPT Editorial Panel meeting for the 2011 CPT production cycle. Therefore, these codes will not appear in the 2010 CPT codebook. However, due to the Category III code early release policy, these codes are effective on July 1, 2010, following the six month implementation period which begins January 1, 2010.

Acoustic cardiography codes 0223T-0225T describe the evaluation and optimization of physiologic data including systolic and diastolic heart sounds and their temporal relationships to the electrocardiogram (ECG).		
Codes 0224T and 0225T also include interrogation and limited reprogramming of a cardiac pacing device to ensure hemodynamic optimization (heart rate parameter and/or automated timing modes, including explicit changes of AV/VV intervals) and facilitate device parameter optimization. Do not report 0224T or 0225T in conjunction with 93288 or 93289.		
Acoustic cardiography services include a rhythm strip ECG. Do not report 93040-93042 in conjunction with 0223T-0225T.		

For complete programming services as a separate procedure, see 93280, 93281, 93283, and 93284.		
●0223T Acoustic cardiography, including automated analysis of combined acoustic and electrical intervals; single, with interpretation and report	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
●0224T multiple, including serial trended analysis and limited reprogramming of device parameter - AV or VV delays only, with interpretation and report	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
●0225T multiple, including serial trended analysis and limited reprogramming of device parameter - AV and VV delays, with interpretation and report	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
●0226T Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
●0227T with biopsy(ies)	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
●0228T Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
●0229T each additional level (List separately in addition to code for primary procedure)	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
(Use 0229T in conjunction with 0228T)		
●0230T Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
●0231T each additional level (List separately in addition to code for primary procedure)	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
(Use 0231T in conjunction with 0230T)		
(For transforaminal epidural injections performed under fluoroscopy or computed tomography, see 64479-64484		

(Do not report 0228T-0231T in conjunction with 76942, 76998, 76999)		
●0232T Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***
(Do not report 0232T in conjunction with 20550, 20551, 20926, 76942, 77002, 77012, 77021, 86965)		
●0233T Skin advanced glycation endproducts (AGE) measurement by multi-wavelength fluorescent spectroscopy	Released Jan 1, 2010 Implemented July 1, 2010	***CPT 2011***

Category III codes 0234T-0259T were accepted at the February 2010 CPT Editorial Panel meeting for the 2011 CPT production cycle. Therefore, these codes will not appear in the 2010 CPT codebook. However, due to the Category III code early release policy, these codes are effective on January 1, 2011, following the six month implementation period which begins July 1, 2010.

Atherectomy for Supra-Inguinal Arteries		
Codes 0234T-0238T describe atherectomy performed by any method (eg, directional, rotational, laser) in arteries above the inguinal ligaments. These codes are structured differently than the codes describing atherectomy performed below the inguinal ligaments (37225, 37227, 37229, 37231, 37233, 37235).		
These supra-inguinal atherectomy codes all include the surgical work of performing the atherectomy plus the radiological supervision and interpretation of the atherectomy. Unlike the atherectomy codes for infra-inguinal arteries, this set of Category III codes does not include accessing and selectively catheterizing the vessel, traversing the lesion, embolic protection if used, other intervention used to treat the same or other vessels, or closure of the arteriotomy by any method. These codes describe endovascular procedures performed percutaneously and/or through an open surgical exposure.		
●0234T Transluminal peripheral atherectomy, including radiological supervision and interpretation; renal artery	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0235T visceral artery (except renal), each vessel	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***

●0236T abdominal aorta	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0237T brachiocephalic trunk and branches, each vessel	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0238T iliac artery, each vessel	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0239T Bioimpedance spectroscopy (BIS), measuring 100 frequencies or greater, direct measurement of extracellular fluid differences between the limbs	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0240T Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with 3-dimensional high resolution esophageal pressure topography	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Do not report 0240T in conjunction with 91010)		
+●0241T with stimulation or perfusion (eg, stimulant, acid or alkali perfusion) (List separately in addition to code for primary procedure)	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Use 0241T in conjunction with 0240T)		
(For esophageal motility studies with 2-dimensional data and stimulant or perfusion, use 91013)		
●0242T Gastrointestinal tract transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Do not report 0242T in conjunction with 91020, 91022)		
●0243T Intermittent measurement of wheeze rate for bronchodilator or bronchial-challenge diagnostic evaluation(s), with interpretation and report	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Use 0243T once per 24 hour period)		
(Do not report 0243T in conjunction with 0244T for the same 24 hour period)		

●0244T Continuous measurement of wheeze rate during treatment assessment or during sleep for documentation of nocturnal wheeze and cough for diagnostic evaluation 3 to 24 hours, with interpretation and report	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0245T Open treatment of rib fracture requiring internal fixation, unilateral (eg, flail chest); 1-2 ribs	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0246T 3-4 ribs	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0247T 5-6 ribs	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0248T 7 or more ribs	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0249T Ligation, hemorrhoidal vascular bundle(s), including ultrasound guidance	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Do not report 0249T in conjunction with 46020, 46221, 46250-46262, 46600, 46945, 46946, 76872, 76942, 76998)		
+◎●0250T Airway sizing and insertion of bronchial valve(s), each lobe (List separately in addition to code for primary procedure)	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Use 0250T in conjunction with 31622, 31634)		
◎●0251T Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Do not report 0251T in conjunction with 31622-31626, 31628-31631, 31634-31636, 31638-31646)		
+◎●0252Teach additional lobe (List separately in addition to code for primary procedure)	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Use 0252T in conjunction with 0251T)		
#●0253T internal approach, into the suprachoroidal space	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***

Code is out of numerical sequence. See 0188T-0261T		
●0254T Endovascular repair of iliac artery bifurcation (eg, aneurysm, pseudoaneurysm, arteriovenous malformation, trauma) using bifurcated endoprosthesis from the common iliac artery into both the external and internal iliac artery, unilateral;	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0255T radiological supervision and interpretation	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
●0256T Implantation of catheter-delivered prosthetic aortic heart valve; endovascular approach	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Code 0256T does not include cardiac catheterization [93501–93572] when performed at the time of the procedure for diagnostic purposes prior to aortic valve placement. Code 0256T includes all other catheterization[s], temporary pacing, intraprocedural contrast injection[s], fluoroscopic radiological supervision and interpretation, and imaging guidance, which are not reported separately when performed to complete the aortic valve procedure)		
●0257T open thoracic approach (eg, transapical, transventricular)	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(Code 0257T does not include cardiac catheterization [93501–93572] when performed at the time of the procedure for diagnostic purposes prior to aortic valve placement. Code 0257T includes all other catheterization[s], temporary pacing, intraprocedural contrast injection[s], all fluoroscopic radiological supervision and interpretation, and imaging guidance, which are not reported separately when performed to complete the aortic valve procedure)		
(Report transthoracic cardiac exposure separately with 0258T, 0259T)		
(Do not report 0256T, 0257T in conjunction with 33210, 33211, 92986, 93503)		
(When prior diagnostic cardiac catheterization has been performed, do not report 0256T, 0257T in conjunction with 93501, 93503, 93508-93533, 93539-93562)		
●0258T Transthoracic cardiac exposure (eg, sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; without cardiopulmonary bypass	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***

●0259T with cardiopulmonary bypass	Released July 1, 2010 Implemented January 1, 2011	***CPT 2011***
(For implantation of catheter-delivered prosthetic aortic heart valve post cardiac exposure, use 0257T)		
(Do not report 0258T, 0259T in conjunction with 32100, 32551, 33210-33211, 33310, 33315, 33400-33413, 39010)		
(Report 1 aortic valve placement procedure per session)		

Category III codes 0260T, 0261T were accepted at the June 2010 CPT Editorial Panel meeting for the 2012 CPT production cycle. Therefore, these codes will not appear in the 2011 CPT codebook. However, due to the Category III code early release policy, these codes are effective on January 1, 2011, following the six month implementation period which begins July 1, 2010.

●0260T Total body systemic hypothermia, per day, in the neonate 28 days of age or younger	Released July 1, 2010 Implemented January 1, 2011	***CPT 2012***
●0261T Selective head hypothermia, per day, in the neonate 28 days or younger	Released July 1, 2010 Implemented January 1, 2011	***CPT 2012***

Category III Codes Release Schedule

Panel Action Web Information		
October 2009	Released Jan. 1, 2010	Implemented July 1, 2010
February – June, 2010	Released July 1, 2010	Implemented Jan. 1, 2011
October 2010	Released Jan. 1, 2011	Implemented July 1, 2011
February – June, 2011	Released July 1, 2011	Implemented Jan. 1, 2012