



TENS FOUND TO PROVIDE CLINICALLY MEANINGFUL REDUCTION IN PAIN.

Health Economics Study Provides the TENS Evidence CMS Seeks

Clinical guidelines published by the American Society of Anesthesiologists Task Force on Chronic Pain Management recommend the use of transcutaneous electrical nerve stimulation (TENS) for chronic low back pain (CLBP) and other chronic non-cancer neuropathic, somatic, or visceral pain syndromes.

In June 2012, however, the U.S. Center for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) which restricts reimbursement to patients in approved clinical trials. The CMS NCD calls for explicit achievement of clinical metrics in order to further evaluate the value of TENS for helping to reduce pain and improve quality of life for patients with CLBP.

“What Medicare is asking for is randomized controlled trials in patient populations with some kind of comparative treatment and evidence that you followed these patients over time,” said Michael Minshall, MPH, Senior Director, Healthcare Economics & Reimbursement at DJO Global.

Minshall and his team performed a retrospective analysis of a commercial and Medicare administrative claims database. After parsing patient records (2008-2010), the researchers identified those that had at least two ICD-9-CM coded claims for low back pain during a consecutive three-month period.

“We looked at real world utilization. We did not exclude patients with comorbidities. We *did* include patients who are high risk for CLBP and other comorbidities. The study’s inclusion and exclusion criteria are pretty minimal if not nonexistent,” Minshall said. “Most published

clinical trials in CLBP are three to six months in length and probably not long enough to clearly assess the value of TENS and may exclude CLBP patients with significant comorbidities and other medical problems.”

Researchers Respond to CMS Call for Rigorous Research

To address Medicare’s call for hard evidence, researchers compared primary outcomes (inpatient hospital and outpatient treatment including physical therapy utilization; incidence of back surgery; and other direct medical costs) across treatment groups. The study used propensity scoring statistical methodology to match nearly 23,000 CLBP patients in a 1:1 fashion with nearly 23,000 demographically and clinically similar CLBP patients who did not use TENS. This methodology allows researchers to compare outcomes between groups of patients who differ only on which treatment they receive while holding all other demographic and clinical variables consistent between the two groups.

“It’s hard to refute the study. There’s 23,000 patients. We followed 23,000 patients for a year before and a year after the device and compared them with 23,000 patients who did not get TENS but had clinically diagnosed back pain,” Minshall said.

TENS Found to Provide Clinically Meaningful Reduction in Pain

Peer-reviewed studies provide evidence that TENS ameliorates back pain. For example, “TENS may be a useful adjuvant in the management of chronic low back pain which may be more difficult to manage than new-onset acute low back pain,” said Robert Pivec MD, with the Rubin Institute for Advanced Orthopedics at the Sinai Hospital of Baltimore. “TENS is [also] an effective non-opioid alternative that not only decreases back pain, but also appears to reduce opioid use.”

The study's extensive review supported Dr. Pivec's clinical experience and revealed some telling health outcomes. Hospital and clinic visits were less for patients treated with TENS. In addition, TENS patients required less use of diagnostic imaging (31 compared to 46 events per 100 patients) and fewer physical therapy visits (94 vs. 107 per 100 patients). Back surgeries were also performed less in the TENS group (7.5 vs. 9.2 surgeries per 100 patients).

Though there is no specific measure of quality of life recorded in administrative claims data, "the fact that the patients went to the doctor less and utilized fewer medical resources is highly indicative that they tended to be feeling better, especially given they started at a lower baseline of health," noted Anthony Strike, Market Manager, Electrotherapy at DJO Global.

TENS Offers Tangible Healthcare Savings for CLBP Patients

"What our study demonstrates and demonstrates pretty clearly is that TENS may provide demonstrable value and improved efficiency for the healthcare system," commented Minshall.

Further analysis emphasizes just how much of a savings. "The economics speak for themselves," said Minshall. Researchers developed the chart on this page to translate their findings into potential offsets of Medicare costs. Of the nearly 50 million Medicare beneficiaries who received care in 2012, we estimated that 1.5 million were treated for CLBP. If medical resource savings observed in our study were applied to the Medicare population, 27,000 back surgeries could be avoided at an estimated cost of nearly \$900 million to Medicare. Prescribing TENS instead of surgery could have saved Medicare not only this tremendous expense, but overall projected cost offsets approaching \$1.3 billion while putting TENS on every Medicare-treated CLBP patient would

cost \$881 million and provide nearly \$418 million in estimated savings.

the physical therapy clinic as well as in a home version with the EMPI Active.

TENS vs. No-TENS in Chronic Low Back Pain (CLBP)

Illustration for Estimated Costs and Projected Savings to Medicare Patients in the USA

Total Number of Medicare Beneficiaries (2012) ¹	Point Prevalence of CLBP ^{2,3}	Estimated % of CLBP Patients Treated ^{4,5}	Estimated Number of Patients w/CLBP Treated in Medicare	
49,435,610	10.2%	30%	1,512,730	
Event	Incremental Event Rate Difference over 1 Year of Follow-Up in All Patients ⁶	Events Avoided from CLBP Patient Population	Average Cost per Event ⁶	Potential Cost offsets over CLBP Patients
Back Surgery	0.018	27,229	\$32,555	\$886,444,457
Imaging	0.146	220,859	\$832	\$183,754,298
Physical Therapy	1.267	1,916,628	\$92	\$176,329,821
ER Visits	0.033	49,920	\$760	\$37,939,260
Opioid Therapy	0.203	307,084	\$46	\$14,125,870
TOTAL POTENTIAL COST OFFSETS				\$1,298,593,705
TENS Cost	\$295.00			
Supply Cost (1 Month)	\$47.90			
6 Month Supply Cost	\$287.40			\$881,013,757
Total Cost Per Pt	\$582.40			
Potential Cost Reductions for payer				\$417,579,948

"Some payors, including CMS, now require that physicians use conservative modalities prior to giving authorization or payment for surgical intervention," said Sharon Wolfington, President of Global Recovery Sciences, DJO Global. "Clinical research has shown that certain risk factors are predictive of readmissions and complications following surgical intervention. As a result, many clinicians are using this data to create patient triage pathways for both conservative care and surgical care based on those risk factors."

TENS Positive for Patient Satisfaction

"Pain is a key driver in a patient's decision to seek treatment from clinicians. Many clinicians are concerned about giving prescriptions for narcotics to reduce pain. The EMPI TENS device has been shown to be effective in meeting those patient and clinician needs," Wolfington said.

"In addition, physicians that offer conservative care options prior to surgery have seen an increase in patient satisfaction. TENS is available both in

Therefore patients can get engaged in their care and continue their pain control treatment from the MD office to the clinic to their home," explained Wolfington.

To encourage patient engagement in overall health and selection of conservative treatments (which reduce the risk of long periods of inactivity and the related health issues), DJO Global launched the *Motion is Medicine* (MIM) initiative. MIM aims to help patients restore motion and improve their lives by addressing four common areas; pain, alignment, strength and stability. MIM encourages CLBP patients to select treatment options which optimize activity level, thereby decreasing their risk for diabetes, heart disease and other conditions associated with low levels of physical activity. ♦

For more information about this TENS Study please visit djoglobal.com/emp and djoglobal.com for more information on Motion is Medicine.