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WORKERS' COMPENSATION BOARD
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NOTICE OF DECISION

Request by EMPI for adjustment to Durable Medical Equipment Fee Schedule pursuant to 12 NYCRR §442.2 (3)

Law and regulations

On March 13 2007, the 2007 workers' compensation reform act was signed into law. Among other things, the act amended subdivision (a) of section 13 of the Workers' Compensation Law (WCL) to explicitly list additional types of durable medical equipment in the list of medical services an employer must promptly provide, pay for, and replace to an injured employee. This subdivision was also amended to require the Chair of the Workers' Compensation Board (Chair) to establish a schedule of charges and fees for such durable medical equipment. These changes became effective 120 days after March 13, 2007, on July 11, 2007.

The Chair adopted a durable medical equipment fee schedule by emergency regulation effective July 11, 2007. The fee schedule is codified as Part 442 of Title 12 of the New York Codes, Rules and Regulations (NYCRR) and provides that the maximum charge for durable medical equipment is the fee payable under the New York State Medicaid Fee program at the time the equipment is provided. Section 442.2(3) of the regulations states,

> "Notwithstanding any other provision to the contrary, the Chair may make other adjustments to the fee schedule as he or she deems appropriate, upon finding that the reimbursement provided for a particular piece of durable medical equipment, medical/surgical supply or other such item under the fee schedule is grossly inadequate to meet the suppliers or pharmacies' costs, and following thirty days notice on its website and consideration of any comments provided in response to such notice. Requests for such adjustments to the fee schedule shall be submitted to the Bureau of Health Management, 100 Broadway-Menands, Albany, New York 12241".

Request for adjustment to fee schedule

By letters dated July 31, 2008, and September 15, 2008, Empi, a manufacturer and provider of non-invasive medical products, through its legal representative, Joshua L. Oppenheimer,

submitted a request to the Workers' Compensation Board's (WCB) Bureau of Health Management for an adjustment to the durable medical fee schedule. Specifically, Empi requested that the Chair adjust the fee for durable medical equipment item E0730 (Transcutaneous Electrical Nerve Stimulation (TENS) device) from the established fee of $76.25 to approximately $300.00.

As justification for the increase, Mr. Oppenheimer stated in the July 31, 2008, letter that Empi was forced to temporarily remove its TENS product line from the New York State workers' compensation market "because the Medicaid rate for TENS devices is so grossly inadequate and does not meet Empi's costs." According to Empi it costs at least three times more than the reimbursement under the fee schedule to produce and distribute TENS devices in New York. Mr. Oppenheimer partly justified the request by stating that Empi received several requests from physical therapists and patients for the TENS devices to be made available after removing them from the New York workers' compensation market. Additional justification for the request provided by Empi as noted in Mr. Oppenheimer's letter is:

- The current Medicaid rate for TENS devices furthers a two-tiered health care system, which is unfair to workers' compensation consumers.
- TENS is a non-systemic, non-pharmacological, and non-addictive treatment option for persons who experience knee, lower back, shoulder, wrist/hand, or cervical pain.
- The daily cost of TENS is significantly less expensive, even at a rate significantly higher than the fee schedule, than the daily cost of pain management drugs such as OxyContin and Percocet, which on average, cost between $5.88 and 9.18 per day.
- TENS devises do not have the adverse effects of the pain management drugs which are known to have negative interactions with other medications, systemic effects, and can be habit forming.
- The state could save money by providing individuals who would otherwise need to rely on pain medications a less costly, equally effective alternative.

Notice of Request and Comments

Pursuant to section 442.2(3) of the regulations, the Chair released Subject Number 046-256 on October 3, 2008, to provide notice of Empi's request to increase the charge on the durable medical equipment fee schedule for item E0730. The Subject Number served to solicit comments on the request and specified that they must be received within 30 days. In response, numerous comments were received from stakeholders; some supported the increase while others opposed it.

Comments were received from 26 stakeholders in favor of increasing the fee as requested by Empi. The stakeholders who supported a fee increase are categorized as follows:

Insurance carrier	1
Attorney	1
Physicians	13 (4 affiliated with the same practice)
Physical therapists	7
DME Suppliers	2
Occupation Therapists	1
Physician Assistant	1

The comments from those who favor a fee increase are summarized as follows:

- Empi TENS devices are of higher quality with superior construction and durability, and provide better outcomes by reducing pain.
- Patient compliance and recovery is better with the Empi TENS devices.
- Empi TENS devices are more comfortable than lower quality, less expensive devices, so they will save money by reducing pain medications, the number of office visits, the need for physical therapy or surgery.
- Empi TENS devices allow for more reporting of treatment which is valuable in minimizing fraudulent claims.
- Several physical therapists and patients have requested the Empi TENS device be made available in New York.
- The intensity of the Empi TENS devices tends to be less painful.
- The less expensive TENS devices are more difficult to use and tend to cease functioning properly, increasing the cost of replacement. They also take longer to fit the device to the patient, provide less stimulation, and lack support from companies supplying them.
- Patients have a better understanding of how to use the Empi TENS devices versus other TENS devices.
- Injured workers' should be able to receive the same TENS devices as other patients with non-work related conditions.
- Empi has the best customer service and technical support, enhancing patient compliance.
- The high quality TENS devices such as Empi allows compliance with therapy data of TENS utilization.
- The fee amount does not come close to Empi's cost to produce a TENS device, forcing Empi to remove the device from the New York workers' compensation market.

Comments were received from 17 stakeholders opposed to increasing the fee as requested by Empi. The stakeholders who opposed a fee increase are categorized as follows:

Physician	1
Insurance Carriers/TPA's	5
Adjuster Services/Bill Review Co.	3
Self Insured Employers	6
Insurance Associations	2

The comments from those opposed to a fee increase are summarized as follows:

- Other less expensive TENS devices are just as effective in treating pain.
- Claimants with TENS devices still require pain medications.
- Supply costs are an additional $70-$100 per month.
- There are many TENS devices currently available at the current fee of $76.25 that are effective in treating pain, with links to internet sites that provide information and pricing for such devices.

- There is no advantage of one TENS device over another, and increasing the fee will not help patients.
- Some suppliers can supply TENS devices to claimants ranging from no cost to $65.
- There is no evidence that the use of TENS devises reduces the need for pain medications.
- TENS devices are used for a very short time and then discarded.
- An adjustment to the fee schedule should not be based upon a single request from a supplier. Raising the fee will allow price gouging for TENS devices by other suppliers.
- An adjustment will set a precedent for future DME fee increases, which will hurt employers, and will burden taxpayers in New York State with higher medical expenses. Increased medical costs will be passed on to policyholders, at a time when cost needs to be decreased.
- Empi's request raises questions about reasonable profit.

A member of the Medical Society of the State of New York's Workers' Compensation Committee commented that while Empi TENS units are a favorite of therapists, there are numerous generic TENS units available for the current fee schedule amounts. The member added that there is no significant advantage to one TENS unit over another and it would not help his patients to increase the fee for TENS units. Further, he believes carriers will be inundated with TENS unit charges, many of which will be for units wholesaling at $50-60.

Chair's review

The fees in the Medicaid durable medical equipment fee schedule are established by the New York State Department of Health (DOH). In order to assess the request, the WCB contacted DOH for information on how the fee for item E0730 was developed. When establishing the Medicaid durable medical equipment fee schedule, DOH must follow its regulation, 18 NYCRR §505.5(2) (i), which states:

> *"Payment for purchase of durable medical equipment must not exceed the lower of:*
>
> *(a) the maximum reimbursable amount as shown in the fee schedule for durable medical equipment, medical/surgical supplies, orthotics and prosthetic appliances and orthopedic footwear; the maximum reimbursable amount will be determined for each item of durable medical equipment based on an average cost of products representative of that item; or*
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> *(b) the usual and customary price charged to the general public for the same or similar products.*

To develop the maximum reimbursable amounts included in the Medicaid durable medical equipment fee schedule, DOH identifies a sample of representative products for the item. It then takes the costs for the representative products in the sample and averages them. When developing this average, neither the lowest nor highest priced products are used. Once the average cost is determined a 50% markup is added. DOH obtains information about products and their costs from the internet and data from the Medical Data Institute.

After receiving the comments, the WCB requested additional information from Empi regarding the cost to produce a TENS device, such as raw materials, labor, use of machinery, and after production costs but excluding marketing and after production customer services. In response, Mr. Oppenheimer, on behalf of Empi, stated that there are five major factors contemplated when determining the cost of TENS devices: "(1) the manufacturing costs (material, labor and factory overhead); (2) distribution costs (maintaining inventories of the product and shipping); (3) regulatory, quality and research and development costs; (4) marketing costs; and (5) fixed costs of the field sales force." These five categories of expenses when totaled and excluding after production costs and profit margin amount to less than $180. The post production services represent approximately an addition 60% per device. Finally, Empi generally seeks to include at least a 10% profit when sell TENS devices. It was based upon this calculation that Empi determined that $300 as a fair reimbursement rate.

The WCB researched the Empi website for price information, but none was posted. In an effort to obtain additional information, the WCB consulted with the DOH. According to information obtained by DOH, the Epix VT is listed for $595 by Masters Medical and $645 by Diamond Athletics Medical Supplies, Inc. The ProMax by Empi is listed as $659.95 by Garfinkel Athletic Medical Supplies and $650 by Diamond Athletic Medical Supplies, Inc. The Nuwave by Empi is listed for $211.58 by Medical Supplies Assistant. The Maxima II is listed for $287.75 by Liberator Medical Supply, $266.49 by Medical Supply Group, and $179.52 by Soy Medical. Further, the DOH provided information from the Medical Data Institute for the Maxima II that the List Price is $595 but the cost price, or dealer cost, is $100 if purchasing 1-9 items, $94 for 10-24 items and $90 for 25 or more items.

Along with Empi's July 31, 2008, request for an adjustment to the durable medical equipment fee to increase the fee for item E0730, Transcutaneous Electrical Nerve Stimulation devices, Mr. Oppenheimer included the California Workers' Compensation Institute's June 2008 article entitled "Pain Management and the use of Opioids in the Treatment of Back Conditions in the California Workers' Compensation System." This article studied the use of opioids for pain management in workers' compensation claims where the primary diagnosis was a back condition without spinal cord involvement, and the associations between the use of opioids for such conditions and key outcomes such as cost and length of disability. This study did not relate at all to the use of TENS for the treatment of pain, but solely studied the effects of the use of opioids. Further, the study only related to the California workers' compensation system.

Neither Empi nor any of entities or individuals who submitted comments, provided cites to or copies of any studies as to whether the use of TENS by workers' compensation claimants in New York reduces the use of prescriptions, including opioids, for the treatment of pain. Neither were any studies submitted or cited to that addressed better outcomes from the use of TENS devices manufactured by Empi as compared to outcomes form the use of other units. Only anecdotal evidence was submitted for these propositions, which was rebutted by anecdotal evidence from those who oppose an adjustment to the fee schedule.

Decision

Based upon the above information and facts I find that a fee increase for durable medical equipment item E0730, Transcutaneous Electrical Nerve Stimulation devices (TENS), is not warranted for the following reasons:

- No evidence, other than anecdotal evidence was submitted to support the contention that the use of TENS devices reduces the amount of prescription pain medications utilized by workers' compensation claimants.
- No evidence, other than anecdotal evidence, was submitted that the use of TENS devices manufactured and sold by Empi are more effective than other lower prices TENS devices in reducing pain and producing better patient outcomes.
- No evidence, other than anecdotal evidence, was submitted that the lack of availability of TENS devices manufactured and sold by Empi is adversely effecting the medical treatment of workers' compensation claimants.
- The New York State Department of Health has found that the $76.25 fee for item E0730 is an appropriate reimbursement amount for TENS device supplied to Medicaid patients.
- Due to the fact the fee for item E0730 is applicable to a multitude of TENS devices on the market, an increase in the fee will allow a much higher reimbursement to all suppliers, including those supplying low cost devices, resulting in a significant increase in the cost of TENS devices supplied to workers' compensation claimants.
- Empi did not provide when requested a detailed breakdown as to the actual cost to manufacture its devices with supporting documentation, rather it provided round figures with no documentation. Further, while Empi advertises three types of TENS devices on its website, it does not identify in its request for which device the adjustment request was made.

Accordingly, the request by EMPI is denied and the reimbursement rate for item E0730, Transcutaneous Electrical Nerve Stimulation devices (TENS), remains as provided in the New York State Medicaid Durable Medical Equipment Fee Schedule.

Dated: April 21, 2009

Zachary S. Weiss
Chair
NYS Workers' Compensation Board