AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

August 26, 2010

Michael Rich
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Tracheo-Esophageal Voice Prosthesis (CR 6743)

Dear Mr. Rich:

Thank you for speaking with me at length regarding Change Request 6743, "Change in Claims Filing Jurisdiction for Tracheo-Esophageal Voice Prosthesis [TEP] HCPCS Code [L8509]." (Oct. 1, 2010 effective date)

The American Speech-Language-Hearing Association (ASHA) is the professional and scientific association representing over 140,000 speech-language pathologists (SLPs), audiologists, and speech-language and hearing scientists. Many SLPs are voice specialists, working in hospitals and physician offices where they perform initial fittings and insertions as well as replacement changes of TEPs after determining the proper specifications. The speech-language pathology profession should be an important source of information as CMS evaluates the practicality and medical appropriateness of the recent Change Request (CR).

Currently, it is typical for persons with a laryngectomy who wear a TEP to purchase the device and have a spare on hand, either kept personally or by the practitioner.

The purpose of this communication is to demonstrate why (1) the CR interferes with the TEP's accessibility to the patient who has a laryngectomy in urgent situations and (2) many providers will be reluctant to invest in a stock of TEPs that could total $1000–2000. These problems will be eliminated if the patient as well as the provider is allowed to purchase the device and be reimbursed by Medicare. The direct patient acquisition process has been common over the past years even though the *Benefit Policy Manual,* Chapter 15, Section 120, does not allow coverage if "a prosthetic device [is] dispensed to a patient prior to the time at which the patient undergoes the procedure."

While the rationale behind Section 15/120 applies to most prosthetic devices, it is illogical and unsafe for TEPs:

- Section 120 presents an example of carrier payment for an intraocular lens or pacemaker prior to the actual surgery, illustrating that" Dispensing a prosthetic device in this manner raises health and safety issues." We will show why, for TEPs, prohibition of advance acquisition and payment creates health and safety issues.
- Section 120 also states that "the need for the device cannot be clearly established until the procedure that makes its use possible is successfully performed." Again, this statement does not apply to TEPs.

The laryngectomy/tracheostomy patient may need to have a replacement for immediate use to prevent choking, aspiration and possible aspiration pneumonia. The timeline for the breakdown of the prosthesis within the body is unpredictable and different for each individual; for some patients, the TEP may deteriorate quickly. When this occurs, liquids including the patient's own saliva leak around or through

the prosthesis into the patient's airway causing aspiration and acute discomfort. The TEP may be plugged until it is replaced, but then the individual loses the capacity to verbally communicate, a serious safety issue. Under the newly enforced acquisition procedure cost constraints may incentivize many providers to wait for a patient to inform them of problems (e.g., leaking) before ordering a replacement device. A leaking TEP is an urgent problem that could cause aspiration and pneumonia, followed by hospitalization. For that reason, it is routinely recommended that a replacement device be available when traveling. CMS should note well that the cost of aspiration pneumonia in terms of a hospital stay is $5000 to $10,000 (DRG 194, without major complications).

To optimally care for the patient, this newly enforced policy would require an extensive inventory of TEPs for all active patients - an unfair financial burden to the provider and safety hazard to the patient.

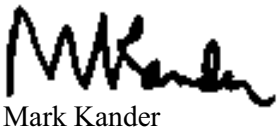
Only a few otolaryngology facilities/practices nationwide would financially be able to maintain an adequate inventory of these products sufficient for the range of patients who might need them urgently. Each patient is measured for an individual prosthetic size and some are further specialized to meet the individual's needs in terms of weighting, esophageal flange size, candida resistance, etc. In addition, some patients fluctuate in size due to the effects of radiation treatment, further expanding inventory requirements. Different companies make different products to meet these individual needs; this increases the acquisition cost and burden making it expensive to stock such a variety of prostheses.

Laryngectomy patients who wear a TEP have airway issues and some are medically compromised. The current common practice of patient procurement allows them to have a back-up and is clearly the most medically sound policy.

I understand that the CR was developed at the request of the MAC/Carrier Medical Directors group. Based on the flaws in the CR, we suspect that many of the MDs in the group endorsed the request for the policy change without familiarity of the various complications associated with a patient who requires a TEP.

Please let me know if ASHA can provide any additional information that may help CMS to revise this policy to accommodate the urgent needs of Medicare patients with laryngectomies. You may contact me by phone at 301-296-5669 or e-mail at mkander@asha.org.

Sincerely,



Mark Kander
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