



AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

June 28, 2018

Joel Kaiser
Director, Division of DMEPOS Policy
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Reimbursement for Indwelling Tracheoesophageal Voice Prosthesis (TEP L8509)

Dear Director Kaiser:

On behalf of the American Speech-Language-Hearing Association, I write to request a reconsideration of the Centers for Medicare & Medicaid Services' (CMS) payment policy associated with indwelling tracheoesophageal voice prosthesis (TEPs). Medicare reclassified this equipment from durable medical equipment to implantable devices effective October 1, 2010, which dramatically and negatively impacted reimbursement for TEPs. ASHA requests a meeting with you at your earliest convenience to discuss this issue in greater detail.

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 198,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students.

ASHA has worked with a coalition of stakeholders, including speech-language pathologists and otolaryngologists, to address the impact of the coverage decision on Medicare beneficiaries who require a TEP. We have submitted written requests to CMS staff advocating for a reconsideration of this policy but remain concerned that beneficiary access and health outcomes are being detrimentally impacted by this policy decision as evidenced by reduction in sites providing this service.

ASHA has informed CMS that the reimbursement value provided is based on pricing data from 1984 and prohibitively less than the equipment's cost. The average floor reimbursement value of HCPCS code L8509 for 2018 is \$94.87 and the ceiling is \$126.50 (with geographic adjustments). Often, the cost of the TEP exceeds \$250.*

Unfortunately, in response to these efforts, CMS has indicated they have not received beneficiary complaints about negative access or health outcomes issues directly from beneficiaries. Therefore, ASHA has engaged our membership and several laryngectomy advocacy organizations to solicit feedback on challenges patients have encountered in accessing health

* ASHA staff have copies of paid invoices confirming this amount.

care providers who provide and/or service TEPs and any resulting negative health outcomes and other challenges that have occurred.

Within one month of a patient call to action, ASHA received phone calls and emails from over 150 patients and providers [See Addendum]. Many expressed concerns over the differential between the price of the device and the Medicare reimbursement value. They stated that many local health care providers no longer provide the TEP or associated services and they often had to travel far distances, sometimes more than two hours, to find a health care provider who could help them. The distance, and in some cases the need to find a caregiver to help transport them to these appointments, often led them to delay care resulting in negative health outcomes including pneumonia.

One unfortunate example is the story of a woman whose son serves as her primary caregiver. She requires services for her laryngectomy and TEP roughly every four weeks but the health care provider is 60 miles away. Accounting for both the drive and length of the appointment they spend about six hours to get her the care she needs. In 2014, her TEP began to leak and her son could not get her to the health care provider quickly enough. She contracted pneumonia, became gravely ill, and was hospitalized for 16 days. An emergency surgery was performed to clear her lungs. Subsequently, she developed a blood clot, which required three months of medication and follow-up post-surgery.

Another example is a gentleman who has had access to a TEP that allows him to voice more naturally than other voice options following a laryngectomy. He is able to continue working instead of using Social Security Disability Insurance and/or Medicare benefits. As he told us,

“I’ve been extremely fortunate in that this facility has offered a wide-range of services supporting laryngectomy patients such as myself, with TEP maintenance near the top of the list. *With* my TEP, I’m a functioning, fully employed 58-year old father of four (and grandfather of one) who can support my family. *Without* my TEP, I would become another name on the social security disability list, drawing a check each month from the government at taxpayer’s expense, and barely getting by (if at all). I would basically become unemployable. Without the fantastic services provided by the staff at University of Jefferson Hospital in Philadelphia, my health would be a continuing question mark, wondering each day if this is the one where the continuous flow of mucus in my throat causes another life-threatening (or ending) bout of pneumonia. I’ve been through that twice, the last time spending three months in the hospital and dropping to under 110 pounds. I think the bill for the appropriate TEP is a bit cheaper than all of that.”

Several of the patients also reported that they were forced to select an artificial larynx, a less desirable and less natural option post laryngectomy device, as opposed to a TEP because of the cost and inability to find a conveniently located provider. They expressed a firm belief that the TEP would improve their ability to communicate and have other important implications for their quality of life.

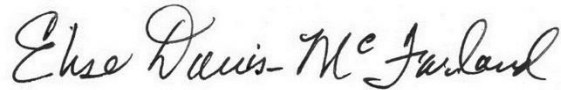
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Through our inquiries to providers on this issue and a survey completed in 2014, we have heard anecdotally that more than 40 health care providers and facilities nationwide have stopped treating TEP patients and/or carrying the devices since this policy was implemented. Given that nearly every patient who reached out to us discussed the need to travel a long distance, it appears that this glut of closings is causing an access and health safety issue that should be of concern to CMS. ASHA stands ready to work with CMS to identify a solution that protects the Medicare trust fund while preserving access to this small, *but important*, portion of the Medicare population. ASHA is prepared to demonstrate, with paid invoices, the variation in cost versus reimbursement that is causing the difficulty in obtaining medically necessary care.

ASHA would appreciate an opportunity to discuss this issue with you at your earliest opportunity to address the discrepancy between payment and cost of this equipment. Please contact Sarah Warren, MA, ASHA's director for health care policy, Medicare, at swarren@asha.org to schedule a meeting.

Sincerely,

A handwritten signature in cursive script that reads "Elise Davis-McFarland".

Elise Davis-McFarland, PhD, CCC-SLP
2018 ASHA President

Addendum



Addendum

Below is a list of emails ASHA has received from patients and providers sharing stories of their experience with indwelling tracheoesophageal voice prosthesis treatment and coverage. Identifying information was removed to protect their privacy.

Email 1

My name is {name redacted} and I have been ordering Prosthesis for 10 years{s}. I pay \$105 for 1 and Medicare sends me a check for \$31.00. I have to buy them just about once a month. I have to work part-time so I can afford to buy medical supplies. It would be a lot easier if Medicare would pay for most of the TEP and other supplies that we have to have, such as brushes, adhesive and a few others.

Email 2

I am reaching out at the suggestion of Atos Medical regarding Laryngectomy patients with tracheoesophageal puncture prostheses (TEP). I service the Eau Claire Area in Wisconsin. My patient{s} travel as much as 80 miles to have their TEP's placed with me. The next nearest service areas are Minneapolis or Marshfield, WI. This would add an additional 1-2 hours of travel for my patients. My hospital has been seriously considering discontinuing my ability to replace TEPs because of the poor reimbursement. They lose money every time one of my patients walks through the door. As you may know, when a TEP starts to leak, the patient is aspirating liquids into their lungs. Waiting for treatment may jeopardize their health and result in hospitalizations with pneumonia. This, of course, could increase the annual cost of medical care for this population. Patients/family may need to take off of work to travel extended distances to have their TEP changed.

Email 3

I'm a 77-year-old laryngectomy patient as of June 2016. I have a Florida Blue Medicare Choice PPO health plan.

Fortunately, I don't have difficulty in obtaining TEP care at Tampa General Hospital. However, the whole situation with reimbursement and the cost of TEP's has been an issue from day number 1. The staff at Florida Blue kept telling us to go to Care Concentric which is their vendor for "supplies." Unfortunately, Care Centric not only doesn't carry TEP supplies, their staff didn't seem to know what a laryngectomy is! It took us many phone calls to discover that TEP's were considered equipment, not supplies. Meantime, we had to buy the TEPs out of pocket since ATOS was not considered "in network," which was an extreme expense I was not expecting.

I came to resent the fact that apparently diabetic equipment and supplies are completely reimbursed but--perhaps because there are now so relatively few of us--not so with laryngectomy supplies.

After I petitioned Florida Blue and Atos helped me deal with them, Florida Blue decided to make ATOS an in network equipment supplier for me at least. I'm allowed one TEP replacement per month for which I am reimbursed 50% after my \$900 equipment deductible is reached. This is

certainly better than it was but still is a lot of money out of pocket as we live primarily on social security and modest IRA savings.

I think a major problem is that the health insurance companies don't sufficiently understand or care about the conditions for a laryngectomies. I know that the electro larynx really does not work for me and the sound is far worse than with a TEP, at least for me. For many of us, not only our breathing properly but the very ability to communicate depends on TEP's.

St. Petersburg, FL

Email 4

This is to let you know about Medicare problem with TEP replacements reimbursement.

As it is now I have to go to Charleston, SC or Jacksonville, FL to get TEP replaced or Medicare would not reimburse them. If Savannah stock them, that would save at least 200 miles each time and Medicare would pay less for the doctors that are needed and other trips I have to take so Medicare would pay less and I would pay less.

If Savannah, GA could stock them then Medicare would pay then we would have to get speech pathologist to order them and doctor to write a prescription and wait on delivery and then back to speech pathologist to put in.

Bluffton S.C.

Email 5

My name is {name redacted}. I live in Athens, GA. I'm 74 years old and have been a {laryngectomy patient} since 1/18/05. I have macular degeneration in eyes, arthritis in my hip, 3 degenerated disc in spine and pacemaker. I can't get help at all in Athens. I've been to 3 ENTs {ear, nose and throat physicians} and SLPs and all said go to Emory in Atlanta. This is 130 miles round trip. The drive is getting stressful and sooner or later impossible.

Email 6

I am writing to you to share our story and why it is vital that we get the reimbursement amount increased for the TEP.

My husband is a laryngectomy. He is 45 years old. He had his surgery 2.5 years ago. We have 4 kids, all elementary school age (6, 8, 9 and 11). Scott works full time. We have private insurance through his employer but they base their reimbursement off Medicare's rate of reimbursement. The TEP gave him a huge part of his quality of life back. He's able to communicate more effectively at work but more importantly he is able to communicate easier with his young children.

We live about an hour outside of Atlanta. We have a gazillion ENT offices close to our home but none of them can replace his TEP because they have all chosen not to, due to the cost they will have to incur because of the low reimbursement. So, Scott has to take time off of work and drive to Emory in Atlanta to get his prosthesis changed in-clinic by an SLP. This is a burden on our family and on him. It is a financial burden on us.

Also, we have thought about moving or looking for a new job for him and we realize we will always have to live somewhere that we are within a close enough proximity to a university hospital that can help manage his TEP.

We are really hoping for some change in this area. There are so many people that are affected by this. It is heart breaking that people go through this horrible cancer and surgery to remove their larynx and then have to decline a quality of life improvement because they don't have access to a provider that will help them manage.

Email 7

I work at the University of Mississippi Medical Center and I am one of the speech therapists that treat head and neck cancer patients. Over 80% of my patient's are laryngectomies. We are the only facility in the state of MS that provides this service and it is very difficult for some of our more rural patients to make it in for routine changes. Most have to drive 3-4+ hours to get here. Many do not have transportation and have to rely on Medicaid transportation. Also, many cannot afford additional product{s} that we know is so beneficial for them (HME, larytubes etc.) because ATOS is out of network with Medicaid and they can't make it in to see us frequently enough to get these additional supplies as they need them. Almost all of our patients are Medicaid patients. We do not have any difficulty purchasing TEPs but reimbursement is extremely low, if at all. Some of our patients have gone over a year without a TEP change because they cannot afford it or don't have easy access to drive 4+ hours to Jackson to see us.

Email 8

First of all, I live in North Alabama. No TEPs are available on hand to have TEP changed out. I have 2 choices; order myself from Atos and provide to {the} health care {provider}, or travel to UAB hospital 96 miles away.

I have used the Provox Vega; the quality and care is so much better. But Medicare will not pay for it, even though they last 2 to 3 times longer.

I had an incident where my TEP came out and had to have another one put in, the ENT loaned me one and I had to replace it in Huntsville.

I ordered a spare so I wouldn't run into that issue again. I ordered the Provox NID. I had to pay \$132.50 up front for this; Medicare and BCBS part B reimbursed me less than \$4 combined.

Email 9

I am a speech pathologist working for a large healthcare system in the Clearwater, FL area and saw that you are gathering information about access for patients with laryngectomies to TEP services. I have been struggling here with that same issue as my organization has been unwilling to provide that service due to the cost of the equipment that is not reimbursed by Medicare. There are no providers that offer TEP services in our county and patients here have to travel to Tampa to the big cancer center there or the VA hospital for veterans in order to have their prosthesis changed. This has been a struggle for many patients who have transportation limitations, and it is a long way for patients to travel to receive this service for basic

communication. I don't have specific numbers of how many patients are affected but I can work on finding out more if that would be helpful. Our ENT groups here have also been frustrated with lack of accessible services for their patients, and some patients elect not to have a TEP due to limited access to a provider to change their prosthesis.

I am trained to provide this service and have been working to do so here, however; it has been difficult to overcome the financial barrier. I am looking into finding philanthropy groups that may be willing to donate funds for this service, however; it would be significantly easier if Medicare would change this policy.

Email 10

My husband, {name redacted}, and I live in Amarillo, Texas. We do not have anyone with experience in Amarillo to put in a TEP. We have one doctor who can put one in but he only does it once about every two years and he is not very good at it. He does not have any TEPs or any supplies that goes with the TEP. If we have to go to him, we have to order our own TEP and guess what size we need. We have to pay for it and just guess what size we need. If we get the wrong size, we have to order another one and pay for it. That has happened to us.

We prefer to go to Houston. Houston is 600 miles from our house. It takes us 2 days to get there and 2 days to get home. At MD Anderson, they can measure my husband's TEP and provide the right size. Our speech pathologist is very knowledgeable about how to handle problems that my husband might have. MDA also has laryngectomy buttons, filters, and supplies that we might need, and they have all the newest equipment to tell us about. It is not always convenient for us to go to Houston. It is a long trip. We don't have anybody close to our house that has any experience dealing with laryngectomy patients. If we have a problem, we don't have anyone to help us in Amarillo.

It would be wonderful if we had someone who could help us and was closer to our house. It would be great if we could have some help financially. It is very expensive to buy our equipment and even more expensive to drive or fly to Houston.

Email 11

My husband {name redacted} had a TEP placed on Dec. 1, 2016. He has had it changed 3 times so far and is due on 6/21/18. We live in Florida 6 months and Vermont 6 months. In Florida it is a short drive to the doctors, but we have to order the new prosthesis ourselves for \$266.00 and do not get any reimbursement. One visit from Vermont to Albany, NY is 120 miles round trip. {During} the first visit to Albany, the office there said they had the prosthesis we needed. I noticed that they submitted the cost to Medicare for \$600.00. I do not know if Medicare reimbursed them. Now we have an {appointment} on 6/21/18 and had to order the prosthesis ourselves for \$266.00 to bring with us. I don't think we will get any reimbursement.

Email 12

{Name redacted} has had to use this voice prosthesis for 13 years now. He has had to have them changed 6-8 times per year, which is quite expensive since he is living on a disability income of about \$1,000 per month. He has tried differed kinds and more expensive prostheses but nothing

seems to work for him. He has yeast that attack the prosthesis and wants to destroy it. He has tried many things to counteract the yeast.

We are wondering when this policy will change. Soon he will be maxing out his credit cards and wondering what avenue to take next. We are happy that the UW Health system in Madison Wisconsin still changes these out. What a sad situation to be in at the mercy of these prostheses to be able to communicate. He is very active and will stay that way. This was not at all his choice. Also in the 13 years he has had this system no one has mentioned anything better to use. It was his doctor that chose this system.
Marshall WI

Email 13

My name is {name redacted} and my husband, {name redacted}, is a laryngectomy {patient} that has used Atos products since 2007. We live in Millsap, Texas. I could tell you many stories of the extreme difficulty we have had, since 2007, involving the problems of reimbursement of Atos products and Medicare. Cancer, in 2007, found us without insurance and without an education of the intricacies of what we now call the *new normal*. You are so right about the health consequences due to limited access to care and other problems that relate to TEP reimbursement. Fast forward to June of 2018 and we now have Medicare & Medicaid to cover his needs, however, we still drive over an hour to his speech pathologist to have his TEP replaced and hopefully not on a weekend.

Email 13

I am happy that you are pursuing this issue on behalf of all the laryngectomy {patients} so they will be able to receive the proper and required indwelling devices other than the ones Medicare says they will provide.

I do not understand why some of them are covered by Medicare and others are not. I had a problem with the Inhealth TEP and the clinician suggested that I switch to the Provox Vega. Unfortunately, the Inhealth TEP is covered by Medicare and Moffitt but the Provox Vega is not. I am relegated to using the Inhealth because I cannot afford to pay \$266.00 for each Provox Vega and more than likely I will need to have it changed ever 4-6 weeks, which will cost me approximately \$800.00/year, this will be a great financial hardship on me since I also have to pay all the other costs for the ATOS items that I require to control my condition that Medicare does not cover.

Additionally, the Inhealth TEP has a tendency to leak after approximately 3 weeks requiring the insertion of a new one. The Provox would probably last about 5 to 6 weeks thereby reducing the need for replacement every 3 weeks which would reduce the cost to Medicare. Further when I have to wait for Moffitt to get the new Inhealth TEP, as I just did for the last 4 weeks, I had to use the TEP plug which is not only uncomfortable but has a tendency to collect dried mucus on it and impacts breathing through the stoma.

Email 14

I got throat cancer in 2004. They took out my larynx. I was 48 years old; I'm 62 now. I can't drink or eat with my mouth. I also can't speak. I use a filter in my throat tube that I breath

through; those filters and clips cost \$150.00 every three weeks. On disability pay that's almost impossible to do on my budget. I have placed three orders; Medicare sent me one check for \$50.00

Email 15

I have been treated at the University of Michigan for 18 years. This is a very high volume clinic that discontinued providing TEPs several years ago specifically due to the loss they experienced on each TEP. My only option was and remains ordering them directly from ATOS at the standard retail price. At one point I went through the exercise of trying to get Medicare reimbursement directly but was denied after numerous appeals because the device "had to be placed by a clinician." Catch 22 if I ever saw one. It does not make any sense that less critical appliances like hands free valves, HMEs, foam squares are covered and the prosthesis, the key to our being able to speak is not. Traveling to the U of M is a 4 hour round trip.

Email 16

I am a recent laryngectomy {patient}. I was shocked at the cost of daily care and equally dismayed to discover that only a small portion of this cost was covered by Medicare. Of particular concern is the cost of a replacement TEP. For no good reason that I can discern a TEP dispensed by a hospital is apparently covered in full while a TEP inserted by a qualified speech therapist is not. The net result is that to avoid the high cost of a replacement I must drive 2 ½ hours to the nearest provider that can supply a Medicare covered TEP. Same device, same simple procedure. This is ridiculous and should be changed to provide fair and equal treatment to all laryngectomy patients.

Bonita Springs, FL

Email 17

My name is {name redacted} and I live in Amarillo, Texas. I had a laryngectomy in Oct. of 2016. I have never smoked so this happening was quite a shock to me and my wife. Like many seniors our age we are on a fixed income. We are both 72 years old. We both payed into Medicare for 30 to 35 years of our working life and need Medicare to return the favor when we need it the most. This is not a large number of people that desperately need help concerning this situation. My prosthesis cost 363.00 every three months and being on a fixed income I can't afford this cost. Many times when I knew I could not afford the cost I would just let it go and the result was liquids of all kind that I drank would leak into my lungs and cause aspiration and trouble breathing. This could lead to more serious health problems that could result in a much higher cost to Medicare.

Email 18

I am writing you to encourage Medicare to consider reimbursing the cost of indwelling voice prostheses (also called a tracheo-esophageal voice prosthesis or TEP) for laryngectomy patients. I wrote Medicare two years ago about this issue and never received a response.

Two years ago I was diagnosed with a chondro-sarcoma of the larynx. This is a rare type of throat cancer that only effects 1/2 of 1% of throat cancers in which cartilage forms around the vocal cords—80% of my oxygen was being cut off and my voice was significantly compromised and I would have eventually died. The cause is unknown, but unrelated to smoking; I have never

smoked. Medicare and my AARP supplement fortunately paid for the vast amount of my surgery, hospitalization, continued testing, office visits, related medical supplies, etc.—over \$100,000—but does NOT cover any of the expense of the indwelling voice prosthesis which is the only thing that allows me to speak. The cost of the prosthesis is about a \$1000 a year. In general my prosthesis works pretty well but the voice therapists are reluctant to experiment with some of the other dozens types of different prostheses which might improve my speech and comfort because of the direct expense to me.

It seems very strange to me that Medicare will not cover the one expense that allows me to breathe, speak, and continue to live a productive life. Not sure of the history or the reasoning behind this policy, but it appears to probably be an inadvertent error that no one seems to be willing to admit and correct.
Boulder, Colorado

Email 19

I got three orders laryngectomy filers cost \$150.00 I got reimbursement for one order- I received check from Medicare for \$50.00. I would love help with this. I'm on disability for life I can't afford the filer laryngectomy clips every three weeks. Medford, MA

Email 20

I am {name redacted}, of Asheville, NC. I have Medicare and a supplement from Aetna, plan F (the best plan). My tracheotomy was done April 10, 2012 and I have been a customer of Atos Medical almost exclusively since that date. Approximately one year after my surgery I began using the Provox Vega, an indwelling prosthesis. Because of pressure issues in my throat, that model prosthesis had an average life for me of three weeks although I had them replaced monthly. Last year, 2017, I began using a new product, the Provox ActiValve which has a magnet to help keep the flap in a closed position when not speaking. This more expensive product lasts me about 6 months and I had the third one installed May 21, 2018. As I buy direct from Atos Medical, Atos can provide the exact cost of all these items over the past 6 years but my guestimate is: 48 Vegas approximating \$247 each = \$11856 and 3 ActiValves @ \$1976.00 each = \$ 5,928 for a **total of \$17,784 spent so far without any reimbursement from Medicare.**

Additionally, my {speech-language} pathologist is 154 miles (2.5 hours) from my home. That's a total of 15,708 miles I've driven (255 hours of my time).

Email 21

I have been in the hospital about 2 times a year, for many years, with aspiration pneumonia completely due to TEP leakage. I don't want to be in there, I don't like to be sick, and I am sure Medicare has better ways to spend that money.

I usually change my own TEPs because I have found limited knowledgeable medical help and TEP inventories available. When the {TEP} starts leaking, or comes out, I need to get it changed - not wait to get an appointment. When anything happens to my TEP, my life basically stops until I get it changed. I cannot speak and must carry tools to resolve the problem with me at all times. In the case of it coming out, I must keep the TEP orifice open and plugged to stop all

leakage, which could be a significant problem. These events can at happen anytime, while doing any activity, in any location.

TEPs can last for varying periods of time, from a few weeks to a few months. They are very expensive for me and I usually wait until they have a problem, i.e. start to leak, before I change them. If they were covered by Medicare, I could take a much more pro-active approach to managing them before they fail and keep us both out of the hospital.

Email 22

I have been a laryngectomy {patient} since 2002 and have used a TEP to speak since that time. I moved to Idaho, from Northern California, in 2003 for a less expensive living environment due to being disabled with limited income.

Having quick access to experienced TEP medical facilities is critical to my wellbeing. If it starts to leak, I usually end up with lung aspirations resulting in being in the hospital with pneumonia.

With good TEP medical services, I can usually resolve the TEP leakage issues before the other complications happen, saving {Medicare} a lot of money in reduced hospital stays and other medical costs.

TEPs are required for us to communicate, cannot be stopped and restarted, and should be covered by Medicare as HME filters and other devices are covered.

Email 23

My name is {name redacted} and I live in Georgia. To my knowledge there are only 2 locations {that provide TEP services} in the state and each is at least 2 hours away

Email 24

I am a cancer survivor. I was diagnosed with stage 4 Esophageal Cancer in 2011. While my wife was still working, our insurance would pay all but 20% of the supplies I needed including the T.E.P. Once my wife retired and I had to go on Medicare, the challenges began. Once the DME {supplier} that had been carrying the {TEP} and where we were able to get it, no longer would carry it. After they supplied the first one after I was on Medicare; I was told when I went to reorder they no longer carried it. When asked they said I was out of their service area. I told them I would come and pick it up. We got the run around until finally with persistence, found out it was because I was on Medicare and they do not pay to cover the cost of the product. I pulled out the Medicare sheet that is sent out as to what they pay....they allowed about \$39.00 for a product costing \$310. And then they paid 80% of that and my insurance was allowed to only pay the remaining 20% of the \$39.

Therefore, this is a very aggravating and frustrating situation. Medicare's refusal to meet fair reimbursement to T.E.P providers has made things extremely difficult for me. I live on a disability check for under \$2,000 a month. The \$310.00 I have to pay out of pocket every 4-6 weeks is a real financial burden on me. If I don't have the money for my T.E.P. I either have to put it on a credit card or I can drive 620 miles from Wichita to M.D. Anderson in Houston,

Texas, as they are a DME {supplier} and due to their being a HUGE Cancer Hospital and have the ability to carry the product. This is ridiculous and very inconvenient!

If this were a cosmetic or elective item, I could somewhat understand Medicare's position. This is a medical supply that myself and so many others need in order to breathe and talk - to live as normal a life as possible after surviving a very serious battle with cancer.

Email 25

I am a laryngectomy patient. I am in my mid seventies and have, over the past 12 years, had great difficulty finding local medical people that feel comfortable providing medical care and assistance for me. Medicare has not been helpful with regard to reimbursement of replacement of indwelling voice prostheses.

I understand that being a laryngectomy patient is rare and many medical personnel— doctors, nurses, speech therapists— do not have the training and equipment and prosthetic devices to provide the care I require. As a result I have gone to the local hospital (Marin General) seeking care for breathing problems, only to be put in an ambulance and transported to Stanford Medical Center. This cost me a considerable amount of money out of pocket.

I have gone to my family doctor when I was having trouble with my prosthetic valve. I was referred to a local specialist who had difficulty seeing my valve and eventually told me that I probably needed a valve replacement but he didn't have one and I should go to Stanford. Stanford is 63 miles from my home. Appointments were made. During the delay, there was bleeding through my stoma, swelling of my neck, and my valve failed completely leaving me entirely voiceless. When I did get an appointment at Stanford, personnel had difficulty removing the old valve. This was a dangerous situation and I could have had major problems. It required another appointment and caused an additional delay, and additional expense.

There are few resources available for most laryngectomy patients. Indwelling prosthesis replacement is expensive and should be done with regularity. We generally have to travel long distances to receive the care that we need. I feel that I am one of the lucky laryngectomy patients, as I can receive capable medical care at Stanford *only* sixty three miles away. Many laryngectomy patients live in other parts of the country and must travel hundreds of miles to receive care. The travel is expensive and difficult for many of us, and for many of us emergency care is unobtainable.

Medicare has not been helpful with regard to reimbursement of replacement of indwelling voice prostheses. We hope that this will improve soon.

Email 26

In November 2016 I had a total laryngectomy. Since the operation I have had to use a TEP so I could talk and to keep from having problems. I had to have several of the TEPs because they started to leak whenever I would drink. The TEP is necessary for me to have some kind of life. The replacement of the TEP is medically necessary to prevent aspiration and the development of pulmonary complications. The TEP is something that I will have the rest of my life. There is no

reason that the TEPs are not covered at 100%. I hope that the people that are going to make that decision will look at it as if they were like me.

Email 27

My story is one you have certainly heard before. I had a total laryngectomy in 2004. I use a TEP to speak.

Before I became eligible for Medicare (I turned 65 in 2006) I was completely reimbursed for my TEPs by my employee insurance. After I became Medicare eligible I was caught in Medicare's "catch 22" and must pay the entire cost from my own pocket. I am one of the lucky ones who can afford my TEPs. There are far too many who have to do without because they can't afford what they need. The unfair denial of all benefits is due to 3 Medicare rules.

1. Only the service provider can submit a claim to Medicare.
2. Medicare only covers a TEP up to \$97 regardless of what it actually costs.
3. The provider may not bill the patient for the excess of the actual cost over the \$97 covered by Medicare.

If a provider (doctor, SLP, whatever) actually installs an ATOS Vega, which is one of the most used indwelling prostheses, they will lose the difference between the \$265 cost of the prosthesis and the \$97 reimbursed by Medicare; a guaranteed loss of \$168 each time. The result is that no provider will do it, since they can't afford the loss. So it appears that Medicare is reducing the cost of providing coverage by rigging the rules so that they don't provide any coverage.

I am president of a support group and I see members that could use an indwelling prosthesis, but don't get one because they can't afford it.

When I first became aware of the situation I submitted a claim to Medicare myself. I knew it was against their rules but I wanted to start an appeal process. This also did no good because the people who deal with appeals have no authority to change any rules, regardless of how unfair or ridiculous they are.

Email 27

My husband had laryngectomy on January 21, 2016. For the first year Loma Linda Medical University in Loma Linda, California provided the TEP if it needed to be changed; then in December of 2016 we received a notice from Loma Linda that as of 2/01/2017 they would no longer supply the TEP.

It is a very hard item to budget for because you never know how long they will last before they start leaking. Medicare does not reimburse nor does IEHP which is our secondary insurance. They denied our claim for reimbursement. We would never have imagined that Loma Linda would stop supplying an item that my husband will need the rest of his life.

It could be a life threatening situation to wait too long to change a leaking TEP. Water can get into your lungs and cause major medical issues, all because we cannot afford to purchase the TEP because of the cost.

Apple Valley, Ca 92307

Email 28

We would love to be part of this process as my mother has been going through multiple changes of her provox at a rate of about 1 per month costing between \$275.00 to \$300.00 each purchase with zero reimbursement. Not only has she endured the pain of having them changed monthly; sometimes twice in a month. Because of cost and few doctors to change the voice prosthesis in a timely manner, she contracted pneumonia in 2014 in which she almost died from the wait of having the device changed. Fluids leaked into her lungs through the device and she was hospitalized for 16 days and 3 months of non-covered medication for a blood clot caused by the operation to clear her lungs. Living with a trach is tough enough without being punished both financially and physically by the changing of these devices. But the devices are absolutely a necessity to keep their dignity. Please reconsider or take into consideration the needs people like my mother who lives with such a difficult everyday experience and then is punished by having to do without because of the cost of these devices.

Email 29

I write to you to ask for your help to improve Medicare reimbursement of indwelling voice prostheses. I used to go to Sound Health in Town and Country, MO since this is where my surgeon who performed my laryngectomy practices. I use to see the SLP {name redacted}, however, any time I had a leak in my prostheses, I would have to worry about coming up with money to replace the TEP. Most of the time it was usually around \$280 - \$350. I tell you that being on disability; it is difficult to come up with that kind of money. I would have to beg, and borrow sometimes just to get the replacement. I did get one free, from the American Cancer Society. They only do one free per lifetime. I also had to go to In-Services held by ATOS Medical at St. Louis University Hospital, under the direction of {name redacted} to be a participating patient to get a free TEP. The units should be considered DME and treated as such by Medicare and all insurance. No one, unless they are without voice, realizes how important it is to communicate by phone and in person. Writing doesn't always work...especially on the phone. Hope writing to you that Medicare does rethink their policy on the payment to Hospitals, Clinics, and any facility that changes patients TEP prostheses.

Email 30

All I can add is what doctor's office would you walk into carrying a medical speech aid that was going to be inserted into your throat? That's what happens when you get a script and are told that you are on your own. Laryngectomy patients don't have political clout because there are few of us...fortunately. With the billions that are being bilked from Medicare and Medicaid, it's absolutely out if this world ridiculous that a TEP isn't covered to the extent that a provider could not be made whole, because a lot of these doctors who handle laryngectomy patients have them mixed into their ENT practice and can't stock several sizes for a handful of laryngectomy patients who may or may not need them at any particular time. A TEP is how we remain healthy, communicate, carry on being taxpayers if able, and are no different from crutches for an injured person, or a cane, or whatever is shopped on TV that can be coded to the two M Bros. Nobody needs or uses a TEP unless their survival depends on it. It's beyond common sense that this item isn't covered the way that it should be.

Email 31

My name is {name redacted} and I received my TEP in January of 2017 at the University of Jefferson Hospital in Philadelphia. We've been extremely fortunate in that this facility has offered a wide-range of services supporting laryngectomy patients such as myself, with TEP maintenance near the top of the list. *With* my TEP, I'm a functioning, fully employed 58-year old father of 4 (and grandfather of 1) who can support my family. *Without* my TEP, I would become another name on the social security disability list, drawing a check each month from the government at taxpayer's expense, and barely getting by (if at all). I would basically become unemployable. Without the fantastic services provided by the staff at Jefferson Hospital, my health would be a continuing question mark, wondering each day if this is the one where the continuous flow of mucus in my throat causes another life-threatening (or ending) bout of pneumonia. I've been through that twice; the last time spending 3 months in the hospital and dropping to under 110 pounds. I think the bill for the TEP is a bit cheaper than all of that.

Whatever we can do to support your efforts, please let us know. This is literally a matter of life-or-death for my family, and for thousands like us. TEP is a fantastic advancement in the world of the laryngectomy (the "speechless"); how can they not let us use it?
Telford, PA.

Email 32

I have been a laryngectomy patient since 2000. I was well taken care of at the start of my new life as a user of voice restoration options available at that time. Being on private insurance at the that time I was subject to the limitations of the policy I was under at the time. The private insurance coverage was part of my job compensation. The income of the job supplied monies for deductibles and copays. I was able to manage the cost of maintaining a voice prosthesis and associated tracheal stoma.

Now, I am retired and on social security and fixed income a source. The cost of my voice supplies continue to rise. The options available for voice restoration are made of more durable materials and provide mounting options for the endless body shapes they must fit. Please, do what can be done to increase Medicare reimbursement rates for voice restoration devices.
Louisville, Kentucky

Email 33

I reside outside a small town and require a 2-hour drive to Duke Hospital for service/replacement at intervals of 2 - 3 months. I am fortunate to have a daughter who drives me at age 87, but the real inconvenience is hers in that it's a 6-hour drive to get to me. Thus, the former annual visit has become 4 to 6 times annually. I am taking action to extend the life of the TEP, but beyond that I see little opportunity for improvement.

Email 34

I have several laryngectomy patients that have a TEP placement. Their durable medical provider will no longer supply the indwelling devices. Some of my patients are veterans and have to drive round trip 8 hours to Portland as the VA hospital provides the devices and incur the cost.

For the Medicare patients, they have to buy the devices out of pocket thru ATOS. ATOS requires that the patient pay up front and Medicare reimburses the patient. Medicare pays less in rural areas for the device. The patients cost is over 100.00.

If the patient is unlucky enough to need a valve with a wide flange, the patient can only get this valve thru Blom-Singer and Blom-Singer doesn't sell directly to the patient.

No one wants to bill the patient for a valve as most providers in our area accept assignment which means that we accept only what Medicare and the secondary pays. The valve plus shipping is over 250.00. The reimbursement via Medicare is around 150.00.

The end result is that patients wait until the device is leaking copious amounts of fluid into the respiratory tract. (I have had patients walk around with a q-tip inside the valve to act as a plug.) Many of these patients end up in the hospital with pneumonia.