**Prior Authorization Review Panel**  
**MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 10/01/2019</th>
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</thead>
<tbody>
<tr>
<td>Policy Number: 0560</td>
<td>Effective Date:</td>
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<tr>
<td></td>
<td>Revision Date: 08/16/2018</td>
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<tr>
<td>Policy Name: Voice Prosthesis for Voice Rehabilitation Following Total Laryngectomy</td>
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</tbody>
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**Type of Submission – Check all that apply:**

- [ ] New Policy
- [ ] Revised Policy*
- [x] Annual Review – No Revisions
- [ ] Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document.*

Please provide any clarifying information for the policy below:

**CPB 0560 Voice Prosthesis for Voice Rehabilitation Following Total Laryngectomy**

Clinical content was last revised on 08/16/2018. No additional non-clinical updates were made by Corporate since the last PARP submission.

Name of Authorized Individual (Please type or print): Dr. Bernard Lewin, M.D.  
Signature of Authorized Individual:

Revised July 22, 2019
Voice Prosthesis for Voice Rehabilitation Following Total Laryngectomy

Aetna considers indwelling tracheo-esophageal (TE) voice prosthesis medically necessary when it is recommended by a laryngologist or a speech-language pathologist for voice rehabilitation following total laryngectomy (see selection criteria in the Appendix).

Aetna considers replacement of indwelling TE voice prosthesis medically necessary. Medically necessary replacement every 3 to 6 months is consistent with the documented life span of most of these prostheses. Replacement is usually carried out as an outpatient procedure.

Notes: Indwelling TE voice prostheses available in the United States include Blom-Singer Indwelling Low-Pressure Voice Prosthesis (Helix Medical Inc., Carpinteria, CA), Provox 2 (Atos Medical, Milwaukee, WI), and VoiceMaster (E. Bension Hood Laboratories, Inc., Pembroke, MA).
Aetna considers hand-held artificial larynx devices such as the Nu Vois (Lauder Enterprises Inc., San Antonio, TX), the OptiVox (Bivona Medical Technologies, Gary, IN), the Servox (Seimens Hearing Instruments, Piscataway, NJ), the SolaTone and the TruTone (Griffin Laboratories, Temecula, CA), and the UltraVoice (UltraVoice, New Town Square, PA) medically necessary.

Aetna considers non-indwelling voice prostheses (e.g., the Provox NiD, Atos Medical, Milwaukee, WI) medically necessary when it is recommended by a laryngologist or a speech-language pathologist for voice rehabilitation following total laryngectomy (see selection criteria in Appendix).

Aetna considers the following experimental and investigational because their clinical value has not been established:

- Pneumatic Bionic Voice Prostheses
- Use of a tracheoesophageal voice prosthesis insufflator.

**Background**

Tracheo-esophageal (TE) voice prostheses allow laryngectomized patients to produce TE speech by shunting air from the lungs into the esophagus and vibrating the esophageal tissue. Blom and Singer were the first to use TE voice prosthesis for voice rehabilitation following total laryngectomy. Panje designed a similar prosthesis with an extra flange that helped to secure the prosthesis in the fistula. This fixation method is now known as indwelling or semi-permanent fixation.

Tracheo-esophageal voice prostheses have been shown to provide good voice and speech results following total laryngectomy as a consequence of disease (e.g., laryngeal tumors). The procedures for restoring phonation after total laryngectomy, usually performed under general or local anesthesia, entail puncturing the back wall of the trachea to form a passage with the front wall of the esophagus. After creation of a hole (tracheostoma), the Blom-Singer or another type of TE prosthesis is inserted and secured using the flanges of the prosthesis. To speak, the patient inhales deeply and as the patient exhales, air is shunted into the esophagus, producing TE speech. There is a 1-way valve on the distal tip of the prosthesis, which is inserted into the esophagus. This allows air to pass from the trachea through the prosthesis and into the esophagus. The valve prevents aspiration from
the esophagus into the trachea. In older models of TE voice prosthesis, the patient had to cover the tracheostoma with his/her thumb to speak. Studies have reported that the short-term success rate for TE speech rehabilitation to be 80 to 90%; however, the long-term success rate is reported to be approximately 70%.

It is important that patients have the manual dexterity to clean the prosthesis 2 to 3 times every day. They should have adequate pulmonary function to force air from the trachea through the prosthesis into the esophagus. Thus, patients who have poor manual dexterity (e.g., individuals with severe rheumatoid arthritis, amputations, or deformities of the upper extremities) or those with severe pulmonary disease and/or repeated pneumonitis are poor candidates for TE voice prosthesis under accepted guidelines. Furthermore, patients should also be motivated in using the prosthesis.

Leakage of fluid (saliva, reflux) through or around a voice prosthesis as well as increased airflow resistance are the main indications to remove the prosthesis for inspection and, if necessary, for replacement. The general life span of TE voice prosthesis is 3 to 6 months. Variations in diet as well as compliance with daily maintenance affect the durability of the prosthesis. Replacement of TE voice prosthesis should only be carried out by a physician or a speech-language pathologist; and is usually performed in an outpatient setting.

Non-Indwelling Voice Prothesis (e.g., the Provox NiD)

Hancock et al (2005) examined the feasibility of and patient satisfaction with the Provox NiD non-indwelling voice prosthesis. Pre- and post-study questionnaires were used to evaluate the patients’ former voice prosthesis and the Provox NiD voice prosthesis. In addition, measurements of pull-out force, maximum phonation time and loudness were made for both voice prostheses. In-vitro measurements of airflow characteristics were also made. Following a 6-week trial, all patients provided feedback on the new voice prosthesis and the results were used to further improve the Provox NiD. This final version of the new voice prosthesis was subsequently tried and evaluated by 10 patients 6 months later. Overall results showed that patient satisfaction with the Provox NiD non-indwelling voice prosthesis was favorable. The pull-out force for the new prosthesis was significantly higher than that for the formerly used prosthesis and its aerodynamic characteristics were better. The authors concluded that the new Provox NiD non-
indwelling voice prosthesis investigated in this study provided a good option for laryngectomized patients using non-indwelling voice prostheses and can potentially improve safety and increase patients' satisfaction with their voice and speech.

In a longitudinal retrospective cohort study, Lewin and colleagues (2014) evaluated the indications, complications, and device life of the Provox NiD in a large cohort at a tertiary US cancer center. These investigators reviewed the records of patients who used the NiD prosthesis (2005 to 2011) for general indicators, device life, and complications. A total of 186 patients who used the NiD were included (median follow-up of 21.4 months). The NiD was placed at initial fit in 41 (22 %) patients, whereas 145 (78 %) tried a NiD after using another type of prosthesis. Most patients used the NiD similarly to an indwelling device. Median NiD device life was significantly longer than that of other non-indwelling prostheses (45 versus 29 days, p = 0.0061), and did not significantly differ from that of standard indwelling devices (45 versus 50 days, p = 0.4263); 38 % (71 of 189) of NiD users had a history of early leakage (less than 8 weeks) using a different prosthesis before trying the NiD. Among patients with a pre-existing history of early leakage, almost 90 % of NiD prostheses outperformed the device life of other products. The authors concluded that the NiD prosthesis offered satisfactory device life on a par with indwelling prostheses in this cohort of NiD users. Coupled with favorable published airflow characteristics and satisfactory trachea-esophageal voice, these data suggested that the NiD offered a durable, low-cost prosthetic alternative in contemporary practice. A unique indication for NiD may be improved device life in some patients with a history of early leakage.

Device Life of the Tracheoesophageal Voice Prosthesis

Lewin and colleagues (2017) noted that voice prosthesis (VP) device life is a limiting factor of TE voice restoration that drives patient satisfaction, health care costs, and overall burden. Historic data suggested that TE VPs have an average device life of generally 3 to 6 months, but these data are typically derived from small samples using only 1 or 2 devices. In a retrospective, observational study, these investigators re-examined current device life in a large, contemporary cancer hospital in the U.S. that uses a wide assortment of VPs. This trial included 390 laryngectomized patients with a tracheoesophageal puncture (TEP) who had VP management at MD Anderson Cancer Center between July 1, 2003, and December 31, 2013. Tracheoesophageal voice-related outcomes were: (i) device life duration to VP removal, and (ii) treatment-related and prosthetic-related
factors influencing device failure. Primary independent variables included treatment history (extent of surgery and radiation history), VP type (indwelling versus non-indwelling, size, specialty features), and reason for removal (leakage, complication, other). Duration was examined using Kaplan-Meier analysis.

Disease, treatment, and patient-specific factors were analyzed as predictors of duration. Overall, 3,648 VPs were placed in the 390 patients (median [range] age, 62 [34 to 92] years). Indwelling prostheses accounted for more than half (56 %) of the devices placed (55 %, 20-Fr diameter; 33 %, 8-mm length). More than 2/3 (69 %) of prostheses were removed because of leakage, while the rest were removed for other reasons. Median device life was 61 days for all prostheses. Indwelling and non-indwelling VPs had median device lives of 70 and 38 days, respectively.

There was no significant difference between specialty prostheses compared with standard devices (median duration, 61 versus 70 days, respectively). The Provox ActiValve (Atos Medical) had the longest life. Neither radiation therapy nor extent of surgery had a meaningful impact on device life. The authors concluded that these findings suggested that VP duration showed a lower durability than historically reported. This may reflect the intensification of treatment regimens that complicated TEP management in an era of organ preservation; however, further investigation is needed.

The Use of a Tracheoesophageal Voice Prosthesis Insufflator for Speech Production After Total Laryngectomy

Starmer and colleagues (2017) noted that there may have a variety of reasons why patients are unable to produce TE speech after total laryngectomy (TL) including poor pulmonary reserve or other co-morbidities that prevent adequate stoma occlusion and intra-tracheal pressure to voice. Other patients find it difficult, uncomfortable, or socially awkward to manually occlude the stoma with the finger or thumb. This study aimed to assess the feasibility of achieving TE speech with a prototype TE voice prosthesis insufflator (TEVPI). These researchers prospectively assessed the feasibility of achieving TE speech with a commercially available continuous positive airway pressure (CPAP) device in 6 TL patients. The intervention was the use of a prototype TEVPI. A battery of acoustic and perceptual metrics were obtained and compared between TEVPI speech and standard TE voice prosthesis (TEVP) speech. Voicing was accomplished with the TEVPI in 5 of 6 participants. On average, the duration of phonation with TEVPI was shorter, not as loud, and perceived to be more difficult to produce compared to TEVP speech. The authors concluded that the TEVPI was a feasible, hands-free
Flexible Esophagoscopy for Placement of a Secondary Tracheo-Esophageal Voice Prosthesis

Tkaczuk and colleagues (2018) noted that TEP for post-laryngectomy speech rehabilitation can be performed at the time of laryngectomy (primary) or at a subsequent time (secondary). Traditionally, the secondary procedure is performed using a rigid esophagoscope. Diseases like esophageal stricture, limited neck extension, and soft-tissue fibrosis can make this procedure technically challenging or impossible. In a preliminary feasibility study, these researchers stated that they developed a novel device to perform a secondary tracheoesophageal puncture using a flexible esophagoscope. These investigators tested the feasibility of a novel device used to create a secondary TEP in post-laryngectomy cadavers. These researchers performed a total laryngectomy on 3 fresh cadavers to establish the feasibility of their prototype. In each cadaver, a flexible esophagoscope was passed into the pharynx with the prototype. The prototype was passed through a working port and deployed to distend the esophagus. The puncture was visualized and a wire was passed via the newly established fistula. The device was activated, securing the wire, and then the esophagoscope and device were removed. There was 100% successful deployment of the prototype device, allowing rapid creation of the puncture and security of the guide-wire in each cadaver. There was no evidence of collateral mucosal injury or esophageal perforation. The authors concluded that the prototype device offered an alternative method to safely and efficiently perform a secondary TEP without the requirement of rigid esophagoscopy that can periodically be technically impossible in this patient population.

Pneumatic Bionic Voice Prostheses

Ahmadi and associates (2018) stated that despite emergent progress in many fields of bionics, a functional Bionic Voice prosthesis for laryngectomy patients (larynx amputees) has not yet been achieved, leading to a lifetime of vocal disability for these patients. These researchers introduced a novel framework of Pneumatic Bionic Voice Prostheses as an electronic adaptation of the Pneumatic Artificial Larynx (PAL) device. The PAL is a non-invasive mechanical voice source, driven
exclusively by respiration with an exceptionally high voice quality, comparable to the existing gold standard of TE voice prosthesis. The investigators stated that, following PAL design closely as the reference, Pneumatic Bionic Voice Prostheses appeared to have a strong potential to substitute the existing gold standard by generating a similar voice quality while remaining non-invasive and non-surgical. These investigators designed the 1st Pneumatic Bionic Voice prosthesis and evaluated its onset and offset control against the PAL device through pre-clinical trials on 1 laryngectomy patient. The evaluation on a database of more than 5 hours of continuous/isolated speech recordings showed a close match between the onset/offset control of the Pneumatic Bionic Voice and the PAL with an accuracy of 98.45 ± 0.54%. When implemented in real-time, the Pneumatic Bionic Voice prosthesis controller had an average onset/offset delay of 10 milliseconds compared to the PAL. The authors concluded that the Pneumatic Bionic Voice prosthesis addressed a major disadvantage of previous electronic voice prostheses, including myoelectric Bionic Voice, in meeting the short time-frames of controlling the onset/offset of the voice in continuous speech. They stated that the PAL can be considered as a simple model of the human larynx with a fixed pair of vocal folds driven exclusively by the variations of the intraoral and subglottal pressure values and without any neural/neuro-muscular input from the missing larynx. The quality of PAL speech is comparable to the existing gold standard of TE voice prostheses and far better than the Electrolarynx. The traditional PAL also holds a significant advantage over the existing gold standard as being non-invasive. They noted that these advantages advocate defining a new pathway in designing Pneumatic Bionic Voice prosthesis as electronic adaptations of the PAL. This study aimed to be the first in this direction and provided a model that describes the PAL voice onset/offset control with a low computational cost suitable for real-time implementations. The next step for these researchers is to combine this solution with a PAL pitch modulation model in real-time and evaluate the quality of the resulting speech against the PAL and the existing gold standard.

Ultrasonography for Sizing Tracheoesophageal Puncture Prostheses

Smith and co-workers (2017) stated that TEP with voice prosthesis placement is the gold standard voice rehabilitation following total laryngectomy. Ultrasonography may be useful to determine tracheoesophageal wall thickness, guiding prosthesis choice. In this study, a total of 14 patients undergoing total laryngectomy and TEP or prosthesis change with 16-MHz ultrasound measurement of the posterior tracheal wall were included; 7 patients underwent secondary TEP, 3 primary TEP,
and 4 TEP changes; 6 patients underwent flap reconstruction, while 8 patients were closed primarily. Average party wall thickness was 9.6 ± 1.7 mm, without a difference (p = 0.08) between primary closure (10.3 ± 1.7 mm) and flap reconstruction (8.6 ± 1.4 mm). Change from the hypothesized sizing was noted in 11 patients (79%). Prosthesis size did not correlate with age (-0.19, p = 0.51), height (-0.12, p = 0.69), weight (0.26, p = 0.38), body mass index (0.22, p = 0.46), or flap status (-0.48, p = 0.079). The authors concluded that these findings suggested that ultrasonography is beneficial in patients with distorted or less predictable anatomy (e.g., flap reconstruction); but also important for those patients undergoing primary closure. These preliminary findings need to be validated by well-designed studies.

Appendix

The following selection criteria apply to an indwelling or non-indwelling TE voice prosthesis for voice rehabilitation following total laryngectomy:

1. Member should have adequate pulmonary function to force air from the trachea through the prosthesis into the esophagus; and

2. Member should have the manual dexterity to care for the voice prosthesis daily.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>CPT codes covered if selection criteria are met:</td>
<td></td>
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<tr>
<td>31611</td>
<td>Construction of tracheoesophageal fistula and subsequent insertion of an arytenoid speech prosthesis (e.g., voice button, Blom-Singer prosthesis)</td>
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<tr>
<td>Other CPT codes related to the CPB:</td>
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<tr>
<td>31360 - 31365</td>
<td>Laryngectomy, total</td>
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<td>HCPCS codes covered if selection criteria are met:</td>
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<tr>
<td>L8500</td>
<td>Artificial larynx, any type</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>-------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>L8501</td>
<td>Tracheostomy speaking valve</td>
</tr>
<tr>
<td>L8505</td>
<td>Artificial larynx replacement battery/accessory, any type</td>
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<tr>
<td>L8507</td>
<td>Tracheo-esophageal voice prosthesis, patient inserted, any type, each [e.g., the Provox NiD]</td>
</tr>
<tr>
<td>L8509</td>
<td>Tracheo-esophageal voice prosthesis, inserted by a licensed health care provider, any type</td>
</tr>
<tr>
<td>L8511</td>
<td>Insert for indwelling tracheoesophageal prosthesis, with or without valve, replacement only, each</td>
</tr>
<tr>
<td>L8512</td>
<td>Gelatin capsules or equivalent, for use with tracheoesophageal voice prosthesis, replacement only, per 10</td>
</tr>
<tr>
<td>L8513</td>
<td>Cleaning device used with tracheoesophageal voice prosthesis, pipet, brush, or equal, replacement only, each</td>
</tr>
<tr>
<td>L8514</td>
<td>Tracheoesophageal puncture dilator, replacement only, each</td>
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<tr>
<td>L8515</td>
<td>Gelatin capsule, application device for use with tracheoesophageal voice prosthesis, each</td>
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HCPCS codes not covered for indications listed in the CPB:

Pneumatic Bionic Voice Prostheses - no specific code:

ICD-10 codes covered if selection criteria are met:

| C32.0 - C32.9 | Malignant neoplasm of larynx |
| D02.0          | Carcinoma in situ of larynx   |
| D14.1          | Benign neoplasm of larynx     |
| Z85.21         | Personal history of malignant neoplasm of larynx |

Tracheoesophageal voice prosthesis insufflator - no specific code:

ICD-10 codes not covered if selection criteria are met:

| Z90.02 | Acquired absence of larynx |

The above policy is based on the following references:


Amendment to
Aetna Clinical Policy Bulletin Number: 0560 Voice Prosthesis for Voice Rehabilitation Following Total Laryngectomy

There are no amendments for Medicaid.