Voice Prosthesis for Voice Rehabilitation Following Total Laryngectomy

Number: 0560

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

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 NuVois (Lauder Enterprises Inc., San Antonio, TX), the OptiVox (Bivona Medical Technologies, Gary, IN), the Servox (Siemens 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 use of a tracheoesophageal voice prosthesis insufflator experimental and investigational for speech production after total laryngectomy because its clinical value has not been established.

**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.
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 solution for restoring speech after TL. Moreover, they stated that although the current model produced inferior acoustic metrics compared with standard TEVP speech, further modification and refinement of the device has the potential to produce much improved speech.

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 "+":*

#### ICD-10 codes will become effective as of October 1, 2015:

#### CPT codes covered if selection criteria are met:

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31611</td>
<td>Construction of tracheoesophageal fistula and subsequent insertion of an alaryngeal speech prosthesis (e.g., voice button, Blom-Singer prosthesis)</td>
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#### Other CPT codes related to the CPB:

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>31360 - 31365</td>
<td>Laryngectomy, total</td>
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</tbody>
</table>

#### HCPCS codes covered if selection criteria are met:

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>L8500</td>
<td>Artificial larynx, any type</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>
</tr>
<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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ICD-10 codes covered if selection criteria are met:

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>C32.0</td>
<td>Malignant neoplasm of larynx</td>
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<td>C32.9</td>
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<tr>
<td>D02.0</td>
<td>Carcinoma in situ of larynx</td>
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<tr>
<td>D14.1</td>
<td>Benign neoplasm of larynx</td>
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<tr>
<td>Z85.21</td>
<td>Personal history of malignant neoplasm of larynx</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


AETNA BETTER HEALTH® OF PENNSYLVANIA

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

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania  revised 08/08/2017