



**VOICE PROSTHESIS FOR VOICE REHABILITATION
FOLLOWING TOTAL LARYNGECTOMY
HS-083**



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

Policy Number: HS-083

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2/2/2012**

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Approximately 136,000 cases of cancer of the larynx are diagnosed each year worldwide, with an estimated overall five-year survival rate of 68%, making it one of the more curable types of cancer of the upper aerodigestive tract. Members with advanced or recurrent squamous cell carcinoma of the larynx typically undergo total laryngectomy in the course of treatment. Total laryngectomy profoundly alters speech, respiration, and the senses of smell and taste. Members benefit from preoperative evaluation and counseling that addresses postoperative functional limitations and includes specific strategies to adjust to these limitations and function maximally. Short-term strategies such as non-verbal modes of communication and longer-term rehabilitation plans should be included. Pretreatment counseling is important for the patient and family to help adjust to post-treatment conditions which may be immediate and severe. The speech/language pathologist may demonstrate devices that will be required for speaking, swallowing or breathing after treatment and provide information about the communication options available after surgery. Effective voice restoration is an important part of post-laryngectomy rehabilitation. Methods of speech available for members who have undergone total laryngectomy are through the use of the electronic artificial larynx or through tracheoesophageal speech.

Artificial Larynx

The artificial larynx, is frequently used to restore speech in post-laryngectomy patients. There are two types of artificial larynx devices: neck and intraoral. The neck type is placed against the skin on the side of the neck, under the chin, or on the cheek. Sound is conducted into the oropharynx and articulated. Intraoral devices are used for members who cannot achieve sufficient sound conduction on the skin. A small tube is placed in the posterior oral cavity, and the generated sound is articulated. The artificial larynx allows immediate voice restoration after surgery and is easy to learn. The device needs little maintenance but does rely on batteries and produces a mechanical sound.

Artificial larynx devices are Class I devices and are therefore exempt from U.S. Food and Drug Administration (FDA) premarket approval (PMA) requirements. There are a number of devices available, including the UltraVoice (UltraVoice), the OptiVox (Bivona Medical Technologies), the Servox Inton® (Siemens Hearing Instruments), and the TruTone™ and SolaTone™ (Griffin Laboratories).

Tracheoesophageal Speech and Devices

Tracheoesophageal speech is accomplished by a surgical voice restoration technique that evolved as a result of a procedure developed by Singer and Blom in 1979. A tracheoesophageal puncture creates a surgical fistula or tract in the wall separating the trachea and esophagus. A catheter is inserted in the tract as a stent. A speech pathologist measures the length of the puncture tract and selects an appropriate size and type of prosthesis. Several days after surgery, the catheter is removed, and a one-way valved prosthesis is placed in the puncture tract. The one-way valve allows air to pass into the esophagus while preventing food and liquid from entering the trachea. The prosthesis allows air from the lungs to pass into the esophagus. Exhalation from the lung then vibrates the pharyngoesophageal segment to produce sound.

To produce speech, the patient occludes the tracheostoma to direct air through the prosthesis into the esophagus. Hands-free external-airflow valves are also available that eliminate the need for finger occlusion. The tracheoesophageal voice prosthesis produces more natural-sounding speech and allows speech restoration within two weeks of surgery.

Tracheoesophageal puncture for speech rehabilitation performed at the time of total laryngectomy is referred to as primary tracheoesophageal puncture. The procedure may also be performed weeks, or even years, following laryngectomy and is referred to as secondary tracheoesophageal puncture. The success rate for voice rehabilitation is generally higher when primary tracheoesophageal puncture is performed. One prospective case

series evaluated the timing of placement of a Blom-Singer voice prosthesis for speech rehabilitation in 71 total laryngectomy patients. The rate of success for voice rehabilitation was 97% for patients who underwent primary tracheoesophageal puncture and 78% for patients who underwent secondary tracheoesophageal puncture. The use of radiotherapy and the age of the patient did not appear to impact the success rate.

There are several types of prostheses available. While some can be changed independently by the patient or caregiver, indwelling prostheses must be changed by a clinician. The patient, family, physician, and speech pathologist should select the prosthesis in concert. Phonation should be sampled with a patent puncture tract.

Postoperative voice rehabilitation is usually provided by a speech and language pathologist. The patient and family are instructed in removal, cleaning and reinsertion of standard prostheses, and the patient is instructed in finger occlusion. Yeast colonization caused by constant exposure to esophageal contents in radiated patients eventually destroys the integrity of the valve. Aspiration may occur if fluids leak through a malfunctioning valve. A voice prosthesis should therefore be changed every three to six months and should be replaced sooner if signs of leakage or increased airflow pressure are present.

Several devices have received FDA PMA approval and are available. These include the Hood VoiceMaster (E. Benson Hood), Provox 2® (Atos Medical), and several Blom-Singer devices (Helix Medical, Inc.).

POSITION STATEMENT

Standard or indwelling tracheoesophageal voice prostheses **are considered medically necessary** if ALL of the following criteria are met:

- Recommended by an otolaryngologist or speech/language pathologist; **AND**,
- Member has undergone a total laryngectomy; **AND**,
- Member or caregiver is willing and able to maintain and replace the device.

The replacement of standard or indwelling tracheoesophageal voice prostheses **is considered medically necessary**:

- Every three to six months; **OR**,
- There is evidence of leakage; **OR**,
- Increased airflow pressure is present.

Handheld electronic artificial larynx devices **are considered medically necessary** if ALL of the following criteria are met:

- Recommended by an otolaryngologist or speech/language pathologist; **AND**,
- Member has undergone a total laryngectomy

CODING

Covered CPT® Codes

31611 Construction of tracheoesophageal fistula and subsequent insertion of an alaryngeal speech prosthesis (e.g., voice button, Blom-Singer prosthesis)

Covered ICD-9-CM Procedure Codes

31.95 Tracheoesophageal fistulization; creation of tracheoesophageal fistula

Covered HCPCS Code

- L8500** Artificial larynx, any type
- L8501** Tracheostomy speaking valve
- L8505** Artificial larynx replacement battery/accessory, any type
- L8507** Tracheoesophageal voice prosthesis, patient inserted, any type, each
- L8509** Tracheoesophageal voice prosthesis, inserted by a licensed health care provider, any type
- L8511** Insert for indwelling tracheoesophageal prosthesis, with or without valve, replacement only, each
- L8512** Gelatin capsules or equivalent, for use with tracheoesophageal voice prosthesis, replacement only, per 10
- L8513** Cleaning device used with tracheoesophageal voice prosthesis, pipet, brush, or equal, replacement only, each
- L8514** Tracheoesophageal puncture dilator, replacement only, each
- L8515** Gelatin capsule, application device for use with tracheoesophageal voice prosthesis, each

Covered ICD-9-CM Diagnosis Codes

- 161.0** Malignant neoplasm of larynx
- 161.1** Malignant neoplasm of supraglottis
- 161.2** Malignant neoplasm of subglottis
- 161.3** Malignant neoplasm of Laryngeal cartilages
- 161.8** Malignant neoplasm other specified sites of larynx
- 161.9** Malignant neoplasm of larynx
- 231.0** Carcinoma in situ of larynx
- V10.21** History of malignant neoplasm of larynx

*Current Procedural Terminology (CPT) 2012 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

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Government Agencies, Professional and Medical Organizations

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2. Hopkins, L.E., & Gross, A.L. (2005). Laryngectomy: an introductory overview. *Florida Journal of Communication Disorders*, 22, 7-18.

HISTORY AND REVISIONS

Date	Action
2/2/2012	<ul style="list-style-type: none">• Approved by MPC. No changes.
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
2/26/2011	<ul style="list-style-type: none">• Approved by MPC.