



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Devices for Voice
Rehabilitation Following Total
Laryngectomy

Effective Date 9/15/2010
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Hyperlink to Related Coverage Policies

Speech/Language Therapy
Speech Generating Devices

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Coverage for electronic larynx devices may be subject to the terms, conditions and limitations of the applicable benefit plan's External Prosthetic Appliances and Devices (EPA) or Durable Medical Equipment (DME) benefit and schedule of co-payments. Please refer to the applicable benefit plan document to determine benefit availability and terms, conditions and limitations of coverage. Under many benefit plans, coverage for EPA and DME is limited to the lowest-cost alternative.

If coverage for electronic larynx devices is available, the following conditions of coverage apply.

CIGNA covers an electronic larynx device as medically necessary when recommended by an otolaryngologist or speech/language pathologist following total laryngectomy.

CIGNA covers a standard or indwelling tracheoesophageal voice prosthesis as medically necessary under the core medical benefits of the plan when recommended by an otolaryngologist or speech/language pathologist following laryngectomy, provided the individual or caregiver is willing and able to maintain and replace the device.

CIGNA covers replacement of standard or indwelling tracheoesophageal voice prostheses every three to six months or when signs of leakage or increased airflow pressure are present.

General Background

The American Cancer Society (ACS) estimates that approximately 12,720 new cases of cancer of the larynx will be diagnosed in the United States in 2010, with an estimated overall five-year survival rate of 62%. Patients 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. Patients 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. The three methods of speech available for patients who have undergone total laryngectomy are esophageal speech, electrolarynx, and tracheoesophageal speech (Pou, 2004; DeVita, 2005, ACS, 2010).

Esophageal Speech: Esophageal speech is accomplished by injecting air into the esophagus and immediately expelling it, causing vibration in the pharyngoesophagus; the vibration is then articulated into speech. The technique is difficult to master and relies on the development of a pseudoglottis after surgery. Pharyngoesophageal muscle spasm, strictures, as well as lack of patient motivation may prevent mastery of esophageal speech. A small percentage of patients are able to use this technique in daily communication.

Electrolarynx: An electrolarynx, or handheld artificial larynx, is frequently used to restore speech in post-laryngectomy patients. There are two types of electrolarynx 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 patients 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 electrolarynx allows immediate voice restoration after surgery, and is used by some patients for permanently. Communication with an electrolarynx is easy to learn, and the device requires little maintenance. The primary disadvantages of the electrolarynx include mechanical sound production and the requirement for a cumbersome external device (Pou, 2004; Lombard, 2003; Rassekh, 2010).

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, Ltd., Newtown Square, PA), the OptiVox (Smiths Medical, Gary, IN), the Servox Inton[®] (Siemens Hearing Instruments, Piscataway, NJ), and the TruTone[™] and SolaTone[™] (Griffin Laboratories, Temecula, CA).

Tracheoesophageal Speech: 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, and it is the most commonly used method of speech restoration following laryngectomy. Tracheoesophageal puncture for speech rehabilitation performed at the time of total laryngectomy (i.e., primary tracheoesophageal puncture) is generally the preferred method in non-irradiated patients who have an understanding of the procedure, although secondary puncture may be performed weeks, or even years, following laryngectomy. 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. This 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 weeks of surgery (Singer, 2004; Pou, 2004; Rassekh, 2010).

Numerous prostheses have received FDA approval through the 510(k) process. While some devices can be changed independently by the patient or caregiver, indwelling prostheses must be changed by a clinician. Prosthesis selection is made jointly by the patient, family, physician, and speech pathologist. Prior to insertion of

any prosthesis, sampling of phonation with a patent puncture tract is recommended. The perceived quality and effort of the sampling are factors that help guide prosthesis selection.

Prosthesis options include the following:

- Blom-Singer (duckbill): If voice quality is effortless, loud and consistent, a higher-resistance device such as duckbill prosthesis is an option. This type of prosthesis is more durable than other types and can be changed by the patient.
- Low resistance/pressure: If voice quality is strained, a lower-resistance prosthesis with a wider diameter may be appropriate. Low-resistance/pressure prostheses can also be changed independently but are less durable and more sensitive to esophageal pressure changes.
- Indwelling: If the patient is unwilling or unable to change the prosthesis independently, an indwelling device may be appropriate. Indwelling prostheses are designed to remain in place for several months. The prosthesis can be cleaned daily by the patient or caregiver while in place, but must be changed by a speech and language pathologist or otolaryngologist (Lombard, 2008).

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

Summary

Electronic larynx devices or tracheoesophageal voice prostheses (standard or indwelling) may be indicated for selected patients following total laryngectomy. Device selection is based on several factors, including the patient's clinical condition, the patient's and/or caregiver's willingness and ability to maintain a device, and the recommendation of an otolaryngologist or speech and language pathologist.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

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

HCPCS Codes	Description
L8500	Artificial larynx, any type
L8507	Tracheo-esophageal voice prosthesis, patient-inserted, any type, each
L8509	Tracheo-esophageal voice prosthesis, inserted by a licensed health care provider, any type
L8511	Insert for indwelling tracheoesophageal prosthesis, with or without valve, replacement only, each

ICD-9-CM Diagnosis Codes	Description
161.0-161.9	Malignant neoplasm of larynx
231.0	Carcinoma in situ of larynx
V10.21	Personal history of malignant neoplasm of larynx

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	09/15/2008	0157	Devices for Voice Rehabilitation Following Total Laryngectomy

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